IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL; JASON FLECK; CONNOR THONEN-FLECK; JULIA MCKEOWN; MICHAEL D. BUNTING, JR.; C.B., *by his next friends and parents*, MICHAEL D. BUNTING, JR. and SHELLEY K. BUNTING; SAM SILVAINE, and DANA CARAWAY. Plaintiffs, v. DALE FOLWELL, *in his official capacity as State Treasurer of North Carolina*; DEE JONES, *in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees*; NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES; NORTH CAROLINA DEPARTMENT OF PUBLIC SAFETY. Defendants.	No. 1:19-cv-272

STATE HEALTH PLAN DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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STATEMENT OF THE CASE

The Court should deny Plaintiffs' motion for summary judgment against the Plan Defendants because their claims are inextricably tied to contested facts.

At the outset of their Memorandum in Support of Plaintiffs' Motion for Summary Judgment, Plaintiffs assert that "health coverage" is part of their employee compensation, and thus the Plan's "sweeping exclusion" for "gender-affirming care" means Plaintiffs receive "less compensation than others" for the same work. ECF No. 179 at 4. Plaintiffs further assert that because the Plan provides certain drugs and surgeries "for other reasons," it should pay for "the same kinds of treatments" for their psychiatric diagnosis of gender dysphoria.

Each of these assertions is incorrect. The General Assembly and courts of North Carolina are clear that state employees do not receive "health coverage" as a part of compensation. Rather, the State "undertakes to make available a State Health Plan," N.C. Gen. Stat. Ann. § 135-48.2, and state employees, such as Plaintiffs, are "given the opportunity to enroll or decline enrollment" in a group plan at the time they are hired (but only if they meet other eligibility criteria, such as working full-time), N.C. Gen. Stat. Ann. § 135-48.42(a). In return for payment of a premium, the Plan pays money to health

care providers to offset the member's cost of treatment for various diagnoses and procedures. Plaintiffs pay the same premiums as other members do, and they receive the same coverage for the same illnesses. ECF No. 137 at 9-10.

Second, "gender affirming care" has no accepted medical definition and does not correspond to the actual delivery of healthcare services, and Plaintiffs offer no definition in their motion for summary judgment. Plaintiffs have invented this artificial category for litigation purposes to distinguish it from "treatments for cisgender employees," but no such distinction exists in the world. ECF No. 179 at 4. Like the rest of the healthcare industry, the Plan uses the medical coding system to determine whether to pay for specific medical procedures to treat a specific diagnosis. ECF No. 137 at 10-11. When one reviews the specific procedures that Plaintiffs do identify, they are offered to *everyone*, including the Plaintiffs themselves, for treatment of the same diagnoses. The Plan's coding and payment practices make this clear. *See* ECF No. 137 at 13-18.

The ambiguity of the category "gender-affirming care" also distracts the Court from understanding that some of the treatments that Plaintiffs seek are not covered for *anyone* on the State Health Plan. Plaintiffs' equal protection claim—that they are denied the "kinds of treatments" offered to "cisgender employees" for "other reasons," ECF No. 179 at 4—cannot justify the

expansion of Plan coverage to services that are offered to *no one else* for any diagnosis.

The Plan's decision not to provide more generous health benefits is not a violation of the equal protection clause, § 1557 of the Affordable Care Act, or Title VII of the Civil Rights Act. The Plan has legitimate, non-discriminatory reasons to deny coverage for hormonal and surgical treatment for gender dysphoria. The Plan's leadership has a fiduciary duty to all Plan members. Consistent with this statutory duty, the Board has chosen to "focus on costs" and limit spending to protect the long-term health and availability of the Plan. The Plan's "fiduciary responsibility to cover basic health" needs for Plan participants, with limited dollars, requires that it focus on coverage for illnesses that affect many Plan members (diabetes, rheumatoid arthritis, and cancer) and is inconsistent with adding additional benefits for small "niche groups" (including not only gender dysphoria, but also adult hearing aids, special infant formula, and acupuncture) Ex. 1 (Jones. Dep.) at 104:20-105:24. This is especially true when, as here, there is considerable uncertainty about whether medical science supports these desired hormonal and surgical interventions.

ARGUMENT

I. Plaintiffs' motion for summary judgment rests on disputed material facts.

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A dispute is genuine if a reasonable jury could return a verdict for the nonmoving party." *Jacobs v. N.C. Admin. Off. of the Cts.*, 780 F.3d 562, 568 (4th Cir. 2015) (internal quotations omitted). "[I]n deciding a motion for summary judgment, a district court is required to view the evidence in the light most favorable to the nonmovant… and to draw all reasonable inferences in his favor." *Harris v. Pittman*, 927 F.3d 266, 272 (4th Cir. 2019). A court "cannot weigh the evidence or make credibility determinations," and thus must "usually" adopt "the nonmovant's version of the facts," even if it seems unlikely that the moving party would prevail at trial. *Walls v. Ford Motor Co.*, 2021 WL 5206388, at *1 (M.D.N.C. Nov. 9, 2021) (Biggs, J.) (quoting *Jacobs*, 780 F.3d at 569 and *Witt v. W. Va. State Police, Troop 2*, 633 F.3d 272, 276 (4th Cir. 2011)).

The parties fundamentally disagree on critical facts underlying Plaintiffs' claims, so the Plan Defendants respectfully submit that this Court may not resolve their claims at summary judgment.

A. The efficacy of Plaintiffs' desired medical treatments presents a crucial dispute of material fact.

First, Plaintiffs have not established the efficacy of the medical treatments that they demand. Plaintiffs assert that undefined "gender affirming care" procedures are medically necessary treatments for gender dysphoria, and they have offered several experts who will testify about the need for hormonal therapy and surgical procedures. Plaintiffs also ask this Court to defer to the WPATH Guidelines as "authoritative standards of care" for transgender individuals, and proof that these treatments are "medically necessary and effective." ECF No. 179 at 17, 20. In doing so, Plaintiffs ask this Court to make a judgment about a significant medical controversy without any review of the current scientific evidence.[1]

"[G]ender dysphoria was, until just a few years ago, a very rare condition." Ex. 3 (Hruz Rep.) at 41. Recent data, however, shows "the number of people seeking care for gender dysphoria is rapidly increasing," *id.* at 42,

[1] Evidence before this Court shows that the WPATH Guidelines are far from a trustworthy resource. Dr. Stephen B. Levine, a licensed psychiatrist and Professor at Case Western Reserve University School of Medicine was a member of WPATH for almost 20 years. Ex. 2 (Levine Rep.) at 1. Dr. Levine explains that WPATH has become "a voluntary membership, activist advocacy organization" that accepts members who are not licensed medical professionals and "can no longer be considered a purely professional or scientific organization." Id. at 36.

and there has been a drastic "transformation of the patient population from early onset males to rapid onset adolescent girls," *id* at 67. For example, "[t]he number of adolescent girls seeking sex transitioning" in the United Kingdom increased "4,000% in the last decade." *Id.* For many decades, the typical patient with gender dysphoria was a biological male with a long, stable history of dysphoria since early childhood. But in the past 10 years, this has changed abruptly, and the typical patient is now an adolescent female with no documented long-term history of gender dysphoria. *Id.* at 67-68. Scientists have not explained this surprising shift, but such a quick change in a patient population suggests that theories of the cause or causes of gender dysphoria that are based on static features like "brain structures" or "genetics" are incorrect. *Id.* at 69.

While the patient population has changed and increased, the physical interventions for gender dysphoria remain experimental. As Dr. Paul McHugh noted in his expert report, "this controversial field has faced increasing scrutiny" in recent years, with "national research reviews in England, Sweden, and Finland" and other studies finding that "the evidentiary base for these experimental treatments is weak;" hormonal and surgical treatments demonstrate "few benefits" and may actually "cause more harm than good." Ex. 4 (McHugh Rep.) at 10.

There are no long-term, peer-reviewed, reliable research studies that allow physicians to know "the percentage of patients receiving gender transition procedures who *are helped* by such procedures, using objective criteria" or the "percentage of patients receiving gender transition procedures who *are harmed* by such procedures, measured with objective criteria." Ex. 2 (Levine Rep.) at 87 (emphasis added).

While patients may say, when interviewed, that they have benefited from hormone and surgical treatment, the current peer-reviewed scientific literature has not found evidence to support these subjective claims. As Plaintiffs note, a diagnosis of gender dysphoria requires more than a feeling of "dissonance" between one's perceived gender and one's biological sex; the patient must also suffer "clinically significant distress or significant impairment of functioning." ECF No. 179 at 17-18. Patients identify depression or anxiety as debilitating symptoms of gender dysphoria, and they assert anecdotally, after hormone therapy or surgery, that they feel less anxious or depressed. But when follow-up studies track *objective* measurements, like use of antidepressants and anti-anxiety medication, there

is no measurable difference between patients who receive hormone therapy or surgery and those who do not.[2]

In particular, the "affirmation" model of care—the basis for the WPATH Guidelines—is not supported by existing medical science. "The available data does not support the contention that 'affirmation' of transgender identity reduces suicide or results in better physical or mental health outcomes generally." Ex. 2 (Levine Rep.) at 45, 45-69. Finland, Sweden, and United Kingdom have retreated from prior medical policies on cross-sex hormones and surgical treatments. Medical providers in these countries now restrict the use of hormones and surgery in minors based on identified gaps in the medical science. *Id.* at 51-55. "The current status of the field of gender affirmation treatments has been labelled 'low quality' science by multiple reviews." *Id.* at 56. Studies have concluded that the field of affirmation treatments is "still at the experimental stage lacking in general acceptance within the relevant

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[2] The lack of valid, reliable scientific data about the effect of gender dysphoria treatments has ethical consequences, especially when a patient seeks surgery. "Since the abandonment of frontal lobotomies in 1967, there has been no other psychological condition for which surgery is performed, and there is no other area of surgical care where the diagnostician is the patient themselves, and the surgeon has no means of confirming or rejecting the diagnosis." Ex. 5 (Lappert Rep.) at 23-24. Valid surgical consent requires that a surgeon be able to ensure that a diagnosis is correct. *Id.* at 24. The surgical procedures involved in gender transition can have very high complication rates, with one procedure having a rate of complication over 50%, making it even more important to have confidence in treatment benefits. *Id.* at 29-39.

scientific communities and without known error rates for the efficacy of the treatment." *Id.*

Striking scientific evidence was made public in 2020. The American Journal of Psychiatry published a study of individuals in Sweden with gender dysphoria. *Id.* at 57-58. Researchers used national health system data to research individuals with gender dysphoria in 2005 and again in 2015. The study sought to determine whether individuals who used cross-sex hormones or underwent surgery had, ten years later, lower use of anti-anxiety medication or anti-depressants, fewer mental health visits, or fewer hospitalizations connected to unsuccessful suicide attempts (*i.e.* improved mental health) when compared to individuals who did not receive these treatments. Ex. 6 (Branstrom & Pachankis; Follow-up Letters). After review of the study's data, outside experts and the authors agreed that the evidence did not show that hormone treatment or surgery improves the mental health of patients with gender dysphoria. Ex. 2 (Levine Rep.) at 57-63. Indeed, patients who received surgery "were more likely to be treated for anxiety disorders" than those who did not. *Id.* at 63.[3]

3 This conclusion—that hormone treatment for gender dysphoria does not reduce mental healthcare needs—is supported by a 2021 study in the peer-reviewed Journal of Sexual Medicine. Looking over time at adolescents who received cross-sex hormones, researchers found the patients' "mental health

Dr. Paul W. Hruz, M.D., Ph.D. is a pediatric endocrinologist and a Professor of Medicine at the Washington University School of Medicine in St. Louis. Ex. 3 (Hruz Rep.) at 2. He is also the *only endocrinologist—i.e.*, a physician with specific expertise in the endocrine system (hormones)—to provide an expert opinion in this case. Dr. Hruz's opinion is that hormone therapy and surgery are "experimental, highly intrusive, and potentially harmful medical procedures" that lack "credible, reliable, and valid scientific support." *Id.* at 7-8. As one example, scientists understand that sex hormones affect brain development, but this knowledge "is in its rudimentary stages right now." Ex. 7 (Hruz Dep.) at 285:1-286:11. Testosterone appears to have some effect on brain development for biological males, and this finding creates "many reasons to be concerned and question" what the effect of puberty suppressing medications or testosterone has on the brain of a biological female. *Id.* at 285:1-287:2. At this time, any effect is completely unknown. Plaintiffs respond to these concerns by citing to guidelines from the Endocrine Society regarding hormone therapy, but the guidelines explicitly state that "the strength of recommendations and the quality of evidence was low or very low"

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utilization remained elevated" even after hormone treatment, and the "use of psychotropic medications increased." Ex. 7 (Hruz Dep.) at 269:8-271:6. *See also* Ex.8 (Hisle-Gorman).

in support of these treatments. Ex. 3 (Hruz Rep.) at 53. "Low" and "very low" are terms of art. A "low recommendation" means that "[f]urther research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that "any estimate of effect is very uncertain." *Id.*

Plaintiffs' experts do not inform the Court about this current, raging scientific controversy. Instead, Plaintiffs shift the argument to assertions that the Plan has changed its mind about the efficacy of Plaintiffs' desired treatments, or that, in any event, any concerns are misplaced. ECF No. 179 at 27-30. In doing so, Plaintiffs improperly shift the burden of proof.

The Plan need not demonstrate that Plan officials are experts on medical care. It is the Plaintiffs who must demonstrate that the medical evidence supporting their proposed treatments is so strong that it would be "irrational" to "disfavor" coverage for such procedures. *Bray v. Alexandria Women's Health Clinic*, 506 U.S. 263, 270 (1993). They cannot. Not a single drug has been FDA-approved for treatment of gender dysphoria. ECF No. 137 at 18.

Plaintiffs assert that these treatments have reduced their symptoms, ECF No. 137 at 5-9, but anecdotal evidence cannot establish that it is *unconstitutional* to reach a different conclusion about medical science. The existing scientific ambiguity demonstrates it would be profoundly

inappropriate for this Court enter an injunction at summary judgment, as Plaintiffs ask, and order the Plan to pay for Plaintiffs' desired medical treatment.

B. Plaintiffs' purported expert evidence is not appropriate for resolution without consideration by the factfinder.

To avoid the ongoing scientific controversy, Plaintiffs place extensive reliance upon guidelines issued by the World Professional Association for Transgender Health and the Endocrine Society. But this Court cannot summarily resolve this case by adopting such opinions as its own. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 584 (1993). Prior to *Daubert*, courts asked whether a scientific opinion is based on a scientific technique that is "'generally accepted' as reliable in the relevant scientific community." *Daubert,* 509 U.S. at 584. Adoption of the Federal Rules of Evidence eliminated this standard. Instead, Plaintiffs must provide more.

Daubert held that to be admissible, expert testimony must be "not only relevant, but reliable"—*i.e.*, it must impart "'scientific knowledge'" "*derived by [a] scientific method*" and "*supported by appropriate validation*." 509 U.S. at 589-590 (emphasis added). Federal Rule of Evidence 702 requires courts to determine not only that expert testimony is "the product of reliable principles

and methods," but also that the expert has "reliably applied" those principles and methods to the facts of the case before admitting testimony.

Reference to the holdings of a professional association can be relevant under *Daubert*, but the WPATH Guidelines do not accurately reflect medical science, having been developed by a "private, activist, non-science organization" that "takes a very narrow and politically-ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals." Ex. 2 (Levine Rep.) at 36, 35-40. "When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive." *Id.* at 89.

C. Plaintiffs' characterization of the Plan's coverage decisions is contradicted by the facts.

Another factual dispute arises, in part, from disagreement over medical efficacy. Because Plaintiffs are certain about the effect of their desired treatments, they assert that no possible motive other than sex stereotyping or discriminatory animus could justify the Plan's coverage decisions. This is not supported by the evidence. The Plan's decision has no animus associated with it. Rather, the timeline is transparent. The Plan received federal funding from the Retiree Drug Subsidy program. When the federal government attached new requirements to this funding—requiring that the Plan cover the Plaintiffs'

desired benefits—the Plan complied, but the Board of Trustees' approval in 2016 was temporary due to their uncertainty regarding the benefits. When this funding condition was enjoined, later to be rescinded, the Plan allowed the benefits to expire when the initial approval sunset. Ex. 1 (Jones Dep.) at 69:9-19; 56:12-57:25. As the courts have repeatedly recognized, health plans are permitted to cover some illnesses and not others. In this case, the Board of Trustees focused on reducing the overall cost of treatment under the Plan and covering illnesses that affect large numbers of members.

D. Plaintiffs have failed to provide any evidence for crucial questions of fact.

Several remaining factual disputes arise from Plaintiffs' failure to develop evidence to carry their burden of proof. Plaintiffs repeatedly refer to "gender-confirming care," but they have never defined or otherwise provided a concrete list of the procedures that comprise such care. Plaintiffs seek injunctive relief for the alleged violation of the Equal Protection clause, ECF No. 75 at 37, but this Court cannot grant summary judgment and order such relief without clarity about exactly how the Plan is to comply. The Plan can no more be ordered to provide undefined "gender-confirming care" than a prison can be ordered to accommodate religious "dietary requirements." *Raymond Lee X v. Johnson*, 888 F.2d 1387 (4th Cir. 1989) (holding "Muslim dietary

requirements" insufficiently clear requirement to impose as an injunction under Fed. R. Civ. P. 65(d)).

Moreover, under both § 1557 of the Affordable Care Act, 42 U.S.C. § 18116, and Title VII, Plaintiffs seek damages. But they have not presented any evidence for these damages. Plaintiffs seek damages for "financial harm," ECF No. 75 at 42, 44-45, but present no calculations or medical bills. Without such evidence, the Court cannot award summary judgment. Plaintiffs allege emotional damages, *id.*, but they have neither identified nor attempted to quantify the "independent compensable harm" that resulted from the alleged violation. *Price v. City of Charlotte, N.C.*, 93 F.3d 1241, 1248 (4th Cir. 1996).

Indeed, Plaintiffs have not submitted any medical records to this Court that prove they suffer from gender dysphoria. As noted in the Plan Defendants' response to the Plaintiffs' Motion to Seal, ECF No. 190 at 6-7, Plaintiffs submitted an expert report from George Brown, M.D., which includes statements about Plaintiffs' medical histories. Dr. Brown's report, however, does not specifically cite any of Plaintiffs' medical records, and he expressly disavowed that he himself was engaged in the practice of medicine (which is required to provide a medical diagnosis). *Id.*

II. Plaintiffs have not provided sufficient evidence to receive summary judgment on their claim pursuant to the Equal Protection Clause of the 14th Amendment.

A. Plaintiffs have not identified a group of individuals, with whom they are similarly situated, who are treated differently.

The Equal Protection Clause of the 14th Amendment is "essentially a direction that all persons *similarly situated* should be treated alike." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 635 (4th Cir. 2020) (quoting *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985) (emphasis in original)). Plaintiffs must therefore produce evidence that the Plan is "treating differently persons *who are in all relevant respects alike*." *Id.* (emphasis in original).[4]

This is a sequential analysis. First, Plaintiffs must make an "initial showing" they have been "intentionally treated differently" from others who are "similarly situated." *Sandlands C & D LLC v. Cty. of Horry*, 737 F.3d 45, 55 (4th Cir. 2013). The court does not apply constitutional scrutiny—whether rational-basis or heightened—until *after* a plaintiff has made this showing of

4 The Defendants note that Plaintiffs can still demonstrate an Equal Protection violation if they can prove that a discriminatory animus motivated the adoption of a facially neutral policy that is neutrally applied. *Williams v. Hansen*, 326 F.3d 569, 584 (4th Cir.2003). Plaintiffs must proceed to trial, however, and allow the jury to weigh competing evidence of the Plan's intent.

similarity. *Id.* Without proof that two groups are "similarly situated," the Court has no basis to proceed with an equal protection analysis. "The Constitution does not require things which are different in fact … to be treated in law as though they were the same." *Roller v. Gunn*, 107 F.3d 227, 234 (4th Cir. 1997) (quoting *Tigner v. Texas,* 310 U.S. 141, 147 (1940)).

To satisfy the "similarly situated" standard, Plaintiffs must identify a comparative group of persons who are (1) materially identical to them but who (2) have received different treatment. "[A]pples should be compared to apples." *Barrington Cove Ltd. P'ship v. R.I. Hous. & Mortg. Fin. Corp.,* 246 F.3d 1, 8 (1st Cir. 2001). Two compared groups must be "identical or directly comparable in all material respects," *LaBella Winnetka, Inc. v. Village of Winnetka,* 628 F.3d 937, 942 (7th Cir. 2010), or "prima facie identical," *Grider v. City of Auburn, Ala.,* 618 F.3d 1240, 1264 (11th Cir. 2010). The Fourth Circuit requires that the "evidence must show an extremely high degree of similarity." *Willis v. Town of Marshall, N.C.,* 275 Fed. App'x. 227, 233 (4th Cir. 2008); *see also LaBella,* 628 F.3d at 942 ("The similarly situated analysis is not a precise formula, but … what is clear is that similarly situated individuals must be very similar indeed.").

Providing different medical treatments for different medical diagnoses does not violate equal protection. "[A] function of medical diagnosis is to

determine in what ways individuals are not similarly situated so that they can be treated accordingly." *Gann v. Schramm*, 606 F. Supp. 1442, 1447 (D. Del. 1985). This remains true even when different diagnoses have the same treatment. *Flaming v. Univ. of Texas Med. Branch*, 2016 WL 727941, at *9 (S.D. Tex. Feb. 24, 2016). An individual with testicular cancer may need testosterone injections, but that person is not 'similarly situated' to someone with gender dysphoria. *McMain v. Peters*, 2018 WL 3732660, at *3-4 (D.Or. Aug. 2, 2018).

This failure to define who is "similarly situated" to the Plaintiffs is exacerbated by the WPATH Guidelines on which Plaintiffs rely. Plaintiffs repeatedly cite the WPATH Guidelines as a "consensus" approach to the medical care they need, ECF No. 179 at 17-19, but when asked about that care, emphasize that the Guidelines are expressly "meant to be flexible standards," Ex. 13 (Brown. Dep.) at 160:8-18, that "individual health professionals and programs may modify themselves." Eli Coleman, et al., STANDARDS OF CARE FOR THE HEALTH OF TRANSSEXUAL, TRANSGENDER, AND GENDER-NONCONFORMING PEOPLE, v.7 at 2 (2012) (WPATH Guidelines). The term "gender affirming care" thus means anything the Plaintiffs, or an individual physician, believes could be helpful to a child or adult with gender dysphoria. This vague concept, which Plaintiffs advance despite the encyclopedic coding

system adopted by the federal government for medical diagnoses and procedures, is not sufficient information to permit the determination whether one Plan participant is "similarly situated" to another.[5]

Plaintiffs, and the two out-of-circuit district court cases they cite, do not acknowledge or even consider this initial requirement of an equal protection analysis. *See, e.g.*, *Fletcher v. Alaska*, 443 F.Supp.3d 1024, 1030-31 (D. Alaska 2020). This failure is most clear in *Boyden v. Conlin*. 341 F.Supp.3d 979, 995 (W.D. Wis. 2018). In that case, the district court assumed, without medical evidence, that a person with an unidentified genetic birth defect ("born without a vagina") is similarly situated to an individual with gender dysphoria, but then held that "no reasonable factfinder" could conclude without additional medical evidence that "a cisgender woman's depression because of small breast size" (which was not covered) "is medically comparable to gender dysphoria." *Id.*

If Plaintiffs want this Court to make similar findings, then at a minimum they need to show "medically comparable" diagnoses. *Id.* Plaintiffs do not. They argue only that if the Plan provides "the same kinds of treatments" for "other

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[5] This vagueness also prevents the Court from simply relying on the WPATH Guidelines to define the healthcare procedures at issue. An injunction must "describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required." Fed. R. Civ. P. 65(d).

reasons," then it must also cover their desired treatment for gender dysphoria. ECF No. 179 at 4. In doing so, Plaintiffs claim that hormones, puberty-delaying hormones, mammoplasty and breast reduction, vaginoplasty, and hysterectomies are available only for "cisgender participants" but not for "transgender people." ECF No. 179 at 12.

This is false. The Plan does not identify or track or record whether any participant is transgender, cisgender, non-binary or otherwise. ECF No. 137 at 14. The Plan evaluates whether the billed medical procedure corresponds to a covered diagnosis. For prescription medicines that are neither costly nor subject to abuse, neither the Plan nor CVS/Caremark (the Plan's Pharmacy Benefit Manager) *ever know* the reason for the prescription (*i.e.* the patient's diagnosis). *Id.* at 17-18. Those claims are paid.

Some prescription drugs are subject to special restrictions because they are expensive or subject to abuse. Each of these drugs must be prescribed for an FDA-approved diagnosis or for cancer treatment. *Id.* When these drugs are prescribed "off-label" for any other use, including treatment of gender dysphoria, they are denied. For example, the Plan requires prior authorization for some testosterone prescriptions. *See* Ex. 9 (CVS/Caremark, Prior Authorization Criteria). The authorization criteria identify the covered diagnoses: primary hypogonadism, hypogonadotropic hypogonadism, and

metastatic mammary cancer. *Id.* No individual ever receives a testosterone prescription to "reaffirm an individual's natal sex" or to "diverge[ ] from an individual's natal sex." ECF No. 179 at 21. Nothing in the authorization document refers to transgender individuals; prescriptions are authorized for both men and women.

The Plan applies the same restrictions—that the prescription is used to treat an FDA-approved diagnosis or to treat cancer—to hormone suppressing drugs that are covered by Specialty Guideline Management: Supprelin (central precocious puberty in all children), Eligard (prostate cancer and certain salivary gland tumors); Vantas (prostate cancer); Zoladex (prostate cancer, endometriosis, breast cancer); Triptodur (central precocious puberty in all children); and Trelstar (prostate cancer). *See* Ex. 10. Plaintiffs qualify for these prescriptions on the exact same basis as every other Plan participant.

For surgeries, again, the Plan authorizes payment based on diagnosis and procedure code. The Plan provides mastectomies for breast cancer, gynecomastia, breast reduction for macromastia (when breast size causes neck, back, and shoulder pain), and for individuals with a high risk of breast cancer. Ex. 11 (Blue Cross Blue Shield of North Carolina, Corporate Medical Policy, Breast Surgeries, August 2020. These patients can also, if they desire, receive breast reconstruction, but this is not the result of a Plan design or "sex

stereotypes." Federal law requires it. Every group health plan that provides "medical and surgical benefits with respect to a mastectomy" must provide "all stages of reconstruction of the breast on which the mastectomy has been performed" and "surgery and reconstruction of the other breast to produce a symmetrical appearance." 29 U.S.C. § 1185b(a).[6]

Payment for a specific procedure is not based on the sex or transgender identity of the patient; rather, the denial of coverage arises from the diagnosis. At deposition, at least some of the Plaintiffs conceded this point. *See*, *e.g.*, Ex. 12 (M. Bunting. Dep.) at 108:11-20 (Plaintiff does not assert that the "Plan does not pay for any of [C.B.'s] medical treatment," but rather that the Plan does not "cover treatment connected to [C.B.'s] gender dysphoria."). *See Saks v. Franklin Covey Co.*, 316 F.3d 337, 342 (2d Cir. 2003) (applying similar analysis to infertility); *In re Union Pac. R.R. Employment Practices Litig.*, 479 F.3d 936, 942, 944 (8th Cir. 2007) (contraceptive coverage).

"Generally, in determining whether persons are similarly situated for equal protection purposes, a court must examine *all* relevant factors." *United States v. Olvis,* 97 F.3d 739, 744 (4th Cir. 1996) (emphasis added). *Sandlands*

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[6] The Plaintiffs claim there is a discrepancy in coverage of hysterectomies, ECF No. 179 at 12, but the Plan has no procedure codes that limit hysterectomies in connection with a diagnosis of gender dysphoria, ECF No. 137 at 15-17.

C & D LLC, 737 F.3d at 55. Plaintiffs' motion for summary judgment fails at this threshold inquiry because they have not produced any evidence to establish that an individual with gender dysphoria is "identical or directly comparable in all material respects," *LaBella Winnetka,* 628 F.3d at 942, or "prima facie identical," *Grider,* 618 F.3d at 1264, to an individual with a different medical diagnosis, such as breast or prostate cancer.

At the summary judgment stage, these relevant factors must be resolved against the Plaintiffs. The Court must assume that the differences between the diagnosis of gender dysphoria and other diagnoses are significant, and that the medical efficacy of the treatments differs, creating a "genuine dispute" of "material fact." Fed. R. Civ. P. 56(a).

B. Plaintiffs have not established that the State Health Plan imposes facial classifications on its beneficiaries

"Whether an employment practice involves disparate treatment through explicit facial discrimination does not depend on why the employer discriminates but rather on the explicit terms of the discrimination." *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991). The Plaintiffs argue that the Plan discriminates, on its face, against the Plaintiffs. They do so based on the

Plan's benefit booklet, which states that the Plan does not cover, among other medical treatments, the following services:

> Treatment or studies leading to or in connection with sex changes or modifications and related care.

The text of this exclusion, however, does not distinguish between individuals on the basis of sex, gender, or transgender status. To be facial discrimination, the provision must distinguish between men and women. It does not. To discriminate against transgender individuals, it must separate the health care available to transgender individuals from the health care available to others. The provision does not.

Plaintiffs attempt to establish facial discrimination under two broad lines of reasoning. First, and primarily, Plaintiffs assert that the State Health Plan improperly denies coverage for certain "medically necessary care … based on an employee's birth-assigned sex." ECF No. 153 at 17. But by focusing on their individual desires for specific medical treatments, Plaintiffs miss the broader context of how those treatments are prescribed, administered, and paid for across the healthcare industry.

Plaintiffs are mistaken in their assertion that the Plan's exclusion of certain coverage is "discriminating against a person for being transgender," "based on gender transition," or "based on an employee's birth-assigned sex."[7] ECF No. 153 at 16-18. The Plan excludes coverage for specific procedures if they are prescribed for treatment of the psychiatric diagnosis of gender dysphoria. Ex. 1 (Jones Dep.) at 15:1-16:23, 117:10-18:5.

Payment hinges solely on the medical condition and the procedure performed to treat it, which is determined independently of the Plan by the patient's chosen healthcare provider. Unlike in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), where the employer both evaluated the Plaintiff's biological sex and terminated the employee after considering that information, a patient's biological sex and/or expressed gender play no role in Plan coverage. For example, the Plan covers breast reduction surgery for a transgender man with a family history of breast cancer, a hysterectomy for a transgender man suffering from endometriosis, testosterone treatment for a transgender woman

7 Plaintiffs improperly conflate these three distinct equal protection claims into a single element of "discrimination." Discrimination based on gender identity and discrimination based on biological sex operate in different ways. Furthermore, Plaintiffs make no effort to clarify whether they allege discriminatory animus, disparate impact, or both. In sum, the breadth and vagueness of Plaintiffs' assertions highlight their misunderstanding of the specific policy grounds for the State Health Plan's coverage policies.

based on specific hormonal needs, or genital constructive surgery for any transgender (or cisgender) person with relevant injuries from a workplace or automobile accident. Ex. 14 (BCBS Decl.) at ¶ 28.

As the Plan has shown, ECF No. 137 at 14, none of its coverage decisions for gender dysphoria consider a patient's sex. It is unclear whether Plaintiffs' claim of discrimination is that *any* coverage decision is subject to heightened scrutiny if *the healthcare provider* considered the patient's biological sex as part of the diagnostic process. Healthcare providers must know a patient's sex for *every* medical diagnosis. While hormones or surgical procedures can alter the visual appearance of a patient, "the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex." Ex. 3 (Hruz Rep.) at 66. As but one example how this is so: under the clinical guidelines for cardiovascular health, male biological sex is, by itself, a risk factor indicating preventive intervention. Ex. 15 (Robie. Dep.) at 70:13-71:25. Competent medical care requires *every diagnosing physician* to know and to consider the patient's biological sex. *Id.* This does not, however, make the

physician an agent of the Plan or mean that the Plan itself has looked beyond the diagnosis that this independent actor has supplied.[8]

Gender dysphoria is a mental illness that affects some people who are transgender and some who are not, Ex. 16 (Ettner Dep.) at 28:11-13, Ex. 17 (Levine Dep.) at 241:24-243:20, and the proportion of transgender individuals who suffer from this condition is entirely unknown. Ex. 13 (Brown Dep.) at 92:17-25. Many transgender people do not suffer from gender dysphoria at all. Ex. 16 (Ettner Dep.) at 28:11-13; Ex. 17 (Levine Dep.) at 241:24-243:20. Furthermore, "there may be people who have symptoms of gender dysphoria, but they personally don't identify as transgender." Ex. 18 (Karasic Dep.) at 27:25-28:17; Ex. 17 (Levine Dep.) at 241:24-243:20. As a result, Plaintiffs' assertion that "transgender individuals are the only people who would ever seek" treatments for gender dysphoria is flatly contradicted by the testimony

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[8] In contrast to the information before a treating physician, the Plan sees only the information on the standard reimbursement form for health insurance, adopted by BCBSNC and the entire healthcare industry. This form does require each healthcare provider to report the patient's sex, but this can be biological sex or expressed gender; the information is irrelevant because the coverage decisions here do not consider this information at all. ECF No. 137 at 10-11. The Plan also receives bills that use the diagnostic codes developed by the World Health Organization and required by HHS, as is the case for every other participant in the healthcare industry. While some diagnostic or procedure codes are sex-specific, *see*, *e.g.*, ECF No. 137 at 10, this does not mean that the Plan has made any decision other than to use coding required by the healthcare industry.

of their own medical experts submitted to this Court. ECF No. 139 at 16 (citing *Toomey v. Arizona*, 2019 WL 7172144 at *6 (D. Ariz. Dec. 23, 2019)).[9]

The Plan's benefits, and limits on coverage, apply equally, and they are implemented *without any knowledge of the beneficiary's sex or gender*. Ex. 14 (BCBS Decl.) at ¶¶ 22,28. The Plan's benefit scheme therefore cannot be shown to discriminate facially on the basis of sex. This remains true even if one assumes, incorrectly, that only transgender individuals suffer from gender dysphoria. Ex. 16 (Ettner Dep.) at 28:11-13; Ex. 17 (Levine Dep.) at 241:24-243:20.

In *Geduldig v. Aiello*, the Supreme Court held that the exclusion of pregnancy from an insurance program was not facially "sex-based" even though only (biological) females become pregnant. 417 U.S. 484, 496 n.20 (1974). There is "no risk from which men are protected and women are not. Likewise, there is no risk from which women are protected and men are not." *Id.* at 496. "The lack of identity between the excluded disability and gender as

9 Plaintiffs rely on the denial of a motion to dismiss in *Toomey v. Arizona*, 2019 WL 7172144 (D.Ariz. 2019) to support their motion for summary judgment. *Toomey* decided only that a particular plaintiff had stated a claim "that is plausible on its face," accepting all allegations and reasonable inferences as true, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard is in sharp contrast to Plaintiffs' motion here for summary judgment, under which the Plaintiffs themselves must produce evidence there is "no genuine dispute as to any material fact."

such under this insurance program becomes clear upon the most cursory analysis." *Id.*

> The program divides potential recipients into two groups—pregnant women and nonpregnant persons. While the first group is exclusively female, the second includes members of both sexes. The fiscal and actuarial benefits of the program thus accrue to members of both sexes.

Id. at 496 n.20. This case is the same. Not all transgender individuals suffer from gender dysphoria. Ex. 16 (Ettner Dep.) at 28:11-13; Ex. 17 (Levine Dep.) at 241:24-243:20; Ex. 13 (Brown Dep.) at 92:17-25. The Supreme Court's reasoning in *Aiello* controls the analysis here:

> The program divides potential recipients into two groups—[individuals who suffer from gender dysphoria and individuals who do not. Even if] the first group is exclusively [transgender (and the evidence shows it is not)], the second group includes [both transgender and non-transgender individuals]. The fiscal and actuarial benefits of the program thus accrue to members of both [groups]

Aiello, 417 U.S. at 496. Under the Plan, transgender females have the same coverage as a transgender males, and both transgender males and females have the same coverage as cisgender males and females.

Plaintiffs may feel that the Plan burdens them unfairly as transgender people, but this does not establish discrimination. *Aiello* holds that an insurance exclusion that disparately impacts members of a particular class is

not discrimination without evidence of discriminatory intent.[10] 417 U.S. at 496 n.20. Plaintiffs have made no effort to establish discriminatory intent beyond vague references to "impermissible stereotyping." This is precisely the type of contested fact that must proceed to trial. The Plan's exclusion of certain treatments for the psychiatric condition of gender dysphoria does not stem from any view about what healthcare Plaintiffs should receive; it stems from judgment about how to best provide medical care for all members in light of existing regulations, the health care needs for all patients covered by the Plan, and limited financial resources. Ex. 1 (Jones Dep.) at 73:4-75:8.

Plaintiffs must proceed to trial and provide more: evidence of discriminatory intent. They cannot prevail only with assertions that gender dysphoria disproportionately affects members of a protected class. *See Lange*

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[10] Plaintiffs argue that *Aiello* has been overruled, ECF No. 188 at 5-6, but this is flatly incorrect. The Pregnancy Discrimination Act and cases cited by Plaintiffs "cast[ ] no doubt on the continuing vitality" of *Aiello*. *Bray*, 506 U.S. at 273 n.3. Nor does *Bostock* permit this Court to depart from *Aiello*'s reasoning and analysis. *Bostock* involved statutory interpretation. 140 S.Ct. at 1738. The Court did not consider whether the same analysis should apply in cases involving the Equal Protection Clause. When a Supreme Court precedent "has direct application in a case, yet appears to rest on reasons rejected in some other line of decisions," the lower court must "follow the case which directly controls, leaving to [the Supreme Court] the prerogative of overruling its own decisions." *Agostini v. Felton*, 521 U.S. 203, 237 (1997).

v. Houston Cty., 499 F. Supp. 3d 1258, 1275-77 (M.D. Ga. 2020) (insurance exclusion for gender dysphoria not facially discriminatory).

C. Plaintiffs have not established any legal authority for their claims that the Plan has an obligation to provide any member with specific medical care or that the refusal to do so is improper.

Plaintiffs' motion for summary judgment devotes significant time and attention to assertions that "medical treatment for gender dysphoria is medically necessary and effective." ECF No. 179 at 17-20. The claim that denial of medically necessary care inherently constitutes discrimination is mistaken, because *the Plan has no obligation to cover medically necessary care for participants*.

Plaintiffs assert that health benefits are "compensation" to employees. ECF No. 179 at 4. This is false. The General Assembly of North Carolina has explicitly provided that "employer-provided fringe benefits," which include "health, life or disability plans," are *not* "compensation." N.C. Stat. § 135-1(7a)(b). "A State employee receives the benefits of the State Health Plan only when needed," so the agency's payment to the Plan to offset the cost of these health benefits is not part of the employee's wages. *Kirk v. State*, 465 S.E.2d 301, 306 (N.C. Ct. App. 1995). "The State endeavors to 'make available a State Health Plan.' But "[m]aking available and providing access

does not create any specific contractual financial obligation." *Lake v. State Health Plan for Tchrs. & State Emps.*, 825 S.E.2d 645, 656 (N.C. Ct. App. 2019).

Plaintiffs' participation or "subscription" to the Plan does not guarantee any particular health benefits. "The value of this benefit [participation in the health plan] cannot be quantified." *Kirk*, 465 S.E.2d at 306. Moreover, the facts clearly indicate that the medical necessity of a given treatment is irrelevant to the State Health Plan's policies. The Plan declines to cover any number of "medically necessary" treatments and procedures, and it is well within its rights to do so. Ex. 1 (Jones Dep.) at 58:12-15; 72:4-6. The Plan is not a doctor. Its duty is not to guarantee maximalist treatment for every member; rather, its duty is to maximize value for the whole of its members. The Plan's "package of services has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered—not 'adequate health care.'" *Alexander v. Choate*, 469 U.S. 287, 303 (1985).

Accordingly, any differences in the "individual services offered" by the Plan stems from its discretionary analysis of the applicable regulations, the relative priority of different treatments, and the available resources—not "because of … its adverse effects" upon Plaintiffs or any other group. *Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 279 (1979).

The federal courts have endorsed insurers' rights to make these decisions. Even when a patient has a fundamental right to a medical procedure and cannot afford to pay for it, the Constitution does not require that the Plan cover it; if anything, this barrier to care (refusal to pay for a procedure) represents a wealth classification based on individuals' ability to pay for certain treatment, not an actionable form of discrimination under the ACA or on equal protection grounds. *See Maher v. Roe*, 432 U.S. 464, 471 (1977). The Plan's policies discriminate against Plaintiffs "only in the same sense that [they] discriminate[ ] against those who might need penile prosthetic implants (which may be medically necessary to cure impotence), Kerato-refractive eye surgery (which may be medically necessary to cure vision defects), hearing aids (which may be medically necessary to overcome deafness), or those who suffer from eating or sleep disorders: they must pay for those procedures or devices themselves." *Saks v. Franklin Covey Co.*, 117 F.Supp.2d 318, 329 (S.D.N.Y. Oct. 2, 2000). All Plan members, including Plaintiffs, receive the actuarial benefit of this—and every other—coverage limit. Just as not all women are pregnant, not all transgender individuals require treatment for gender dysphoria.

Finally, it is a "legitimate purpose" to "limit[] health care costs." *Saah v. Contel Corp.*, 978 F.2d 1256 (4th Cir.1992) (per curiam). *See also Boyd v.*

Bulala, 877 F.2d 1191, 1197 (4th Cir.1989) ("[C]ap on [malpractice] liability bears a reasonable relation to a valid legislative purpose—the maintenance of adequate health care services."). "[S]o long as the line drawn by the State is rationally supportable, the courts will not interpose their judgment as to the appropriate stopping point" even if members of a protected class are disproportionately affected by the lack of coverage. *Aiello*, 417 U.S. at 495.

As one member of the Board of Trustees stated, his goal is "not to limit increases in cost" but to actually "cut the cost of healthcare for our state workers" because some individuals "are paying 20, 25 percent of their monthly income on healthcare on the State Health Plan." Robie.Dep.73:3-11. Once the Plan starts adding niche benefits, "then I have to keep going" for "[e]verybody who comes in and wants a benefit … because I can't discriminate." Jones.Dep.104:25-105:24. Plaintiffs suggest that this rationale weakens when the marginal cost of additional coverage is low, but there is no *de minimus* exception permitting Court intrusion when only "moderate alterations" to premium "variables" are needed. *Aiello*, 417 U.S. at 495-96. "The State has a legitimate interest in maintaining the self-supporting nature of its insurance program" and nothing in the Constitution requires a "more comprehensive" one. *Id.* at 496.

III. The Plaintiffs' remaining claims are not supported by the evidence.

A. Plaintiffs have not provided sufficient evidence to support a grant of summary judgment under § 1557 of the Affordable Care Act.

Plaintiffs seek summary judgment for injunctive relief and damages under § 1557 of the Affordable Care Act, alleging that the failure to cover hormone treatment and surgery for gender dysphoria is "discrimination based on sex in healthcare." ECF No. 179 at 30-32.[11]

To the extent Plaintiffs claim the Plan's decision not to cover each and every possible treatment for gender dysphoria reflects discrimination "on the basis of sex," this argument has been addressed above. Also relevant to the § 1557 claim, however, is the fact that the U.S. Department of Health and Human Services ("HHS") has now expressly disavowed the factual analysis and conclusions reached in its earlier 2016 rule interpreting the scope of § 1557. In 2016, HHS stated that transition-related treatment could no longer be considered "cosmetic or experimental;" refusal to cover hormone treatment

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[11] Plaintiffs cite another district court ruling on a motion to dismiss as support for a grant of summary judgment. ECF No. 179 at 28 (citing *C.P. by & through Pritchard v. Blue Cross Blue Shield of Illinois*, 536 F. Supp.3d 791 (W.D. Wash. 2021). *CP* held only that "[p]laintiffs provide enough [unspecified] factual support" to make an allegation of discrimination "plausible." The case is irrelevant on summary judgment, especially as the court did not identify the "factual support" it found persuasive. *Id.*

or surgery on such a basis "is now recognized as outdated and not based on current standards of care." 81 Fed. Reg. 31429 (May 18, 2019).

The revised 2020 Rule studied this factual question, received extensive comment, and the agency concluded after a "review of the most recent evidence" that the 2016 statement "was an erroneous assertion." 85 Fed. Reg. 37187 (June 19, 2020). The current Rule found that "there is, at a minimum, a lack of scientific and medical consensus to support this assertion," and the "lack of scientific and medical consensus—and the lack of high-quality scientific evidence supporting such treatments—is borne out by other evidence." *Id.*

With their claim under § 1557, Plaintiffs ask this Court to do what HHS has refused: impose a view about appropriate care for gender dysphoria in a way that "inappropriately interfere[s] with the ethical and medical judgment of health professionals." 85 Fed. Reg. 37187. "A medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical." *Id.*[12]

[12] Plaintiffs have provided no alternative theories or evidence in support their § 1557 claim other than the claim of facial discrimination rejected above.

Plaintiffs have also provided no evidence of damages. Under both § 1557 of the Affordable Care Act, 42 U.S.C. § 18116, and Title VII, Plaintiffs seek damages, but have presented no evidence for this Court to consider. Although Plaintiffs allege "financial harm," ECF No. 75 at 42, 44-45, they present no calculations or medical bills. Similarly, Plaintiffs allege emotional damages, *id.*, but have not identified or quantified the "independent compensable harm" that resulted from the alleged statutory violation. *Price v. City of Charlotte, N.C.*, 93 F.3d 1241, 1248 (4th Cir. 1996). Without such evidence, the Court cannot award summary judgment to Plaintiffs on either the § 1557 claim or the Title VII claim.

B. Plaintiff Caraway has not produced sufficient evidence to support her Title VII claim.

The Court should deny Caraway's motion for summary judgment and dismiss her Title VII claim. ECF No. 137 at 25-33; ECF No. 193 at 1-6. Caraway misunderstands the application of Title VII to fringe benefits, asserting that her health benefits are "compensation." ECF No. 179 at 4. This is false. As discussed earlier, "employer-provided fringe benefits" which include

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Because § 1557 adopts the "enforcement mechanisms provided for and available under" the referenced civil rights statutes, 42 U.S.C. § 18116(a), and because Title IX does not permit a claim based on "disparate impact," *Doe v. Fairfax Cty. Sch. Bd.*, 403 F.Supp.3d 508, 515 (E.D. Va. 2019), Plaintiffs cannot assert a disparate impact claim in this case either.

"health, life or disability plans" are *not* "compensation." N.C. Stat. § 135-1(7a)(b).

Manhart, the case Caraway relies upon, makes this analysis clear. In *Manhart*, the Supreme Court considered whether a pension plan could "require[ ] female employees to make monthly contributions to the fund which were…higher than the contributions required of comparable male employees." *City of Los Angeles, Dep't of Water & Power v. Manhart*, 435 U.S. 702, 705 (1978). The Court rejected such a distinction, because Title VII's "focus on the individual is unambiguous" and "precludes treatment of individuals as simply components of a racial, religious, sexual, or national class." *Id.* at 708. Therefore, even if "[w]omen, as a class, do live longer than men," *id.* at 707, the employer could not charge different amounts based on sex.

In response, the employer made an argument very similar to Caraway's. Just as Caraway argues that it is unfair that the Plan does not pay for all of her treatments, Manhart's employer argued that a *failure* to charge different contributions "would itself violate Title VII because of its disproportionately heavy impact on male employees." *Id.* at 710 n.20. The Court rejected this analysis. "This suggestion has no force in the sex discrimination context because each retiree's total pension benefits are ultimately determined by his *actual life span*; any differential in benefits paid to men and women in the

aggregate is thus "based on [a] factor other than sex." *Id.* The same logic applies here. Caraway's health care payments "are ultimately determined by" her *actual medical needs*; "any differential in benefits paid … in the aggregate is thus based on a factor other than sex." *Id.*

CONCLUSION

Plaintiffs ask this Court to conceptualize their case as involving an by the Plan on the autonomy of transgender individuals, but this profoundly misstates the facts, the law, and the procedural posture. The State Health Plan does not restrict Plaintiffs' medical care. The Plan does not classify Plan members based on whether they identify as transgender, cisgender, non-binary, non-gendered, or otherwise. The Plan does not provide different health coverage to Plaintiffs. The discrimination alleged by Plaintiffs is that the Plan cannot cover a medication or treatment for one diagnosis—for example, a mastectomy for a man or woman with breast cancer—without also paying for medical treatment for *a different diagnosis*. This is not the law.

Respectfully submitted, this the 19th day of January, 2022.

/s/ John G. Knepper
Wyo. Bar. No. 7-4608
LAW OFFICE OF JOHN G. KNEPPER, LLC
1720 Carey Ave. Suite 590
Cheyenne, WY 82001
Telephone: (307) 632-2842
Facsimile: (307) 432-0310
john@knepperllc.com

/s/ Kevin G. Williams
N.C. Bar No. 25760

/s/ Mark A. Jones
N.C. Bar No. 36215
BELL, DAVIS & PITT, P.A.
100 N. Cherry St. Suite 600
Winston-Salem, NC 27101
Telephone: (336) 722-3700
Facsimile: (336) 722-8153
kwilliams@belldavispitt.com
mjones@belldavispitt.com

CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that this Brief complies with the Court's expanded word limit using the word count feature of the word processing software in making this certification.

/s/ John G. Knepper
Wyo. Bar. No. 7-4608
LAW OFFICE OF JOHN G. KNEPPER, LLC
1720 Carey Ave. Suite 590
Cheyenne, WY 82001
Telephone: (307) 632-2842
Facsimile: (307) 432-0310
john@knepperllc.com

/s/ Kevin G. Williams
N.C. Bar No. 25760

/s/ Mark A. Jones
N.C. Bar No. 36215
BELL, DAVIS & PITT, P.A.
100 N. Cherry St. Suite 600
Winston-Salem, NC 27101
Telephone: (336) 722-3700
Facsimile: (336) 722-8153
kwilliams@belldavispitt.com
mjones@belldavispitt.com

IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,
Plaintiffs,
V.
DALE FOLWELL, et al.,
Defendants.

No. 1:19-cv-272-LCB-LPA

DEPOSITION
OF
DEE JONES

IN HER INDIVIDUAL CAPACITY
and
30(b)(6) DESIGNEE FOR NC STATE HEALTH PLAN

AUGUST 3, 2021

THIS TRANSCRIPT IS NOT COMPLETE
PORTIONS OF THIS TRANSCRIPT AND/OR EXHIBITS
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AFTER REVIEW OF TRANSCRIPT BY ATTORNEYS WITHIN 30
DAYS OF DATE OF DEPOSITION PER PROTECTIVE ORDER

PNC PLAZA DOWNTOWN
301 Fayetteville Street, Suite 1700
Raleigh, North Carolina

Reported by: Michelle Maar, RDR, RMR, FCRR

Q. And in 2016, did the Plan's benefits coverage provide for blanket exclusions for treatment of gender dysphoria?

A. Yes.

Q. I would like to show you what I'm marking as Plaintiffs' Exhibit 1.

(Exhibit 1 is marked for identification.)

MS. RAVI: I'll give you a moment to review the document. I know it's lengthy.

MR. RULEY: You've seen it before.

THE WITNESS: I've seen it once or twice.

BY MS. RAVI:

Q. Do you recognize this document?

A. I do.

Q. What is this?

A. It is the 80/20 PPO Plan Benefits Booklet for the period January 1 through December 31 of 2016.

Q. Would you turn to the page marked as PLAN DEF2711.

In the 2016 Plan Year, did the Plan exclude from coverage treatment or studies leading to or in connection with sex changes or modifications and related care?

A. Yes.

Q. If you could turn to the page marked PLAN DEF2699.

In the 2016 Plan Year, did the Plan exclude from coverage psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation?

A. Yes.

Q. If I refer to these two exclusions from coverage today as the exclusions, will you know what I'm talking about?

A. Yes.

Q. All right. When was this exclusion language added to the Plan documents?

A. As I understand it, back into the '90s in some capacity.

Q. And with the exception of Plan Year 2017, has the exclusion been in place continuously since it was introduced?

A. As I understand it, yes.

Q. And is that correct for the 80/20 PPO Plan?

A. Yes.

Q. Is that also correct for the 70/30 PPO Plan?

A. Yes.

Q. And for the High-Deductible Health Plan?

A. Yes.

Q. Who is eligible to enroll in the State Health Plan?

A. There was nobody that said oh, we should let it sunset, oh, we should push it forward and bring it up for vote.

Q. I'll hand you what I've marked as Plaintiffs' Exhibit 8.

(Exhibit 8 is marked for identification.)

BY MS. RAVI:

Q. Do you recognize this document?

A. Generally, yes.

Q. Have you seen it before?

A. I have not seen it with the track changes.

Q. What is this document?

A. It appears to be a draft of a resolution relative to the coverage that suggests that the state will follow the law and, if the, there's any repeal of the law or notice by the Department of Health and Human Services that this benefit will no longer be required to be provided under federal law.

Q. And looking at the document marked PLAN DEF35963, does this appear to be the cover e-mail attaching that document?

A. It does.

Q. What is the date on the cover e-mail?

A. January 23, 2017.

Q. So turning to the attachment PLAN DEF44771, who

Q. Did you discuss this recommendation with the State Treasurer?

A. No.

Q. Is it correct that care must be medically necessary to be covered by your Plan?

A. Yes. But the Plan does not cover all medically necessary treatment.

Q. At the time of this draft resolution, was it the Plan's position that gender transition services were medically necessary care?

MR. RULEY: Objection, form.

THE WITNESS: Again, a lot of things are medically necessary that the Plan doesn't cover. And a lot is not, it's maybe a little bit of a loaded word. But that is what it says here.

BY MS. RAVI:

Q. I'm sorry -- could you clarify when you say that is what it says here?

A. It says here in the resolution that the board approve medically necessary coverage.

Q. Medically necessary coverage of gender transition services?

A. Yes.

Q. Regarding the position on whether or not gender transition services are medically necessary coverage, has

drafted this document?

A. I do not know. But based on the e-mail, it would appear that some combination of Blake Thomas and Lotta Crabtree.

Q. And why was this resolution drafted?

A. My guess is there is -- well, it's not really a guess -- it's based on following the law and whether or not the coverage is mandated or not. That was the general reason for covering it in the first place was because of the risk of losing federal funding.

Q. And the resolution states that the Board of Trustees approve medically necessary coverage of gender transition services for the 2017 Benefit Year.

Is that right?

A. That's what it says, yes.

Q. And it states that that was in response to a final rule issued by the Department of Health and Human Services?

A. Yes.

Q. Turning to the fourth WHEREAS clause, it states that the State Treasurer recommends that this benefit only be offered so long as it is required to be offered under federal law.

Is that correct?

A. Yes.

A. That is correct.

Q. What was the basis for that reference?

A. This is the Treasurer's words. I'm not aware of what he was referring to. I don't disagree with it. But these are his words.

Q. All right. Are you aware of the Treasurer's basis for this statement?

A. No.

Q. Does the Plan believe the treatment for gender dysphoria is medically uncertain?

A. Yes.

Q. When did this view develop?

A. Please repeat.

Q. When did this view develop?

A. I would say over several years. In 2016, it's very clear that while the presentations had a lot of supporting documentation, the basis of the sunsetting or the removal of the exclusion was based on the 1557 Rule and the need to keep the federal funding.

And the Plan at the time, the staff used and put forth all sorts of other information when we just went through.

But since that time, we have new staff, we have a small staff, we manage contracts, and we have limited clinical staff.

benefits and any benefits that might apply to a broad swath of the population with a not guaranteed but a strong proponent of lower costs in the future.

And so that's where legal and medical uncertainty -- I don't have to cover medically necessary treatment. We cover a lot of it. But in this case, we don't.

Q. Prior to this statement coming out on October 25, 2018, did Plan staff discuss the legal uncertainty that's referenced here?

A. Yes.

Q. Did Plan staff discuss the medical uncertainty that's referenced here?

A. Yes.

Q. Let's turn back to Exhibit 5. And if you can turn to Page 10 of this document.

Plaintiffs' Interrogatory Number 3 asks the Plan to discuss the factual basis for each governmental interest that the Plan contends supports the exclusion.

Is that right?

A. Yes.

Q. And is it correct, turning to the next page, the Plan states that the Plan has not identified any valid, reliable, peer-reviewed longitudinal studies that support the efficacy of the plaintiffs' desired treatment?

A. I'm sorry -- where are you?

Q. I am at the bottom of Page 11, last paragraph.

A. Okay.

That would be true.

Q. Is a peer-reviewed, longitudinal study that supports the efficacy of treatment a prerequisite for the Plan to cover a proposed benefit?

A. Not necessarily. When we evaluate, as I think we said earlier, it's a holistic review. There's no single pathway to coverage. It has to be a broad swath of membership, that there's a benefit for multiple people.

There's a cost component to it. There's a downstream cost component to it. There's got to be some common -- not experimental for sure.

There's got to be some common understanding in the medical community that it is a treatment that will produce a downstream effect that's positive.

So, you know, it's very difficult to come back and say well, peer-reviewed, longitudinal studies -- I'm not a clinician and I'm not a researcher, so it's, you know -- but to the extent that we have not found any real evidence that it's absolutely black and white, this particular issue.

You know, I think it goes, well, it should go without saying this is not a personal issue for me. I don't get, I have no personal opinion about this.

Because I walk through the front door at the office, and I'm a fiduciary. This is all about the cost and maintaining this benefit for 740,000 people who expect it every single day and the retirees that have an expectation of the benefit when they retire.

And so every decision I make -- and I'm speaking for myself -- is about that. It's all about that every day.

It breaks my heart 9 times out of 10 when I have to decline a benefit, 9 times out of 10.

When I see people that need hearing aids, I would love to give them a hearing aid, I would love to.

I have nothing against transgender people. I would be more than happy to provide the benefit. But it's not my decision. I'm a fiduciary first. And I'm responsible for 740,000 people. This is not personal. This is all about money very simply put.

I've been charged with reducing the costs of the Plan to operate since the day I started. And we have done just that.

You know, there's some discussions about how much money the Plan has saved. Well, it's because we've worked really hard to do that. We've taken out all extraneous benefits.

We used to cover benefits for a small population

not personal. This is not something that I get to make a choice about. Because if I had every single group that comes in to ask for a benefit, if I covered that, then I would be completely, completely avoiding my fiduciary responsibility to cover basic health. That's what the Plan Benefits Booklet says, right?

The Plan Benefits Booklet identifies every single thing I cover. And it provides healthcare. We want every member of the Plan to have good healthcare. We want the -- and the reality is we have a lot of members who have diabetes. We have a lot of members who have orthopedic issues. We have a lot of members who have RA. We have really a lot of members who have cancer. And they want to be, they want to be covered.

And so it's really difficult for me to just say, you know, I can take this group of 25 and this group of 10 and these -- if you add all that up -- I'll, I'll totally admit that the cost of this benefit is not going to break the Plan, never was, never will.

But it -- I can't do it for that group and not do it for the group that wants it for their infants, for, you know, for a certain feeding formula for that infant group, and I can't do it for the hearing aid group, and I can't do it for the group that really wants acupuncture.

Because once you start adding those, then I have

to keep going. Everybody who comes in and wants a benefit, I'll have to do it because I can't discriminate.

I'm not discriminating. This is about what the Plan can afford in the environment that we're in today -- which is I have a General Assembly that's funding me at 4 percent when my trend rate is 7 plus. And that's not even absolutely certain.

I have a 28.8 billion unfunded liability for retiree healthcare that I, myself, am ready to have in a few years.

And so, you know, this is all about being a government plan. And I don't get to, I don't get to pick and choose. I'm not a commercial plan.

So let's start with that. A commercial plan, they have revenues, right? You go out and sell widgets, and you sell a lot of widgets, and then you decide how much you want to put into the benefit. And you can have your member, your staff, your employees pay.

I would bet most employers -- I was paying 100 bucks when I was at Time Warner. I was paying for the family, and I wasn't fully subsidized.

At the State Health Plan, we've got people who, a whole lot of employees have to work one week out of a month just to cover their Health Plan for their family.

And the effort to just institute a 25 dollar

-- if that's okay.

MS. RAVI: Alan, I think we're taking another 5 to 10 minute break, and then we'll be back.

(Off the record)

MR. RULEY: I have just a few follow-up questions for you.

EXAMINATION

BY MR. RULEY:

Q. Would you find Exhibit 1 please. Would you turn to Page 50 please.

Page 50 is titled What Is Not Covered? Is that right?

A. That is correct.

Q. And are these basically exclusions, a list of exclusions?

A. Yes.

Q. And would you look at the fourth bullet point.

A. Yes.

Q. What is that exclusion?

A. Any experimental drug or any drug or device not approved by the Food and Drug Administration (FDA) for the applicable diagnosis or treatment.

Q. Then turning the page to Page 51, the fourth bullet point from the bottom, what is that exclusion?

A. Surgical procedures for psychological or emotional reasons.

Q. And would those exclusions also potentially apply to coverage for gender dysphoria?

A. Yes.

Q. Earlier, you mentioned HBRs. What are they again please?

A. Health Benefit Representatives. They are actually defined in statute. And they work at the various employing units. I mentioned there are 408. They are liaisons to the Plan. So the Plan teaches them, keeps them apprised of the benefits being offered. But they're responsible for their employer's employees and getting them enrolled and making sure they understand the processes.

Q. So are they employed by the State Health Plan or by others?

A. By the others.

Q. All right. Thank you.

On costs -- would you get Exhibits 6 and 7 please.

Looking at Exhibit 6, for example, look at the first e-mail on Exhibit 6, Page DEF61647, the January 22, 2017 e-mail.

A. Yes.

Q. And that reports, as of 1-21, a total paid of 287.57.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Declaration of
STEPHEN B. LEVINE, M.D.
Version of APRIL 28, 2021

SECTION I. CREDENTIALS - KNOWLEDGE, TRAINING, and EXPERIENCE:

1. Education - Academic Appointments - Research Grants: I am a Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and also maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, and became a Full Professor in 1985. I have been the recipient of the following grants for scientific research and/or program development:

a. 23 separate pharmaceutical company grants to study various prosexual medications

b. U.S. National Institute of Health grant for the study of sexual consequences of Systemic Lupus Erythematosis. Co-principal investigator

c. 5 separate grants from the private Sihler Mental Health Foundation

— to create the Program for Professionals which evaluated medical and religious leaders accused of sexual offenses

— to establish a Center for Marital and Sexual Health

— to create a placebo controlled research study on Clomipramine for Premature ejaculation

— to create a follow-up study of clergy accused of sexual impropriety

— to establish a new clinical service for women with breast cancer

2. Medical-Psychiatric Specialty Areas of Focus - Recent Addresses : Since July 1973 my specialties have included psychological problems and conditions relating to sexuality and sexual relations including sexual identity issues, therapies for sexual problems, and the relationship between love and intimate relationships and wider mental health. In 2005, I received the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association. Over the years I have lectured frequently to professional groups. During the previous two years, these lectures have included:

a. March 12, 2021-*The Mental Health Professionals 'Role with the Transgendered: Making the Controversies Clear*, given to Grand Rounds at the University Hospitals of Cleveland

b. May 1, 2021 Psychotherapeutic Approaches to Sexual Problems, an Invited lecture to the American Psychiatric Association Annual Meeting (similar lecture in May 2020)

c. Seven years of six-hour Continuing Education Courses at the American Psychiatric Association Meetings on Love and Sexuality

d. Grand Rounds at Cleveland Clinic Foundation on Sexuality Education of Psychiatric Residents on June 25, 2020

e. Grand Rounds at Cleveland Clinic Foundation June 2019 *Transgenderism: Beware!* Repeated by invitation at Akron General Hospital and at National meeting of American Association of Behavioral Health in 2019 in Washington, DC

f. Three-hour workshop at Society of Sex Therapy and Research in April 2020 on Therapy for Sexual Problems

g. Workshop on "Lets talk about sex!" at the American Association of Directors of Psychiatric Residency Training in March 2020 in Dallas, Texas

h. Three-hour continuing education seminar with Massachusetts Department of Corrections *Gender Identity Staff* Fall 2019 in Foxboro, Ma

i. Also, I have been a visiting professor at Stanford University and St. Elizabeth's Hospital in DC as well a grand rounds presenter at various departments of psychiatry over many years.

j. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010) and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five other solo authored books, I authored *Psychotherapeutic Approaches to Sexual Problems*, published in 2020; it has a chapter titled "The Gender Revolution."

k. While I am a frequent reviewer of submitted papers to the Archives Sexual Behavior, Journal of Sex & Marital Therapy, and Journal of Sexual Medicine.

l. I am an infrequent or occasional reviewer for 25 other journals in various medical specialties and psychological and sociologic journals on topics related to human sexuality.

3. Founder of the Case Western Gender Identity Clinic - former WPATH Chairman of the Standards of Care Committee: I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic evaluated and treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the *Chairman of the WPATH Standards of Care Committee* that developed the 5th version of its Standards of Care. In 1993 the Case Western Reserve University Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director. In 2020, the clinic was renamed the Gender Diversity Clinic.

4. Court Appointed Expert: In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. After providing a six-hour workshop to the mental health professionals in the system, I was retained by the Massachusetts Department of Corrections in 2007 as a consultant on the treatment of transgender inmates. I have been in that role continuously since.

5. Experience as an Expert Witness: I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment, of transgenderism and gender dysphoria, particularly as it relates to children, in 2019 in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District,

Dallas County, TX (the "*Younger* litigation"). Before and particularly after that contribution, I have given testimony in:

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

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

c. Witness for Massachusetts Dept. of Corrections in their defense of a lawsuit brought by prisoner Katheena Soneeya. March 22, 2011 Deposition in Boston and October 2018 in Cleveland and 2019 in Boston.

d. Witness for State of Florida vs. Reyne Keohane July 2017

e. Pennsylvania legislative testimony. Written submission and live testimony before a committee of the Pennsylvania legislature. March 2020. (Engaged by Pennsylvania Family Institute.)

f. In the Interests of the Younger Children. Expert testimony by deposition and at trial in Dallas, TX. (Engaged by Texas counsel Odeneal & Odeneal.) (Dallas Cty. Dist. Ct. 2019)

g. Doe v. Madison Metropolitan School District. Expert declaration submitted February 19, 2020, rebuttal declaration submitted August 14, 2020.

h. Hecox v. Idaho. Expert declaration submitted June 4, 2020. (D. Idaho)

i. In the matter of Rhys & Lynn Crawford (Washington State). 3/30/2021 Tingley v. Washington State.. (W.D. Wa.)

j. London: Queen (Quincy Bell) vs. Tavistock and Portman Clinics and NHS in High Court of London, Decision handed down on December 1, 2020. I was the only American to submit a report. The Court found that puberty blocking hormones could not be administered to

youth and that for any 16 or 17 year old to obtain hormonal therapy for gender dysphoria they must have court approval for its administration.

k. London 2 : In the High Court of Justice Queen's Bench Division administrative court. The Queen (on the application of) L. and Hampshire County Council. (A matter of education about transgender identities in schools; not yet decided.)

l. Expert in this case Kadal v. Folwell: I have been retained by the defense in this case to serve as an expert witness. My compensation is $400 per hour and such payments are in advance of any written opinions to avoid conflicts of interest and independent judgment.

7. A more complete review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

8. Summary of Issues: In this declaration, I offer information and my expert opinions concerning a number of aspects of the phenomenon of Gender Dysphoria and transgender identity (i.e., Gender Discordance, Gender Incongruity), as well as a discussion of competing views among mental health and other professionals as to the appropriate assessment and therapeutic methods-practices for patients who experience gender dysphoria. At many points in this statement, I provide citations to published, peer-reviewed articles that provide foundational or additional supporting or relevant information. A summary of the key points I discuss in this statement includes:

a. Sex as defined by biology and reproductive function cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset among other things. Data from one population (e.g. adults) cannot be assumed to be applicable to others (e.g. children). (Section II.B.)

c. Among psychiatrists and psychotherapists who practice in the area, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria. Existing studies do not provide a basis for a reliable scientific conclusion as to which therapeutic responses result in the best long-term outcomes for affected individuals — thus the field remains in an experimental stage. (Sections II.E, II.F.)

d. For example, a majority of children (in several studies, a large majority) who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. It is not currently known how to distinguish children who will persist from those who will not — thus the majority of patients will do best with no "affirmation" treatments in childhood and we cannot reliably determine which patients would do better with "affirmation" treatments which can involve life-long damage to healthy organs and natural biological processes. (Section IV.) See consistent findings in detailed discussions of the new National Gender Dysphoria Review Guidelines from Sweden, Finland, England, the Cochrane Review, and science articles below.

e. Some recent studies suggest that active affirmation of transgender identity in young children will substantially reduce the number of children naturally outgrowing or "desisting" from transgender identity. This raises ethical and public health concerns that "affirmation" treatments will increase the number of individuals who suffer the multiple long-term

physical, mental, and social limitations that are strongly associated with living life as a transgender person. (Section IV.)

f. Thus, social transition is itself an important intervention with profound implications for the long term mental and physical health of the child. When a mental health professional evaluates a child or adolescent and then recommends social transition, presumably that professional is available to help with interpersonal, familial, and psychological problems that may arise. However, many adolescents transition without mental health assessment and ongoing care, leaving themselves and their families on their own to deal with subsequent problems. (Section IV.)

g. In most cases, parental involvement is necessary for an accurate and thorough diagnosis of a child or adolescent presenting with gender dysphoria or a desire for a transgender identity, as well as for effective psychotherapeutic treatment and support of the young person. (Section V.)

h. The knowledge base concerning the cause and treatment of gender dysphoria available today has been repeatedly characterized in multiple reviews as of "low scientific quality". (Section VI.) (See detailed analysis below).

i. There are currently no studies that show that affirmation of transgender identity in young children reduces suicide, suicidal ideation, or improves long-term outcomes as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much *higher* rates of suicide and *negative* physical and mental health conditions than does the general population thus it remains unclear how much benefit, if any, is provided by the experimental treatments required for medical transitioning. (Section VI.)

j. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is *scientifically baseless and unethical* to assert that a child or adolescent who expresses an interest in a transgender identity will kill him or herself — or is more likely to do so — unless adults and peers affirm that child in a transgender identity. (Section VI.)

k. Putting a child or adolescent on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including: sterilization (whether chemical or surgical) and associated regret and sense of loss; inability to experience orgasm (for trans women); physical health risks associated with exposure to elevated levels of cross-sex hormones; surgical complications and life-long after-care; alienation of family relationships; inability to form healthy romantic relationships and attract a desirable mate; elevated mental health risks. (Section VII.) In my opinion, putting children through such risks who are very likely to naturally grow out of gender dysphoria into acceptance of their biological sex and gender is an experimental and unethical practice. This is especially true given the affirmation treatments have untested and unproven long-term outcomes.

l. Informed consent is ethically required for potentially life-altering psychological or medical procedures. However, the informed consent process in such complex cases is also complex. In some cases, it may not be possible to obtain meaningful informed consent to place a child on a psychological pathway that carries with it lifetime risks of the serious injuries, harms, and damages (including sterilization, limited sexual response, and social marginalization) that I detail in this report. A child is not competent, of course, to weigh how these potentially devastating life-long risks and issues will impact his or her lifetime happiness. At a minimum, informed consent of parents is essential, although it may not be sufficient. Withholding accurate information

— from patients or parents — on risks and benefits or misrepresenting the current state of research in this controversial field should be viewed as a serious ethics violation and reported to the proper licensing authorities. There is substantial evidence from science publications and also from journalist research that the "affirmation" treatment industry (i.e., often referred to as the Transgender Treatment Industry) is providing misleading information to the public and the legal system. For example, it is not the case that puberty halting hormone treatments are "easily reversed". (Section VIII.)

m. Research reviews support my opinion that gender affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate — meaning the rates of clinical errors as manifested by desistance, increased mental suffering, educational failure, vocational inconstancy, or social isolation have not been established. See, e.g., Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020 ; See, e. g., Swedish Agency for Health Technology Assessment and Assessment of Social Services, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se, English Proofreading: Project group and Jan Adolfsson, SBU ["*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."]*

Within the last two years, detailed research reviews exposing multiple and serious methodological and ethical flaws in the research of Bränström, and Panchankis and Turban, and other "affirmation" supporters have pinpointed fundamental methodological errors in their papers which claim to support affirmation treatment. These reviews, also support my opinions that gender

affirmation treatments remain experimental and have never been accepted by the relevant scientific community and have no known nor published error rate. See, Kalin N. H. (2020). Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process. *The American journal of psychiatry*, *177*(8), 764. https://doi.org/10.1176/appi.ajp.2020.20060803; Biggs M. (2020). Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. *Archives of sexual behavior*, *49*(7), 2227–2229. https://doi.org/10.1007/s10508-020-01743-6; D'Angelo, R., Syrulnik, E., Ayad, S., Marchiano, L., Kenny, D. T., & Clarke, P. (2020). One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Archives of sexual behavior*, 10.1007/s10508-020-01844-2. Advance online publication. https://doi.org/10.1007/s10508-020-01844-2;

n. Bases for Expert Opinions and Review-Opinions regarding the Expert Declarations in this case by Drs. Schechter and Brown. I have reviewed dozens of scientific articles, national science reviews and guidelines (England (NICE), Sweden, Finland, Cochrane Review, association positions, the Complaint and Answer in this case, the plaintiff's medical records, and all expert declarations in this case. I have formulated opinions regarding the reports by Drs. Schechter and Brown. In my opinion, Drs Schechter and Brown failed to properly disclose and discuss the ongoing international debates and controversies as to whether Transgender Treatment Industry methods and procedures are unproven, experimental, and potentially more harmful than helpful to vulnerable patients. Similarly, Drs Schechter and Brown failed to properly disclose and discuss the recent and very public exposes documenting significant methodological failures and flaws in trans treatment science. Finally, Drs Schechter and Brown failed to report or discuss the recently published national reviews and research documenting the "weak" and methodologically defective

research foundations of the Transgender Treatment Industry including recent reviews from Great Britain (NICE), Sweden, Finland, the Cochrane Review, the 2020 Carmichael report, the Griffin study, the Zucker study and other important work published within the last 24 months.. [See, e.g. Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1 BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227], and Devita Singh, Susan J. Bradley and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org] and related research discussed in detail below.

SECTION II. BACKGROUND IN THIS FIELD

A. The biological base line of sex

9. Sex is permanently "assigned" at conception by DNA: The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. Sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. Medical technology can be used to determine a fetus's sex before birth. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection. What the general public may not understand, however, is that every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can obtain a "sex change" or a "gender transition" process are misleading and scientifically impossible. In reality, the typical "transgender" Gender Discordant patient has normal healthy sex organs but struggles

with Gender Discordant feelings and perceived identity. Such patients can receive cosmetic surgeries and hormone treatment — but such methods never actually "transition" a patient to "another sex." In my opinion, these views are generally accepted by the relevant scientific community in the fields of biology, zoology, neonatology, genetics, pediatrics, and psychiatry.

10. The self-reported gender of a child, in contrast, arises in part from how others label the infant: "I love you, son (daughter)." This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child's sex is the natural outcome in >99% of children everywhere, anomalous gender discordant identity formation begs for understanding. Is it biologically shaped or influenced? Is it biologically determined? Is it the product of how the child was privately regarded and treated? Does it stem from trauma-based rejection of maleness or femaleness, and if so flowing from what trauma? Is it a symptom of another, as of yet unrevealed emotional disturbance? Is it the result of a social contagion process — such as anorexia or bulimia may be, or from Internet involvement with trans websites? The ongoing scientific, clinical, and societal debate over such issues awaits reliable answers; while some offer authoritative opinions on these questions, they are not scientifically proven. In my opinion, these views are generally accepted by the relevant scientific community.

11. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape and development, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as menstruation. These are genetically programmed biological

consequences of sex which also serve to influence the consolidation of gender identity during and after puberty. In my opinion, these views are generally accepted by the relevant scientific community.

12. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex and Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238 ("Reflections"). In my opinion, these views are generally accepted by the relevant scientific community.

B. Definition and diagnosis of gender dysphoria

13. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's sex as determined by their chromosomes and their thousands of genes, and the gender with which they eventually subjectively identify or to which they aspire. Today's American Psychiatric

Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to note that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry. The process by which DSM classifications are created involves voting by committee — this is not a reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with all three of the plaintiff's experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be "re-orienting its research away from DSM categories."] In my opinion, these views are generally accepted by the relevant scientific community.

14. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross gender patterns; onset after homosexual lifestyle;

adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no prior indications of cross-gender tendencies or identity. The early childhood onset pathway and the more recently observed onset around puberty pathway are relevant to this matter. Whereas, the onset of cross-gender identifications in the preschool years suggests temperamental and intrafamilial shaping forces, the post pubertal onset of what is now commonly referred to a rapid onset gender dysphoria seems to be heavily influenced by social forces. These derive primarily from the Internet and educational environments. The vulnerability to such social contagion may stem from conspicuous or subtle mental health problems or the child's misunderstanding of the normality of early pubertal discomfort with one's body, previous peer relationships, and despair about future gender-based social roles. The newly acquired trans identity is often passionately held as it explains away past and current unhappiness and emotional or behavioral problems.

Changing Complexities in Young Gender Dysphoric (GD) Patients

15. The Social Contagion Hypothesis. To avoid the methodological error of confirmation bias, clinicians and researchers generate and test alternative hypotheses. It is currently unclear how many new gender discordant patients have been influenced by social contagion processes. During the last 10-15 years, there have been multiple reports from multiple nations reporting a dramatic increase in the number of gender discordant patients as well as a dramatic change in the reported sex ratio of young patients presenting to clinics with trans gender identities. In the 20th century, the biologic male to biologic female ratio was consistently 3-4:1 in most North American and European clinics. Now some clinics are reporting a 7:1 ratio of girls to boys. Biological theories of gender dysphoria (e.g., "immutable", genetic, brain structures, etc.) appear unlikely to explain large, rapid demographic shifts in gender discordant patients. A social contagion - social influence theory has arisen in an attempt to help explain these dramatic demographic changes. In decades

past, gender discordant children and teens typically aspired to become a member of the opposite sex while more recently, patients are increasingly likely to define themselves as "non-binary persons" meaning that they have elements of both sex-genders within them or they have none of these elements. Such teens often report being influenced by trans websites and trans "influencers" on internet sources such as video blogs on YouTube. These onsite shows reportedly reach millions and teach adolescents to consider their problems, worries, discomforts, and anticipated social roles to be typical experiences of the unfolding of a biologically-determined trans self. In addition to YouTube and other internet sources, patients reportedly have been influenced by school trans awareness training programs teaching the normality of trans current and future lives — without an accurate discussion or depiction of the known risks and benefits.

A multi-disciplinary analysis that includes developmental psychology and the history of psychiatry provides additional support for the socialization hypothesis. Mental health professionals have long experience with adolescent females experiencing social worries that help to create anorexia nervosa, bulimia, and self-harm through cutting, burning, and piercings. Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls demonstrate heightened susceptibility to a social contagion of psychiatric symptoms. She reports that" teenage girls share symptoms via social contagions because their friendship processes involve "co-rumination"— that is, taking on the emotional pain and concerns of their friends. This is a potential — and as yet uninvestigated hypothesis — as to the reports of" clusters" and "friend groups" of teen girls who are adopting trans identity and "transitioning" together (See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13). Prof. Rose's investigations note that adolescent girls seem more willing to adopt a friend's pain and even suspend reality to "get on the

symptom team" of their friends. (See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths' Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Further, reliable-valid scientific research is needed to address these complex issues. See also, McCall, B. and Nainggolan, L., Medscape *Transgender Teens: Is the Tide Starting to Turn?* https://www.medscape.com/viewarticle/949842#vp_1 ["The vast majority of youth now presenting with gender dysphoria are adolescents who suddenly express revulsion with their sex from birth, and 70% of them were born female. Many of them have comorbidities such as anxiety, attention deficit hyperactivity disorder, autism spectrum traits, and depression, Malone explains, which need to be considered. This newer presentation — which has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. One recent US survey found a 4000% increase (over 40-fold) since 2006, and there have been similar large increases reported in Finland, Norway, the Netherlands, Canada, and Australia. The London GIDS clinic reported a 30-fold increase in referrals over the past decade – and again they were primarily adolescent girls who said they now identify as boys.

It should be noted that rapid, unpredicted changes in the demographics of trans patients (i.e., from chronically discordant, early onset males to rapid onset adolescent females) calls into question the usefulness and accuracy of predictions emanating from research conducted on previous, demographically and clinically different patient groups. This again highlights the complex, little known, and experimental nature of trans phenomenon as well as the experimental treatment methods of the current Transgender Treatment Industry. See, rapid and unpredicted demographic changes: [A US survey found a 4000% increase (over 40-fold) since 2006]

"National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 ; similar large increases have been reported in Finland: Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." *Adolescent Health, Medicine and Therapeutics* Volume 9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 ; and in Norway ; and in the Netherlands: de Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." *Pediatrics* 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. ; and in Canada: Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." *Archives of Sexual Behavior* 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8, and others.

16. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (See, K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance 'Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., Int'l J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence"). The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

17. The criteria used in DSM-5 to identify Gender Dysphoria ("Gender Incongruence" is another term used) include a number of signs of discomfort with one's natal sex and vary

somewhat depending on the age of the patient, but in all cases require "clinically significant distress or impairment in important areas of functioning" such as social, school, or occupational settings. When these criteria in children, (or adolescents, or adults) are not met, two other diagnoses may be given. These are: Other Specified Gender Dysphoria and Unspecified Gender Dysphoria. Specialists sometimes refer to children who do not meet criteria as being "subthreshold."

18. In a complex, experimental, and little understood field such as transgender medicine, generating and exploring alternative hypotheses is essential to our efforts to help alleviate the tragic suffering of our patients. One such alternative is to teach coping and resilience skills to gender discordant children. Such training could include a realization that a wide range of behaviors are available within their biologically concordant gender roles. Acquiring a broader perspective on the patient's natal sex roles might be a better solution for some than permanent damage to healthy sex organs via hormone and surgical "transitioning" procedures. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that are based on constrictive notions of what men and women can be. See, S. Levine (2017), Ethical Concerns About Emerging Treatment Paradigms for Gender Dysphoria, J. of Sex & Marital Therapy at 7, DOI: 10.1080/0092623X.2017.1309482 ("Ethical Concerns"). A young child's, even an adolescent's, understanding of this topic is quite limited. Nor do they have the perspective that discomfort with the body and perceived social role is not new to civilization; what is new is the option to become a trans person.

With most complex behavioral problems of child and adolescents, patients and families receive psychiatric attention that includes a thorough developmental history from parents, prolonged interviews with the patient, and a therapeutic approach which involves to some extent the parents, the patient, and the three together with or without medication assistance. Tragically, in too many gender clinics, young patients are not treated with the standard of care, complex, multi-disciplinary, evidence-based approach. Children are too often quickly referred to gender "specialists" — which generally means therapists who deeply believe (based on clinical-political ideology and not the relevant science) that every young person who is questioning his or her gender identity or declaring a trans identity should be quickly affirmed and supported in their atypical identity. Moreover, the ideological fashions of these therapists and the organizations that support them have effectively convinced many — contrary to the relevant science — that any other approach to these youth is dangerous, harmful, and might even lead to suicide. Other evidence-based, more methodologically sound approaches such as the generation and testing of alternative hypotheses as required by proper health care standards — are denigrated and ideologically labeled "conversion therapy."

The ideologically based indoctrination efforts to ban evidence based alternative treatments as "conversion therapy" can have harmful effects on our vulnerable patients. For example, many traditional therapists claim to not know how to take care of these gender discordant patients, as though they are not children who are suffering. This rationalization may only be a reflection of the fear of being attacked for performing dreaded, and now in some locations, illegal, "conversion therapy". In this way, qualified mental health professionals have failed to develop a robust experience with alternative ways of investigating patients 'and their families 'lives as they do with all other child and adolescent psychiatric problems. [The recently released National Guidelines

for Gender Dysphoria patients from Sweden and Finland do appear to be moving towards a much greater emphasis on alternative methods including psychosocial support, therapy, and long-term psycho-social evaluations — perhaps for years — prior to engaging in any "affirmation" medical interventions (hormones or surgery) See, e.g. "Finland Issues Strict Guidelines for Treating Gender Dysphoria" at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ ["Western countries around the world are *grappling with how to treat the exponentially growing number of children and adolescents being referred to gender clinics* for puberty blockers, cross-sex hormones and gender-affirming surgery. Finland recently issued very strict clinical guidelines for the treatment of children with gender dysphoria including: … clear differentiation in treatment guidelines between early-onset childhood gender dysphoria and adolescent-onset gender dysphoria…the guidelines acknowledge and recognize that identity exploration is a natural phase of adolescence and *restrict medical interventions* until "identity and personality development appear to be stable"….There is a *prioritization of psychotherapeutic non-invasive interventions* as the first course of action "due to variations in gender identity in minors"…. A *requirement* that there be *"no contraindications" prior to initiation of puberty blocker or cross-sex hormone interventions*… [such contraindications should include the presence of psychiatric illnesses such as depression, anxiety, or autistic conditions. Such disorders are reportedly present in over 50% of all gender discordant patients]…. and no surgical interventions are allowed for children under the age of 18." ; See also, a Swedish National Investigative Report regarding cases of gender incongruence in children and young people, Article number 2021-3-7302 Published www.socialstyrelsen.se, March 2021. [Since our initial investigative report was published in 2015, the number of young people referred for investigation has *increased sharply, both in Sweden and internationally*. … *The reasons for the increase are not yet clear.*]

Such external pressures on providers should not be underestimated. Leaders in the field of gender dysphoria have been attacked, dissenters have been fired, and reputations have been sullied by activists who believe they know best how other people's children should be treated. The fact that science has not yet established the ideal treatment approaches to the diversity of situations does not seem to matter to these passionate persons.

19. Confirmation bias is a hazardous cognitive error that occurs throughout all of medicine and science. Confirmation bias is the methodologically defective tendency to process information by only looking for, and interpreting, evidence consistent with existing beliefs, favorite theories, and pre-conceived notions. This bias is a serious and potentially dangerous methodological error that leads a person or a field to ignore information that is contrary to what is common, fashionable, or has been taught to be the popular or "politically correct" theory of the day. It is often associated with a weak understanding of how science establishes the legitimacy of a therapy. Confirmation bias is often associated with the belief that because a therapeutic approach has been long employed or supported by powerful forces, adequate reliable-valid science must have previously established the popular approach. Both of the essential concepts of "gender affirmative treatment" and "conversion therapy" are based on such a misunderstanding.

20. The expected initial evaluation of a trans person typically begins with the patient who tells the evaluator, " "I am trans." The patient relates his or her symptoms of discomfort which may or may not fulfill DSM-5 criteria for Gender Dysphoria. Ideally a developmental history is taken from the parents and the patient to consider what is known as a differential diagnostic process to determine what other conditions may underlie these symptoms. The extent to which this latter process is undertaken depends upon the therapists *beliefs* about the origin of trans identities and the long term effectiveness of affirmative responses. To the extent that life-changing affirmative

treatment programs are *believed* to be already scientifically well established, the differential diagnosis process tends to be glibly superficial. The patient is typically pleased with the rapid affirmation recommendation, although the parents are often horrified by the failure to consider previous struggles the child and family have undergone. Alternative treatment approaches or hypotheses are given short shrift (i.e., confirmation bias). When one grasps the fact that the scientific process underlying affirmation is woefully inadequate "weak evidence" based on often defective research, one can begin to see that confirmation bias can create an unethical process that places patient futures in jeopardy.

C. The inequitable impact of gender dysphoria on minority and vulnerable groups

21.. In considering the appropriate response to gender dysphoria, it is important to know that certain groups of children have an increased prevalence and incidence of trans identities. These include: children of color, children with mental developmental disabilities, including children on the autistic spectrum (at a rate more than 7x the general population), children residing in foster care homes, adopted children (at a rate more than 3x the general population), children with a prior history of psychiatric illness, and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys). (G. Rider at 4; See, G. Rider et al. (2018), *Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study*, Pediatrics at 4, DOI: 10.1542/peds.2017-1683. (In a large sample, non-white youth made up 41% of the set who claimed a transgender or gender-nonconforming identity, but only 29% of the set who had a gender identity consistent with their sex.) See, D. Shumer & A. Tishelman (2015), *The Role of Assent in the Treatment of Transgender Adolescents*, Int. J. Transgenderism at 1, DOI: 10.1080/15532739.2015.1075929; See also, D. Shumer et al. (2016), Evaluation of Asperger Syndrome in Youth Presenting to a Gender Dysphoria Clinic, LGBT Health, 3(5) 387 at 387 ; See

also, Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health, Vol. 2(1) 76 at 77 ; See also, L. Edwards-Leeper et al. (2017), Psychological Profile of the First Sample of Transgender Youth Presenting for Medical Intervention in a U.S. Pediatric Gender Center, Psychology of Sexual Orientation and Gender Diversity, 4(3) 374 at 375 ("Psychological Profile") ; See, also R. Kaltiala-Heino et al. (2015), *Two Years of Gender Identity Service for Minors: Overrepresentation of Natal Girls with Severe Problems in Adolescent Development*, Child and Adolescent Psychiatry & Mental Health, 9(9) 1 at 5**.** In the 2015 Finland gender identity service statistics, 75% of adolescents assessed "had been or were currently undergoing child and adolescent *psychiatric treatment* for reasons other than gender dysphoria."); these data are consistent with Littman's research. See, L. Littman (2018), *Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria*, PLoS ONE 13(8): e0202330 at 13 (Parental survey concerning adolescents exhibiting Rapid Onset Gender Dysphoria reported that *62.5% of gender dysphoric adolescents had "a psychiatric disorder or neurodevelopmental disability* preceding the onset of gender dysphoria."). Properly protecting vulnerable, marginalized patients from experimental, potentially dangerous treatments should be an essential concern to trans gender treatment industry but has not been.

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

22. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three very different paradigms, often without being aware of, or at least without acknowledging, the

distinctions. I attempt to summarize these three as though they are equally valid. I do not actually consider this to be true.

23. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical medical illness that causes suffering, comparable, for example, to prostate cancer, a disease that is curable before it spreads. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria. The underlying assumption is that all types of gender dysphoria have their ultimate origin in "brain structures", often determined embryonically. Although numerous studies have been undertaken to attempt to demonstrate a distinctive physical "brain structure" associated with transgender identity, as of yet there is no credible, reliable-valid scientific evidence that these patients have any defining abnormality in brain structure that precedes the onset of gender dysphoria. See, Mueller, De Cuypere & T'Sjoen. Transgender research in the 21st century: A selective critical review from a neurocognitive perspective. American Journal of Psychiatry 174: 12, 2017.

It should be noted that gender dysphoria is *a psychiatric rather than a medical diagnosis*. Since its inception in DSM-III, it has always and only been specified in the psychiatric DSM manuals. Notably, *gender dysphoria is the only psychiatric condition to be treated by surgery*, even though no endocrine or surgical intervention package corrects any identified biological abnormality (cf body integrity identity disorder (BIID) (See, Levine, *Reflections,* at 240.) In my opinion, the "affirmation" treatment protocols using endocrine and surgical "treatments" to change a psychiatric condition are not accepted by the relevant scientific community, are supported by

only "weak evidence" from methodologically defective research studies, and have no known, nor published error rates. Actual attempts at publishing error rates has come under the concept of "regrets" focused only only on patient injuries and misery following genital re-assignment surgery. There is much more to the human experience of trans patients regrets over time than the questionable, methodologically defective claims quoted by some of 2%. For example, in the Bränström., et.al., study, an enormous part of the sample was "lost" and never followed up. The authors failed to explore available data to see how many of these patients have de-transitioned, died via suicide, etc. One has to wonder why the suicide rate is reportedly so very high for patients who received trans genital surgery. In sum, these "treatments" remain experimental and poorly studied and we'll need much more and much higher quality scientific research before we will know if such "treatments" are actually helping or injuring patients. Is is essential to note that hormonal and surgical treatments for gender discordant patients have been increasingly done over a 50 year period and yet no reliable-valid protocols for evaluation or treatment have been properly researched, nor generally accepted by the relevant scientific community, nor published with methodologically sound error rates**.** For decades, vulnerable patients struggling with gender identity issues have deserved better, more effective, less experimental, less hazardous, less ideologically tainted, and properly researched treatments — they are still waiting.

24. Gender dysphoria can be effectively and alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (Levine, *Reflections*, at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply

uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play.

The developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's lifetime. This includes gender. While some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner, this is not supported by science. In contrast, this paradigm points to the sudden enormous increase in incidence of child and adolescent gender dysphoria over the last twenty years in North America and Europe. This points to sociological-psychological processes rather than a biological one. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, where the sex ratios were reversed as compared to North America and Europe. This, too, points to the powerful effect of cultural influences. See, Levine, Ethical Concerns, at 8 (citing M. Aitken, T. D. Steensma, et al. (2015), Evidence for an Altered Sex Ratio in Clinic-Referred Adolescents with Gender Dysphoria, J. of Sexual Medicine J. 12(3) 756 at 756-63).

25. In recent years, for adolescent patients, intense involvement with online transgender communities and virtual friends who have never been seen in person is reportedly the rule rather than the exception, The developmental paradigm does not preclude external social influences.

26. The third paradigm through which gender dysphoria is alternatively conceptualized is political (not scientific) — from a sexual minority rights perspective. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender or a non-binary person is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying causes, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy, the education of pediatricians, endocrinologists, and many mental health professionals, and local ordinances prohibiting "conversion therapy." Activists, legal professionals, and politicians should note that this *political* hypothesis — as powerful as it has become — has never been *scientifically* validated and might, in the end, be far damaging than helpful to suffering, vulnerable gender discordant patients.

E. Competing models of therapy

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

The "watchful waiting" therapy model

28. I review below the uniform finding of follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood if left untreated. (See infra ¶ 60.)

29. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach avoids hormonal treatments to allow for the developmental nature of gender identity in children to naturally resolve —that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

a. (Model 1 of watchful waiting) Treating any other psychological co-morbidities—that is, other mental illnesses as defined by the DSM-5—that the child may exhibit (separation anxiety, be bedwetting, attention deficit disorder, obsessive-compulsive disorder, depression) without a focus on gender

b. (Model 2 of watchful waiting) No treatment at all for anything, but a regular follow-up appointment. This might be labeled a "hands off" approach

The psychotherapy model: Alleviate distress by identifying and addressing causes

30. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience.

31. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her natal sex. (Levine, *Ethical Concerns*, at 8.) I and others have reported success in alleviating distress in this way for at least some patients, whether or not the patient's sense of discomfort or incongruence with his or her natal sex entirely disappeared. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

32. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciate the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" in order to be kind, compassionate, caring, noncompetitive, and devoted to others 'feelings and needs. Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture. Men, of course, can be emotionally expressive, just as they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

33. Many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system. See, S. Levine (2017), *Transitioning Back to Maleness*, Arch of Sexual Behavior at 7, DOI: 10.1007/s10508-017-1136-9) ("*Transitioning*").

34. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria itself, there

is no sharp line between "watchful waiting" and the psychotherapy model in the case of prepubescent children.

35. To my knowledge, there is no credible, reliable-valid scientific evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents and women. *Controlled studies have never been attempted*. On the other hand, anecdotal case report evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient's biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I published a paper recently on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine, *Transitioning*, at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. Recently, a paper reviewing the phenomenon of de-transition has been published in which the authors claims to have identified *60,000 case reports world wide* on the Internet. See Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094.

The affirmation therapy model

36. While it is widely agreed that the therapist should not directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc. associated with transgender identity. These advocates treat any question about the causes of the

child's transgender identification as inappropriate, and assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by the MHP who is providing supportive guidance concerning the child's gender identity.

37. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of suicide or severe psychological damage. I address claims about suicide and health outcomes in Section VI below.

38. Some advocates also assert that this "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals. However, one respected academic in the field has recently written that, on the contrary, "almost all clinics and professional associations in the world" do not use "gender affirmation" for prepubescent children and instead "delay any transitions after the onset of puberty." See, J. Cantor (2019), Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, J. of Sex & Marital Therapy at 1, DOI: 10.1080.0092623X.2019.1698481.

39. Even the Standards of Care published by WPATH, an organization which in general leans strongly towards affirmation in the case of adults, does not specify affirmation of transgender identity as the indicated therapeutic response for young children, but — given that the majority of such children naturally grow out of the problem — rather calls for a careful process of discernment and decision specific to each child, by the family in consultation with the mental health professional.

40. Further, the DSM-5 added—for both children and adolescents—a requirement that a sense of incongruence between biological and felt gender must last at least six months as

a precondition for a diagnosis of gender dysphoria, precisely because of the risk of "transitory" symptoms and "hasty" diagnosis that might lead to "inappropriate" treatments. See, K. Zucker (2015), *The DSM-5 Diagnostic Criteria for Gender Dysphoria*, in C. Trombetta et al. (eds.), Management of Gender Dysphoria: Multidisciplinary Approach, DOI 10.1007/978-88-470-5696-1_4 (Springer-Verlag Italia 2015).

41. I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics, and is not supported by credible, reliable-valid scientific evidence**.** Rather, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents and the MHP and the child are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.

42. Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

F. Patients Differ Widely and Must Be Considered Individually.

43. In my opinion, it is not possible to make a single, categorical statement about the proper treatment of children presenting with gender dysphoria or other gender-related issues. There is no single pathway of development and outcomes governing transgender identity, nor one that predominates over the large majority of cases. Instead, as individuals grow up and age, depending on their differing psychological, social, familial, and life experiences, their outcomes differ widely. I can, however, categorically opine that unproven, experimental affirmation "treatments" should not be used on uninformed or misinformed patients and families.

44. As to causes in children, details about the onset of gender dysphoria may be found in an understanding of family relationship dynamics. In particular, the relationship between the parents and each of the parents and the child, and each of the siblings and the child should be well known by the MHP. Further, a disturbingly large proportion of children who seek professional care in connection with gender issues have *a wider history of psychiatric co-morbidities*. See Becerra-Culqui TA, Liu Y, Nash R, Cromwell L, Flanders WD, Getahun D, Giammattei SV, Hunkeler EM, Lash TL, Millman A, Quinn VP, Robinson B, Roblin D, Sandberg DE, Silverberg MJ, Tangpricha V, Goodman M. Mental Health of Transgender and Gender Nonconforming Youth Compared With Their Peers. Pediatrics. 2018 May;141(5):e20173845. doi: 10.1542/peds.2017-3845. Epub 2018 Apr 16. PMID: 29661941; PMCID: PMC5914494. A 2017 study from the Boston Children's Hospital Gender Management Service program reported that: "Consistent with the data reported from other sites, this investigation documented that 43.3% of patients presenting for services had significant psychiatric history, with 37.1% having been prescribed psychotropic medications, 20.6% with a history of self-injurious behavior, 9.3% with a prior psychiatric hospitalization, and 9.3% with a history of suicide attempts." See, Perez-Brumer A, Day JK, Russell ST, Hatzenbuehler ML. Prevalence and Correlates of Suicidal Ideation Among Transgender Youth in California: Findings From a Representative, Population-Based Sample of High School Students. J Am Acad Child Adolesc Psychiatry. 2017 Sep;56(9):739-746. doi: 10.1016/j.jaac.2017.06.010. Epub 2017 Jul 5. PMID: 28838578; PMCID: PMC5695881.

L. Edwards-Leeper, *Psychological Profile.*) It seems likely that an even higher proportion will have had prior undiagnosed psychiatric conditions.

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

45. In almost any discussion of the diagnosis and care of patients suffering gender dysphoria or exhibiting transgender characteristics, the World Professional Association for Transgender Health (WPATH) and its Standards of Care will be mentioned. Accordingly, I provide some context concerning that private, activist, non-science, organization.

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

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

48. WPATH takes a very narrow and politically-ideologically driven view on increasingly controversial issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. *These are, obviously, conflicted, incompatible, and contradictory goals*. (Levine, *Reflections*, at 240.) WPATH is supportive to those who want Sex Reassignment Surgery ("SRS") even though such surgery is *not supported by credible, reliable-valid scientific research*, not accepted by the

relevant scientific community, and has no known error rates, and no careful systematic follow-up using agreed upon criteria to even assess multifaceted failure rates. Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization. Such views have been literally shouted down and effectively silenced by the large numbers of nonprofessional adults who attend the organization's biennial meetings. Such "mob rule" is quite incompatible with appropriate, competent methodological discussions.

49. The Standards of Care ("SOC") is the product of an enormous effort, but it is not a politically neutral document. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations are clearly in sharp conflict. The most serious limitations and defects of the Standards of Care, however, are not primarily political. They are caused by the decades-long and continuing lack of credible, rigorous research in the field, which allows room for passionate convictions and ongoing controversies on how to care for the transgendered. See, e.g. Vrouenraets et al, *Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,* Journal of Adolescent Health 57 (2015) 367e373. [The Endocrine Society and the World Professional Association for Transgender Health published guidelines for the treatment of adolescents with gender dysphoria (GD). The guidelines recommend the use of gonadotropin-releasing hormone agonists in adolescence to suppress puberty. However, in actual practice, *no consensus exists whether to use these early medical interventions* … Conclusions: As long as *debate* remains on these seven themes and *only limited long-term data are available*, *there will be no consensus on treatment*. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required.]

50. In recent years, WPATH has fully adopted — in the absence of reliable-valid scientific research — some mix of the medical and civil rights paradigms. It has downgraded the role of

counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this state is not. (Levine, *Reflections*, at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance. In clear violation of ethics rules, licensing regulations, and legal requirements — informed consent is neither standardized nor reasonably complete. The informed consent process is essential to protect the fundamental right of all patients to control their health care with informed choices. Informed consent documentation is needed to protect the doctor and the patient by verifying that the patient understands the potential benefits and the risk of specific harms including the risks of proceeding with such experimental gender affirmation treatments in the face of the ongoing lack of scientific evidence that might demonstrate these treatments are safe and effective. Additional risks include the lack of any credible long term scientific follow-up studies showing the safety and effectiveness of such experimental treatments over time. Finally, informed consent documents should verify a patient has been presented with and thoughtfully considered alternative treatments including no treatment. It should be noted that these informed consent processes are often violated by practitioners especially in treatment industries shaped by political ideology.

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

welcome skepticism nor competent scientific debate and analysis and therefore, deviates from the philosophical core of medical science.

52. For example, in 2010 the WPATH Board of Directors voted (note this is a consensus-seeking and not a reliable-valid scientific methodology) to issue a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology This position was debated but voted down (note this is a consensus-seeking and not a reliable-valid scientific methodology) adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013. By declaring that all forms of gender identity (some list over 120 different labels) are normal, the WPATH voting process involved fiat and not a proper-rigorous scientific analysis and consideration of alternate ways of defining mental abnormalities. The WPATH voting process was done to bolster the self-esteem of patients and to decrease social discrimination. It was not based on evidence. See, WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

53. In my experience some members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by Mental Health Professionals (MHPs) who are not deeply experienced with recognizing and treating frequently associated psychiatric co-morbidities. Because the 7th version of the WPATH Standards of Care recommendations deleted the requirement for psychotherapy, trans care facilities that consider these standards sufficient are permitting patients to be counseled to transition by means of social presentation (patient self-report), hormones, and surgery by individuals inexperienced with ongoing psychotherapy rather than those with medical or PhD degrees who are more likely during their careers to have considered the developmental forces shaping identity and behavior.. As a result of the downgrading of the role

of the psychiatric assessment of patients, new "gender affirming" clinics have arisen in many urban settings that quickly (sometimes within an hour's time) recommend transition. Concerned parents who brought their child or teen to a professional office expecting to learn what is going on with their child instead often leave feeling overwhelmed, disoriented, and fearful for the future health and safety of that child. Some report being treated as though if they are the enemy of the child because they are not immediately supportive of the clinics 'affirmative responses. I am concerned that such defective practices are increasingly wide-spread. Such practices are the result of political advocacy and are not based on credible, reliable-valid science. Patients and their families are not told they are entered an experimental and potentially dangerous process.

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

54. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition and/or hormone therapy, gender dysphoria does *not* persist through puberty. A recent article reviewed 11 existing follow-up studies and reported that "every follow-up study found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance See, S. Adelson & American Academy of Child & Adolescent Psychiatry (2012), Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents, J. Am. Acad Child Adolescent Psychiatry 51(9) 957 at, 963 ("Practice Parameter").

"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." A third summarized the existing data as showing that "Symptoms of GID at prepubertal ages decrease or disappear in a considerable percentage of children (estimates range from 80-95%)." A 2021 publication found that 12% of previously evaluated grade school aged children persisted in their trans identities many years later. (Singh, Bradley, and Zucker, Frontiers of Psychiatry. See, P. T. Cohen-Kettenis, H. A. Delemarre-van de Waal et al. (2008), *The Treatment of Adolescent Transsexuals: Changing Insights*, J. Sexual Medicine 5(8) 1892 at 1895.

55. It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist. (Zucker, Gender Dysphoria in Children and Adolescents, in Principles and Practices of Sex Therapy 6th edition, Guilford Press, 2020; Levine, *Ethical Concerns*, at 9.) Even severity of gender dysphoria is not a strong predictor of persistence. It is also apparent in the adolescent phenomenon of rapid onset of gender dysphoria following a gender normative childhood that childhood gender identity is not inherently stable. Some of these individuals desist and others evolve dramatically to become more non-binary and accepting of their complex male and female identifications.

56. Desistance (a patients' willing reacceptance of their biological sex through normal developmental processes) within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I observe an increasingly vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years. However, reliable-valid scientific data on outcomes for this age group with and without therapeutic interventions is not yet available. A recent review of de-transitioning claimed to have identified 60,000 case histories in

a search of proliferating websites devoted to this topic (Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126). In the past WPATH has simply declined to discuss this vital topic, another example of WPATH's political consensus-seeking, *increasingly anti-science methodology*.

57. In contrast, there is now data that suggests that a therapy that encourages social transition dramatically changes outcomes and often "locks in" a patient's journey into a life course of dependence on experimental hormone "treatments". A prominent group of authors has written that "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." Similarly, a comparison of recent and older studies suggests that when an "affirming" methodology is used with young children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their natal sex—instead persist in a transgender identity. (Zucker, *Myth of Persistence*, at 7.)18

58. Indeed, a review of multiple studies of boys treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child's natal sex, Studies that began before the widespread use of social transition for young children reported desistance rates in the range of 80-98%. A more recent study reported that fewer than 20% of boys who engaged in a partial or complete transition prior to puberty desisted when surveyed at age 15. See (T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582. ; See, C. Guss et al. (2015), Transgender and Gender

Nonconforming Adolescent Care: Psychosocial and Medical Considerations, Curr. Opin. Pediatrics 26(4) 421 at 421 ("TGN Adolescent Care").

3) Another study found that social transition by the child was found to be strongly correlated with persistence for natal boys, but not for girls. (Zucker*, Myth of Persistence,* at 5 (citing T.D. Steensma, J.K. McGuire et al. (2013), *Factors Associated with Desistance & Persistence of Childhood Gender Dysphoria: A Qualitative Follow-up Study*, J. of the Am. Academy of Child and Adolescent Psychiatry. 52, 582.)

Some vocal practitioners of prompt affirmation and social transition claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.20 This is a very large change as compared to the desistance rates documented apart from social transition. Some researchers who generally advocate prompt affirmation and social transition also acknowledge a causal connection between social transition and this change in outcomes. See, Guss, *TGN Adolescent Care*, at 2. "The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood." "Youth with persistent TNG [transgender, nonbinary, or gender-nonconforming] identity into adulthood . . . are more likely to have experienced social transition, such as using a different name . . . which is stereotypically associated with another gender at some point during childhood."

59. Accordingly, I agree with a noted researcher in the field who has written that social transition in children must be considered "a form of psychosocial treatment." (Zucker, *Debate,* at 1.)

60. So far as I am aware, no study yet reveals whether the life-course mental and physical health outcomes for this relatively new class of "persisters" are more similar to the non-transgender

population, or to the notably worse outcomes exhibited by the transgender population generally. *See, e.g.,* B. Ehrensaft (2015), *Listening and Learning from Gender-Nonconforming Children,* The Psychoanalytic Study of the Child 68(1) 28 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted 'and asked to return to his or her assigned gender."

61. However, I agree with Zucker who has written, "…we cannot rule out the possibility that early successful treatment of childhood GID [Gender Identity Disorder] will diminish the role of a continuation of GID into adulthood. If so, successful treatment would also reduce the need for the long and difficult process of sex reassignment which includes hormonal and surgical procedures with substantial medical risks and complications." See, Zucker, *Myth of Persistence*, at 8 (citing H. Meyer-Bahlburg (2002), *Gender Identity Disorder in Young Boys: A Parent- & Peer-Based Treatment Protocol*, Clinical Child Psychology & Psychiatry 7, 360 at 362.).

By the same token, a therapeutic methodology for children that *increases* the likelihood that the child will continue to identify as the opposite gender into adulthood will *increase* the need for the long and potentially problematic processes of hormonal and genital and cosmetic surgical procedures.

62. Given these facts, *encouraging social transition in children remains controversial*. Supporters of such transition acknowledge that "Controversies among providers in the mental health and medical fields are abundant . . . These include differing assumptions regarding . . . the age at which children . . . should be encouraged or permitted to socially transition . . . . These are complex and providers in the field continue to be at odds in their efforts to work in the best interests of the youth they serve." See, A. Tishelman et al. (2015), *Serving Transgender Youth: Challenges,*

Dilemmas and Clinical Examples, Prof. Psychol. Res. PR. at 11, DOI: 10.1037/a0037490 ("*Serving TG Youth*") Transition then, should be undertaken only subject to standards, protocols, and reviews appropriate to actual clincial experiments [Clincial experiments involve time-honored careful processes with Institutional Review Board — human subjects protections — approval required, a predetermined method of evaluation, primary and secondary endpoints and safeguards to protect the rights of patients to truly informed consent. These protections are not present in the Transgender Treatment Industry when vulnerable patients are receving "treatments" that lack sufficient proof of efficacy and safety.]

63. In sum, therapy for young children that encourages transition cannot be considered to be neutral, but instead *is an experimental procedure* that has a high likelihood of changing the life path of the child, with highly unpredictable effects on mental and physical health, suicidality, and life expectancy. Claims that a civil right is at stake do not change the fact that what is proposed is a social and medical experiment on vulnerable patients. (Levine, *Reflections,* at 241.)

IV. THE AVAILABLE DATA DOES NOT SUPPORT THE CONTENTION THAT "AFFIRMATION" OF TRANSGENDER IDENTITY REDUCES SUICIDE OR RESULTS IN BETTER PHYSICAL OR MENTAL HEALTH OUTCOMES GENERALLY.

64. I am aware that organizations including The Academy of Pediatrics and Parents, Families and Friends of Lesbians and Gays (PFLAG)) have published statements that suggest that all children who express a desire for a transgender identity should be promptly supported in that claimed identity. This position appears to rest on the belief —which is widely promulgated by certain advocacy organizations—that science has already established that prompt "affirmance" is best for all patients, including all children, who present indicia of transgender identity. As I discuss later below, this belief is scientifically incorrect, and ignores both what is known and what is unknown.

65. It is instructive to consider how policies are constructed by professional and lay organizations. Professional association vote on policies that are formulated in small committees. Such consensus processes are not a reliable valid scientific methodology. These professional, political, or community support groups do not rely upon scientifically tested methodologies, although they claim to have done so. All methodologically informed workers, even among those who work in this arena, have in the past and continue to conclude that there is low level science underlying treatment patterns and the policies that encourage them. A "low" level is defined by specific criteria of validity or trustworthiness.

Professional associations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, the American Medical Association supported eugenic proposals to "improve the quality of the human stock" by coercive sterilization of "defective and undesirable Americans" and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). The AMA's support was a political not a scientific process.

Similarly, the American Breeders Association founded a Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and a Rockefeller Institute for Medical Research recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

With the support of the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of those supported in institutions or maintained at public expense. The model law encompassed the "feebleminded, insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent" — including "orphans, ne'er-do-wells, tramps, the homeless and paupers". Eighteen states passed laws based on the 1922 model legislation and sixty-four thousand people were forcibly sterilized.

The lesson from the eugenics era is that associations can lend their weight and prestige to social movements believing that they are speaking from a foundation of science when in fact they are articulating political or ideological concepts. Such pseudoscientific voting consensus processes are neither valid, reliable, nor evidence-based.

This methodological critique is relevant to the understanding of WPATH. The American Academy of Pediatrics, the American Endocrine Society American Psychiatric Association, the American Psychological Association and similar groups have voted (not a scientific methodology) to declare supportive policies that are clearly not based on credible, reliable-valid science. These policies often do not acknowledge the glaring background deficiencies of what they put forward. Beyond the policy is the absence of controlled studies, the absence of prospective follow up studies and the discussion of the error rate of interventions. It might be useful to consider that there is a loose entity that can be labelled the Transgender Treatment Industry (TTI). The TTI generates considerable income for hospitals, clinicians, and pharmaceutical companies. Members of the TTI have a vested interest in believing that science has already justified their existence. As sterilization is the expected adult outcome of endocrine and surgical treatments of the procedures undertaken in youth, the TTI must have developed strong rationalizations to justify creating infertility. Will one day the medical profession look at support for transitioning youth in the same manner the

eugenics movement is now regarded? (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320 ;

The DSM and the International Classification of Diseases- ICD) system have confused courts in the past. These catalogues of recognized diseases are produced by consensus-seeking methodologies (non-scientific voting) which are presented as based on competent science, but actually lack robust reliability and validity data and provide no error rates. They are created by a committee voting system that submits recommendations to other committees. Disease categories are voted upon — voting is not a scientifically valid methodology (See, eugenics history). Both the DSM and the ICD are are essentially *medical dictionaries of disorders* designed to standardize the use of diagnostic labels and are primarily useful to insurance companies. When the DSM-5 was published, the NIH made clear in public that research using its categories would not be supported because of the DSM-5's lack of validity. When it was recommended to put Gender Incongruence in a separate section of the ICD, authors wrote that it was designed to decrease social discrimination against and bolster self esteem of transgendered persons. See Reed GM, Drescher J, Krueger RB, Atalla E, Cochran SD, First MB, Cohen-Kettenis PT, Arango-de Montis I, Parish SJ, Cottler S, Briken P, Saxena S. Disorders related to sexuality and gender identity in the ICD-11: revising the ICD-10 classification based on current scientific evidence, best clinical practices, and human rights considerations. World Psychiatry. 2016 Oct;15(3):205-221. doi: 10.1002/wps.20354. Erratum in: World Psychiatry. 2017 Jun;16(2):220. PMID: 27717275; PMCID: PMC5032510.

The Knowledge Base Concerning The Causes And Treatment Of Gender Dysphoria Has Low Scientific Quality

66. In 2009 the Endocrine Society published clinical guidelines for the treatment of patients with persistent gender dysphoria. See, Hembree, W. C. *et al.* Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 94, 3132-3154, doi:10.1210/jc.2009-0345 (2009)). The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. This guideline used the GRADE (Recommendations, Assessment, Development, and Evaluation) system for rating clinical recommendations. The publication stated, "the strength of recommendations and the quality of evidence was low or very low." Low recommendations indicate "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate". Very low recommendations mean that "any estimate of effect is very uncertain". These guidelines were updated eight years later. See,. Hembree, W. C. *et al.* Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*, doi:10.1210/jc.2017-01658 (2017) ' The low quality of evidence….. persists to the current day as the controversy over these "treatments" is accelerating in recent years."

Similarly, a 2020 Cochrane review of hormonal treatment outcomes for male-to-female transitioners older than 16 years found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." It is remarkable that decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking. See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic

Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020. https://doi.org/10.1002/14651858.CD013138.pub2 at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013138.pub2/full

Two systematic reviews commissioned by the US-based Endocrine Society in 2017 concur with the finding of the weak evidence base, stating that the finding of benefits of hormonal interventions in terms of "psychological functioning and overall quality of life" comes from "low-quality evidence (i.e., which translates into low confidence in the balance of risk and benefits)." Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines, which have now been broadly adopted by a number of medical societies.

In The Society for Evidence-Based Gender Medicine (SEGM)'s view, the "low confidence in the balance of risks and benefits" of hormonal interventions calls for extreme caution when working with gender-dysphoric youth, who are in the midst of a developmentally-appropriate phase of identity exploration and consolidation. While there may be short-term psychological benefits associated with the administration of hormonal interventions to youth, they must be weighed against the long-term risks to bone health, fertility, and other as yet-unknown risks of life-long hormonal supplementation.

Further, the irreversible nature of the effects of cross-sex hormones, and the potential for puberty blockers to alter the natural course of identity formation should give pause to all ethical clinicians. Studies consistently show that the vast majority of patients with childhood-onset gender distress who are not treated with "gender-affirmative" social transition or medical interventions grow up to be LGB adults. However, socially-transitioned and puberty-suppressed children have

much higher rates of persistence of transgender identification (96%), necessitating future invasive and risky treatments. The trajectory of the novel, and currently the most common presentation of gender dysphoria, which emerges for the first time in adolescence following a gender-normative childhood is unknown. The increasing number of desisters and detransitioners suggest the rate of regret within this novel cohort will not be as rare as previously estimated.

It is SEGM's position that the significant uncertainties regarding the long-term risk/benefit profile of gender-affirmative hormonal interventions call for noninvasive approaches (e.g. psychotherapy, social support, coping and resilience training,) as the first line of treatment for youth. If pursued, invasive and potentially irreversible interventions for youth should only be administered in clinical trial settings with rigorous study designs capable of determining whether these interventions are beneficial. *In addition to undergoing rigorous psychological and psychiatric evaluations*, patients and their families should participate *in a valid informed consent process*. This process must accurately disclose *the many uncertainties regarding the long-term mental and physical health outcomes of these experimental interventions.* See, Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643

67. Recently several countries reviewed existent relevant scientific data

a. Finland suggested that clinicians wait until age 26 to administer hormones and surgical treatments for trans individuals.

b. Sweden found no scientific studies that explain the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria. They found no studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria. Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium. The scientific activity during 2018 and 2019. seems high. Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. *No relevant randomized controlled trials in children and adolescents were found*.

A number of relevant issues were not considered during Sweden's review: proportion of care seekers who qualify for a formal diagnosis of gender dysphoria; proportion of children with gender dysphoria who have been given puberty blockers; proportion of teens administered cross-sex hormones; proportion who obtain surgery. See, Swedish Agency for Health Technology Assessment and Assessment of Social Services, "Gender dysphoria in children and adolescents: an inventory of the literature: A systematic scoping review at https://www.sbu.se/307e

c. Great Britain: the National Institute of Health and Care Excellence (NICE) reviewed the treatments offered for Gender Dysphoria in Great Britain in 2020. , NICE undertook two systematic evidence reviews of the use of GnRH agonists ("puberty blockers") and cross-sex hormones as treatments for gender dysphoric patients <18 years old. These reviews were led by Dr Hilary Cass OBE and published in March 2021. The evidence for using puberty blocking drugs to treat young people struggling with gender identity is "very low quality." The studies were small and "subject to bias and confounding". … "The quality of evidence for these outcomes was assessed as very low certainty." … When the clinical effectiveness of GnRH analogues was

compared with psychological support, social transitioning but no medication or no intervention NICE could not draw conclusions because of the (defective) way the studies had been designed. The studies were "all small" and lacked control groups. … There was "very little data" on any additional interventions - such as counseling or whether other medications were provided along with taking puberty blockers. *The review found no evidence of cost-effectiveness of treatment*. See, National Institute for Health and Care Excellence - NICE, Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria, 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334888&returnUrl=search%3fq%3dtransgender%26s%3dDate

The NICE review of cross-sex hormones after age 16 looked at improved mental health, quality of life and body image. *The evidence was of "very low" quality.* "Any potential benefits of gender-affirming hormones must be weighed against *the largely unknown long-term safety profile of these treatments* in children and adolescents with gender dysphoria," See, National Institute for Health and Care Excellence - NICE, Evidence review: Gender-affirming hormones for children and adolescents with gender dysphoria, 11 March 2021, at https://www.evidence.nhs.uk/document?id=2334889&returnUrl=search%3ffrom%3d2021-03-10%26q%3dEvidence%2bReview%26to%3d2021-04-01

d. A Review by Professor Carl Heneghan and editor of British Medical Journal Findings echo what has just been stated but emphasized the exponential rise in referrals to Gender Identity Service since 2011. This has been noted by many others see Arch Dis Child 2018;103:631–6. doi:10.1136/archdischild-2018-314992. The BMJ review noted serious methodological flaws in research and reviews, saying, “together these reviews included 16 studies with 1,132 participants

(transgender males (54%); transgender females (37%) and (7.6%) control subjects reported. *Controls were not matched for important confounders, which means caution should be applied to any conclusions drawn" and" We found no randomized controlled trials or controlled trials*."… Multiple studies were funded by the drug manufacturers "Six studies were funded by industry: 4 received funding from Ferring Pharmaceuticals (Delemarre-van de Waal 2006, Staphorsius (2015), Schagen 2016 and Hannema 2017).... "The *numbers in the ten studies are small* and most are *retrospective case reports* or small case series. *Many are done in single clinics* and *lack long-term longitudinal outcomes on the effects (both benefits and harms) of puberty blockers*. It is also *hard to disentangle effects from the use of gender affirming hormones*. We found four studies reporting on the use of GnHRa alone: Schagen 2016; Staphorsius 2015; Costa 2015and Delemarre-van de Waal 2006.

" Problems within these studies, however, *make it difficult to assess whether early pubertal changes regress under GnRHa treatment and whether prolonged puberty suppression is safe*. For example, there is a *lack of controls*, and in one study that included controls, these were *inadequate as relatives and friends of the participants were asked to participate*, serving as age-matched controls. A *lack of blinding was also problematic*. One study (Costa 2015) that focused on a measure of psychosocial well-being highlighted that getting older has previously been positively associated with maturity and well-being (see Getting older, getting better? Personal strivings and psychological maturity across the life span.)

The BMJ review also discussed Gender-affirming cross-sex hormone hormones (CSHs). They noted, "Oestrogens and testosterone induce masculine or feminine physical characteristics, and should only be taken in the context of medical supervision to monitor risks (e.g., polycythaemia in transgender males, venous thromboembolism in transgender females).

For transgender females, oestrogen therapy alone is often insufficient to produce the desired feminizing effects. Other treatments are therefore used in an off label manner. For example spironolactone, an aldosterone antagonist with weak oestrogenic properties is commonly used to support oestrogen therapy – off label. Cyproterone acetate has progestational and antiandrogenic properties, but it can lead to hepatic toxicity including jaundice, hepatitis. Hepatic failure has also been reported (fatalities reported, usually after several months, at dosages of 100 mg and above). See, Gender-affirming hormone in children and adolescents, British Medical Journal, 25th February 2019 at https://blogs.bmj.com/bmjebmspotlight/2019/02/25/gender-affirming-hormone-in-children-and-adolescents-evidence-review/

68. In evaluating claims of scientific or medical knowledge, it is important to understand that it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion and ideological fervor are too often *confused with reliable knowledge*, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising of:

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

b. A single case or series of cases (what could be called anecdotal evidence); (Levine, *Reflections*, at 239.)

c. A series of cases with a control group;

d. A cohort study;

e. A randomized double-blind clinical trial;

f. A review of multiple trials;

g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets. The current status of the field of gender affirmation treatments has been labelled "low quality" science by multiple reviews with existing studies suffering from *numerous methodological defects and misreporting of data* thus the field is *still at the experimental stage* lacking in general acceptance and without known error rates.

68. Before the recent reviews discussed above were published, prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. . . . [T]he proposed benefits of treatment to eliminate gender discordance…must be carefully weighed against… possible deleterious effects." (Adelson et al., *Practice Parameter,* at 968–69.) Similarly, the American Psychological Association has stated, "…because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children." See, American Psychological Association, Guidelines for Psychological Practice with Transgender & Gender Nonconforming People (2015), Am. Psychologist 70(9) 832 at 842.

69. Critically, "there are *no randomized control trials* with regard to treatment of children with gender dysphoria." (Zucker, *Myth of Persistence,* at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases,

or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine, *Reflections*, at 239.) See, American Psychological Association, Guidelines for Psychological Practice with Transgender & Gender Nonconforming People (2015), Am. Psychologist 70(9) 832 at 842.

70. Large gaps exist in the medical community's knowledge regarding the long-term effects of Sex Reassignment Surgery and other gender identity disorder treatments in relation to their positive or negative correlation to suicidal ideation, attempts, and completion. What is known, however, is not encouraging.

Effective Criticism of Recently Published Research

71. In 2020, Bränström and Panchankis, published a study claiming that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." They claimed their research provided the first empirical evidence that gender transition surgeries had long-term benefits. (See, Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734.). Nine letters were submitted to the editor from MDs, PhDs, and other methodologists that clarified methodological blunders and/or what appear to be potentially manipulative deceptions. These were published in August 2020. The writers concluded that, "These methodological shortcomings *preclude any statement on the suitability of early surgery in persons seeking treatment for gender non-congruence based on the results presented in this article*." They noted evidence supporting the theory that these "errors" could well be purposeful and designed to support an ideological perspective when they noted, "people diagnosed with gender incongruence *have a dramatically worse overall mental health outcome (after "transitioning" treatments)* than the general

population, which is, in fact, the answer to their stated aim and research question, *but this (essential) finding* is not even referred to in the title or in the Conclusions section *of the article*." (See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

Other serious flaws were highlighted "For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation?" The authors failed to find out. "A drop in hospitalizations for suicide attempts *alone* provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, *this omission is glaring*. The *lack of control subjects*, the *limited 1-year time frame*, and *the avoidance of examining completed suicides and psychiatric hospitalizations* are substantial study shortfalls."…"The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, *this study lacks the evidence to support its pro gender-affirmation surgery conclusion*." See, Van Mol, A., , Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

" The study *confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex*. However, the study does not demonstrate that either hormonal treatment or surgery has *ANY* effect on this morbidity. It seems that the main message of this article is that *the incidence of mental health problems and suicide*

attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors some how ignored this most essential finding] …" See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

" The data presented in Figure 1 in the article support findings from previous studies showing that transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress."… "Because of the limitations in the study design, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. "Therefore, the authors 'conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries cannot be supported." See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149.

" Bränström and Pachankis study on mental health treatment and suicide attempts … is misleading because the study design is flawed." "The authors first found what was already known *… the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning")*. The authors then explored *if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect* (odds ratio = 1.0), but *they do find a trend toward INCREASED risk of suicide attempts* as a function of years since starting *HORMONAL* treatment. They somehow failed to publish this essential finding. In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate

these negative outcomes to the number of years since surgery. Contrary to what the authors repeatedly claim, they do not employ a longitudinal design *but conduct a retrospective analysis unfit for their research question*. First, the authors include only persons who were alive in 2014. That means that those *who died by SUICIDE before 2014—and hence were at highest risk for suicide attempt—are EXCLUDED ((Negligence or Fraud?) and confound the results*. Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, *the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment*; it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors 'finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and is not a proxy for improved mental health. Because the authors do not present data prior to gender affirming surgery, *the study is uninformative with regard to the effects on psychiatric morbidity*. Moreover, *the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with HIGH risk for SUICIDE attempt.* Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes." See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165.

"The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population. However, the title of the article implies that gender corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide gender affirming surgeries to transgender individuals who seek them." In my opinion, this conclusion *is not supported by the data* presented in the article. The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not. Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment"). By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery. This corresponds to an odds ratio of 2.37 (95% CI= 1.01–

5.56, p=0.047). Hence, among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not. Whether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, the data presented in the article do *not* support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria." See, Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170.

"Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of ***increased*** mental health treatment due to this surgery, fits the data in the article and ***overturns*** the authors 'stated conclusions, suggesting that sex reassignment surgery is in fact associated with increased mental health treatment See, Ring, A. (PhD) and Malone, W. , Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

Taken together, these nine separate criticisms and the editor's decision to publish each of them in less than a year after e-publication, constitutes a illustration of the dangers of confirmation bias.

The authors admitted their conclusions were in error and that "more research" is needed to answer the questions they raised. The authors admitted, "Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming care*... (and) ...* When comparing the mental health treatment outcomes between the two groups (Table 1), we found no significant difference in the prevalence of treatment for

mood disorders and no significant difference in the prevalence of hospitalization-suicide attempts. " Bränström and Panchankis admitted they had failed to note that "individuals diagnosed with gender incongruence who had received gender-affirming surgery were *more likely to be treated for anxiety disorders* compared with individuals diagnosed with gender incongruence who had NOT received gender-affirming surgery. 'and "While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, like most extant research on the topic, *the design is incapable of establishing a causal effect* of gender affirming care on mental health treatment utilization. see Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals 'Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

In sum, too many ideologically tainted and methodologically defective research studies suffer from these kinds of serious errors, improper analyses and deceptive conclusions. Such poorly designed and improperly conducted research studies continue to prevent gender transition "affirmation" treatments from being generally accepted by the relevant scientific community. Finally, the Error Rates for such unproven, experimental "treatments" as well as for the foundational politically-based transgender ideology, are unknown, not peer-reviewed, and are thus unpublished.

72. Review of the Carmichael, et al, UK study of 2020: This research looked at 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. In sum, the authors … " *identified no changes in psychological function but noted that "*changes in bone density were consistent with suppression

of growth". Most importantly, the authors noted the lack of research support for such treatments, stating "Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex. All achieved suppression of gonadotropins by 6 months. The studies conclusions noted "We identified no changes in psychological function. Changes in BMD were consistent with suppression of growth. Larger and longer-term prospective studies using a range of designs are needed to more fully quantify the benefits and harms of pubertal suppression in GD" ." See, Polly Carmichael, Gary Butler, Una Masic, Tim J Cole, Bianca L DeStavola, Sarah Davidson, Elin M. Skageberg, Sophie Khadr, Russell Viner. 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 and https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1

https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1

BBC summary: https://www.bbc.com/news/uk-55282113 " Later reviewers noted a number of defects in the study design including the failure to follow up lost subjects over the nine-year study. There were only 44 patients available for analysis.; the study also lacked a control group; the study emphasized hypothesized biological origin of GD but excluded other possibilities; the study established that puberty blockers are highly likely to lead to cross-sex hormones and thus are not "easily reversible"; the authors also failed to note these drugs suppressed growth of height; the authors also failed to emphasize that self harm did not improve since they found no differences between baseline and later outcomes for overall psychological distress See also, Schumm, WR

and Crawford, DW, Is Research on Transgender Children What It Seems? Comments on Recent Research on Transgender Children with High Levels of Parental Support, The Linacre Quarterly, 2020, Vol. 87(1) 9-24. DOI: 10.1177/0024363919884799

73. Olson-Kennedy, J, has at times been an advocate for social transitioning of grade school youth and the employment of puberty blockers. Along with other researchers she summarized a number of the ongoing serious defects in the field's understanding of transgender patients. " Clinically useful information for predicting individual psychosexual development pathways is *lacking*." "Transgender youth are at high risk for poor medical and psychosocial outcomes [with or without affirmation treatments]." "Longitudinal data examining the impact of early social transition and medical interventions *are sparse*." "Existing tools to understand gender identity and quantify gender dysphoria *need to be reconfigured* to study a more diverse cohort of transgender individuals." Given their observations and their knowledge of the studies of non intervention leading to desistance, one must wonder how such advocates rationalize putting children on a path that will eventually lead to cross gender hormones and surgery. They have stated that "Extensive research is needed to improve understanding of gender dysphoria, and transgender experience, particularly among youth. Recommendations include *identification of predictors of persistence* of gender dysphoria from childhood into adolescence {cannot yet be done with scientific certainty], and *a thorough investigation into the impact of interventions for transgender youth*. I agree with this recommendation but in my opinion we should first do careful, competent prospective controlled follow up studies and only *then* make potential hazardous policy recommendations that put patients at risk. Finally, they suggest that *examining the social environments of transgender youth is critical for the development of appropriate interventions* necessary to improve the lives of transgender people. Despite this recommendation, it is ironic that

such multi-disciplinary research, analysis, and treatment is now being blocked and threatened as "conversion therapy" by political advocates. [See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236]

Suicide, suicidal ideation, suicide attempts, suicidal manipulations

74. With respect to suicide risks, individuals with gender dysphoria are well known to have a higher risk of committing suicide or otherwise suffering increased mortality before and after not only social transition, but also before and after SRS. (Levine*, Reflections,* at 242.) For example, in the United States, the death rates of trans veterans are *comparable to those with schizophrenia and bipolar diagnoses but 20 years earlier* than expected. These crude death rates include significantly elevated suicide rates. (Levine, *Ethical Concerns,* at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. The Swedish follow-up study found a suicide rate in the post-Sex Reassignment Surgery (SRS) population *19.1 times greater than that of the controls after affirmation treatment*; both studies demonstrated elevated mortality rates from *medical and psychiatric conditions*. (Levine, *Ethical Concerns,* at 10.) See, C. Dhejne et al. (2011), Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4).

75. Advocates of immediate and unquestioning affirmation of social transition in children who indicate a desire for a transgender identity sometimes assert that any other course will result

in a high risk of suicide in the affected children and young people. *Contrary to these assertions, no reliable-valid scientific studies show that affirmation of children (or anyone else) reduces suicide*, *prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response*, as I have described above.

A 2020 article, J. Turban et al., *Puberty Suppression for Transgender Youth and Risk of Suicidal Ideation*, Pediatrics 145(2), DOI: 10.1542/peds.2019-1725, has been incorrectly and misleadingly described in some press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not directly make that claim, nor permit that conclusion. It has been rigorously criticized for not emphasizing that both those treated and not treated with puberty blockers had high suicidal ideation rates and more children on these drugs were hospitalized for suicidal plans than the untreated. See, e.g., Hruz, Mayer and Schumm January 26m 2020, and M.Biggs Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Arch Sex Behav. 2020 Oct;49(7):2227-2229. doi: 10.1007/s10508-020-01743-6. Epub 2020 Jun 3.

76. Any discussion of suicide when considering younger children involves very long-range and *very uncertain, inaccurate* predictions. Suicide in pre-pubescent children is rare and the existing studies of gender identity issues in pre-pubescent children do *not* report significant incidents of suicide. *The current estimated suicide rate of trans adolescents is the same as teenagers who are in treatment for serious mental illness*. What trans teenagers do demonstrate is more suicidal ideation and attempts (however serious) than other teenagers. See, A. Perez-Brumer, J. K. Day et al. (2017), Prevalence & Correlates of Suicidal Ideation Among Transgender Youth in Cal.: Findings from a Representative, Population-Based Sample of High Sch. Students, J. Am. Acad Child Adolescent Psychiatry 56(9), 739 at 739.

77. In sum, ***claims that affirmation will reduce the risk of suicide for children are not based on credible, reliable-valid science***. Such claims overlook the lack of even short-term supporting data as well as the lack of studies of long-term outcomes resulting from the affirmation or lack of affirmation of transgender identity in children. It also overlooks the other tools that the profession does have for addressing depression and suicidal thoughts in a patient once that risk is identified including cognitive behavioral therapy and other proven interventions. (To Do Full citation?) (Levine, *Reflections*, at 242.)

A number of data sets have also indicated significant concerns about wider indicators of physical and mental health, including ongoing functional limitations including: abuse, depression, and psychiatric hospitalizations and increased cardiovascular disease, cancer, asthma, and COPD. Worldwide estimates of HIV infection among transgendered individuals are up to 17-fold higher than the cisgender population. Looking at such data may provide an indirect explanation for the high prevalence of suicidality both before and after transition from adolescence to older age among trans populations. See, (Levine, *Informed Consent,* at 6 **;** See, also G. Zeluf, C. Dhejne et al. (2016), *Health, Disability and Quality of Life Among Trans People in Sweden—A Web-Based Survey*, BMC PUBLIC HEALTH 16(903), DOI: 10.1186/s12889-016-3560-5. See, C. Dhejne, R. Van Vlerken et al. (2016), *Mental Health & Gender Dysphoria: A Review of the Literature*, Int'l Rev. of Psychiatry 28(1) 44.

78. Similarly, ***no scientific studies show that affirmation of pre-pubescent children leads to more positive outcomes*** (mental, physical, social, or romantic) by, e.g., age 25 or older ***than does "watchful waiting" or ordinary psychotherapy***. Because children's affirmation, social transition, and the use of puberty blockers for transgender children are a recent phenomenon, it could hardly be otherwise.

79. Thus, given the lack of credible science evidence for suicide reduction, transition of any sort must be justified, if at all, as a life-*enhancing* measure, not a lifesaving measure — although there is no credible to support either hypothesis. (Levine, *Reflections,* at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand. They also often do not understand that the current gender affirmation "treatment" data for life saving or enhancement are so weak, sparse, and poorly gathered that they do not permit us to know if gender affirmation interventions will increase or decrease a patient's risk of suicide or reduced depression ***or even an improved life.*** How many years will go by before such research is competently completed? See, C. Dragon, P. Guerino, et al. (2017), *Transgender Medicare Beneficiaries & Chronic Conditions: Exploring Fee-for-Service Claims Data*, LGBT Health 4(6) 404, DOI: 10.1089/lgbt.2016.0208.

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

80. As some research has already demonstrated, enabling and affirming social transition in a prepubescent child appears to be highly likely to increase the odds that the child will in time pursue pubertal suppression and persist in a transgender identity into adulthood. I consider the ethical implications of this intervention in the next section. Here, I emphasize that the Mental Health Professional (MHP), pediatrician, and parent must consider long-term as well as short - term implications of life as a transgender individual when deciding whether to permit or encourage a child to socially transition.

81. The multiple studies from different nations that have documented ***the increased vulnerability of the adult transgender population to substance abuse, mood and anxiety disorders, suicidal ideation, and other health problems stand as a warning***: Given these well-documented data, ***assisting a child down the road to becoming a transgender adult is an ominous***

decision. Data about trans adults remind all concerned that a casual assumption that transition will improve the child's life is ***not*** justified beyond his or her short term happiness about gender expression. The possibility that steps along this pathway, while lessening the relatively minor pain of gender dysphoria, *could lead to additional future sources of crippling emotional and psychological pain*, are too often not properly considered by advocates of social transition and not considered at all by the trans child. (Levine, *Reflections,* at 243.). The informed consent process for parents considering this option ethically should spell out short-term gains and long-term risks (beginning at early puberty risks). What follows is a discussion of the medical, social, and psychological risks of affirmation interventions ("transition").

A. Physical risks associated with transition

82. Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** *to be one of the major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. *See* C. Guss et al., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5

("cross-sex hormones . . . may have irreversible effects"); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility"). (*See supra* ¶ 21.)

83. Loss of sexual response. Puberty-blockers prevent maturation of the sexual organs and response. Some and perhaps many transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood, and ***are unable ever to experience orgasm***. To my knowledge, data quantifying this impact has not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine, *Informed Consent,* at 6.) (Perelman and Watters, 2016) Delayed Ejaculation in Handbook of Clinical Sexuality for. Mental Health Professionals 3rd edition, New York, Routledge**).**

84. Other effects of hormone administration. While it is commonly said that the effects of puberty blockers are reversible after cessation, in fact ***controlled, reliable-valid research studies have never been done*** as to how completely this is true. However, it is well known that ***many effects of cross-sex hormones cannot be reversed*** should the patient later regret his transition. This is dramatically evident among females 'deeper voice quality after testosterone administration and the loss of muscle mass among males on estrogen for long periods of time. After puberty, the individual who wishes to live as the opposite sex will in most cases *have to take cross-sex hormones for life.*

85. The long-term health risks of this major alteration of hormonal levels ***have not yet been quantified*** in terms of exact risk *thus appropriate, ethical, complete informed consent* ***is not***

yet possible *for such experimental "treatments"*. However, a recent study found *greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals* taking estrogen. Those authors concluded, "it is critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of hormone. 32 *See* Tishelman et al*., Serving TG Youth* at 6-7 (Long-term effect of cross-sex hormones "is an area where we currently have *little research to guide us*"). treatment." See, D. Getahun et al. (2018), *Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study*, Annals of Internal Medicine at 8, DOI:10.7326/M17-2785.

Others similarly noted that administration of cross-sex hormones creates "an additional *risk of thromboembolic events"—which is to say blood clots* (Guss et al., *TGN Adolescent Care* at 5), *which are associated with strokes, heart attack, and lung and liver failure*. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view of such risks including the risk of reduced life expectancy. See, Blosnich, J. R., Brown, G. R., Wojcio, S., Jones, K. T., & Bossarte, R. M. (2014). Mortality among veterans with transgender-related diagnoses in the Veterans Health Administration, FY2000–2009. LGBT Health, 1, 269–276. doi:10.1089/lgbt.2014.0050

86. Health risks inherent in complex surgery. Complications of surgery exist for each procedure, and complications in surgery affecting the reproductive organs and urinary tract can have significant anatomical and functional complications for the patient's quality of life.

87. Disease and mortality generally. The MHP, the patient, and in the case of a child the parent, must also be aware of the wide sweep of strongly negative health outcomes among transgender individuals. *Shortened life expectancy has been repeatedly documented* in Sweden, US, and Denmark. See, Levine, Informed Consent, at 5 (citing T. van de Grift, G. Pigot et al.

(2017), A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen, J. Sexual Medicine 14(12) 1621.).

B. Social risks associated with transition

88. Family and friendship relationships. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own often do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine, *Ethical Concerns,* at 5.)

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

90. Sexual-romantic risks associated with transition. After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her natal sex, many potential cisgender mates lose interest. When a trans person does not pass well, he discovers that the pool of those interested consists largely of individuals looking for exotic sexual experiences rather than genuinely loving relationships. (Archives Sexual Behavior April 2021) (Levine, *Ethical Concerns*, at 5, 13.) Nor is the problem all on the other side; transgender individuals commonly become strongly narcissistic, unable to give the level of attention to the needs of another that is necessary to sustain a loving relationship. See, S. Levine, *Barriers to Loving: A Clinician's Perspective*, at 40 (Routledge, New York 2013). The percentage of transitioned patients who will become increasingly suicidal as they fully realize the depth of the social isolation experienced by many transgender patients has never been studied and is thus unknown.

91. Social risks associated with delayed puberty. The social and psychological impact of remaining puerile (not growing) for, e.g., three years while one's peers are undergoing puberty, and of undergoing puberty at a substantially older age, have ***not been systematically studied***, although clinical mental health professionals often hear of distress and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines while their peers are developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine, *Informed Consent,* at 9.) We should recall that puberty introduces sexual desire, changes socialization patterns, and enables teens to enter into early romantic relationships all of which can

lead to maturation, self-confidence, and an understanding of the complexity of partner relationship. *Delaying puberty can reasonably be assumed to increase the adolescent's sense of isolation, otherness, and being an outsider.*

C. Mental health costs or risks

92. One would expect the negative physical and social impacts reviewed above to adversely affect the mental health of individuals who have transitioned. In addition, adult transitioned individuals find that living as the other (or, in a manner that is consistent with the stereotypes of the other as the individual perceives them) is a continual challenge and stressor, and many find that they continue to struggle with a sense of inauthenticity in their transgender identity and bear consequent chronic uneasiness. (Levine, *Informed Consent,* at 9.) In addition, individuals often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with puberty. Thus, transition can result in deflection from mastering personal challenges at the appropriate time, or addressing underlying psychiatric conditions that require treatment. *The percentage of transitioned patients who will become increasingly suicidal due to deflection from mastering personal challenges at the appropriate time, has never been studied and is thus unknown.*

93. Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a transgender identity. Indeed, Swedish researchers in a long- term study (up to 30 years since Sex Reassignment Surgery (SRS), with a median time since SRS of > 10 years) concluded that ***individuals who have SRS should have postoperative lifelong psychiatric care***. (Dhejne, Long Term, at 6-7.) With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs.

10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.

Regret following transition is not an infrequent phenomenon.

94. The large numbers of children and young adults who have desisted as documented in both group and case studies each represent "regret" over the initial choice in some sense.

95. The phenomenon of desistance or regret experienced *later* than adolescence or young adulthood, or among older transgender individuals, has to my knowledge ***not been quantified or well-studied.*** However, it is a real phenomenon. I myself have worked with multiple individuals who have abandoned trans female identity after living in that identity for years, and who would describe their experiences as "regret".

96. I have seen several Massachusetts inmates and trans individuals in the community abandon their [trans] female identity after several years. (Levine, *Reflections,* at 239.) In the gender clinic which I founded in 1974 and am still part of, we have seen many instances of individuals who claimed a transgender identity for a time, but ultimately changed their minds and reclaimed the gender identity congruent with their sex.

97. More dramatically, a surgical group prominently active in the SRS field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form. See Djordjevic ML, Bizic MR, Duisin D, Bouman MB, Buncamper M. Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery. J Sex Med. 2016 Jun;13(6):1000-7. doi: 10.1016/j.jsxm.2016.02.173. Epub 2016 May 4. PMID: 27156012.

98. I noted above an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet*. See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126).

99. Thus, misleading reports of clinical experience, publications that misreport evidence, and the unregulated content of the Internet - many falsely claiming transitions are "easily reversible" — prevent the sobering acceptance of what has previously been asserted for decades — for most all such patients "once a transgendered person, always a transgendered person", whether referring to a child, adolescent, or adult, male or female.

VI. MEDICAL ETHICS & INFORMED CONSENT

A. The obligation of the mental health professional to enable and obtain informed consent

100. I have reviewed above the knowledge and experience that, in my view, a mental health professional should have before undertaking the responsibility to counsel or treat a child who is experiencing gender dysphoria or transgender identification. The MHP who undertakes this type of responsibility must also be guided by the ethical principles that apply to all health care professionals. One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must

weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, ethics prohibit the treatment.

101. A distinct ethical responsibility of physicians, when a significant risk exists of adverse consequences to any procedure or therapy, is to ensure that the patient understands and is legally able to consent to these unproven, experimental, high risk, often irreversible, potentially harmful "treatments", and does consent. To achieve informed consent, the MHP, pediatrician, or other physician must do at least the following:

a. Must reasonably inform him- or herself regarding the particular situation of his patient;

b. Must reasonably inform him- or her self concerning the state of knowledge concerning the relevant methodologies and outcomes and the unproven, experimental nature of these "treatments";

c. Must honestly inform the patient concerning not only the benefits of treatment, but also the risks and downsides of treatment, and alternative treatments *including no treatment at all as well as the lack of competent scientific study to determine accurate predictions of risks and benefits in this experimental field.*

d. Must conclude that the patient (or the decision maker, such as parent or healthcare power of attorney) has comprehended what he or she has been told and possesses a cognitive capacity to make a decision based on an adequate understanding of his or her unique life circumstances.

102. Perfunctory "consent" is inadequate to fulfill the professional's ethical obligation to obtain **truly** informed consent. At the very least, a patient (or parent) considering the life-altering

choice of transition should be helped or indeed required by their clinicians to grapple with four relevant questions:

a. " What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?

b. "What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?

c. "What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?

d. "What have you considered the nature of your life will be in 10 to 20 years?" (Levine, *Informed Consent,* at 3.)

e. "Are you fully aware that national science reviews done in England, Sweden, Finland and the US have all noted the lack of credible scientific evidence supporting these experimental treatments? Are you fully aware that the few long-term research studies done in this field support the hypothesis that *patients, in the long run, may be* ***more harmed than helped*** *by these experimental "treatments*"?

103. The answers of the patient will enable the professional to make a judgment about how realistic he or she is being. For example, the biological boy who envisions himself as a happy, attractive, socially accepted 21-year-old girl in future college years has probably not been adequately informed of—or has mentally blocked—hard data concerning the mental health and social wellbeing of the transgender population in their 20s, and is failing to consider the material risk that he, as a transgender individual, will not be perceived as attractive to either sex, and the impact that this may have on his future well-being.

104. Most commonly, meaningful engagement with difficult and painful questions such as those above requires a process that will consist of multiple discussions in a psychotherapeutic or counseling context, not merely "disclosure" of facts. In my experience, a too-rapid or too-eager attachment to some outcome is a warning that the patient is not able to tolerate knowledge of the risks and alternative approaches.

105. In my experience, in the area of transgender therapy, rather than the type of information and engagement that I have described, even mental health professionals too often encourage or permit decisions based on a great deal of patient and professional blind optimism about the future that is not grounded in competent, peer reviewed published, reliable-valid scientific research. (Levine, *Ethical Concerns*, at 3-4.) In understanding how the medical and psychological profession is taught how to deal with these patient/ family problems, it is quite clear that knowledge of the scientific limitations of affirmative therapy is not emphasized. Thus, many practitioners passionately, but erroneously, negligently, and unethically, believe that controlled studies with adequate follow-up are the basis for what they have been taught. It is difficult to provide informed consent if the professional is not informed or ideologically driven to be misinformed. Consumer fraud in health care can take place via gross negligence.

B. The interests of the patient, as well as necessary disclosures and consent, must be considered from a life course perspective.

106. The psychiatrist, pediatrician, or psychologist treating a child must have in view not merely (or not even primarily) making the child "happy" now, but making him or her as healthy and happy as possible across the entire trajectory of life, to the extent that is predictable. Certainly, avoiding suicide is one important aspect of a "life course" analysis, and recognizes that "today" is not the only goal. **But as we have demonstrated above, there is no credible scientifically reliable-valid evidence that these experimental treatments actually reduce life-time risk of**

suicide in these patients. There are many more factors across the future decades of the patient's life that also need to be taken into account.

107. Further, in my opinion, a patient can meaningfully be said to know what will make him "happy" over the long term, prior to receiving, understanding, and usually discussing the type of information that I have described above in connection with informed consent. With respect to (most) children who are not equipped to understand, evaluate, and feel the life implications of such information, it is doubtful that there is any meaningful way in which they can be said to "know" what will make them happy over the long term. It is for similar reasons that parents ordinarily make a great many decisions, both large and small, for their young children.

108. Of particular relevance to the life course perspective, when gender-typical men and women undergo elective sterilization, there is a distinct likelihood of eventual regret, in some patients to the point of suicidal despondency. It has been documented that *the younger the age of sterilization, the greater incidence of regret and increased numbers of requests to reverse the sterilized state*. Thus, the medical profession and the courts are quite clear about sterilization: the adult patient must be cognitively able to prudently consider the future consequences in terms of his or her life circumstances. In minors sterilization should be done only to save a life. See A. Burgart et al. (2017), *Ethical Controversy About Hysterectomy for a Minor*, Pediatrics 139(6), DOI:10.1542/peds.2016-3992. This observation has implications for facilitating or even permitting children or adolescents to embark on a path of social transition that within a few years may psychologically steer that individual towards sterilizing chemical or surgical procedures. *See* S. D. Hillis et al. (1999), *Post-sterilization Regret: Findings from the United States Collaborative Review of Sterilization*, Obstetrics & Gyn 93(6) 889; A. Burgart et al. (2017), *Ethical Controversy About Hysterectomy for a Minor*, Pediatrics 139(6),

DOI:10.1542/peds.2016-3992; K. Curtis et al. (2006), *Regret Following Female Sterilization at a Young Age: A Systematic Review*, Contraception 73, 205, DOI:10.1016/j.contraception.2005.08.006; A. Tamar-Mattis (2009), *Exploring Gray Areas in the Law About DSD and Sterilization*, Endocrine Today, October ed., https://www.healio.com/endocrinology/reproduction-androgen-disorders/news/print/endocrine-today/%7Bc6029f85-28ac-43f4-9e7e-0fc897f6313f%7D/exploring-gray-areas-in-the-law-about-dsd-and-sterilization.

C. Special concerns and ethical rules governing experimentation on patients

109. When psychiatric or medical research is done on subjects the informed consent process is far more rigorous than in ordinary medical and psychiatric procedures. For example, in a recent study of an agent to assist women who are distressed by their lack of sexual desire that I was a part of, the Informed Consent document was 19 pages long.

110. As reported in multiple national science reviews of this field, the *absence* of competently designed, long-term outcome research studies demonstrating more benefits than damages for gender affirmation interventions ("transitioning treatments") means that *the claimed therapeutic interventions for* these conditions ***are still at a primitive stage of development, and should be considered to be experimental,*** rendering adequately informed consent all the more essential**,** all the more required by ethical and licensing rules-regulations and all the more difficult to obtain. Claims that a civil right is at stake for differently gender identifying people do not change the fact that informed consent is an international recognized fundamental human right and that what is proposed is a social and medical experiment. (Levine, *Reflections,* at 241.) (See, Nuremberg Code, Informed Consent Laws in each state, and The Joint Commission on

Accreditation of Healthcare Organizations, or JCAHO [an organization based in the United States that accredits over 20,000 healthcare organizations and programs in the country.] as well as the relevant Health Care Profession Licensing Rules and Regulations in each state.)

111. "Informed consent is often defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the A) nature of the intervention, its risks, and benefits, as well as B) the risks and benefits of alternative treatments and C) the risks and benefits of no treatment".

112. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science. The infamous Tuskegee experimental studies, the Nazi and Imperial Japanese wartime experimental research on prisoners, the use of lobotomies, the recovered memory therapy movement, the "multiple personality disorder" therapy movement, and the rebirthing therapy movement, all invite comparisons with what is happening to too many gender discordant children and adolescents. In my opinion, health care professionals have ethical, professional, and moral responsibilities to protect the rights of patients and their families to be fully and accurately informed about the risks, benefits, natural history, alternatives, and state of science for the full range of experimental gender affirmation "treatments". See, https://www.nobelprize.org/prizes/medicine/1949/moniz/article/ Properly accomplished informed consent is not controversial. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients 'right to informed consent. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998].

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

113. Some advocates assert that various mental health pathologies commonly observed in patients who have transitioned result from societal prejudice, and would not occur if society were different. This is, of course, a hypothesis rather than demonstrated fact, and it is in any case ethically irrelevant to the treatment of an individual patient. If a therapy or life course under consideration for a child will predictably lead to social and family isolation and unemployment later in life given society as it exists, for a MHP or other advisor to recommend or encourage that path nonetheless seems to lose sight of the welfare of the patient. To do so appears to be intentionally using the child as not merely an experiment, but as a change-agent—potentially at great personal cost—rather than seeking the lifetime best interests of that child. (Levine, *Ethical Concerns,* at 9.) It seem audacious of advocates whose primary qualification is being trans oneself to tell parents how their child should be treated.

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

114. Obviously, most children cannot give legally valid consent to a medical procedure. This is not a mere legal technicality. Instead, it is a legal reflection of a reality of human development that is highly relevant to the ethical requirement of informed consent quite apart from law. The argument that the child is consenting to the transition by his happiness ignores the fact just described.

115. Each age group poses different questions about risk comprehension. (Levine, *Informed Consent*, at 3.) While the older patient is perhaps more likely to be formally mental ill and be unrealistic sometimes to the point of being delusional, the young child is chronically unable to comprehend large and complex issues such as the meaning of biological sex, the meaning of gender, and the risks and life implications attendant on social, hormonal, and ultimately surgical transition.

116. In my experience, when clinicians actually attempt to understand patients 'motives for the repudiation of their natal gender, the developmental lack of sophistication underlying their reasons can become apparent. What must a 12-year-old, for example, understand about masculinity and femininity that enables the conviction that "I can never be happy in my body?" (Levine, *Ethical Concerns,* at 8.) Obviously, this unavoidable gap in comprehension and ability to foresee must be still larger for younger children.

117. Similarly, one cannot expect a 17-year-old to grasp the complexity of married life with children when 38. One cannot expect a ten-year-old to understand the emotional growth that comes from a first long term love relationship including sexual behavior. One cannot expect a six-year-old to comprehend the changes in his psyche that may come about as the result of puberty. In some States or under some circumstances "mature minors" may be legally empowered to grant consent to certain medical procedures. Arguments have been made that minor adolescents are capable of providing legal informed consent if the physician thinks the patient is reasonable. See Clark & Virani. This wasn't a split-second decision: An empirical ethical analysis of transgender youth capacity, rights, and authority to consent to hormone therapy. Archives of Sexual Behavior published on line 27 January, 2021 doi.org/10.1007s11673-020-10086-9. Such thinking makes use of the idea that trans people including trans youth are special cases and do not have to follow cultural and scientific truths. This is an argument that I profoundly reject.

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

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

120. The transgender clinical arena is growing increasingly uncertain as more attention has been paid to the lack of fundamental studies to support the current widespread fashions of professional recommendations and confirmation bias has been identified in recent highly acclaimed but deeply flawed work. While the general public is now accustomed to reading about trans culture wars, my opinion is that of a clinician who respects scientific methods of ascertaining best treatments. More caution is indicated when the consequences are greater. It has been repeatedly demonstrated in medicine that one size does not fit all. One must reject the idea that if a young person is trans, nothing else matters—the treatment should be immediate affirmation and endocrine support. All must realize that 50 years after trans treatment began to spread across the world, despite more than 10,000 publications, it is not known whether the burgeoning Transgender Treatment Industry is helping or damaging most GD patients.

121. It is my opinion that the scientific community finds the following matters to be uncertain, controversial, or incorrect.

— Gender dysphoria is a serious, physical brain based medical illness that causes suffering that must be treated by hormones and surgery if patients seek such treatments.

— All patients who label themselves as transgendered, regardless of the >120 sub-labels that may be invoked, gender all should be offered the same physical body-changing treatments, if they so desire.

— Hormones and surgery improve the lives of the transgendered in the long run.

— "Above all do no harm" principle can be sidestepped when administering hormones and removing healthy breast and genital tissues in the case of trans persons because it is "medically necessary" –that is, these patients represent a special exception to 2500 years of medical ethics.

-The uncertain long-term adjustments of trans adults, the rates of detransition, disappointment, and chronic depressive, anxiety, and substance abuse disorders do not need to be calculated nor should what is known about high psychiatric morbidity following hormonal and/or surgical treatment should not slow the affirmative treatment policy of trans youth.

--Civil rights considerations are more important than unanswered relevant scientific questions.

XX. SUMMARY OPINIONS:

122. There are no long-term, peer-reviewed published, credible, reliable and valid, research studies documenting or establishing:

a. The percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria.

b. The percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria.

c. The reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

d. The mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood.

e. The percentage of various types of childhood functional challenges and psychiatric diagnoses of trans identified children

f. The percentage of patients whose new trans identity has been created by involvement in social media.

123. The above list of six issues can stimulate new research whose results may shape future trans care. In the meantime, those with gender dysphoria or a trans identity have a right to be more fully informed about what is known as do their physicians. Physicians, psychologists, parents, and patients have a right to be *protected* from these current experimental, politically tainted, fashionable "treatments".

124. Informed consent is designed to protect the rights of patients and families, the cognitive and ethical processes of physicians, and the ethical and legal duties of health care institutions. The need for credible, reliable-valid science is also essential to protect each of these entities. The informed consent document for affirmative treatments of youth should specify that up to 88% of children without affirmation will desist (heal naturally without treatment) from their childhood-onset trans preoccupations. Physicians always need to know the patient's original sex because while gender identity can dramatically change, biological sex and its unique susceptibilities to disease does not.

125. The Transgender Treatment Industry's policies and advocacies are a niche group of well meaning mental health professionals, endocrinologists, plastic and urological surgeons, and transgendered individuals. Many in their individual professions have differing opinions. They should not be viewed as speaking for all of medicine on these highly controversial issues.

126. Science not politics needs to drive trans care. The medical professions has many tragic examples of when political sensibilities drive medical treatments. When policy is made by voting in the face of low quality science, claims that treatments are evidence-based should be considered misleading and deceptive.

127. No medical, surgical, or psychiatric treatment is invariably successful in producing an agreed upon outcome. In other branches of medicine and psychiatry risks and benefits, outcomes and error rates are better known, far less controversial, and much better proven by credible, reliable-valid scientific research. Error rates for gender affirmation diagnoses, errors rates for predictions of effective vs. harmful affirmation treatments, error rates for increases or decreases in suicidal risk following affirmation treatments, remain unknown. In the field of gender affirmation intervention there has been a rush to treat and a remarkable absence of ethical concern based on obvious scientific limitations as outlined in this report.

128. **Expert Witness Report Methodological Limitations**: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly

to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United

States of America that the foregoing is true and correct.

Date: _____

Signed: _____ Scheduled for Signature 4/29/2021

Stephen B. Levine, M.D.

to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United

States of America that the foregoing is true and correct.

Date: May 1, 2021

Signed: Stephen B Levine MD Scheduled for Signature 4/29/2021

Stephen B. Levine, M.D.

Stephen B. Levine, M.D. Curriculum Vita

Brief Introduction

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

Personal Information

Date of birth 1/14/42

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

Board Certification 6/76 American Board of Neurology and Psychiatry

Education

1963 BA Washington and Jefferson College

1967 MD Case Western Reserve University School of Medicine

1967-68 internship in Internal Medicine University Hospitals of Cleveland

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

1970-73 Psychiatric Residency, University Hospitals of Cleveland

1974-77 Robert Wood Johnson Foundation Clinical Scholar

Appointments at Case Western Reserve University School of Medicine

1973 - Assistant Professor of Psychiatry

1979 - Associate Professor

1982 - Tenure

1985 - Full Professor

1993 - Clinical Professor

Honors

Summa Cum Laude, Washington & Jefferson

Teaching Excellence Award - 1990 and 2010 (residency program)

Visiting Professorships:

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

Named to America's Top Doctors consecutively since 2001

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

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

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

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

Professional Societies

1971 - American Psychiatric Association; fellow

2005 - American Psychiatric Association - **Distinguished Life Fellow**

1973 - Cleveland Psychiatric Society

1973 - Cleveland Medical Library Association

- 1985 - Life Fellow
- 2003 - Distinguished Life Fellow

1974 - Society for Sex Therapy and Research

- 1987-89 - President

1983 - International Academy of Sex Research

1983 - Harry Benjamin International Gender Dysphoria Association

- 1997-98 - Chairman, Standards of Care Committee

1994-99 - Society for Scientific Study of Sex

Community Boards

1999-2002 - Case Western Reserve University Medical Alumni Association

1996-2001 - Bellefaire Jewish Children's Bureau

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

Editorial Boards

1978-80 Book Review Editor Journal Sex and Marital Therapy

Manuscript Reviewer for:

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

Prospectus Reviewer for:

- Guilford
- Oxford University Press

- Brunner/Routledge
- Routledge

Administrative Responsibilities

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

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

Co-leader of case conferences at DELRLLC.com

Recent Expert Witness Appearances

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

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

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

Witness for State of Florida vs. Reyne Keohane July 2017

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

Consultancy

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

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

Virginia Department of Corrections - evaluation of an inmate

New Jersey Department of Corrections - evaluation of an inmate

Idaho Department of Corrections - workshop 2016

Grant Support/Research Studies

TAP - studies of Apomorphine sublingual in treatment of erectile dysfunction

Pfizer - Sertraline for premature ejaculation

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

NIH - Systemic lupus erythematosis and sexuality in women

Sihler Mental Health Foundation

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

Alza - controlled study of a novel SSRI for rapid ejaculation

Pfizer - Viagra and self-esteem

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

Johnson & Johnson - controlled studies of Dapoxetine for rapid ejaculation

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

Lilly-Icos - study of Cialis for erectile dysfunction

VIVUS - study for premenopausal women with FSAD

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

Medtap - interview validation questionnaire studies

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

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

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

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

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

National registry trial for women with HSDD

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

Palatin - study of SQ Bremelanotide for HSDD and FSAD

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

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

HRA - qualitative and cognitive interview study for men experiencing PE

Publications

A) Books

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

B) Research and Invited Papers

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

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

5) Some thoughts on the pathogenesis of premature ejaculation. J. Sex & Marital Therapy 1975; 1:326-334

6) Marital Sexual Dysfunction: Introductory Concepts. Annals of Internal Medicine 1976;84:448-453

7) Marital Sexual Dysfunction: Ejaculation Disturbances 1976; 84:575-579

8) Yost MA: Frequency of female sexual dysfunction in a gynecology clinic: An epidemiological approach. Archives of Sexual Behavior 1976;5:229-238

9) Engel IM, Resnick PJ, Levine SB: Use of programmed patients and videotape in teaching medical students to take a sexual history. Journal of Medical Education 1976;51:425-427

10) Marital Sexual Dysfunction: Erectile dysfunction. Annals of Internal Medicine 1976;85:342-350

11) Articles in Medical Aspects of Human Sexuality

    (a) Treating the single impotent male. 1976; 10:123, 137

    (b) Do men enjoy being caressed during foreplay as much as women do? 1977; 11:9

    (c) Do men like women to be sexually assertive? 1977;11:44

    (d) Absence of sexual desire in women: Do some women never experience sexual desire? Is this possibility genetically determined? 1977; 11:31

    (e) Barriers to the attainment of ejaculatory control. 1979; 13:32-56.

    (f) Commentary on sexual revenge.1979;13:19-21

    (g) Prosthesis for psychogenic impotence? 1979;13:7

    (h) Habits that infuriate mates. 1980;14:8-19

    (i) Greenberger-Englander, Levine SB. Is an enema an erotic equivalent?1981; 15:116

    (j) Ford AB, Levine SB. Sexual Behavior and the Chronically Ill Patients. 1982; 16:138-150

    (k) Preoccupation with wife's sexual behavior in previous marriage 1982; 16:172

    (l) Co-existing organic and psychological impotence. 1985;19:187-8

    (m) Althof SE, Turner LA, Kursh ED, Bodner D, Resnick MI, Risen CB. Benefits and Problems with Intracavernosal injections for the treatment of impotence. 1989;23(4):38-40

12) Male Sexual Problems. Resident and Staff Physician 1981:2:90-5

13) Female Sexual Problems. Resident and Staff Physician 1981:3:79-92

14) How can I determine whether a recent depression in a 40 year old married man is due to organic loss of erectile function or whether the depression is the source of the

dysfunction? Sexual Medicine Today 1977;1:13

15) Corradi RB, Resnick PJ Levine SB, Gold F. For chronic psychologic impotence: sex therapy or psychotherapy? I & II Roche Reports; 1977

16) Marital Sexual Dysfunction: Female dysfunctions 1977; 86:588-597

17) Current problems in the diagnosis and treatment of psychogenic impotence. Journal of Sex & Marital Therapy 1977; 3:177-186

18) Resnick PJ, Engel IM. Sexuality curriculum for gynecology residents. Journal of Medical Education 1978; 53:510-15

19) Agle DP. Effectiveness of sex therapy for chronic secondary psychological impotence Journal of Sex & Marital Therapy 1978; 4:235-258

20) DePalma RG, Levine SB, Feldman S. Preservation of erectile function after aortoiliac reconstruction. Archives of Surgery 1978; 113-958-962

21) Conceptual suggestions for outcome research in sex therapy Journal of Sex & Marital Therapy 1981; 6:102-108

22) Lothstein LM. Transsexualism or the gender dysphoria syndrome. Journal of Sex & Marital Therapy 1982; 7:85-113

23) Lothstein LM, Levine SB. Expressive psychotherapy with gender dysphoria patients Archives General Psychiatry 1981; 38:924-929

24) Stern RG Sexual function in cystic fibrosis. Chest 1982; 81:422-8

25) Shumaker R. Increasingly Ruth: Towards understanding sex reassignment surgery Archives of Sexual Behavior 1983; 12:247-61

26) Psychiatric diagnosis of patients requesting sex reassignment surgery. Journal of Sex & Marital Therapy 1980; 6:164-173

27) Problem solving in sexual medicine I. British Journal of Sexual Medicine 1982; 9:21-28

28) A modern perspective on nymphomania. Journal of Sex & Marital Therapy 1982; 8:316-324

29) Nymphomania. Female Patient 1982;7:47-54

30) Commentary on Beverly Mead's article: When your patient fears impotence. Patient Care 1982; 16:135-9

31) Relation of sexual problems to sexual enlightenment. Physician and Patient 1983 2:62

32) Clinical overview of impotence. Physician and Patient 1983; 8:52-55.

33) An analytical approach to problem-solving in sexual medicine: a clinical introduction to the psychological sexual dysfunctions. II. British Journal of Sexual Medicine

34) Coffman CB, Levine SB, Althof SE, Stern RG Sexual Adaptation among single young adults with cystic fibrosis. Chest 1984; 86:412-418

35) Althof SE, Coffman CB, Levine SB. The effects of coronary bypass in female sexual, psychological, and vocational adaptation. Journal of Sex & Marital Therapy 1984; 10:176-184

36) Letter to the editor: Follow-up on Increasingly Ruth. Archives of Sexual Behavior 1984; 13:287-9

37) Essay on the nature of sexual desire Journal of Sex & Marital Therapy 1984; 10:83-96

38) Introduction to the sexual consequences of hemophilia. Scandanavian Journal of Haemology 1984; 33:(supplement 40).75-

39) Agle DP, Heine P. Hemophila and Acquired Immune Deficiency Syndrome: Intimacy and Sexual Behavior. National Hemophilia Foundation; July, 1985

40) Turner LA, Althof SE, Levine SB, Bodner DR, Kursh ED, Resnick MI. External vacuum devices in the treatment of erectile dysfunction: a one-year study of sexual and psychosocial impact. Journal of Sex & Marital Therapy

41) Schein M, Zyzanski SJ, Levine SB, Medalie JH, Dickman RL, Alemagno SA. The frequency of sexual problems among family practice patients. Family Practice Research Journal 1988; 7:122-134

42) More on the nature of sexual desire. Journal of Sex & Marital Therapy 1987; 13:35-44

43) Waltz G, Risen CB, Levine SB. Antiandrogen treatment of male sex offenders. Health Matrix 1987; V.51-55.

44) Lets talk about sex. National Hemophilia Foundation January, 1988

45) Sexuality, Intimacy, and Hemophilia: questions and answers . National Hemophilia Foundation January, 1988

46) Prevalence of sexual problems. Journal Clinical Practice in Sexuality 1988;4:14-16.

47) Kursh E, Bodner D, Resnick MI, Althof SE, Turner L, Risen CB, Levine SB. Injection Therapy for Impotence. Urologic Clinics of North America 1988; 15(4):625-630

48) Bradley SJ, Blanchard R, Coates S, Green R, Levine S, Meyer-Bahlburg H, Pauly I, Zucker KJ. Interim report of the DSM-IV Subcommittee for Gender Identity Disorders. Archives of Sexual Behavior 1991;;20(4):333-43.

49) Sexual passion in mid-life. Journal of Clinical Practice in Sexuality 1991 6(8):13-19

50) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DR, Resnick MI. Intracavernosal injections in the treatment of impotence: A prospective study of sexual, psychological, and marital functioning. Journal of Sex & Marital Therapy 1987**;** 13:155-167

51) Althof SE, Turner LA, Risen CB, Bodner DR, Kursh ED, Resnick MI. Side effects of self-administration of intracavernosal injection of papaverine and phentolamine for treatment of impotence. Journal of Urology 1989; 141:54-7

52) Turner LA, Froman SL, Althof SE, Levine SB, Tobias TR, Kursh ED, Bodner DR. Intracavernous injection in the management of diabetic impotence. Journal of Sexual Education and Therapy 16(2):126-36, 1989

53) Is it time for sexual mental health centers? Journal of Sex & Marital Therapy 1989**;**

54) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Sexual, psychological, and marital impact of self injection of papaverine and phentolamine: a long-term prospective study. Journal of Sex & Marital Therapy

55) Althof SE, Turner LA, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Why do so many men drop out of intracavernosal treatment? Journal of Sex & Marital Therapy. 1989; 15:121-9

56) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Self injection of papaverine and phentolamine in the treatment of psychogenic impotence. Journal of Sex & Marital Therapy. 1989; 15(3):163-78

57) Turner LA, Althof SE, Levine SB, Risen CB, Bodner D, Kursh ED, Resnick MI. Treating erectile dysfunction with external vacuum devices: impact upon sexual, psychological, and marital functioning. Journal of Urology 1990; 141(1):79-82

58) Risen CB, Althof SE. An essay on the diagnosis and nature of paraphilia Journal of Sex & Marital Therapy 1990; 16(2):89-102.

59) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Through the eyes of women: the sexual and psychological responses of women to their partners' treatment with self-injection or vacuum constriction therapy. International Journal of Impotence Research (supplement 2)1990; 346-7.

60) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. A comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. . International Journal of Impotence Research (supplement 2)1990; 289-90

61) Kursh E, Turner L, Bodner D, Althof S, Levine S. A prospective study on the use of the vacuum pump for the treatment of impotence.International Journal of Impotence Research (supplement 2)1990; 340-1.

62) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of intracavernous therapy in the treatment of erectile dysfunction in Journal of Sex & Marital Therapy 1991; 17(2):101-112

63) Althof SE, Turner LA, Levine SB, Risen CB, Bodner DB, Kursh ED, Resnick MI. Long term use of vacuum pump devices in the treatment of erectile dsyfunction in Journal of Sex & Marital Therapy 1991;17(2):81-93

64) Turner LA, Althof SE, Levine SB, Bodner DB, Kursh ED, Resnick MI. A 12-month

comparison of the effectiveness of two treatments for erectile dysfunction: self injection vs. external vacuum devices. Urology 1992;39(2):139-44

65) Althof SE, The pathogenesis of psychogenic impotence. J. Sex Education and Therapy. 1991; 17(4):251-66

66) Mehta P, Bedell WH, Cumming W, Bussing R, Warner R, Levine SB. Letter to the editor. Reflections on hemophilia camp. Clinical Pediatrics 1991; 30(4):259-260

67) Successful Sexuality. Belonging/Hemophilia. (Caremark Therapeutic Services), Autumn, 1991

68) Psychological intimacy. Journal of Sex & Marital Therapy 1991; 17(4):259-68

69) Male sexual problems and the general physician, Georgia State Medical Journal 1992; 81(5): 211-6

70) Althof SE, Turner LA, Levine SB, Bodner DB, Kursh E, Resnick MI. Through the eyes of women: The sexual and psychological responses of women to their partner's treatment with self-injection or vacuum constriction devices. Journal of Urology 1992; 147(4):1024-7

71) Curry SL, Levine SB, Jones PK, Kurit DM. Medical and Psychosocial predictors of sexual outcome among women with systemic lupus erythematosis. Arthritis Care and Research 1993; 6:23-30

72) Althof SE, Levine SB. Clinical approach to sexuality of patients with spinal cord injury. Urological Clinics of North America 1993; 20(3):527-34

73) Gender-disturbed males. Journal of Sex & Marital Therapy 19(2):131-141, 1993

74) Curry SL, Levine SB, Jones PK, Kurit DM. The impact of systemic lupus erythematosis on women's sexual functioning. Journal of Rheumatology 1994; 21(12):2254-60

75) Althof SE, Levine SB, Corty E, Risen CB, Stern EB, Kurit D. Clomipramine as a treatment for rapid ejaculation: a double-blind crossover trial of 15 couples. Journal of Clinical Psychiatry 1995;56(9):402-7

76) Risen CB, Althof SE. Professionals who sexually offend: evaluation procedures and preliminary findings. Journal of Sex & Marital Therapy 1994; 20(4):288-302

77) On Love, Journal of Sex & Marital Therapy 1995; 21(3):183-191

78) What is clinical sexuality? Psychiatric Clinics of North America 1995; 18(1):1-6

79) "Love" and the mental health professions: Towards an understanding of adult love. Journal of Sex & Marital Therapy 1996; 22(3)191-20

(a) Reprinted in Issues in Human Sexuality: Current & Controversial Readings with Links to Relevant Web Sites, 1998-9, Richard Blonna, Editor, Engelwood, Co. Morton Publishing Company, 1998

80) The role of Psychiatry in erectile dysfunction: a cautionary essay on the emerging

treatments. Medscape Mental Health 2(8):1997 on the Internet. September, 1997.

81) Discussion of Dr. Derek Polonsky's SSTAR presentation on Countertransference. Journal of Sex Education and Therapy 1998; 22(3):13-17

82) Understanding the sexual consequences of the menopause. Women's Health in Primary Care, 1998

(a) Reprinted in the International Menopause Newsletter

83) Fones CSL, Levine SB. Psychological aspects at the interface of diabetes and erectile dysfunction. Diabetes Reviews 1998; 6(1):1-8

84) Guay AT, Levine SB, Montague DK. New treatments for erectile dysfunction. Patient Care March 15, 1998

85) Extramarital Affairs. Journal of Sex & Marital Therapy 1998; 24(3):207-216

86) Levine SB (chairman), Brown G, Cohen-Kettenis P, Coleman E, Hage JJ, Petersen M, Pfäfflin F, Shaeffer L, vanMasdam J, Standards of Care of the Harry Benjamin International Gender Dysphoria Association, 5th revision, 1998. International Journal of Transgenderism at http://www.symposion.com/ijt

(a) Reprinted by the Harry Benjamin International Gender Dysphoria Association, Minneapolis, Minnesota

87) Althof SE, Corty E, Levine SB, Levine F, Burnett A, McVary K, Stecher V, Seftel. The EDITS: the development of questionnaires for evaluating satisfaction with treatments for erectile dysfunction. Urology 1999;53:793-799

88) Fones CSL, Levine SB, Althof SE, Risen CB. The sexual struggles of 23 clergymen: a follow-up study. Journal of Sex & Marital Therapy 1999

89) The Newly Devised Standards of Care for Gender Identity Disorders. Journal of Sex Education and Therapy 24(3):1-11,1999

90) Levine, S. B. (1999). The newly revised standards of care for gender identity disorders. Journal of Sex Education & Therapy, 24, 117-127.

91) Melman A, Levine SB, Sachs B, Segraves RT, Van Driel MF. Psychological Issues in Diagnosis of Treatment (committee 11) in Erectile Dysfunction (A.Jarden, G.Wagner, S.Khoury, F. Guiliano, H.Padma-nathan, R. Rosen, eds.) Plymbridge Distributors Limited, London, 2000

92) Pallas J, Levine SB, Althof SE, Risen CB. A study using Viagra in a mental health practice. J Sex&Marital Therapy.26(1):41-50, 2000

93) Levine SB, Stagno S. Informed Consent for Case Reports: the ethical dilemma between right to privacy and pedagogical freedom. Journal of Psychotherapy: Practice and Research, 2001, 10 (3): 193-201.

94) Alloggiamento T., Zipp C., Raxwal VK, Ashley E, Dey S. Levine SB, Froelicher VF. Sex, the Heart, and Sildenafil. Current Problems in Cardiology 26 June 2001(6):381-416

95) Re-exploring The Nature of Sexual Desire. Journal of Sex and Marital Therapy 28(1):39-51, 2002.

96) Understanding Male Heterosexuality and Its Disorders in Psychiatric Times XIX(2):13-14, February, 2002

97) Erectile Dysfunction: Why drug therapy isn't always enough. (2003) Cleveland Clinic Journal of Medicine, 70(3): 241-246.

98) The Nature of Sexual Desire: A Clinician's Perspective. Archives of Sexual Behavior 32(3):279-286, 2003 .

99) Laura Davis. What I Did For Love: Temporary Returns to the Male Gender Role. International Journal of Transgenderism, 6(4), 2002 and http://www.symposion.com/ijt

100) Risen C.B., The Crisis in the Church: Dealing with the Many Faces of Cultural Hysteria in The International Journal of Applied Psychoanalytic Studies, 1(4):364-370, 2004

101) Althof SE, Leiblum SR (chairpersons), Chevert-Measson M. Hartman U., Levine SB, McCabe M., Plaut M, Rodrigues O, Wylie K., Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction in World Health Organization Conference Proceedings on Sexual Dysfunctions, Paris, 2003. Published in a book issued in 2004.

102) Commentary on Ejaculatory Restrictions as a Factor in the Treatment of Haredi (Ultra-Orthodox) Jewish Couples: How Does Therapy Work? Archives of Sexual Behavior, 33(3):June 2004

103) What is love anyway? J Sex & Marital Therapy 31(2):143-152,2005.

104) A Slightly Different Idea, Commentary on Y.M.Binik's Should Dyspareunia Be Retained as a Sexual Dysfunction in DSM-V? A Painful Classification Decision. Archives of Sexual Behavior 34(1):38-39, 2005. http://dx.doi.org/10.1007/s10508-005-7469-3

105) Commentary. Pharmacologic Treatment of Erectile Dysfunction: Not always a simple matter. BJM USA; Primary Care Medicine for the American Physician, 4(6):325-326, July 2004

106) Leading Comment: A Clinical Perspective on Infidelity. Journal of Sexual and Relationship Therapy, 20(2):143-153, May 2005.

107) Multiple authors. Efficacy and safety of sildenafil citrate (Viagra) in men with serotonergic antidepressant-associated erectile dysfunction: Results from a randomized, double-blind, placebo-controlled trial. Submitted to Journal of Clinical Psychiatry Feb 2005

108) Althof SE, Leiblum SR, Chevert-Measson M, Hartman U,Levine SB,McCabe M, Plaut M, Rodrigues O, Wylie K. Psychological and Interpersonal Dimensions of Sexual Function and Dysfunction. Journal of Sexual Medicine, 2(6): 793-800,

November, 2005

109) Shifren JL, Davis SR, Moreau M, Waldbaum A, Bouchard C., DeRogatis L., Derzko C., Bearnson P., Kakos N., O'Neill S., Levine S., Wekselman K., Buch A., Rodenberg C., Kroll R. Testosterone Patch for the Treatment of Hypoactive Sexual Desire Disorder in Naturally Menopausal Women: Results for the INTIMATE NM1 Study. Menopause: The Journal of the North American Menopause Society 13(5) 2006.

110) Reintroduction to Clinical Sexuality. Focus: A Journal of Lifelong Learning in Psychiatry Fall 2005. III (4):526-531

111) PDE-5 Inhibitors and Psychiatry in J Psychiatric Practice 12 (1): 46-49, 2006.

112) Sexual Dysfunction: What does love have to do with it? Current Psychiatry 5(7):59-68, 2006.

113) How to take a Sexual History (Without Blushing), Current Psychiatry 5(8): August, 2006.

114) Linking Depression and ED: Impact on sexual function and relationships in Sexual Function and Men's Health Through the Life Cycle under the auspices of the Consortium for Improvement of Erectile Function (CIEF),12-19, November, 2006.

115) The First Principle of Clinical Sexuality. Editorial. Journal of Sexual Medicine,4:853-854, 2007

116) Commentary on David Rowland's editorial, "Will Medical Solutions to Sexual Problems Make Sexological Care and Science Obsolete?" Journal of Sex and Marital Therapy, 33(5), 2007 in press

117) Real-Life Test Experience: Recommendations for Revisions to the Standards of Care of the World Professional Association for Transgender Health International Journal of Transgenderism, Volume 11 Issue 3, 186-193, 2009

118) Sexual Disorders: Psychiatrists and Clinical Sexuality. Psychiatric Times XXIV (9), 42-43, August 2007

119) I am not a sex therapist! Commentary to I. Binik and M. Meana's article Sex Therapy: Is there a future in this outfit? Archives of Sexual Behavior, Volume 38, Issue 6 (2009), 1033-1034

120) Solomon A (2009) Meanings and Political Implications of "Psychopathology" in a Gender Identity Clinic: Report of 10 cases. Journal of Sex and Marital Therapy 35(1): 40-57.

121) Perelman, MA., Levine SB, Fischkoff SA. Randomized, Placebo-Controlled, Crossover Study to Evaluate the Effects of Intranasal Bremelanotide on Perceptions of Desire and Arousal in Postmenopausal Women with Sexual Arousal Disorder submitted to Journal of Sexual Medicine July 2009, rejected

122) What is Sexual Addiction? Journal of Sex and Marital Therapy.2010

May;36(3):261-75

123) David Scott (2010) Sexual Education of Psychiatric Residents. Academic Psychiatry, 34(5) 349-352.

124) Chris G. McMahon, Stanley E. Althof, Joel M. Kaufman, Jacques Buvat, Stephen B. Levine, Joseph W. Aquilina, Fisseha Tesfaye, Margaret Rothman, David A. Rivas, Hartmut Porst. Efficacy and Safety of Dapoxetine for the Treatment of Premature Ejaculation: Integrated Analysis of Results From 5 Phase 3 Trials Journal of Sexual Medicine 2011 Feb;8(2):524-39.

125) Commentary on Consideration of Diagnostic Criteria for Erectile Dysfunction in DSM V. Journal of Sexual Medicine July 2010

126) Hypoactive Sexual Desire Disorder in Men: Basic types, causes, and treatment. Psychiatric Times 27(6)4-34. 2010

127) Male Sexual Dysfunctions, an audio lecture, American Physician Institute 2013

128) Fashions in Genital Fashion: Where is the line for physicians? Commentary on David Veale and Joe Daniels' Cosmetic Clitoridectomy in a 33-year-old woman. Archives of Sexual Behavior, epub ahead of print Sept 24, 2011. Arch Sex Behav (2012) 41:735–736 DOI 10.1007/s10508-011-9849-7

129) Review: Problematic Sexual Excess. Neuropsychiatry 2(1):1-12, 2012

130) The Essence of Psychotherapy. Psychiatric Times 28 (2): August 2, 2012 translated into Portuguese and republished in Revista Latinoamericana de Psicopatologia Fundamental (latin-American Journal of Fundamental Psychopathology) in press 2012.

131) Parran TV, Pisman, AR, Youngner SJ, Levine SB.Evolution of remedial CME course in professionalism: Addressing learner needs, developing content, and evaluating outcomes. *Journal of Continuing Education in the Health Professions,* 33(3): 174-179, 2013.

132) Love and Psychiatry. Psychiatric Times November 2013

133) Orgasmic Disorders, Sexual Pain Disorders, and Sexual Dysfunction Due to a Medical Condition. Board Review Psychiatry 2013-2014 Audio Digest CD 27. Audio recording of a one-hour lecture available October 2013.

134) Towards a Compendium of the Psychopathologies of Love. Archives of Sexual Behavior Online First December 25, 2013 DOI 10.1007/s10508-013-0242-6 43(1)213-220.

135) Flibanserin. (editorial) Archives of Sexual Behavior 44 (8), 2015 November 2015. DOI: 10.1007/s10508-015-0617-y

136) Martel C, Labrie F, Archer DF, Ke Y, Gonthier R, Simard JN, Lavoie L, Vaillancourt M, Montesino M, Balser J, Moyneur É; other participating members of the Prasterone Clinical Research Group. (2016) Serum steroid concentrations

remain within normal postmenopausal values in women receiving daily 6.5mg intravaginal prasterone for 12 weeks.J Steroid Biochem Mol Biol. 2016 May;159:142-53. doi: 10.1016/j.jsbmb.2016.03.016

137) Reflections of an Expert on the Legal Battles Over Prisoners with Gender Dysphoria. J Am Acad Psychiatry Law 44:236–45, 2016

138) Cooper E, McBride J, Levine SB. Does Flibanserin have a future? Psychiatric Times accepted October 23, 2015.

139) Levine SB, Sheridan DL, Cooper EB. The Quest for a Prosexual Medication for Women, Current Sexual Health Reports (2016) 8: 129. doi:10.1007/s11930-016-0085-y

140) Why Sex Is Important: Background for Helping Patients with Their Sexual Lives., British Journal of Psychiatry Advances (2017), vol. 23(5) 300-306; DOI: 10.1192/apt.bp.116.016428

141) Flibanserin: Offene Forshungsfragen , Zeitschrift für Sexualforschung. 29: 170-175, 2016. This is a translation of (134).

142) Commentary on "Asexuality: Orientation, paraphilia, dysfunction, or none of the above? Archives Sexual Behavior, Archives of Sexual Behavior April 2017, Volume 46, Issue 3, pp 639–642 DOI: 10.1007/s10508-017-0947-z

143) Sexual Dysfunction in Clinical Psychiatry, Psychiatric Times, March 2017

144) Ethical Concerns About the Emerging Treatment of Gender Dysphoria. Journal of Sex and Marital Therapy, 44(1):29-44. 2017. DOI 10.1080/0092623X.2017.1309482

145) The Psychiatrist's Role in Managing Transgender Youth: Navigating Today's Politicized Terrain. CMEtoGO® Audio Lecture Series, May 2017

146) Transitioning Back to Maleness, Archives of Sexual Behavior, 2017 Dec 20. doi: 10.1007/s10508-017-1136-9. [Epub ahead of print]; 47(4), 1295-1300, May 2018

147) Informed Consent for Transgender Patients, Journal of Sex and Marital Therapy, 2018 Dec 22:1-12. doi: 10.1080/0092623X.2018.1518885. [Epub ahead of print]

C) Chapters

1) Overview of Sex Therapy. In Sholevar GP (ed) The Handbook of Marriage and Marital Therapy. New York. Spectrum Publications, 1981 pp417-41

2) Why study sexual functioning in diabetes? In Hamburg BA, Lipsett LF, Inoff GE, Drash A (eds) Behavioral & Psychosocial Issues in Diabetes: Proceedings of a National conference. Washington, DC. US Dept. of Health & Human Services. PHS NIH, Pub. #80-1933

3) Sexual Problems in the Diabetic in Bleicher SJ, Brodoff B (eds) Diabetes Mellitus and Obesity. Williams and Wilkins, 1992

4) Clinical Introduction to Human Sexual Dysfunction. In Pariser SF, Levine SB, McDowell M (eds) Clinical Sexuality. New York, Marcel Dekker Publisher, 1983.

5) Psychodynamically-oriented clinician's overview of psychogenic impotence. In RT Segraves (ed) Impotence. New York, Plenum, 1985

6) Origins of sexual preferences. In Shelp EE (ed) Sexuality and Medicine. D. Reidel Publishing co. 1987. Pp39-54.

7) Hypoactive Sexual Desire and Other Problems of Sexual Desire. In H. Lief (ed). The Treatment of Psychosexual Dysfunctions/ III. American Psychiatric Press, chapter 207.pp2264-79, 1989

8) Psychological Sexual Dysfunction. In Sudak H (ed) Clinical Psychiatry. Warren H. Green. St. Louis, 1985

9) Male sexual dysfunction. In Sudak H (ed) Clinical Psychiatry. Warren H. Green. St. Louis, 1985

10) Sexuality and Aging. In Sudak H (ed) Clinical Psychiatry. Warren H. Green. St. Louis, 1985

11) Homosexuality. In Sudak H (ed) Clinical Psychiatry. Warren H. Green. St. Louis, 1985

12) Individual and intrapsychic factors in sexual desire. In Leiblum SR, Rosen RC (eds). Clinical Perspectives on Sexual Desire Disorders. Guilford Press, New York, 1988, pp21-44

13) Gender Identity Disorders. In Sadock B, Kaplan H(eds). Comprehensive Textbook of Psychiatry, Baltimore, William and Wilkins, 1989, pp 1061-9

14) Intrapsychic and Interpersonal Aspects of Impotence: Psychogenic Erectile Dysfunction. In Leiblum SR, Rosen RC (eds). Erectile Disorders: Assessment and Treatment. Guilford Press, New York, 1992

15) Psychological Factors in Impotence. In Resnick MI, Kursh ED, (eds.) Current Therapy in Genitourinary Surgery, 2nd edition. BC Decker, 1991, pp549-51

16) The Vagaries of Sexual Desire. In Leiblum SR, Rosen RC (eds). In Case Studies in Sex Therapy. Guilford Press, New York, 1995

17) Rosenblatt EA. Sexual Disorders (chapter 62). In Tasman A, Kay J, Liberman JA (eds). Psychiatry Volume II, W.B.Saunders, Philadelphia. 1997, pp 1173-2000.

18) Althof SE. Psychological Evaluation and Sex Therapy. In Mulcahy JJ (ed) Diagnosis and Management of Male Sexual Dysfunction Igaku-Shoin, New York, 1996, pp74-88

19) Althof SE, Levine SB. Psychological Aspects of Erectile Dysfunction. In Hellstrum WJG (ed) Male Infertility and Dysfunction. Springer-Verlag, New York, 1997. pp 468-73

20) Paraphilias. In Comprehensive Textbook of Psychiatry/VII. Sadock BJ, Sadock VA

(eds.) Lippincott Williams & Wilkins, Baltimore, 1999, pp1631-1645.

21) Women's Sexual Capacities at Mid-Life in The Menopause: Comprehensive Management B. Eskind (ed). Parthenon Publishing, Carnforth, UK, 2000.

22) Male Heterosexuality in Masculinity and Sexuality:Selected Topics in the Psychology of Men, (Richard C. Friedman and Jennifer I. Downey, eds) Annual Review of Psychiatry, American Psychiatric Press, Washington, DC, W-18. pp29-54.

23) R.T.Segraves. Introduction to section on Sexuality: Treatment of Psychiatric Disorders-III (G.O.Gabbard, ed), American Psychiatric Press, Washington, DC, 2001

24) Sexual Disorders (2003) in Tasman A, Kay J, Liberman JA (eds). Psychiatry 2nd edition, Volume II, W.B.Saunders, Philadelphia. Chapter 74

25) What Patients Mean by Love, Psychological Intimacy, and Sexual Desire (2003) in SB Levine, CB Risen, SE Althof (eds) Handbook of Clinical Sexuality for Mental Health Professionals, Brunner-Routledge, New York, pp.21-36.

26) Infidelity (2003) in SB Levine, CB Risen, SE Althof (eds) Handbook of Clinical Sexuality for Mental Health Professionals, Brunner-Routledge, New York, pp57-74

27) Preface (2003) in SB Levine, CB Risen, SE Althof (eds) Handbook of Clinical Sexuality for Mental Health Professionals, Brunner-Routledge, New York, pp xiii-xviii

28) A Psychiatric Perspective on Psychogenic Erectile Dysfunction (2004) in T.F. Lue (ed) Atlas of Male Sexual Dysfunction, Current Medicine, Philadelphia Chapter 5

29) Levine, SB., Seagraves, RT. Introduction to Sexuality Section, Treatment of Psychiatric Disorders, 3rd edition (Gabbard GO, editor), American Psychiatric Press, 2007

30) Risen CB, (2009)Professionals Who Are Accused of Sexual Boundary Violations *In Sex Offenders: Identification, Risk Assessment, Treatment, and Legal Issues* edited by Fabian M. Saleh, Albert J. Grudzinskas, Jr., and John M. Bradford, Oxford University Press, 2009

31) What Patients Mean by Love, Intimacy, and Sexual Desire, in Handbook of Clinical Sexuality for Mental Health Professionals edited by Levine SB, Risen, CB, and Althof, SE, Routledge, New York, 2010

32) Infidelity in Handbook of Clinical Sexuality for Mental Health Professionals edited by Levine SB, Risen, CB, and Althof, SE, Routledge, New York, 2010

33) Scott DL, Levine, SB. Understanding Gay and Lesbian Life in Handbook of Clinical Sexuality for Mental Health Professionals edited by Levine SB, Risen, CB, and Althof, SE, Routledge, New York, 2010

34) Levine, SB, Hasan, S., Boraz M. (2009) Male Hypoactive Sexual Desire Disorder (HSDD) in Clinical Manual of Sexual Disorders (R. Balon and RT Segraves, eds), American Psychiatric Press, Washington, DC.

35) Levine, SB. Sexual Disorders in Fundamentals of Psychiatry (by Allan Tasman and Wanda Mohr,eds.) http://eu.wiley.com/WileyCDA/WileyTitle/productCd-0470665777.html

36) Infidelity in Principles and Practices of Sex Therapy (I Binik, K. Hall, editors), 5th edition, Guilford Press, New York, 2014.

37) Why is Sex Important? In Handbook of Clinical Sexuality for Mental Health Professionals 3rd ed. [SB Levine, CB Risen, SE Althof, eds] New York. Routledge, 2016, Chapter 1

38) The Rich Ambiguity of Key Terms: Making Distinctions. In Handbook of Clinical Sexuality for Mental Health Professionals 3rd ed. [SB Levine, CB Risen, SE Althof, eds] New York. Routledge, 2016. Chapter 4

39) The Mental Health Professional's Treatment of Erection Problems . In Handbook of Clinical Sexuality for Mental Health Professionals 3rd ed. [SB Levine, CB Risen, SE Althof, eds] New York. Routledge, 2016 Chapter 11

40) Why is Sex Important? In Sexual Health in the Couple: Management of Sexual Dysfunction in Men and Women [L Lipshultz, A Pastuszak, M Perelman, A Giraldi, J Buster, eds.] New York, Springer, 2016.

41) Sommers, B., Levine, S.B., Physician's Attitude Towards Sexuality; Psychiatry and Sexual Medicine: A Comprehensive Guide for Clinical Practitioners, in press 2019

42) Boundaries And The Ethics Of Professional Misconduct in A. Steinberg, J. L. Alpert, C A. Courtois(Eds.) Sexual Boundary Violations In Psychotherapy:Therapist Indiscretions, & Transgressions, & Misconduct American Psychological Association, In Press 2019

D) Book Reviews

1) Homosexualities: A Study of Diversity Among Men and Women by Alan P. Bell and Martin S. Weinberg, Simon and Schuster, New York, 1978. In Journal of Sex & Marital Therapy 1979; 5:

2) Marriage and Marital Therapies: Psychoanalytic, Behavioral & System Theory Perspectives by TJ Paolino and BS McCrady. Brunner/Mazel, New York, 1978. In Journal of Sex & Marital Therapy 1979; 5:

3) Management of Male Impotence. Volume 5 International Perspectives in Urology AH Bennett, (ed) Williams and Wilkins, Baltimore, 1992. In American Journal of Psychiatry, 1984

4) The Sexual Relationship by DE Scharff, Routledge & Kegan Paul, 1982 in Family Process 1983;22:556-8

5) Phenomenology and Treatment of Psychosexual Disorders, by WE Fann, I Karacan, AD Pokorny, RL Williams (eds). Spectrum Publications, New York, 1983. In American Journal of Psychiatry 1985;142:512-6

6) The Treatment of Sexual Disorders: Concepts and Techniques of Couple Therapy, G Arentewicz and G Schmidt. Basic Books, New York, 1983. In American Journal of Psychiatry 1985;142:983-5

7) Gender Dysphoria: Development, Research, Management. BN Steiner (ed). Plenum Press, 1985 in Journal of Clinical Psychiatry, 1986

8) Gender Dysphoria: Development, Research, Management. BN Steiner (ed). Plenum Press, 1985 in Contemporary Psychology 1986:31:421-2 [titled, The Limitations of Science, the Limitations of Understanding]

9) Psychopharmacology of Sexual Disorders by M Segal (ed) John Libbey & Co Ltd, London, 1987 in American Journal of Psychiatry 1987;144:1093

10) "The Sissy Boy Syndrome" and the Development of Homosexuality by R Green. Yale University Press, New Haven, 1987. In American Journal of Psychiatry 1988;145:1028

11) Male Homosexuality: A contemporary psychoanalytic perspective by RC Friedman, Yale University Press, New Haven, 1988 in Journal of Clinical Psychiatry 1989;50:4, 149

12) Sexual Landscapes: Why we are what we are, why we love whom we love. By JD Weinrich, Charles Schribner's Sons, New York, 1987 in Archives of Sexual Behavior 21 (3):323-26, 1991

13) How to Overcome Premature Ejaculation by HS Kaplan, Brunner/Mazel, New York, 1989 in Journal of Clinical Psychiatry 51(3):130, 1990

14) Clinical Management of Gender Identity Disorders in Children and Adults R. Blanchard, BN Steiner (eds) American Psychiatry Press, Washington, DC, 1990. In Journal of Clinical Psychiatry 52(6):283, 1991

15) Psychiatric Aspects of Modern Reproductive Technologies. NL Stotland (ed) American Psychiatric Press, Washington DC, 1990. In Journal of Clinical Psychiatry 1991;52(9):390

16) Homosexualities: Reality, Fantasy, and the Arts. CW Socarides, VD Volkan (eds). International Universities Press, Madison, Connecticut, 1990. In Journal of Clinical Psychiatry 1992;(10)

17) Reparative Therapy of Male Homosexuality: A New Clinical Approach. J Nicolosi, Jason Aronson, Northvale NJ, 1992. In Contemporary Psychology 38(2):165-6, 1993 [entitled Is Evidence Required?]

18) Male Victims of Sexual Assault, GC Mezey, MB King (eds) Oxford University Press, New York, 1992. In Journal of Clinical Psychiatry 1993;54(9):358,

19) AIDS and Sex: An Integrated Biomedical and Biobehavioral Approach. B Voeller, JM Reinisch, M Gottlieb, Oxford University Press, New York, 1990. In American Journal of Psychiatry

20) Porn: Myths for the Twentieth Century by RJ Stoller, Yale University Press, New Haven, 1991. In Archives of Sexual Behavior 1995;24(6):663-668

21) Sexual Dysfunction: Neurologic, Urologic, and Gynecologic Aspects. R Lechtenberg, DA Ohl (eds) Lea & Febiger, Philiadelphia, 1994. In Neurology

22) The Sexual Desire Disorders: Dysfunctional Regulation of Sexual

23) Motivation. HS Kaplan Brunner/Mazel, New York, 1995. In Neurology 1996; 47:316

24) Femininities, Masculinities, Sexualities: Freud and Beyond. N. Chodorow. The University Press of Kentucky, Lexington, 1994. Archives of Sexual Behavior 28(5):397-400,1999

25) Sexual Function in People with Disability and Chronic Illness:A Health Professional's Guide by ML Sipski, CJ Alexander. Aspen Publishers, Gaitersburg, Md, 1997. In Journal of Sex Education and Therapy, 1998;23(2):171-2

26) Sexual Aggression by J Shaw (ed). American Psychiatric Press, Washington, DC, 1998. In American Journal of Psychiatry, May, 1999

27) The *Wounded* Healer: Addiction-Sensitive Approach to the Sexually Exploitative Professional by Richard Irons and Jennifer P. Schneider. Jason Aronson, Northvale, N.J., 1999 in American Journal of Psychiatry 157(5):8-9,2000.

28) Culture of the Internet by Sara Kiesler (editor), Lawrence Erlbaum Associates, Mahway, New Jersey, 1997. 463pp in Journal of Sex Research in press, 2001

29) Psychological Perspectives on Human Sexuality. Lenore T. Szuchman and Frank Muscarella (editors), Wiley and Sons, New York, American Journal of Psychiatry, April, 2002

30) "How Sexual Science Operates" a review of Sex, Love, and Health in America: Private Choices and Public Policies. EO Laumann and RT Michael, editors. Chicago, University of Chicago, 2001 in Second Opinion, The Park Ridge Center for the Study of Health, Faith, and Ethics, 11:82-3, April, 2004.

31) Sexual Orientation and Psychoanalysis: Sexual Science and Clinical Practice. R.C.Friedman and J.I. Downey (eds). New York. Columbia University Press. in Archives of Sexual Behavior (2003) 31(5):473-474

32) Prozac on the Couch: Prescribing Gender in the Era of Wonder Drugs, Jonathon Michel Metzl. Duke University Press, Durham, 2003 in American Journal of Psychiatry, November, 2004.

33) Sex and Gender by M. Diamond and A.Yates Child Psychiatric Clinics of North America W. B. Saunders, Philadelphia, Pennsylvania, 2004, 268 pp in Archives of Sexual Behavior April 2007 on line publication in Dec.2006 at http://dx.doi.org/10.1007/s10508-006-9114-7

34) Getting Past the Affair: A program to help you cope, heal, and move on—together or

apart by Douglas K. Snyder, Ph.D, Donald H. Baucom, Ph.D, and Kristina Coop Gordon, Ph.D, New York, Guilford Press, 2007 in Journal of Sex and Marital Therapy,34:*1-3*, 2007

35) Dancing with Science, Ideology and Technique. A review of Sexual Desire Disorders: A casebook Sandra R. Leiblum editor, Guilford Press, New York, 2010. In Journal of Sex Research 2011.

36) What is more bizarre: the transsexual or transsexual politics? A review of Men Trapped in Men's Bodies: Narratives of Autogynephilic Transsexualism by Anne A. Lawrence, New York, Springer, 2014. In Sex Roles: a Journal of Research, 70, Issue 3 (2014), Page 158-160, 2014. DOI: 10.1007/s11199-013-0341-9

37) There Are Different Ways of Knowing. A review of: How Sexual Desire Works: The Enigmatic Urge by Frederick Toates, Cambridge, UK, Cambridge University Press, in Sexuality and Cu1ture (2015) 19:407–409 DOI 10.1007/s12119-015-9279-0

38) The Dynamics of Infidelity: Applying Relationship Science to Clinical Practice by Lawrence Josephs, American Psychological Association, Washington, DC, 2018, pp. 287, $69.95 in Journal of Sex and Marital Therapy 10.1080/0092623X.2018.1466954, 2018. For free access: https://www.tandfonline.com/eprint/UgiIHbWbpdedbsXWXpNf/full

39) Transgender Mental Health by Eric Yarbrough, American Psychiatric Association Publications, 2018, Journal and Marital & Sexual Therapy, https://doi.org/10.1080/0092623X.2018.1563345 .

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

EXPERT WITNESS DECLARATION of

PAUL W. HRUZ, M.D., Ph.D.

1. RETAINED AS EXPERT WITNESS - VITAE: I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this declaration. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my CV is attached as Exhibit A to this declaration.

2. EDUCATION - ACADEMIC APPOINTMENTS: I received my Doctor of Philosophy degree from the Medical College of Wisconsin in 1993. I received my Medical Degree from the Medical College of Wisconsin in 1994. I am an Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes at Washington University School of Medicine. I also have a secondary appointment as Associate Professor of Cellular Biology and Physiology in

the Division of Biology and Biological Sciences at Washington University School of Medicine. I served as chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012-2017. I served as the Director of the Pediatric Endocrinology Fellowship Program at Washington University from 2008-2016.

3. HISTORY OF BOARD CERTIFICATIONS: I am board certified in Pediatrics and Pediatric Endocrinology. I have been licensed to practice medicine in Missouri since 2000. I also have a temporary license to practice telemedicine in Illinois during the COVID-19 pandemic. My professional memberships include the American Diabetes Association, the Pediatric Endocrine Society, and the Endocrine Society.

4. SCIENTIFIC PUBLICATIONS IN PEER REVIEWED JOURNALS: I have published 60 scholarly articles over my academic career spanning over two decades. This includes peer-reviewed publications in the leading journals in the fields of metabolism, cardiology, HIV, and ethics including the Gastroenterology, Circulation, Diabetes, Science Signaling, the Journal of Biological Chemistry and FASEB Journal. See, my current Curriculum Vitae attached as Exhibit A.

5. EDITORIAL DUTIES - RESEARCH GRANTS: I have served as a Reviewer for a number of leading science journals in relevant fields including the Journal of Clinical Endocrinology and Metabolism, the Journal of Biological Chemistry, Diabetes, Scientific Reports and PlosOne. I have received over 4.6 million dollars in governmental and non-governmental funding for scientific research including grants from the National Institutes of Health, the American Diabetes Association, The American Heart Association, the March of Dimes, and the Harrington Discovery Institute. I am a member of the Alpha Omega Alpha Medical Honor Society and have received the Armond J Quick Award for Excellence in Biochemistry, the Eli Lilly Award

for Outstanding Contribution to Drug Discovery, and the Julio V Santiago Distinguished Scholar in Pediatrics Award.

6. CLINICAL EXPERIENCE: During the more than 20 years that I have been in clinical practice, I have participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development. I was a founding member of the multidisciplinary Disorders of Sexual Development (DSD) program at Washington University. I continue to contribute to the discussion of complex cases and the advancement of research priorities in this field. In the care of these patients, I have acquired expertise in the understanding and management of associated difficulties in gender identification and gender transitioning treatment issues. I have trained and/or supervised hundreds of medical students, residents and clinical fellows in the practice of medicine.

7. CONSULTS-DISCUSSIONS REGARDING THE RELEVANT SCIENCE and CLINICAL ISSUES: In my role as a scientist and as the director of the Division of Pediatric Endocrinology at Washington University, I extensively studied the existing scientific research literature related to the incidence, potential etiology, and treatment of gender dysphoria as efforts were made to develop a Transgender Medicine Clinic at Saint Louis Children's Hospital. I have participated in local and national meetings where the endocrine care of children with gender dysphoria has been discussed in detail and debated in depth. I have met individually and consulted with several pediatric endocrinologists (including Dr. Norman Spack) and other professionals specializing in sexual health (including Eli Coleman) who have developed and led transgender programs in the United States. I have also consulted with, met with, and had detailed discussions with dozens of parents of children with gender dysphoria to understand the unique difficulties experienced by this patient population. I continue to evaluate the ongoing experimental

investigation of this condition. I am frequently consulted by other medical professionals to help them understand the complex medical and ethical issues related to this emerging field of medicine.

8. IN MY OPINION, A LACK OF SCIENTIFIC SUPPORT and THE ETHICAL PRINCIPLE OF INFORMED CONSENT CURRENTLY PROHIBIT MY PARTICIPATION IN HORMONAL "AFFIRMATION-TRANSITION" TREATMENTS FOR GENDER DYSPHORIA IN CHILDREN: Pediatric patients referred to our practice for the evaluation and treatment of gender dysphoria are cared for by an interdisciplinary team of providers that includes a psychologist and pediatric endocrinologist who have been specifically chosen for this role based upon a special interest and professional knowledge and training in this rare patient population. Due to the documented, important, ethical concerns regarding the safety, efficacy, and scientific validity of controversial, unproven, and experimental treatment paradigms, I have not personally engaged in the delivery of gender affirming medical interventions to children with gender dysphoria. Given the unproven long-term benefits and the well-documented risks and harms of "transitioning" children, I decline to participate in such experimental treatments until the science has proven that the relative risks and benefits of this approach warrant such procedures. My decision is strengthened by the knowledge that the vast majority of children who report gender dysphoria will, if left untreated, grow out of the problem — a natural coping-developmental process — and willingly accept their biological sex. Despite differences in country, culture, decade, follow-up length and method, multiple studies have come to a remarkably similar conclusion: Very few gender dysphoric children still want to transition by the time they reach adulthood. Many turn out to have been struggling with sexual orientation issues rather than Gender Discordant "transgender" identity. The exact number of children who experience realignment of gender identity with biological sex by early adult life varies by study. Estimates within the peer

reviewed published literature range from 50-98%, with most reporting desistance in approximately 85% of children prior to the widespread adoption of the "gender affirmation only" approach. Thus, desistance (i.e., the child accepting their natal, biological sex identity and declining "transitioning" treatments) is the outcome for the vast majority of affected children who are not actively encouraged to proceed with sex-discordant gender affirmation. Since there are no reliable assessment methods for identifying the small percentage of children with persisting sex-gender identity discordance from the vast majority who will accept their biological sex, and since puberty blocking treatments, hormone transition treatments, and surgical transition treatments are all known to have potentially life-long devastating, negative effects on patients, I and many colleagues view it as unethical to treat children with an unknown future by using experimental, aggressive, and intrusive gender affirming medical interventions. See, J. Cantor, Ph.D. summary of multiple research studies at http://www.sexologytoday.org/2016/01/do-trans-kids-stay-trans-when-they-grow_99.html, and other publications reviewed in detail below).

9. PEER-REVIEWED, PUBLISHED RESEARCH IN CREDIBLE SCIENCE-MEDICAL JOURNALS: My opinions as detailed in this declaration are based upon my knowledge and direct professional experience in the subject matters discussed. The materials that I have relied upon are the same types of materials that other experts in my field of clinical practice rely upon when forming opinions on the subject including hundreds of published, peer reviewed scientific research (and clinical) articles. A list of the most relevant articles is attached as Exhibit B to this declaration and many are cited and discussed in this report.

10. PREVIOUS LEGAL CASES AS AN EXPERT WITNESS: Over my career, I have provided expert medical record review and testified at deposition in less than a dozen cases. Related to the litigation of issues of sex and gender, I have been designated as an expert witness

in Joaquín Carcaño et al v. Patrick McCrory, Jane Doe v. Board of Education of the Highland School District, Ashton Whitaker v. Kenosha Unified School District, Terri Bruce v. State of South Dakota, and Cause DF-15-09887-SD of the 255th Judicial Circuit of Dallas County, TX regarding the dispute between J.A. D.Y. and J.U. D.Y., Children. Only in the last case did I testify at trial. I have also served as a science consultant or subjected written testimony for court cases in Canada (B.C. Supreme Court File No. E190334) and Great Britain (Bell v Tavistock).

11. COMPENSATION: I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide. I am paid in advance for all written opinions or testimony to avoid potential conflicts of interest.

12. BASES FOR OPINIONS - My opinions documented in this report are based on my 1) knowledge, training, and clinical experience in caring for thousands of patients over many years; (2) detailed methodological reviews of hundreds of relevant peer-reviewed science publications; (3) consults, discussions, and team analyses with colleagues and other experts in the field, including attendance and participation in various professional conferences, and 4) analysis of evidence in this case including medical records, Plaintiffs' expert reports, the NC State Health Plan, legal documents (i.e. complaint, response, etc.). My investigation in this case is ongoing and I will supplement, amend or update this report as additional information becomes available for review including discovery, experts, and observations of witnesses. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study regularly rely upon when forming opinions on these subjects.

Evidence Reviewed: My investigation is continuing and additional evidence will be reviewed as it becomes available.

12A. Peer Reviewed Published Research Articles and related materials, etc. (See citations below and also attached Exhibit B).

12B. Relevant case documents — legal complaint, response, disclosures, North Carolina Health Plan, Plaintiffs' medical records, all expert witness declarations, and other evidence as it becomes available.

13. OPINIONS regarding Plaintiffs' Expert Witness Disclosures:

A. The Plaintiffs' Expert Disclosures Failed to Accurately Report, Review, or Properly Disclose to the Court the Dangerous Methodological Limitations, Flaws, Errors, and Defects in the Gender Transition Industry's Research Base including the Well-Known, Well-Documented *International Controversies* regarding the Relevant Science and Interventions (sometimes mis-labeled as "treatments"). I have reviewed the expert declarations in this case from Plaintiffs' experts Drs Brown, Green, and Schechter. In my opinion, these appear to be political-ideological-advocate-activist opinions in support of the Gender Affirmation Medical Enterprise's ("transgender") movement and not competent, appropriate, scientific, methodological opinions. All three of Plaintiffs' experts improperly support the use of experimental, highly intrusive, and potentially harmful medical procedures despite the lack of credible, reliable, and valid scientific support for such treatments. In my opinion, their reports all failed to include a cogent, detailed, methodological discussion of *the serious, ongoing, scientific, medical, and societal controversies* regarding the etiology, treatment, and long-term outcomes of "gender affirmation" (sometimes mis-labeled as "transitioning") theories, methods, practices, procedures, and treatments. This omission in all three reports is quite remarkable as the scientific errors, omissions, failures, and

defective methodologies of the field of transgender medicine have produced heated controversy and garnered worldwide attention in 2020 and 2021. In the analysis that follows, I cite published analyses of Gender Transition Industry research noting significant and internationally recognized errors and defects such as low quality study designs, selective "cherry-picking" of data, and the improper misreporting of key study findings.

B. Specifically, the Plaintiffs' Expert Disclosures Failed to Accurately Report the Serious Methodological Limitations, Flaws, and Defects in the Gender Transition Industry's Methods for the Diagnostic-Labelling of "Gender Dysphoria": The Plaintiffs' expert disclosures offer misleading opinions about diagnostic systems. For example, the DSM (Diagnostic and Statistical Manual of the American Psychiatric Association) involves an often controversial consensus seeking, (not scientific evidence seeking), political-voting process that began historically as an attempt to construct a reliable dictionary for psychiatry. The DSM has historically included unreliable, since debunked, diagnoses such as "multiple personality disorder" that fueled a harmful "craze" damaging vulnerable patients until scientists, legal professionals, juries, and licensing boards put a stop to it. (See the detailed discussion below). It is important for legal professionals to understand that the DSM was created using a consensual, political process of committees and voting and does not depend upon an evidence-based, uniformly valid and reliable scientific process. Small groups of professionals, often with ideological agendas, can form committees and create "diagnoses" to be voted into the DSM. Much of DSM content is decided by the "voting" of small committees of advocates and activist practitioners whose judgment may suffer from significant financial conflicts of interest — as appears to be the case with the plaintiffs' experts in this case.

C. The Plaintiffs' Expert Disclosures Failed to Accurately Disclose and Discuss the Well-Documented Methodological Limitations, Flaws, and Defects in Gender Identity ("transgender") Subjective Clinical Assessments: The clinical assessment methodology in Sex Discordant Gender medicine is currently limited to self-report information from patients without objective scientific markers, medical tests, or scientific assessment tools. There are no reliable radiological, genetic, physical, hormonal, or biomarker tests that can establish gender identity or reliably predict treatment outcomes. A few hours of conversation with often poorly trained social workers often provides the only gatekeeping process to severe and irreversible iatrogenic surgical and hormonal injuries. Most importantly*, the long-term effects of "transitioning" have never been scientifically validated*. No valid-reliable methodology for such assessments has been accepted by the relevant scientific community and it appears that no known error rates for such assessments have ever been published. A more detailed discussion of the foundational science documenting the limitations and methodological defects in this field is offered below.

D. The Plaintiffs' Expert Disclosures Fail to Accurately Report Essential Methodological Problems in the Gender Transition Industry. Foundational Research including Sampling Errors, the Misreporting of Findings, the Misreporting of Relevant History, misquoting of research studies, "low quality" research designs, failures to complete randomized clinical trials, and widespread Confirmation Bias including the failure to properly explore Alternative Hypotheses (e.g., Social Contagion, Mental Illness, Complex Developmental Processes, Family Dynamics, etc.), and Other Failures of Basic Scientific Methodology: The plaintiffs' expert disclosures failed to properly discuss and disclose alternative theories/hypotheses for the rapid and nearly exponential increase of transgender cases — such as social contagion, mental illness, and/or complex developmental processes—especially as reportedly driven by news media, social media

"YouTube "influencers" (who reportedly sell "transitioning" to vulnerable youth on social media), educational systems (that reportedly pressure 1st graders to "identify as non-binary"), as well as political-activist "pro-transition" health care workers (too few of whom seem to have carefully reviewed and understood the relevant scientific history and ongoing controversies in this field).

E. The Plaintiffs 'Expert Disclosures Failed to Accurately Report Methodological and Other Problems in the Plaintiffs' Medical Records: I have also reviewed the Plaintiffs' medical records in this case. These records demonstrate many of the scientific errors, limitations, methodological errors, and informed consent errors discussed in detail below. "This includes confirmation bias, reliance on unverified patient reports, failure to consider alternative hypotheses, and failure to provide patients with the information necessary for truly informed consent."

14. TERMINOLOGY - BIOLOGICAL SEX: Biological sex is a term that specifically refers to a member of a species in relation to the member's capacity to either donate (male) or receive (female) genetic material for the purpose of reproduction. Sex thus cannot be "assigned at birth" because it is permanently determined by biology at conception. This remains the standard definition that has been accepted by the relevant scientific community and used worldwide by scientists, medical personnel, and society in general for decades. The scientific and clinical measurement of sex is done with highly reliable and valid objective methodologies. Visual medical examination of the appearance of the external genitalia is the primary methodology used by clinicians to recognize sex. In cases where genital ambiguity is present, additional testing modalities including chromosomal analysis, measurement of hormone levels, radiographic imaging of internal sexual anatomy and biological response to provocative testing are utilized.

The measurement and assessment of biological sex has been documented by valid-reliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex is very low, below 1%.

15. TERMINOLOGY - GENDER: Gender, a term that had traditionally been reserved for grammatical purposes, is currently used to describe the psychological and cultural characteristics of a person in relation to biological sex. Gender in such new definitions would therefore exist only in reference to subjective personal perceptions and feelings and societal expectations, but not biology. The term "gender" is currently used in a variety of ways and has thus become a controversial and unreliable term that means different things to different observers often varying according to political and ideological positions. The only definition of gender accepted by the worldwide, relevant *scientific* (biology, genetics, neonatology, zoology, medicine, etc.) community retains the historic biological connection to reproductive purpose with other definitions mired in controversy. The reliability and validity of various usages of the term "gender" is currently quite controversial and the relevant scientific community has accepted no use other than in relation to biological sex, which includes participate in activities related to reproduction. The serious dangers of incorrectly using the term "gender" is acknowledged by the Endocrine Society (Bhargava, A., Arnold, A. P., Bangasser, D. A., Denton, K. M., Gupta, A., Hilliard Krause, L. M., Mayer, E. A., McCarthy, M., Miller, W. L., Raznahan, A., & Verma, R. (2021). Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement. *Endocrine reviews*, bnaa034. Advance online publication. https://doi.org/10.1210/endrev/bnaa034) In addition, the error rate for multiple uses of the term "gender" outside of the accepted biologically related use is unknown, untested, and unpublished. The measurement and assessment of biological sex and gender has been documented by valid-

reliable research published in credible journals, and is accepted by the relevant scientific community. The error rate for the measurement and assessment of biological sex and gender is very low, below 1%.

16. TERMINOLOGY - GENDER IDENTITY: Gender identity refers to a person's individual experience and perception and unverified verbal patient reports of how they experience being male or female or a combination of these or other categories. The term "gender identity" is currently controversial. It is a term that means very different things to different observers often varying according to political, ideological, religious, and other factors. There is no current worldwide definition of "gender identity" accepted by the relevant scientific (cf. clinical) community. The reliability and validity of the term "gender identity" is controversial and not accepted by the relevant scientific community. The measurement error rate for non-biological "gender identity" is unknown, untested, and unpublished and could be very high.

17. TERMINOLOGY - SEXUAL ORIENTATION: Sexual orientation refers to a person's enduring pattern of arousal and desire for intimacy with males, females, or both.

18. TERMINOLOGY - DNA and CHROMOSOMES: Sex is genetically encoded at the moment of conception due to the presence of specific DNA sequences (i.e. genes) that direct the production of signals that influence the formation of the bipotential gonad to develop into either a testis or ovary. This genetic information is normally present on X and Y chromosomes. Chromosomal sex refers to the normal complement of X and Y chromosomes (i.e. normal human males have one X and one Y chromosome whereas normal human females have two X chromosomes). Genetic signals are mediated through the activation or deactivation of other genes and through programmed signaling of hormones and cellular transcription factors. The default

pattern of development in the absence of external signaling is female. The development of the male appearance (phenotype) depends upon active signaling processes.

19. BIOLOGICAL SEX IS BINARY — NOT A CONTINUUM — FOR 99%+ of MAMMALS INCLUDING HUMANS: For members of the human species (and virtually all mammals), sex is normatively aligned in a binary fashion (i.e., either male or female) in relation to biologic purpose. The presence of individuals with disorders of sexual development (along the range of the established Prader scale) does not alter this fundamental reality. Medical recognition of an individual as male or female is correctly made at birth in nearly 99.98% of cases according to external phenotypic expression of primary sexual traits (i.e., the presence of a penis for males and presence of labia and vagina for females). The recognition of an individual as male or female made at birth according to biological features has been documented by valid-reliable research published in credible journals, and is generally accepted by the relevant scientific community. The error rate for the measurement and assessment of an individual as male or female made at birth according to biological features is very low indeed, certainly below 1%.

20. THE GENITAL-BIOLOGICAL FUNCTION OF REPRODUCTION: Due to genetic and hormonal variation in the developing fetus, normative development of the external genitalia in any individual differs with respect to size and appearance while maintaining an ability to function with respect to biologic purpose (i.e. reproduction). Internal structures (e.g. gonad, uterus, vas deferens) normatively align in more than 99.9%+ of mammals with external genitalia, including humans. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, developmental biology, genetics, and other relevant fields. In my opinion, all relevant sciences agree that the development of genital structures is intrinsically oriented to biological reproduction.

21. BIOLOGICAL ASSESSMENT OF SEX: Reliance upon external phenotypic expression of primary sexual traits is a highly accurate, reliable and valid means to assign biologic sex. In over 99.9% of cases, this designation will correlate with internal sexual traits and capacity for normal biologic sexual function. Sex is therefore not "assigned at birth" but is rather recognized at birth. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, psychiatry, neonatology, biology, genetics, gynecology, and other fields.

22. DISORDERS OF SEXUAL DEVELOPMENT ARE VERY RARE: Due to the complexity of the biological processes that are involved in normal sexual development, it is not surprising that a very small number of individuals are born with defects in this process (1 in 5,000 births). Defects can occur through either inherited or de *novo* mutations in genes that are involved in sexual determination or through environmental insults during critical states of sexual development. Persons who are born with such abnormalities are considered to have a disorder of sexual development (DSD). Most often, this is first detected as ambiguity in the appearance of the external genitalia. Such detection measurements are reliable and valid and accepted by the relevant scientific community. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, neonatology, gynecology, psychiatry, biology, genetics, and other fields. **See,** Leonard Sax (2002) How common is lntersex? A response to Anne Fausto-Sterling, The Journal of Sex Research, 39:3, 174-178, DOI: 10.1080/00224490209552139

23. DISORDERS OF SEXUAL DEVELOPMENT ARE NOT A THIRD SEX: Normal variation in external genital appearance (e.g. phallic size) does not alter the basic biologic nature of sex as a binary trait. "Intersex" conditions represent disorders of normal development, not a third sex. In my opinion, this view is generally accepted by the relevant scientific communities in

endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

24. DISORDERS OF SEXUAL DEVELOPMENT REQUIRE ASSESSMENTS OF OBJECTIVE EVIDENCE: The medical care of persons with disorders of sexual development (DSDs) is primarily directed toward identification of the etiology of the defect and treatment of any associated complications. Similar to other diseases, diagnostic tools such as the Prader scale are used to assess, measure, and assign a "stage" to the severity of the deviation from normal (e.g. assessments of objective, reliable evidence). In children with DSDs, characterization based upon phenotype alone does not reliably predict chromosomal sex nor does it necessarily correlate with potential for biological sexual function. Decisions on initial sex assignment in these very rare cases require detailed assessment of objective, reliable medical evidence by a team of expert medical providers. In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

25. INTERSEX CONDITIONS REQUIRE PROPER CONSIDERATION OF ALTERNATIVE HYPOTHESES AND TREATMENT PLANS: Standard medical practice in the treatment of persons with DSDs has evolved with growing understanding of the physical, psychological, and psychiatric needs and outcomes for affected individuals. Previously, it was felt that a definitive sex assignment was necessary shortly after birth with the belief that this would allow patients with a disorder of sexual development to best conform to the assigned sex and so parents-caregivers could help socialize the child to the assigned sex. Current practice is to defer sex assignment until the etiology of the disorder is determined and, if possible, a reliable prediction can be made on likely biologic and psychologic outcomes. When this cannot be done with

confidence, a presumptive sex assignment is made. Factors used in making such decisions include chromosomal sex, phenotypic appearance of the external genitalia, and parental desires. The availability of new information can, in rare circumstances, lead to sex reassignment. Decisions on whether to surgically alter the external genitalia to align with sex are generally deferred until the patient is able to provide consent. See, Lee, P. A. et al. Global Disorders of Sex Development Update since 2006: Perceptions, Approach and Care. Horm Res Paediatr 85, 158-180, doi:10.1159/000442975 (2016)). In my opinion, this view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

26. METHODOLOGICAL DEFECTS of the GENDER TRANSTION INDUSTRY - WHY IS THE TRANSGENDER MEDICINE FIELD STILL SO CONTROVERSIAL AFTER DECADES OF RESEARCH? :

A. The field of transgender medicine has long ignored basic, substantive, foundational science methodologies and ethics requirements (e.g. unverified patient reports are not a reliable basis for sterilizing vulnerable patients, unverified human memory reports are subject to contamination and misreporting, poorly designed-misreported treatment studies that show more damage than benefits are not a suitable basis for sterilizing vulnerable patients, etc.

B. Despite several highly defective research efforts, the Gender Transition Industry has failed to prove long term benefits that outweigh the reported harms, dangers, and serious injuries of "gender affirmation" interventions -- including inability to reach orgasm, vaginal atrophy, compromised cognitive function, lifelong reliance on medication and repeated surgical intervention to deal with the cumulative effects of these iatrogenic

harms, stunted growth, damage to social support systems, increased risk of serious suicide attempts, etc. In my opinion, the relevant scientific community agrees that Transgender Transition treatments are controversial, unproven, untested, and experimental – and thus not medically necessary – given the current state of scientific knowledge that exists.

C. The Gender Transition Industry has repeatedly presented false, deceptive, and misleading information to the public and to patients regarding the known risks, dangers, injuries and benefits of "affirmation treatments". (E.g. the Branstrom, Turban, and related research errors of omission and misreporting.)

D. Without competent, valid, peer reviewed published research support; the Gender Transition Industry relies upon support from "professional associations". Yet such associations are engaged in consensus-seeking-political voting methodologies and not evidence-based, peer reviewed science. Such political-professional associations have made similar, disastrous mistakes in the past. For example, the American Medical Association supported racist, "junk" science eugenics "treatments" in the 1930s and the American Psychiatric Association did not act to prevent or halt the harms of the repressed-memory/multiple personality industry of the 1990s.

E. As a result of these many defects of methodology and ethics, the Gender Transition Industry and its "treatments" are not generally accepted by the relevant scientific community.

F. As a result of these many defects of methodology and ethics, the Gender Transition Industry's assessments and "treatments" have no known nor published error rate.

G. A key investigative hypothesis is whether the Gender Transition Industry is simply the latest harmful "junk science" fad and consumer fraud in the medical-psychiatric industry following the misadventures of lobotomies, recovered memory therapy, multiple personality disorder, rebirthing therapy, and others.

H. National science reviews in England, Sweden, Finland and by the Cochrane Review have all uncovered serious methodological and ethical failures in the Gender Transition Industry – thus supporting the alternative investigative hypothesis that the Gender Transition Industry is engaged in a form of hazardous consumer fraud resulting in harm to many vulnerable patients. **(E.g., In Expósito-Campos P. A Typology of Gender Detransition and Its Implications for Healthcare Providers. J Sex Marital Ther. 2021;47(3):270-280. doi: 10.1080/0092623X.2020.1869126. Epub 2021 Jan 10. PMID: 33427094, the authors claim to have identified *60,000 case reports* of detransitioners world-wide on the Internet.)**

27. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY--LIMITATIONS and HAZARDS OF RELYING ON UNVERIFIED PATIENT SELF-REPORT DATA WITH NO OBJECTIVE EVIDENCE: IN CONTRAST TO DISORDERS OF SEXUAL DEVELOPMENT, GENDER DYSPHORIA CANNOT BE RELIABLY, OBJECTIVELY ASSESSED AS IT IS BASED ON PATIENT SELF-REPORTS (no blood tests, no x-rays, no lab results, no objective data) : Individuals who verbally report experiencing significant distress due to perceived discordance between gender identity and sex cannot currently be reliably, validly, and objectively assessed as experiencing "gender dysphoria". (See, American Psychiatric Association. Diagnostic and statistical manual of mental disorders. 5th ed, (2013). Although gender perceptions, feelings, and "identity" usually align with biological sex, some individuals

report experiencing discordance in these distinct traits. Specifically, for example, biologic females may report experiencing that they identify as males and biologic males may report experiencing that they identify as females. As gender by definition is distinct from biological sex, one's gender identity does not change a person's biological sex. There is currently no known reliable and valid methodology for assessing the accuracy or nature of unverified, verbal reports of discordant "identity". There is thus no known "error rate" for relying upon such reports to engage in hormonal and surgical treatments that might result in lasting, irreversible damages to normal, healthy organs and the destruction of normal biological functions (e.g. sterility) as the current research documents. In my opinion, my view is generally accepted by the relevant scientific communities in endocrinology, urology, surgery, neonatology, gynecology, psychiatry, biology, genetics, and other fields.

28. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS -- THE RELEVANT SCIENCE DOCUMENTS THAT MENTAL HEALTH CARE PROFESSIONALS ARE UNRELIABLE HUMAN "LIE DETECTORS" ("often no better than flipping a coin"): Currently, there is no known methodology for reliably discerning true from false patient reports without corroborating evidence such as radiology, lab tests, or other objective evidence. The Gender Transition Industry's sole reliance upon patient self-report data carries unknown risks of errors, misinformation, deception and lasting harm to patients from treatments that deliberately damage healthy organs and destroy essential normal bodily processes thus often producing sterility. Assessment of gender dysphoria currently depends almost entirely upon unverified, self-

reported evidence provided by patients. A patient's spoken or written reports of alleged "memories" of symptoms and behaviors are the only source of evidence for the diagnosis in many cases. This is a source of potentially profound unreliability in patient care as the relevant science documents that physicians are poor "lie detectors" — often no more reliable in discerning false reports than flipping a coin — and sometimes much worse. The relevant research also documents that even though humans (including therapists) are poor "lie detectors" many poorly trained physicians and mental health professionals personally – and falsely -- believe they are "experts" at this complex and difficult task. See, e.g., Vrij, Aldert, Granhag, P. and Porter, S. (2010) Pitfalls and opportunities in nonverbal and verbal lie detection. Psychological Science In The Public Interest, 11 (3). pp. 89-121. ISSN 1529-1006 10.1177/1529100610390861. " The final error that I will highlight is that professional lie catchers tend to overestimate their ability to detect deceit. Research has consistently shown that when professional lie catchers and laypersons are compared, "*professionals are more confident in their veracity judgments but are NO more accurate*". Emphasis added. See also, Rosen, G. M. and Phillips, W.R., A Cautionary Lesson from Simulated Patients, *Journal of the American Academy of Psychiatry and Law*, 32, 132-133, (2004).

29. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY HEALTH CARE PROFESSIONALS -- SOCIAL MEDIA "INFLUENCERS" ARE REPORTEDLY TRAINING PATIENTS TO FABRICATE SYMPTOMS TO GAIN RAPID ACCESS TO "TRANSITION" INTERVENTIONS. Because Mental Health Professionals and Physicians are not capable of reliably discerning true from false patient reports, nobody knows how many Gender Dysphoria

patients have been coached-trained to deceive providers to gain easier and more rapid access to hormones/surgery: An important methodological error of the gender transition industry is the reliance on patient self-reports alone — and the lack of objective corroborative evidence (no x-rays, no blood tests, no genetic tests, no MRI's, etc) — to engage in experimental "treatments" causing sterility and other long-term harms. One potential hazard of this limited, unreliable self-report methodology can be seen in the recently reported increase of "rapid onset gender dysphoria" ROGD in adolescent females. For decades, the large majority of GD patients were early onset males. In contrast, in just the past 5 years, the majority of new GD patients are female patients with no long-term GD history. Many of the "rapid onset" adolescent patients' parents have reported a very rapid onset of GD symptoms linked to peer or school pressures or YouTube "training" —thus coming out as "trans" in groups of friends or following school "gender training" programs. At the same time, there have been reports of YouTube "Trans Influencers" whose "video blogs" are watched by millions as they provide detailed coaching to their adolescent girl followers on how to "lie to medical providers to obtain easier access to TG hormone and surgical treatments rapidly". The reliance upon unverified self-report data –an unreliable diagnostic methodology -- may well be one source of the ongoing and internationally reported failure of research on Gender Transition Industry interventions (sometimes mislabeled as "treatments) to provide consistent, reliable and valid evidence of long term benefits that would offset the well-documented long-term harms, injuries, and damages (e.g. sterility, stunted growth, bone loss, etc) produced by this burgeoning medical industry.

30. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA UNRELIABLY ASSESSED BY MENTAL HEALTH PROFESSIONALS --

THE SCIENCE OF MEMORY SHOWS THAT UNVERIFIED PATIENT "MEMORY" REPORTS COULD BE QUITE INACCURATE THUS PRODUCING ADDITIONAL RISKS OF UNRELIABLE DIAGNOSIS AND HARMFUL INTERVENTIONS: Decades of scientific research studies have shown that human memory reports — often the sole source of evidence for providers to engage a Gender Dysphoria patient in hazardous, experimental "gender transition" treatments — are subject to manipulation, implantation, contamination by post-event sources, source amnesia, and other errors. As world memory expert Prof. Elizabeth Loftus has noted, "False memories, once created — either through misinformation or though suggestive processes — can be experienced with a great deal of emotion, a great deal of confidence and a lot of detail, even though they're false." See Loftus, E. F. (2002) Memory Faults and Fixes. Issues in Science & Technology, National Academies of Science, 18, # 4, pp 41-50 See, also, e.g., Loftus, E. F. (2005) Planting misinformation in the human mind: A 30-year investigation of the malleability of memory. Learning and Memory, 12, 361-366.

31. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the reliance upon often science-illiterate mental health professionals to assess unverified patient reports -- ALTHOUGH MUCH OF MEDICINE BECAME SCIENCE-BASED IN THE 20th CENTURY — THE MENTAL HEALTH FIELDS REPORTEDLY CONTINUES TO LAG BEHIND:

The Gender Transition Industry often involves social workers or other mental health professionals "assessing" patients reporting Gender Dysphoria to determine if they will benefit from "affirmation" medical interventions. Given the extraordinary lack of competent, methodologically sound research (See, reviews by England, Sweden, Finland, the Cochrane review and others below) justifying the use of gender affirmation "treatments" there is no method for

mental health professionals to reliably determine who might benefit from experimental interventions. Such unreliable assessment protocols risk harm to patients as they depend upon the widespread unreliable method of having psychotherapists depend upon "clinical judgment" methodologies to make life-changing decisions and offer "professional" opinions with little or no scientific validity. See, e.g., Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, November 2008, vol 9, no 2 i-ii. The past President of the Association for Psychological Science, Prof. Walter Mischel, stated "*the current disconnect between psychological science and clinical practice is an unconscionable embarrassment".* See, Mischel, W. Connecting Clinical Practice to Scientific Progress, Psychological Science in the Public Interest, Vol 9, No 2, 2009.

Over the past century many components of the health care system — surgery, radiology, laboratory testing, internal medicine, pharmacological systems, etc. — became science-driven and far more effective and reliable. Courts are often unaware that this transformation — moving from widespread use of unreliable methodologies ("junk science") to the widespread use of reliable science-based methodologies — has, in many ways, not yet occurred in the mental health system. See, e.g., West, Catherine, 'An Unconscionable Embarrassment', Association for Psychological Science, Observer, October 2009, See, http://www.psychologicalscience.org/index.php/publications/observer/2009/october-09/an-unconscionable-embarrassment.html ; See, also Baker, T., McFall, R. & Shoham, V., Current Status and Future Prospects of Clinical Psychology: Toward a Scientifically Principled Approach to Mental and Behavioral Health Care, Psychological Science in the Public Interest, Vol. 9, No. 2 (2009); see also, Harrington, A., Mind Fixers: Psychiatry's Troubled Search for the Biology of Mental Illness, W. W. Norton & Company; 1st edition, April 16, 2019 ; See also, Dawes, R.M.,

House of cards: Psychology and psychotherapy built on myth, New York: Free Press (1997); See also, Garb, H. N., & Boyle, P. A (2003). Understanding why some (mental health) clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudo-science in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.

32. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESSED BY MENTAL HEALTH PROFESSIONALS: DYSPHORIC REPORTS ARE COMMON FROM CHILDREN WITH A RANGE OF ILLNESSES: Reports of feelings of anxiety, depression, isolation, frustration, and embarrassment are not unique to children with gender dysphoria, but rather are common to children who differ physically or psychologically from their peers. Difficulties are accentuated as children progress through the normal stages of neuro-cognitive and social development. In my clinical practice of pediatric endocrinology, this is most commonly seen in children with diabetes. Attempts to deny or conceal the presence of disease rather than openly acknowledge and address specific needs can have devastating consequences including death. With proper acknowledgment of the similarity and differences between children with gender dysphoria and other developmental challenges, prior medical experience in treating a range of reported troubles can guide the development of effective approaches to both alleviate suffering and minimize harm to school aged and adolescent children experiencing gender dysphoria.

33. METHODOLOGICAL DEFECTS of the GENDER TRANSITION INDUSTRY include the KNOWN LIMITATIONS OF RELYING ON UNVERIFIED, PATIENT SELF-REPORT DATA ASSESED BY MENTAL HEALTH PROFESSIONALS -- COURTS SHOULD

BE AWARE THAT CLINICAL EXPERIENCE IN THE MENTAL HEALTH FIELDS - WHERE CLINICIANS OFTEN LACK ACCURATE FEEDBACK — IS OFTEN OF LIMITED VALUE :

As the Gender Transition Industry routinely permits poorly qualified social workers or other mental health professionals to subjectively make life changing decisions in Gender Dysphoria cases — such mental health professionals often unreliably overestimate their ability to offer such "crystal ball" assessments and predictions. Few of these professionals seem aware of the research showing the grave limitations on the experience, judgment, and methodologies of mental health professionals. See, e.g., Tracey, T.J., Wampold, B.E., Lichtenberg, J.W., Goodyear, R. K., (2014) Expertise in Psychotherapy: An Elusive Goal, American Psychologist, Vol. 69, No. 3, 218-229. "In a review of expertise across professions, Shanteau (1992) identified several professions in which practitioners develop expertise, which he defined as increased quality of performance that is gained with additional experience. These professions, which demonstrate there can be a relation between experience and skill, include astronomers, test pilots, chess masters, mathematicians, accountants, and insurance analysts. Shanteau also identified several professions for which experiential expertise was not demonstrated, including [mental health professionals]. He attributed the differences between the two types of professions to the *predictability of their outcomes and the unavailability of quality feedback.*" For example, airline pilots, or even more clearly Navy fighter pilots who land on aircraft carriers practice their professions in full view of hundreds of people. If they err, people die. If they are, off course, unstable, or inaccurate in their performance, immediate consequences, retraining or loss of profession is the immediate outcome. In contrast, a social worker, psychologist, or psychiatrist, sitting alone in a room with a troubled patient can make erroneous statements, use unreliable methodologies (e.g., naively believing whatever

patients tell them or believing that they are "professional human lie detectors"), believe false and misleading notions about human memory, demonstrate ignorance of the serious defects in transgender treatment research, and fail to properly inform patients of the risks and benefits of treatments, etc. Mental health professionals can make such egregious errors for decades without receiving timely, accurate feedback. Without accurate feedback there is a failure of the learning process and improvements are difficult or not possible. Such limiting processes can continue for many years of practice. This is why mental health professions have been listed as doing the type of work that often does not lead to improvements in "clinical experience"— even over many years of practice. Gender discordant ("transgender") patients are rarely, if ever, informed of these limitations on mental health professionals' knowledge, training, or experience nor the limitations of mental health "assessments" based on unverified self-reported "memory" data.

34. HISTORICALLY, THE MEDICAL and SOCIAL SCIENCES HAVE AT TIMES BEEN IMPROPERLY TAINTED BY POLITICAL IDEOLOGIES. IT IS IMPORTANT FOR LEGAL PROFESSIONALS — ESPECIALLY JUDGES —TO UNDERSTAND THE ESSENTIAL DIFFERENCES BETWEEN METHODOLOGICALLY COMPETENT, TESTABLE-TESTED-RELIABLE-VALID PEER REVIEWED SCIENCE v. the CONSENSUS-SEEKING, VOTING PROCESSES OF POLITICAL-PROFESSIONAL ASSOCIATIONS and RELATED ORGANIZATIONS:

Professional Association voting processes are not a reliable nor valid scientific methodology. Professional, political, or other association consensus-seeking voting processes and procedures are neither reliable nor valid, nor tested and proven scientific methodologies. They are votes taken by committees - too often small committees of activists and ideologues with inadequate methodological training. Such non-scientific voting processes and procedures have never been

accepted as reliable and valid scientific methods by the relevant scientific community. Such voting processes and procedures have no known error rate. Historically, it should be noted that "professional associations" have a tainted history of supporting unproven, controversial notions that were later proven to be improper, unreliable, and/or unethical.

A. The American Medical Association (AMA): As an example of professional association support of controversial ideologies, AMA supported eugenic proposals to "improve the quality of the human stock" by coercive *sterilization* of "defective and undesirable Americans" and selective breeding. During the 1890's the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meetings of the American Medical Association. Dr. Ochsner recommended surgical vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868).

The controversial support of the AMA for such racist, eugenics ideologically-tainted pseudoscientific notion was a political and not a scientific process. Similarly, the American Breeders Association founded an Eugenics Record Office with an advisory board that included a Harvard physiologist, a Princeton psychiatrist, a University of Chicago economist, and Alexis Carrel of the Rockefeller Institute for Medical Research, a recipient of the Nobel Prize in Medicine. This movement was focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003).

With the support of professional associations like the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of the "socially inadequate", that is, those supported in institutions or maintained at public expense. The model law encompassed the "feebleminded,

insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent" — including "orphans, ne'er-do-wells, tramps, the homeless and paupers". Eighteen states passed laws based on the 1922 model legislation and sixty-four thousand people were forcibly sterilized. Supporters included Margaret Sanger who in her 1932 essay "My Way to Peace" proposed that "the whole dysgenic population would have its choice of segregation or *sterilization*" (Sanger, M., My Way To Peace, Birth Control Review, Jan 17, 1932; Singleton, M.M. The 'Science 'of Eugenics: America's Moral Detour, Journal of American Physicians and Surgeons, Vol 19, No 4, Winter 2014.)

A key lesson from this tragic era is that the non-scientific, consensus-seeking voting processes of "associations" can produce danger to the public and patients. Although directed by persons who know or should know how to conduct proper scientific methods, association voting methods are politically-ideologically tainted processes — and not based upon valid-reliable, methodologically-competent science. Again, such professional "associations" operate via consensus-seeking and ideology and not evidence-seeking scientific methodologies. Such professional organizations make decisions by voting and not by conducting ethical, scientifically valid, methodologically reliable, peer reviewed and published science with known error rates.

B. The World Professional Association for Transgender Health (WPATH), The Amercican Academy of Pediatrics (AAP), and the Endocrine Society: This methodological critique and history of association **errors and misadventures** is quite informative when assessing the "professional association" consensus seeking methodologies including voting and political activities such as those of WPATH, the AAP, the American Endocrine Society and similar groups as they adopt support for the "politically correct" but scientifically defective, ideologically driven Gender Transition Industry. Consensus seeking (voting) methods are not scientific evidence-based

methodologies. Courts should take case not to be deceived by the "positions" of Associations – no matter how large or vocal. The net effect of many the Gender Transition Industry's methods and procedures is the sterilization of tens of thousands of children, adolescents, and adults. This is a sobering reminder of previous, now infamous, medical misadventures. (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320 ;

C. The Diagnostic and Statistical Manual of the American Psychiatric Association (DSM): A final example of the methodological limitations of relying upon "association voting" methods is the Diagnostic and Statistical Manual of the American Psychiatric Association. The DSM (and also the International Classification of Diseases- ICD) system(s) have confused some courts in the past. Simply put, reliability data, validity methodological analyses, and error rates are not supplied nor supported by the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM).

Today's American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (Version 5) employs the term "Gender Dysphoria" and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other. It is important to reiterate that the DSM is not a reliable-valid scientific journal publication. The DSM began as an attempt to create a dictionary for psychiatry. The process by which DSM classifications are created involves voting by committee — this is not a reliable-valid scientific process. The committees' recommendations are approved or rejected by superordinate committees. DSM content is largely decided by consensus-seeking methodologies — such as "voting" by small committees of advocates and activist practitioners whose judgment may suffer from significant

financial conflicts of interest — as appears to be the case with all three of the Plaintiffs' experts in this case. The limitations of the DSM methodology are well known in the relevant scientific community. In my opinion, these views are generally accepted by the relevant scientific community.

The DSM has become increasingly controversial in recent years – including being "dumped" by the National Institute of Mental Health as a key basis for research funding. See, Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is *withdrawing support for the APA's manual*. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency … would be "re-orienting its research away from DSM categories."] See also, https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment. Patients with mental disorders deserve better. NIMH has launched the Research Domain Criteria (RDoC) project to transform diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system."]

In sum, professional association "positions" are not based upon competent, credible, reliable and valid scientific methodologies. Professional association "positions" on gender affirmation assessments and treatments remain very socially, medically, and scientifically controversial – and increasingly so. The association "positions"—since they are produced by voting and not methodologically reliable-valid evidence -- have not been generally accepted by the relevant scientific community and they have no known, nor published, error rates.

35. MEDICINE and SOCIAL SCIENCE HAVE AT TIMES BEEN TRAGICALLY TAINTED AND THOUSANDS OF PATIENTS DAMAGED BY RELIANCE ON METHODOLOGICALLY DEFECTIVE PATIENT SELF-REPORTS and ANECDOTAL EVIDENCE:

Case histories, case reports, and verbal patient reports-statements and medical records of individual patients are all helpful sources of information and at times essential to the proper treatment of individual patients. Such information has often proven helpful in generating testable hypotheses for scientific research. Such self-report and anecdotal information, however, can contain errors, distorted memories, misinterpretations, delusions, confusions, manipulations, and other kinds of errors. In sum, case histories, case reports, and the statements and medical records of individual patients are anecdotal case histories or patient reports (stories of often unknown reliability). Such evidence is not sufficient for reliable, valid, tested, proven, peer reviewed scientific methodologies. Case histories, case reports, and the statements and medical records of individual patients have never been accepted by the relevant scientific community as reliable, valid, peer-reviewed published scientific research. Such case histories, case reports, and the statements and medical records of individual patients have no known error rates with some care

reports being highly accurate documentation of objective evidence and others being filled with highly subjective, uncorroborated, unverified verbal reports of patient emotional states.

An example of disastrous medical misdirection from anecdotal patient reports is the Repressed Memory Therapy (RMT) movement of the late 1980s and 1990s. This explosive epidemic of "recovered memories" and "multiple personality disorder" (MPD) patients led to the rapid creation of "specialty clinics" and hospital units throughout the nation as tens of thousands of new RMT and MPD patients accused parents of horrific crimes.

The intense furor resulted in the FBI investigating hundreds of anecdotal crime reports from psychotherapy patients. After years of investigations, Kenneth Lanning, the Director of the FBI Behavioral Unit, reported the lack of corroborative evidence for the patient allegations following "recovered memory therapy". He suggested that "therapists needed to explain" why so many therapy patients came to adopt, fervently believe in, and report radically transformed, terrifying alterations to their own biographies including "new memories" of torture at the hands of "satanic international cults" engaged in the rape, murder, and cannibalism of children. Social psychologist Richard Ofshe called the belief in satanic ritual abuse the "Achilles' heel" of the recovered memory movement, since the newly "remembered" reports of murder, cannibalism, and fetuses aborted in "rituals" not only sounded extreme and incredible but were not linked to corroborating evidence (e.g. many patients claiming "memories" of being ritually cut open for "sacrificial birth" had zero scars and upon OB-GYN exam had never given birth). Despite the lack of validating evidence as documented by the FBI's intensive, nation-wide investigation, in a national survey published in 1994, conducted by Gail Goodman and her colleagues, 13 percent of 7,000 therapists surveyed reported that they had "elicited recovered memories of ritual abuse", and these respondents "overwhelmingly believed" the "memories" were real. Two additional major studies—one

American, one British—came to the same conclusion as the FBI's Lanning in 1994. Funded with $750,000 from the federal government, Gail Goodman and her team examined many thousands of patient's anecdotal stories of satanic ritual abuse and failed to find any corroborative evidence for the stereotypical, rote, detailed patient reports of multi-generational cults that sexually abused, killed, and/or ate children. (See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.). Thus, prior to WPATH and prior to the ideological fervor of the Gender Affirmation Medical Enterprise, the Recovered Memory Therapy Industry had shown how "politically correct" ideological fervor can overcome a lack of credible scientific evidence and engage in unrproven, experimental "treatments" on tens of thousands of unsuspecting, vulnerable patients.

Subsequent research and many dozens of malpractice lawsuits and licensing revocations documented that the very similar to identical self-reported "memories" provided by "recovered memory" patients to law enforcement and the media were actually the result of memory contamination by unethical, pseudoscientific psychotherapy methods and media-therapist fueled social contagion fears of a criminally abusive "patriarchy". The patients' new, horrific pseudo-memories
were shown to be the result of ideologically driven pseudoscientific "treatments" including hypnosis, "age regression", dream interpretation, guided imagery, use of family photographs to stimulate "recovered memories", interpretation of physical symptoms as so-called "body memories", and coercive group therapy sessions similar to Maoist indoctrination groups. See, Ofshe, R. and Watters, E. (1996) Making Monsters: False Memories, Psychotherapy, and Sexual hysteria. 2nd Edition. University of California Press; See also, Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer.).

Hundreds of lawsuits and media exposes shut down many of the Repressed Memory Therapy – Multiple Personality Disorder (RMT-MPD) clinics. State licensing boards then proceeded to revoke or restrict the licenses of multiple leaders of the RMT-MPD movement. See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; See also, Barden RC: Reforming the Mental Health System: Coordinated, Multidisciplinary Actions Ended "Recovered Memory" Treatments and Brought Informed Consent to Psychotherapy. Psychiatric Times. 2014;31(6): June 6, 2014.

It is important to note that the relevant professional associations including the American Medical Association, the American Psychiatric Association, the American Psychological Association and others (social worker and therapist associations, etc.) were not protective of the public and did little or nothing to expose the dangerous, pseudoscience fads and frauds of the RMT-MPD movement. In contrast, these political-professional associations protected the lucrative RMT-MPD industry that created tens of thousands of new patients requiring years of expensive treatments. The exposure of the dangers and damages of the RMT-MPD industry was done by a small number of civil attorneys, scientists, juries, and science-literate journalists. This example should give pause to those attempting to rush to fund and rapidly expand the experimental Gender Transition Industry.

In sum, some of the most tragic misadventures in the history of medicine involved the science illiterate reliance upon uncorroborated patient "stories"— self-reported evidence — as the sole basis for proceeding with controversial, experimental treatments on vulnerable patients (e.g. Lobotomies, Rolfing, Primal Screaming, Recovered Repressed Memories, Multiple Personality Disorder, Rebirthing Therapy, Coercive Holding Therapy, Reparenting, etc.). Understanding the important distinctions between scientifically valid-reliable, methodologically sound research

versus unreliable, anecdotal evidence and unverified patient "memories" is essential to efforts to protect the integrity of the scientific process as well as the quality and safety of medical care. Sex discordant gender ("transgender") assessments are currently made almost solely on unverified, uncorroborated "memory" reports of vulnerable patients.

36. PATIENTS' RIGHTS TO TESTED, PROVEN TREATMENTS and INFORMED CONSENT HAVE BEEN VIOLATED IN THE PAST BY ETHICAL FAILURES IN THE MEDICAL and MENTAL HEALTH SYSTEMS. USING EXPERIMENTAL PROCEDURES and UNPROVEN "TREATMENTS" ON UNINFORMED, VULNERABLE PATIENTS IS UNETHICAL and IMPROPER. Some of the most tragic chapters in the history of medicine include violations of informed consent and improper experimentation on patients using methods and procedures that have not been tested and validated by methodologically sound science — such is the case with the Gender Transition Industry. The history of the infamous Tuskegee studies, the Nazi and Imperial Japanese wartime experiments, lobotomies (e.g., Dr. Egas Moniz received the 1949 Nobel Prize in Medicine for inventing lobotomies as a "treatment" for schizophrenia! See, https://www.nobelprize.org/prizes/medicine/1949/moniz/article/), recovered memory therapy-multiple personality disorders, rebirthing therapy (see, e.g. See, Janofsky, M. Girl's Death Brings Ban on Kind of 'Therapy'. New York Times. April 18, 2001, See, also Peggy Lowe, Rebirthing team convicted: Two therapists face mandatory terms of 16 to 48 years in jail, Rocky Mountain News, April 21, 2001, coercive holding therapy (See, Hyde, J. "Holding therapy appears finished, State orders the last practitioner of holding therapy to end controversial method" Deseret News, Feb 13, 2005), and other tragic examples should serve as a stark warning to medical providers to properly protect the rights of patients and their families to a proper informed consent process and to not be subjected to experimental, unproven interventions such as gender transition

"treatments". It is now universally agreed that medical and psychotherapy patients have a right to proper informed consent. Professional ethics codes, licensing rules and regulations, hospital rules and regulations, state and federal laws, and biomedical conventions and declarations all protect patients' right to informed consent discussions of the risks and benefits of proposed treatments and alternative treatments including no treatment. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998, ["Informed consent is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks, and benefits, as well as of alternatives with their risks and benefits"]. See, also, Katz, A., Webb, S., and Committee on Bioethics, Informed Consent in Decision-Making in Pediatric Practice, Pediatrics, August 2016, 138 (2) e20161485; DOI: https://doi.org/10.1542/peds.2016-1485 at https://pediatrics.aappublications.org/content/138/2/e20161485

Tragically, however, as I will discuss in detail below, we now have much evidence supporting increasing concerns that the true risks and benefits of Sex Discordant Gender ("transgender") transition "treatments*" are NOT being properly and ethically presented to patients by providers* (surgeons, endocrinologists, therapists, etc). Similarly, many of the published "pro-transition" research studies reviewed in this declaration *have misrepresented to the public the actual risks and benefits of gender affirming medical interventions*. The Gender Transition Industry has produced research claiming evidence supporting the use of controversial "treatments" when, in fact, their own study data more likely support the alternative hypothesis that *so-called "transition" intervention procedures might produce higher risks of anxiety and more serious suicide attempts requiring hospitalization.* (See detailed discussions below). Expert witnesses in cases involving issues related to Sex Discordant Gender Transition interventions are duty bound

and required by licensing rules to truthfully and fully disclose to courts and legal professionals ***the well-documented risks, international controversies, and published misrepresentations*** involving the still unproven Gender Transition methods and procedures.

37. METHODOLOGICAL ERRORS - ONE OF THE MOST SERIOUS OF ALL METHODOLOGICAL ERRORS, CONFIRMATION BIAS, PLAGUES THE RESEARCH OF THE GENDER TRANSITION INDUSTRY:

Confirmation bias is one of the most serious and potentially dangerous errors in the assessment-diagnosis-treatment process of medicine. One of the key methodologies in science and in proper investigations-assessments of all kinds — including expert witness review and testimony— is *the generation and testing of multiple alternative investigative hypotheses*. From US Public Junior High Schools (typically first taught to 8th Graders) through competent MA, MSW, and all Ph.D. and M.D. graduate programs, students and professionals at all levels are taught that the central methodology for science and for a proper assessment-diagnosis-treatment or expert witness report involves the *generation and testing of alternative investigative hypotheses.* Investigative hypotheses, once generated, should be rationally, properly, and fairly explored to see if actual, factual evidence supports or refutes the hypotheses. A common and serious error in improper assessments-diagnoses-treatments is "confirmation bias," the failure to generate and then explore alternative investigative-assessment-diagnostic hypotheses. In confirmation bias the science-naïve physician, investigator, expert, or therapist applies a narrow "tunnel vision" process to support a single, favorite, biased, pre-conceived hypothesis in a case. [See, Garb, H. N., & Boyle, P. A (2003). Understanding why some clinicians use pseudoscientific methods: Findings from research on clinical judgment. In S. O. Lilienfeld, S. J. Lynn, &. J. M. Lohr (Eds.), Science and pseudoscience in clinical psychology (pp. 17–38). New. York, NY: Guilford Press.;

See also, See, Plous, Scott (1993). The Psychology of Judgment and Decision Making. p. 233; Nickerson, Raymond S. (June 1998). "Confirmation Bias: A Ubiquitous Phenomenon in Many Guises". Review of General Psychology 2 (2): 175–220. doi:10.1037/1089-2680.2.2.17 ; See, Joshua Klayman and Young-Won Ha, Confirmation, Disconfirmation, and Information in Hypothesis Testing, Psychological Review, 1987, Vol.94, No. 2, 211-228.] Currently, too many Gender Transition Industry advocate-activist-providers appear to violate the requirement to properly generate, explore, and disclose alternative hypotheses for assessments-diagnoses and treatments. In my opinion such failures, including the activist-ideologue demand that all alternative hypotheses and treatments be banned as forms of "conversion" therapy, risk ***institutionalizing confirmation bias*** —a dangerous form of negligent practice. See, Smith, T. Summary of AMA Journal of Ethics article on cognitive biases, Four widespread cognitive biases and how doctors can overcome them (e.g., confirmation bias, anchoring bias, affect heuristic, and outcomes bias) at https://www.ama-assn.org/delivering-care/ethics/4-widespread-cognitive-biases-and-how-doctors-can-overcome-them. ("Physicians are human and, therefore, constantly vulnerable to cognitive bias. But this imperfection is not just theoretical. It can have huge effects on patient care.")

38. METHODOLOGICAL ERRORS of the GENDER t INDUSTRY- CONFIRMATION BIAS CAN PREVENT COMPLEX, COMPREHENSIVE DIAGNOSIS AND TREATMENT EXPLORING ALTERNATIVE HYPOTHESES:

By demanding the immediate and un-investigated "affirmation" of a Sex Discordant Gender Identity ("transgender") patient's requests for so-called" transitioning" — without conducting a detailed, proper, medical assessment of alternative hypotheses — the Gender Transition Industry is attempting to enforce and institutionalize the methodological failure of "confirmation bias". By

labelling all forms of psychotherapy, coping and resilience training, cognitive behavioral therapy for depression-anxiety, or other options as "conversion therapy", the Gender Transition Industry is failing to treat individual patients according to the basic requirements and principles of competent medical assessment, diagnosis, and treatment. As I will discuss in detail in the methodological analyses below, the current scientific evidence does not support the current treatments nor methods endorsed and aggressively marketed and demanded by the Gender Transition Industry. The Gender Transition Industry's general refusal to properly investigate or even consider alternative hypotheses, alternative diagnoses, and alternative treatments is, in my view, unethical misconduct. For example, many peer reviewed, properly conducted, published research reports demonstrate that cognitive-behavioral therapy is a very low-risk, safe, and highly effective treatment for depression and anxiety disorders. See, e.g., Mor N, Haran D. Cognitive-behavioral therapy for depression. J Psychiatry Relat Sci. 2009;46(4):269-73. PMID: 20635774, https://pubmed.ncbi.nlm.nih.gov/20635774/ ; [A review of "Twenty-nine Random Control Trials were included in three separate meta-analyses. Results showed multi-modal CBT was more effective than no primary care treatment (d =0.59), and primary care treatment-as-usual (TAU) (d = 0.48) for anxiety and depression symptoms."] See, e.g., Twomey, C., O'Reilly, G. and Byrne, M. Effectiveness of cognitive behavioural therapy for anxiety and depression in primary care: a meta-analysis, Family Practice, Volume 32, Issue 1, February 2015, Pages 3–15, https://doi.org/10.1093/fampra/cmu060. The political taint is so strong that some activist-providers reportedly fail to offer and engage in CBT therapy with depressed-anxious Gender Dysphoric patients for fear of being attacked as engaging in "conversion" therapy. Again, the institutionalization of medical negligence (e.g., confirmation bias) harms vulnerable patients.

39. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT - Ideological Overreach can Lead to Unethical Misconduct and Licensing Violations. Misrepresenting medical-scientific research, deceptively hiding methodological errors, or failing to honestly report ongoing international controversies to courts, patients, or guardians should be properly investigated as misconduct. Licensing boards and professional associations produce and should properly enforce ethics rules and requirements governing the conduct of health care professionals to protect the rights of patients and parents.

40. PROPER INVESTIGATIONS OF DECEPTIVE MISCONDUCT - Plaintiffs' EXPERT DR BROWN's METHODOLOGICAL FAILURES SHOULD BE INVESTIGATED: In my opinion, Plaintiffs' expert Dr. Brown, appears to have engaged in misconduct by his signed opinion in this case stating "***Nor is there any uncertainty or dispute in the medical field regarding the medical necessity of this care***." As the detailed methodological analysis below amply documents, Dr. Brown's expert declaration in this case appears to document an example of unusual ignorance or potentially, a deceptive failure to properly report on, and inform the court of, the ongoing international controversies and debates regarding Gender Transition interventions ("treatments") (e.g. See the relevant multiple, national science reviews cited below from Great Britain, Sweden, and Finland, as well as the Cochrane Review all exposing the serious methodological defects, controversies, and methodological failings of Gender Transition research as documented below).

41. THE ACTUAL PREVALENCE OF GENDER DYSPHORIA and PATIENTS THAT IDENTIFY AS GENDER DISCORDANT ("transgender") IS UNKNOWN BUT IT APPEARS TO BE INCREASING AT A RAPIDLY ACCELERATING RATE THUS SUPPORTING AN ALTERNATIVE HYPOTHESIS OF SOCIAL CONTAGION: Estimates reported in in the DSM-

V (a diagnostic manual that functions via voting and more as a dictionary than a valid scientific methodology) were between 0.005% to 0.014% for adult males and 0.002% to 0.003% for adult females. Thus, gender dysphoria was, until just a few years ago, a very rare condition. It is currently unknown whether these DSM estimates were falsely low due to under-reporting or:

— whether changing societal acceptance of transgendered identity and the growing number of medical centers providing interventions for gender dysphoria has led to increased reporting of persons who identify as transgender

- or whether the reported educational programs aggressively promoting "non-binary" identification to elementary to high school students to college students have greatly increased the numbers of youth adopting a transgender identity

- or whether the reported wave of "trans You Tube influencers" watched by millions each day as they aggressively "sell" the transgender lifestyle has added to a social contagion effect with vulnerable lonely, depression, anxious, or autistic youth.

— or other causal process.

A key unanswered research question is whether a social contagion process is leading to vast and rapid increases in the numbers of patients identifying as gender discordant ("transgender"). How many of the new waves of thousands of cases are 'false reports' that will dissipate with time and normal development over time? For example, the Gender Identity Development Service in the United Kingdom, which treats only children under the age of 18, reported that it received 94 referrals of children in 2009/2010 and 1,986 referrals of children in 2016/2017 **a relative increase of 2,000%**. See, "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS. NHS.uk (undated), http://gids.nhs.uk / sites / default / files /content_uploads /referralfigures-2016- 17.pdf.

Reportedly, similar social contagion processes led to tens of thousands of patients and families being harmed by controversial diagnoses such as multiple personality disorder" (MPD and controversial interventions including "recovered memory therapy (RMT). RMT and MPD patients, once considered extremely rare (some 300 MPD patients reported worldwide prior to the 1980s-1990s social contagion epidemic) erupted into a flood of tens of thousands of patients and affected families in the 1990s. These very controversial disorders and treatments were greatly reduced by dozens of civil lawsuits against RMT-MPD therapists, international news exposure of scientific evidence debunking these notions, and international news reporting of the civil litigation, licensing prosecutions, and licensing revocations of well-known RMT-MPD practitioners. (See, e.g., Belluck, P. Memory Therapy Leads to a Lawsuit and Big Settlement [$10.6 Million], The New York Times, Page 1, Column 1, Nov. 6, 1997; Pendergrast, M. (2017). The repressed memory epidemic: How it happened and what we need to learn from it. New York, NY: Springer).

Recent data indicates that the number of people seeking care for gender dysphoria is rapidly increasing with some estimates as high as 20-fold and more. See, Chen, M., Fuqua, J. & Eugster, E. A. Characteristics of Referrals for Gender Dysphoria Over a 13-Year Period. Journal of Adolescent Health 58, 369-371, doi:https://doi.org/10.1016/j.jadohealth.2015.11.010 (2016) ; 4. "GIDS referrals figures for 2016/17," Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content_uploads/referral-figures-2016-17.pdf.) See, Zucker K. J. (2017). Epidemiology of gender dysphoria and transgender identity. *Sexual health*, *14*(5), 404–411. https://doi.org/10.1071/SH17067. Data from England show *increases of 4,000% for female to male patients and in America data show increases of 20,000% for young women* ***(e.g. from .01 to 2%)***. Estimates vary considerably in relation to how sex-gender identity discordance is defined. See, Zhang, Q., Goodman, M., Adams, N., Corneil, T., Hashemi, L.,

Kreukels, B., Motmans, J., Snyder, R., & Coleman, E. (2020). Epidemiological considerations in transgender health: A systematic review with focus on higher quality data. *International journal of transgender health*, *21*(2), 125–137. https://doi.org/10.1080; Poteat, T., Rachlin, K., Lare, S., Janssen, A. & Devor, A. in *Transgender Medicine: A Multidisciplinary Approach* (eds Leonid Poretsky & Wylie C. Hembree) 1-24 (Springer International Publishing, 2019); Flores AR, Herman JL, Gates, GJ, Brown TNT. How Many Adults Identify as Transgender in the United States? Los Angeles, CA: The Williams Institute; 2016. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf. Accessed April 28, 2021.

42. EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS ***NOT*** GENETICALLY NOR BIOLOGICALLY DETERMINED: There is strong disconfirming evidence (e.g., Popperian falsifiability) against the theory that gender identity is determined at or before birth and is unchangeable. This comes from A) identical twin studies where siblings share genetic complements and prenatal environmental exposure but have differing gender identities. See, Heylens, G. et al. Gender identity disorder in twins: a review of the case report literature. J Sex Med 9, 751-757, doi:10.1111/j.1743-6109.2011.02567.x (2012) and B) the very recent and massive increase in the numbers of GD patients over a very short time span. This argues against a biological-genetic hypothesis. See Leinung MC, Joseph J. Changing Demographics in Transgender Individuals Seeking Hormonal Therapy: Are Trans Women More Common Than Trans Men? Transgend Health. 2020 Dec 11;5(4):241-245. doi: 10.1089/trgh.2019.0070. PMID: 33644314; PMCID: PMC7906237.

43. REPLICATED RESEARCH EVIDENCE SUPPORTS THE HYPOTHESIS THAT GENDER IDENTITY IS ***NOT*** IMMUTABLE: Further evidence that gender identity is not fixed and immutable comes from established peer reviewed literature demonstrating that the vast

majority (80-95%) of children who express gender dysphoria revert to a gender identity concordant with their biological sex by late adolescence. This natural developmental "cure" of gender dysphoria requires no direct "treatment" and prevents the hormonal and surgical destruction of normal, healthy organs and bodily processes (e.g. prevents sterilization of the child). See Singh D, Bradley SJ, Zucker KJ. A Follow-Up Study of Boys With Gender Identity Disorder. Front Psychiatry. 2021 Mar 29;12:632784. doi: 10.3389/fpsyt.2021.632784. PMID: 33854450; PMCID: PMC8039393. It is not currently known whether individuals with gender dysphoria persistence have differing etiologies or severity of precipitating factors compared to desisting individuals. See, Drummond, K. D., Bradley, S. J., Peterson-Badali, M. & Zucker, K. J. A follow-up study of girls with gender identity disorder. Dev Psychol **44**, 34-45, doi:10.1037/0012-1649.44.1.34 (2008); Steensma, T. D., McGuire, J. K., Kreukels, B. P., Beekman, A. J. & Cohen-Kettenis, P. T. Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J Am Acad Child Adolesc Psychiatry **52**, 582-590, doi:10.1016/j.jaac.2013.03.016 (2013).

44. VIRTUALLY ALL TRANSGENDER PATIENTS ARE BORN WITH HEALTHY NORMAL SEX ORGANS AND NO KNOWN BRAIN OR GENETIC ABNORMALITIES: Most people with gender dysphoria, do not have a disorder of sexual development. As documented in their medical record, such patients typically have normally formed sexual organs. The presence of normal, functional sex organs prior to the initiation of hormone administration or surgical "transition" operations is typical in transgender patients. I note that hormonal treatments and surgery to remove healthy, normal organs (the genitals of GD patients) both destroy the function of healthy organs (e.g., producing the life-long sterilization of GD patients). Such so-called apparently injurious "treatments" are very controversial and occur nowhere else in medicine that

I am aware of with the exception of requests for the amputation of healthy limbs in patients suffering from the very controversial "body integrity identity disorder". See, Elliott, T., Body Dysmorphic Disorder, Radical Surgery and the Limits of Consent, *Medical Law Review*, Volume 17, Issue 2, Summer 2009, Pages 149–182, https://doi.org/10.1093/medlaw/fwp001 **[**In 2000 there was a media furor, when it was disclosed that a Scottish surgeon had operated upon two adult male patients reportedly suffering from a rare form of a psychological condition known as body integrity identity disorder, in each case amputating a healthy leg. Since then, the question of whether such surgery is ethically or legally permissible has been a matter of debate. The subject raises issues as to the extent to which it is proper to treat adults with psychiatric or psychological disorders with radical surgery, particularly where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed]. Similarly, Gender Transition interventions also involve treating patients "with psychiatric or psychological disorders with radical surgery, where the appropriate diagnosis and treatment of the underlying disorder is uncertain or disputed."

The primary use of psychotherapy as a means to treat body dysmorphic disorder contrasts with the approaches used by the Gender Transition Industry. See, Hadley, S. J., Greenberg, J., & Hollander, E. (2002). Diagnosis and treatment of body dysmorphic disorder in adolescents. *Current psychiatry reports*, *4*(2), 108–113. https://doi.org/10.1007/s11920-002-0043-4; Allen, A., & Hollander, E. (2000). Body dysmorphic disorder. *The Psychiatric clinics of North America*, *23*(3), 617–628. https://doi.org/10.1016/s0193-953x(05)70184-2

45. THE ETIOLOGY (CAUSE) OF GENDER DYSPHORIA IS CURRENTLY ***UNKNOWN*** and the "TREATMENTS" are of **UNCERTAIN EFFICACY** - THUS THE CURRENT THEORIES and TREATMENTS REMAIN EXPERIMENTAL and CONTROVERSIAL: The etiology of gender dysphoria in individuals with sex-gender identity

discordance remains unknown. Alternative hypotheses include some as yet unidentified biological cause, prenatal hormone exposure, genetic variation, postnatal environmental influences, family dynamics, other forms of mental illness, an abnormal detour from developmental identity processes, social contagion effects on suggestible-vulnerable subjects, or a combination of multiple factors. Based upon the available evidence, it is most likely that sex-gender identity discordance is multifactorial with both genetic and environmental influences, differing in both kind and degree in any affected individual. Importantly, these potential contributing factors are hypothesized to be contributory, but not determinative of the condition. See, Saleem, Fatima, and Syed W. Rizvi. "Transgender Associations and Possible Etiology: A Literature Review." Cureus 9, no. 12 (2017): e1984

46. THE CONCEPT OF "NEUROLOGICAL SEX" IS EXPERIMENTAL, UNVERIFIED, HAS NO KNOWN ERROR RATE and is NOT ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY: The recently coined concept of "neurological sex" as a distinct entity or a basis for classifying individuals as male or female has no scientific justification. Limited emerging data has suggested structural and functional differences between brains from normal and transgender individuals. These data do not establish whether these differences are innate and fixed or acquired and malleable. The remarkable neuronal plasticity of the brain is well known, well documented, and has been studied extensively in gender-independent contexts related to health and disease, learning, and behavior. See, Fatima Yousif Ismail, Ali Fatemi, and Michael V. Johnston, "Cerebral Plasticity: Windows of Opportunity in the Developing Brain," European Journal of Paediatric Neurology 21, no. 1 (2017).

47. GENDER IDENTITY IDEOLOGY IS A POLITICAL, NOT SCIENTIFIC THEORY: A key alternative investigative hypothesis in efforts to understand the rise of reports of gender

discordance and social-political-medical attempts to create a transgender movement is that such ideas are not based upon sound scientific biological, genetic, or related principles and data but rather are based upon ideology and driven by political advocacy. Although worldviews among scientists and physicians differ widely, similar to society at large, science must remain firmly grounded in testable, valid, and reliable assessments of physical reality — not ideologically tainted perceptions and belief systems. The inherent link between human sexual biology and teleology (e.g. human reproduction) is self-evident and fixed. Breithaupt H. The science of sex. *EMBO Rep*. 2012;13(5):394. Published 2012 May 1. doi:10.1038/embor.2012.45. As an investigative hypothesis, the historical foundation of gender identity ideology appears to be grounded in Critical Theory, which may provide a basis to understand the level of extreme methodological confusion, defects, and errors in the Gender Transition Industry. For example, "transgender" activists often support clearly contradictory theories and arguments at the same time (e.g. the claim that Gender Dysphoria (GD) and "trans identity" are" immutable", "genetic", or based on "brain structures" while simultaneously claiming GD is also "fluid" and thus capable of changing on a daily basis). Association of critical theory with the Gender Transition Industry reflects a controversial ideological foundation for the provision of hormonal and surgical interventions that have potential to permanently damage essential bodily functions including the sterilization of vulnerable patients. (See, e.g., Pluckrose, and Lindsay, J. , Cynical Theories: How Activist Scholarship Made Everything about Race, Gender, and Identity—and Why This Harms Everybody, Pitchstone Publishing, August 25, 2020).

48. GENDER IDENTITY IDEOLOGY and the GENDER TRANSITION INDUSTRY--INCLUDING INTERVENTIONS -- HAVE NO RELIABLE-VALID SCIENTIFIC BASIS and HAVE NEVER BEEN ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and

HAVE NO KNOWN NOR PUBLISHED ERROR RATE: The political-ideological claims of proponents of transgenderism, which include opinions such as "Gender identity is the primary factor determining a person's sex" and "Gender is the only true determinant of sex" and individuals have "sex assigned at birth" must be viewed in their proper philosophical context. There is no scientific basis for redefining sex on the basis of a person's subjective, psychological sense of 'gender'.

49. IN CONTRAST TO SEX DISCORDANT GENDER "TRANSGENDER" IDEOLOGY, THE BIOLOGICAL BASIS OF SEX IS FIRMLY GROUNDED IN VALID-RELIABLE SCIENCE, ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY AND HAS A VERY LOW ERROR RATE: The prevailing, constant, tested, proven, and accurate designation of sex as a biological trait grounded in the inherent purpose of male and female anatomy and as manifested in the appearance of external genitalia at birth remains the proper scientific and medical standard. Redefinition of the classification and meaning of sex based upon pathologic variation is not established medical fact. See, e.g., Mittwoch, U. (2013), Sex determination. EMBO reports, 14: 588-592. https://doi.org/10.1038/embor.2013.84

Potential Harm to Vulnerable Patients Resulting from Experimental Gender Dysphoria Treatments

50. THE ETHICAL FOUNDATIONS of MEDICINE — FIRST DO NO HARM: The fundamental purpose of the practice of medicine is to treat disease and alleviate suffering. An essential tenet of medical practice is to avoid doing harm in the process. Efforts to rely upon clear, valid, reliable, and definitive evidence on how to best accomplish treatment goals is the essential ethical, professional, scientific, and clinical goals of physicians. The current Gender Transition Industry violates this essential principle by using experimental treatments on vulnerable

populations without properly informing them of the actual risks and limitations of the treatments. See, Jonson AR, Siegler M, Winslade, WJ: Clinical Ethics, New York: McGraw Hill, 1998.

51. THE ETHICAL FOUNDATIONS of MEDICINE — REQUIRE US TO STRIVE TO HELP THOSE IN DISTRESS WITH COMPASSION, KINDNESS, and EMPATHY AND TO **NOT** VIOLATE PATIENTS' and PARENTS' RIGHTS BY ENGAGING IN EXPERIMENTAL, UNPROVEN, INTERVENTIONS ("TREATMENTS") LEADING POTENTIAL TO PERMANENT DAMAGE TO MANY PATIENTS – INCLUDING STERILIZATION: Persons with gender dysphoria as defined in the DSM-V report experiencing significant psychological distress related to their condition with elevated risk of depression, suicide, and other morbidities. Thus, attempts to provide effective medical care to affected persons are clearly warranted. Efforts to effectively treat persons with gender dysphoria require respect for the inherent dignity of those affected, sensitivity to their suffering, and maintenance of objectivity in assessing etiologies and long-term outcomes. In my opinion, the use of unproven, experimental treatments on vulnerable patients and the publication of grossly methodologically defective research are violations of the ethical foundations of medicine.

52. IN THE ETHICAL PRACTICE OF MEDICINE, VALID-RELIABLE SCIENCE SHOULD PRECEDE INVASIVE, RISKY, DAMAGING TREATMENT PROTOCOLS - THREE CURRENT APPROACHES: There is an urgent need for high quality controlled clinical research trials to determine ways to develop supportive dignity affirming social environments that maintain affirmation of the ***scientifically accepted biological reality***. To date, three approaches have been proposed for managing children with gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry **47**, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008).) The first approach, often referred to

as "conversion" or "reparative therapy", is directed toward actively supporting and encouraging children to identify with their biological sex. The second "neutral" or "watchful waiting" approach, motivated by understanding of the natural history of transgender identification in children, is to neither encourage nor discourage transgender identification, recognizing that *the vast majority of affected children if left alone are likely to eventually realign their reports of gender identification with their sex*. This approach may also include the use of scientifically validated treatments (e.g. CBT) for the patient's anxiety, depression, social skills deficits or other issues. See, van Bentum, J. S., van Bronswijk, S. C., Sijbrandij, M., Lemmens, L., Peeters, F., Drukker, M., & Huibers, M. (2021). Cognitive therapy and interpersonal psychotherapy reduce suicidal ideation independent from their effect on depression. *Depression and anxiety*, 10.1002/da.23151. Advance online publication. https://doi.org/10.1002/da.23151; Gallagher, M. W., Phillips, C. A., D'Souza, J., Richardson, A., Long, L. J., Boswell, J. F., Farchione, T. J., & Barlow, D. H. (2020). Trajectories of change in well-being during cognitive behavioral therapies for anxiety disorders: Quantifying the impact and covariation with improvements in anxiety. *Psychotherapy (Chicago, Ill.)*, *57*(3), 379–390. https://doi.org/10.1037/pst0000283. The third "affirming" approach is to actively encourage children to embrace transgender identity with social transitioning followed by hormonal therapy leading to potential surgical interventions and life-long sterilization. See, Walch A, Davidge-Pitts C, Safer JD, Lopez X, TangprichaV, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective.J Clin Endocrinol Metab. 2021;106(2):305-308. doi:10.1210/clinem/dgaa816 .

53. ANOTHER CONTROVERSY — THE "WATCHFUL WAITING" TREATMENT MODALITY INVOLVES NO MEDICAL TREATMENT AND IS CURRENTLY THE BEST SCIENTIFICALLY SUPPORTED INTERVENTION FOR YOUNG CHILDREN REPORTING

GENDER DYSPHORIA: Desistance (i.e. realignment of expressed gender identity to be concordant with sex) provides the greatest lifelong benefit and is the outcome in the vast majority of patients and should be maintained as a desired goal. Any coerced, required, societally mandated, scientifically untested, intervention that would or could unnecessarily interfere with the likelihood of a normal, non-traumatic, developmental, resolution of gender dysphoria is unwarranted and potentially harmful. The gender affirming approach, which includes use of a child's preferred pronouns, use of sex-segregated bathrooms, other intimate facilities and sleeping accommodations corresponding to a child's gender identity, has limited, "very weak", "sparse" scientific support for short-term alleviation of dysphoria and ***no long-term outcomes data demonstrating superiority over the other approaches***. (See, National reviews of England, Sweden, Finland, the Cochrane review, the Griffin review, the Carmichael review and others). Claims that the other approaches have been scientifically disproven are simply false. In stark contrast to the ideologically tainted, "voted in", recommendations of Professional Associations, decades of peer-reviewed, published scientific research, including the pioneering work of Dr. Kenneth Zucker, have supported the efficacy of a more conservative "watchful waiting" approach for the majority of patients experiencing gender dysphoria. See, Zucker, K. J. On the "natural history" of gender identity disorder in children. J Am Acad Child Adolesc Psychiatry 47, 1361-1363, doi:10.1097/CHI.0b013e31818960cf (2008); Bradley, S. J. & Zucker, K. J. Gender Identity Disorder: A Review of the Past 10 Years. Journal of the American Academy of Child & Adolescent Psychiatry 36, 872-880, doi:10.1097/00004583-199707000-00008.). In sum, the treatment protocols and recommendations of politically influenced, non-science associations (WPATH, Pediatrics Assn, APA) who engaged in "voting", consensus-seeking methodologies (not science)

are not accepted by the relevant ***scientific*** community, are not based upon competent-credible, methodologically sound science, and have no known, nor published error rate.

54. HARMFUL EFFECTS OF AFFIRMATION TREATMENT — INCLUDING EFFECTS OF PUBERTAL SUPPRESSION TREATMENTS ARE ESTABLISHED and ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY:

"To sum up how puberty suppression works, a thought experiment might be helpful. Imagine two pairs of biologically and psychologically normal identical twins -a pair of boys and a pair of girls -where one child from each pair undergoes puberty suppression and the other twin does not. Doctors begin administering GnRH analogue treatments for the girl at, say, age 8, and for the boy at age 9. Stopping the gonadal hormone pathway of puberty does not stop time, so the puberty-suppressed twins will continue to age and grow -and because adrenal hormones associated with puberty will not be affected, the twins receiving GnRH analogue will even undergo some of the changes associated with puberty, such as the growth of pubic hair. However, there will be major, obvious differences within each set of twins. ***The hormone suppressed twins' reproductive organs will not mature***: the testicles and penis of the boy undergoing puberty suppression will not mature, and the girl undergoing puberty suppression will not menstruate. The boy undergoing puberty suppression will have less muscle mass and narrower shoulders than his twin, while the breasts of the girl undergoing puberty suppression will not develop. The boy and girl undergoing puberty suppression will not have the same adolescent growth spurts as their twins. ***So all told, by the time the untreated twins reach maturity, look like adults, and are biologically capable of having children, the twins undergoing puberty suppression will be several inches shorter, will physically look more androgynous and childlike, and will not be biologically capable of having children***. This is a thought experiment, but it illustrates some of the effects that puberty suppression would

be expected to have on the development of a growing adolescent's body." See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36.

55. METHODOLOGICAL FLAWS IN THE GENDER TRANSTION INDUSTRY—THE ENDOCRINE SOCIETY HAS REPORTED THAT THE QUALITY OF EVIDENCE FOR GENDER DYSPHORIA TREATMENTS IS CURRENTLY ***"LOW OR VERY LOW"*** (Key Quote: ***"ANY estimate of effect is VERY uncertain***") — THUS THERE IS CLEARLY NO GENERAL ACCEPTANCE IN THE RELEVANT SCIENTIFIC COMMUNITY AND THE ERROR RATE IS UNKNOWN and COULD WELL BE VERY HIGH : The Endocrine Society published 2009 clinical guidelines for the treatment of patients with persistent gender dysphoria. See, Hembree, W. C. et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab **94**, 3132-3154, doi:10.1210/jc.2009-0345 (2009). The recommendations include temporary suppression of pubertal development of children with GnRH agonists (hormone blockers normally used for children experiencing precocious puberty) followed by hormonal treatments to induce the development of secondary sexual traits consistent with one's gender identity. In developing these guidelines, the authors assessed the quality of evidence supporting the recommendations made with use of the GRADE (Recommendations, Assessment, Development, and Evaluation) system for rating clinical guidelines. As directly stated in the Endocrine Society publication, ***"the strength of recommendations and the quality of evidence was low or very low."*** According to the GRADE system, low recommendations indicate "Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate." Very low recommendations mean that **"any estimate of effect is very uncertain"**. (See, Guyatt G H,

Oxman A D, Vist G E, Kunz R, Falck-Ytter Y, Alonso-Coello P et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations BMJ 2008; 336 :924 doi:10.1136/bmj.39489.470347.AD). An updated set of guidelines was published in September of 2017. See, Hembree, W. C. et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab, doi:10.1210/jc.2017-01658 (2017). The low quality of evidence presented in this document persists to the current day as ***the controversy over these "treatments" is accelerating in recent years***.

56. METHODOLOGICAL FLAWS IN RESEARCH of the GENDER TRANSITION INDUSTRY—THE WPATH GUIDELINES (7th version) NOTE SERIOUS LIMITATIONS OF THE EXISTING SCIENTIFIC DATA: Clinical Practice Guidelines published by the World Professional Association for Transgender Health (WPATH) - (an advocacy-political, consensus-seeking organization, whose positions are based on voting and not a scientific, evidence-based process) which is currently in its 7th iteration, similarly, though less explicitly, acknowledge the limitation of existing scientific data supporting their recommendations given and "the value of harm-reduction approaches". Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W. J., Monstrey, S., Adler, R. K., Brown, G. R., Devor, A. H., Ehrbar, R., Ettner, R., Eyler, E., Garofalo, R., Karasic, D. H., . . . Zucker, K. (2012). Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *International Journal of Transgenderism, 13*(4), 165–232. https://doi.org/10.1080/15532739.2011.700873

57. INTERVENTIONS ("TREATMENTS") OF CHILDREN WITH POTENTIALLY HARMFUL HORMONES TO INTERVENE IN THE LIFE OF A CHILD WHO IS HIGHLY

LIKELY (80%+) TO RESOLVE THE GENDER DYSPHOTIA ISSUE NATURALLY — IS RISKY, UNSCIENTIFIC and UNETHICAL. IATROGENIC DAMAGES TO PATIENTS — INCLUDING LIFE-LONG STERILITY, STUNTED GROWTH, INCREASED HEART ATTACK RISKS, ETC. — ARE OFTEN IRREVERSIBLE: Treatment of gender dysphoric children who experience persistence of symptoms with hormones (pubertal suppression and cross-hormone therapy) carries significant risk. It is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility and often result in sterility, which in many cases is irreversible. See, Nahata, L., Tishelman, A. C., Caltabellotta, N. M. & Quinn, G. P. Low Fertility Preservation Utilization Among Transgender Youth. Journal of Adolescent Health **61**, 40-44, doi:https://doi.org/10.1016/j.jadohealth.2016.12.012 (2017)). Emerging data also show that treated patients have lower bone density which may lead to increased fracture risk later in life. See, Klink, D., Caris, M., Heijboer, A., van Trotsenburg, M. & Rotteveel, J. Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria. The Journal of Clinical Endocrinology & Metabolism 100, E270-E275, doi:10.1210/jc.2014-2439 (2015)). Other potential adverse effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. See, Seal, L. J. A review of the physical and metabolic effects of cross-sex hormonal therapy in the treatment of gender dysphoria. Annals of Clinical Biochemistry 53, 10-20, doi:10.1177/0004563215587763 (2016); Banks, K., Kyinn, M., Leemaqz, S. Y., Sarkodie, E., Goldstein, D., & Irwig, M. S. (2021). See also, Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. *Hypertension (Dallas, Tex.: 1979)*, HYPERTENSIONAHA12016839. Advance online publication.

https://doi.org/10.1161/HYPERTENSIONAHA.120.16839; Getahun, D., Nash, R., Flanders, W. D., Baird, T. C., Becerra-Culqui, T. A., Cromwell, L., Hunkeler, E., Lash, T. L., Millman, A., Quinn, V. P., Robinson, B., Roblin, D., Silverberg, M. J., Safer, J., Slovis, J., Tangpricha, V., & Goodman, M. (2018). Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study. *Annals of internal medicine*, *169*(4), 205–213. https://doi.org/10.7326/M17-2785; Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643.

58. LONG TERM EFFECTS OF THE CURRENT EXPERIMENTAL "GENDER AFFIRMING" MEDICAL INTERVENTIONS — FOR CHILDREN and ADULTS — ***ARE UNKNOWN and UNPROVEN*** – THIS HAS BEEN WELL KNOWN SINCE 2011 and EARLIER. SUCH TREATMENTS ARE ***NOT*** GENERALLY ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY and HAVE ***NO*** KNOWN NOR PUBLISHED ERROR RATE. CURRENT GENDER TRANSITION INDUSTRY STUDIES OFTEN SUFFER FROM SEVERE METHODOLOGICAL LIMITATIONS: Since strategies for the treatment of transgendered children as summarized by the Endocrine Society guidelines are relatively new, long-term outcomes are unknown. Evidence presented as support for short-term reductions in psychological distress following social transition in a "gender affirming" environment remains inconclusive. When considered apart from advocacy-based agendas, multiple potential confounders are evident. The most notable deficiencies of existing research are the absence of proper control subjects and lack of randomization in study design. See, Hruz, P. W. Deficiencies

in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q* **87**, 34-42, doi:10.1177/0024363919873762 (2020). Although appropriate caution is warranted in extrapolating the outcomes observed from prior studies with current treatments, adults who have undergone social transition with or without surgical modification of external genitalia continue to have ***rates of depression, anxiety, substance abuse and suicide far above the background population***. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

59. MEDICAL TREATMENTS BASED ON PSEUDO-SCIENCE and POLITICAL IDEOLOGIES CONTRARY TO THE RELEVANT-RELIABLE-VALID SCIENCE COULD RESULT IN IRREVERSIBLE HARMS TO MANY PATIENTS WHO WOULD OTHERWISE HAVE RECOVERED NATURALLY FROM GENDER DYSPHORIA: Of particular concern is the likelihood that forced-coerced, or naively requested gender transition "treatments" and social changes could interfere with known very high rates of natural-untreated resolution of sex-gender discordance. Any activity that encourages or perpetuates transgender persistence for those who would otherwise desist could cause significant harm, particularly in light of the current treatment paradigm for persisting individuals. As noted, sterility can often be expected with hormonal or surgical disruption of normal gonadal function. See, Cheng PJ, Pastuszak AW, Myers JB, Goodwin IA, Hotaling JM. Fertility concerns of the transgender patient. Transl Androl Urol. 2019 Jun;8(3):209-218. doi: 10.21037/tau.2019.05.09. PMID: 31380227; PMCID: PMC6626312.

60. YOUNG CHILDREN and PARENTS ARE OFTEN NOT PROPERLY INFORMED or ARE NOT COMPETENT TO GIVE INFORMED CONSENT TO PROCEED WITH EXPERIMENTAL, HAZARDOUS TREATMENTS THAT COULD POTENTIALLY RESULT IN PERMANENT STERILITY: This is a particularly concerning issue given that children are likely to be incapable of giving truly informed consent. See, Geier, C. F. Adolescent cognitive control and reward processing: Implications for risk taking and substance use. Hormones and Behavior 64, 333-342, doi:https://doi.org/10.1016/j.yhbeh.2013.02.008 (2013). This concern remains valid when applied to hormonal or surgical treatments that will result in lifelong sterility. In addition, parents are often manipulated and coerced by misinformed political activists or providers who threaten them with dire warnings that the only two options are "treatment or suicide". These "threats" ignore data that challenge this biased assumption. See, D'Angelo, R., Syrulnik, E., Ayad, S. *et al.* One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. *Arch Sex Behav* **50,** 7–16 (2021). https://doi.org/10.1007/s10508-020-01844-2

61. AN ALTERNATIVE HYPOTHESIS FOR THE RAPID INCREASE IN GENDER DYSPHORIA — SOCIAL CONTAGION PROCESSES — HAS BEEN IMPROPERLY IGNORED BY TRANSGENDER ACTIVISTS and PROVIDERS: Social and psychological support with dignity for adolescents with gender dysphoria does not necessitate acceptance of a unproven, experimental understanding of human sexuality in schools. Rather, policy requirements including social contagion promoting educational processes that can increase the prevalence and persistence of transgender identification have significant potential for inducing long-term harm to affected children.

62. COMPETENT, METHODOLOGICALLY SOUND, LONG-TERM TREATMENT OUTCOME RESEARCH ON GENDER DYSPHORIA INTERVENTIONS HAS NEVER BEEN

DONE: There remains a significant and unmet need to improve our understand of the biological, psychological, and environmental basis for the manifestation of patient reports of discordance of gender identity and biological sex in affected individuals. (Olson-Kennedy, J. et al. Research priorities for gender nonconforming/transgender youth: gender identity development and biopsychosocial outcomes. Current Opinion in Endocrinology, Diabetes and Obesity **23**, 172-179, doi:10.1097/med.0000000000000236 (2016)). In particular, there is a concerning lack of randomized controlled trials comparing outcomes of youth with gender dysphoria who are provided public encouragement for "affirming" social gender transition and how such transitioning affects the usual and natural progression to resolution of gender dysphoria in most affected children. Such studies can be ethically designed and executed with provisions for other dignity affirming measures to both treatment groups. See Sugarman J. Ethics in the design and conduct of clinical trials. Epidemiol Rev. 2002;24(1):54-8. doi: 10.1093/epirev/24.1.54. PMID: 12119856; And https://clinicalcenter.nih.gov/recruit/ethics.html

63. DUE TO THE LACK OF QUALITY, CREDIBLE SUPPORTIVE RESEARCH GENDER AFFIRMING ("TRANSITION") INTERVENTIONS REMAIN EXPERIMENTAL and HIGHLY CONTROVERSIAL – "***GENDER AFFIRMING" USES OF THE RELEVANT HORMONAL MEDICATIONS ARE NOT APPROVED BY THE FDA***: Gender identity is consolidated during puberty and adolescence as young people's bodies become more sexually differentiated and mature. How this normally happens is not well understood, so it is imperative to be cautious about interfering with this complex natural process. Far from being cautious and prudent in using puberty blockers to treat gender dysphoria, too many providers engaged in gender affirming medical interventions are conducting an unethical and risky experiment that does not come close to the ethical standards demanded in other areas of medicine. No one really knows all

the potential consequences of puberty blocking as a treatment for gender dysphoria, but there are some known effects of pubertal suppression on children who are physiologically normal, and these carry long-term health risks. Children placed on puberty blockers have slower rates of growth in height, and an elevated risk of low bone-mineral density. Another possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation. (See, Arain, M., Haque, M., Johal, L., Mathur, P., Nel, W., Rais, A., Sandhu, R., & Sharma, S. (2013). Maturation of the adolescent brain. *Neuropsychiatric disease and treatment*, *9*, 449–461. https://doi.org/10.2147/NDT.S39776). When followed by cross-sex hormones, known and potential effects include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. Tragically, those children who persist in their transgender identity and take puberty blockers and cross-sex hormones are ***expected to become sterile***. Given what we already know about puberty blocking and how much remains unknown, it is not surprising that the use of GnRH analogues for puberty suppression in children with gender dysphoria ***is not FDA-approved.*** The off-label prescription of these drugs is legal ***but unethical*** outside the setting of a carefully controlled and supervised clinical trial. See, Hruz, Mayer, and McHugh, "Growing Pains." Trans activist professionals act as if there is a firm scientific consensus that it is safe and effective to treat gender dysphoria by using GnRH analogues to suppress normal puberty indefinitely. But this is far from the reality, as I, together with Mayer and McHugh, have pointed out: ***"Whether puberty suppression is safe and effective when used for gender dysphoria remains unclear and unsupported by rigorous scientific evidence."*** Thus, is not generally accepted by the relevant scientific community. Instead of regarding puberty blocking as a "prudent and scientifically proven treatment option," courts of law, parents, and the medical community ***should view it as a "drastic and experimental measure.***"

(See, Hruz, Mayer, and McHugh, 2017) The use of any **experimental medical treatment on children** calls for "especially intense scrutiny, since children cannot provide proper legal consent to experimental medical treatments — especially treatments that may **harm natural gender processes and produce sterility**. The rapid acceptance of puberty suppression as a treatment for gender dysphoria with little scientific support or scrutiny should raise concerns about the welfare of the children who receive such treatments. In particular, we should question the claim that it is both physiologically and psychologically "reversible." This includes the alteration of a temporally dependent developmental process. After an extended period of pubertal suppression one cannot "turn back the clock" and reverse changes in the normal coordinated pattern of adolescent psychological development and puberty (See, Hruz, Mayer, and McHugh, "Growing Pains, The New Atlantis: A Journal of Technology and Society, Spring 2017, pg 3-36.) See, also Vijayakumar N, Op de Macks Z, Shirtcliff EA, Pfeifer JH. Puberty and the human brain: Insights into adolescent development. Neurosci Biobehav Rev. 2018 Sep;92:417-436. doi: 10.1016/j.neubiorev.2018.06.004. Epub 2018 Jul 1. PMID: 29972766; PMCID: PMC6234123. ; See also, Choudhury S, Culturing the adolescent brain: what can neuroscience learn from anthropology?, *Social Cognitive and Affective Neuroscience*, Volume 5, Issue 2-3, June/September 2010, Pages 159–167, https://doi.org/10.1093/scan/nsp030

64. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE: The controversies regarding the risks and potential dangers of the transgender industry cannot be silenced by "cancel culture". As Steven Levine, MD of Case Western has noted, "Among psychiatrists and psychotherapists who practice in the area, ***there are currently widely varying views*** concerning both the causes of, and appropriate therapeutic responses to, gender dysphoria in children. Dr Levine went on to state, "***Existing***

studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals." Although political advocates have asserted that the "affirmation therapy" model is accepted and agreed with by the overwhelming majority of mental health professionals, many respected academics and providers in the field strongly disagree. For example, J. Cantor, Ph.D. (McGill) published the following opinion in 2019, "almost all clinics and professional associations in the world" do NOT use "gender affirmation" for prepubescent children and instead "delay any transitions until after the onset of puberty." See, "J. Cantor (2019), Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, J. of Sex& Marital Therapy, 1, DOI: 10.1080.0092623X.2019.1698481.

65. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – NOTE THE ATTACKS ON DR RYAN's BOOK:

In the midst of this ongoing international, raging controversy, transgender and allied political activists have attempted to silence open public debate on the risks and benefits of transgender medical procedures and political ideologies. For example, Ryan Anderson, Ph.D. a policy analyst wrote a book analyzing the scientific and policy issues involved in assessing the risks and benefits of the current practices of the Transgender Treatment Industry. See, Anderson, R., *When Harry Became Sally: Responding to the Transgender Moment*, Encounter Books. Despite widespread scientific interest and positive reviews, the book was banned from sale by the Amazon Corporation. Too many lives are at stake for such blatant suppression of open scientific discussion. Several positive reviews of Dr Ryan's book were posted by ***notable members of the relevant scientific-ethical community*** including: Paul McHugh, MD, University Distinguished Professor of Psychiatry, Johns Hopkins University School of Medicine. (Dr McHugh was trained

at Harvard College and Harvard Medical School. He served as the Chairman of Psychiatry at Johns Hopkins Medical School for decades) and Melissa Moschella, PhD, who served at Columbia University as Director of the Center for Biomedical Ethics in the Department of Medicine and currently at The Catholic University of America. (Dr. Moschella was trained at Harvard College and her PhD is from Princeton University) and Maureen Condic, Associate Professor of Neurobiology and Adjunct Professor of Pediatrics, University of Utah Medical School. (Dr. Condic's training includes a B.A. from the University of Chicago, and a Ph.D. from the University of California, Berkeley) and John Finnes, Ph.D., Professor of Law at Oxford University for 40 years, now Emeritus. (LL.B. from Adelaide University (Australia) and Ph.D. in 1965 from Oxford University as a Rhodes Scholar at University College Oxford.)

International experts from a variety of relevant science - legal - ethical fields consider the issue of proper and harmful transgender treatments ***to be a serious controversy that must not be silenced***. Other scholars in this contentious field have been threatened and/or silenced by the political and ideological allies of the Gender Transition Industry. Consider, for example, the case of Alan Josephson, MD, a distinguished psychiatrist. In the fall of 2017 Dr Josephson appeared on an off campus panel symposium — not affiliated with his university — at the Heritage Foundation and shared his scientific, professional opinions on the experimental medicalization of gender dysphoric youth. The university responded by demoting him and then effectively firing him. Professor Josephson has filed a federal lawsuit to protect this academic rights to free speech. (See, Josephson v. Bendapudi, filed in the U.S. District Court for the Western District of Kentucky). The ongoing attempts to ban books and aggressively silence academic debate or "cancel" professionals with alternative views are clear demonstrations of the ongoing and intense controversies surrounding the Gender Transition Industry. See, Kearns, M., Gender Dissenter Gets

Fired, Jan 12, 2019. "Allan M. Josephson is a distinguished psychiatrist who, since 2003, has transformed the division of child and adolescent psychiatry and psychology at the University of Louisville from a struggling department to a nationally acclaimed program. In the fall of 2017 he appeared on a panel at the Heritage Foundation and shared his professional opinion on the medicalization of gender-confused youth. The university responded by demoting him and then effectively firing him.". Theories in the midst of an international firestorm of controversy are clearly not "generally accepted" by the relevant scientific community.

66. "CANCEL CULTURE" POLITICAL-ACTIVIST ATTEMPTS TO CONTROL THIS DEBATE ARE HARMFUL TO SCIENCE – E.G., ATTACKS ON DR LITTMAN's RESEARCH:

Consider also the example of Dr. Lisa Littman at Brown University. Lisa Littman, M.D., MPA was a researcher at Brown University Medical School. Dr. Littman conducted extensive surveys to assess the experiences of parents involved in an online community for parents of transgender children or "gender skeptical" parents and children. There were 256 completed surveys. Their children were mostly adolescents or young adults. The parents reported that about 80 percent of their (mostly adolescent) children announced their transgender identity "out of the blue" without the long-term history generally associated with gender dysphoria. The parents also reported that transgender identity was linked with mental health issues (an often repeated, reliable finding in multiple studies from multiple nations). The parents also reported that their children's mental health worsened after they came out as transgender as did relationships with family members. The parents also reported a ***decline*** in the children's social adjustment after the announcement (e.g. more isolation, more distrust of non-transgender information sources, etc.).

The publication of the Littman paper was greeted by the outrage of trans activists who denounced the paper and Dr. Littman, calling it "hate speech and transphobic". Brown University had initially produced a press release for the paper stating the Littman research provided bold new insights into transgender issues. Once the political attacks began, the university, removed it from their announcements. Fortunately, in this case, there was also a counter-outcry from scientists, decrying Brown University and the political activists for threatening academic freedom and censoring scientific research that might assist in the treatment of gender dysphoria.

There was also reportedly an academic petition signed by members of the relevant scientific community. For example, Lee Jussim, PhD., Chair of the Psychology Department at Rutgers University wrote, "If the Littman study is wrong, let someone produce evidence that it is wrong. Until that time, if the research p*sses some people off, who cares? Galileo and Darwin p*ssed people off too. Brown University should be ashamed of itself for caving to sociopolitical pressure. Science denial, anyone?" Similarly, Richard B. Krueger, MD (a Harvard Medical School graduate) of Columbia University College of Physicians and Surgeons, board certified psychiatrist specializing in the treatment of sexual disorders wrote, "Brown University's actions in its failure to support Dr. Littman's peer reviewed research are abhorrent". Similarly, Nicholas Wolfinger, PhD (UC Berkeley, UCLA), currently Professor of Family and Consumer Studies at the University of Utah wrote: "The well-being of trans youth and other sexual minorities is best served by more research, not less".

The onslaught of attacks resulted in the journal asking Dr. Littman to publish a "corrected" version of the paper. After careful review, the paper was again published with additional information but no methodological nor data corrections – as no such errors were found. See, https://www.psychologytoday.com/us/blog/rabble-rouser/201903/rapid-onset-gender-dysphoria.

See also, Littman, L. , Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, PLOS ONE March 19, 2019, https://doi.org/10.1371/journal.pone.0214157. Dr. Littman's paper was a key initial step in the alternative investigative hypothesis that the very recent and enormous increase in teenage girls seeking "gender transitioning" is due to a social contagion process at school, in peer groups, and on the internet. This theory has yet to be tested in detail.

67. UNDERLYING PATIENT BIOLOGY IS NOT CHANGED BY ALTERING BODILY FEATURES TO "PASS" AS THE OPPOSITE SEX NOR DO SUCH ALTERATIONS CHANGE BIOLOGICAL DISEASE VULNERABILITIES ASSOCIATED WITH GENETICALLY-DEFINED SEX: Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by genetic makeup, normatively by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally-defined sex. (See "Institute of Medicine (US) Committee on Understanding the Biology of Sex and Gender Differences. Exploring the Biological Contributions to Human Health: Does Sex Matter?" Wizemann TM, Pardue ML, editors. Washington (DC): National Academies Press (US); 2001. PMID: 25057540.) For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the individual with sex-discordant gender identity to become "a complete man" or "a complete woman," this is not biologically attainable. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with limitations, costs, and risks, as I

detail later. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ("Informed Consent"); S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. Am. Acad Psychiatry Law 44, 236 at 238 ("Reflections").

68. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ONE OF THE MOST CONTROVERSIAL AND CONTENTIOUS ISSUES IN TRANSGENDER SCIENCE IS THE RECENT EPIDEMIC OF ADOLESCENT FEMALE TO MALE GENDER DISCORDANT PATIENTS:

How prevalent is the Sudden Onset Gender Dysphoria Epidemic in Teen Girls first described by the research of Dr Littman at Brown University?

In Great Britain, centralized medical care provides data to track health care phenomenon ... *the number of adolescent girls seeking sex transitioning exploded over FOUR THOUSAND 4,000% in the last decade.* Similarly, in America, where we lack the same kinds of centralized health care data, it has been reported that in 2018 2% (2 in 100) of high school students identified on surveys as "transgender" — this is 200 times greater response — a 20,000% increase — over reports during past decades which showed a rate of only .01 percent (one in 10,000 people). See, Johns MM, Lowry R, Andrzejewski J, et al. Transgender Identity and Experiences of Violence Victimization, Substance Use, Suicide Risk, and Sexual Risk Behaviors Among High School Students — 19 States and Large Urban School Districts, 2017. MMWR Morb Mortal Wkly Rep 2019;68:67–71.

Along with this increase in transgender patients and identifiers, has come ***a radical and recent transformation of the patient population*** from early onset males to rapid onset adolescent girls. Thus currently the majority of new patients with sex-gender discordance are not males with

a long, stable history of gender dysphoria since early childhood —as they were for decades — but instead adolescent females with no documented long-term history of gender dysphoria — thus they experienced "rapid onset" transgender identification. Whole groups of female friends in colleges, high schools, and even middle schools across the country are reportedly coming out together in peer group clusters as "transgender." These are girls who — by detailed parental reports and self-reports — had never experienced any discomfort in their biological sex until they heard a coming-out story from a speaker at a school assembly or discovered the internet (YouTube) community of trans "influencer video stars."

This extraordinary change in new patient demographics appears more consistent with a theory of social contagion than of "immutable identification", "brain structures", "genetics", or other biological hypotheses. Many unsuspecting parents, whose children have never shown any signs for gender discordant feelings or ideas, are awakening to find their daughters in thrall to hip trans YouTube stars and "gender-affirming" educators and activist therapists who push life-changing interventions on these young girls—including double mastectomies and hormonal puberty blockers that can potentially cause permanent infertility. See, Littman L. Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. PLoS One. 2018 Aug 16;13(8):e0202330. doi: 10.1371/journal.pone.0202330. Erratum in: PLoS One. 2019 Mar 19;14(3):e0214157. PMID: 30114286; PMCID: PMC6095578.

69. EXPLORING ALTERNATIVE HYPOTHESES: WHY ARE WE SEEING A RAPID RISE OF ADOLESCENT FEMALE TRANS IDENTITY PATIENTS… often in social clusters?

Generating, Considering, and Testing Alternative Theories prevents the Methodological Error of Confirmation Bias:

We should consider the genetics theory of transgender identity. But his theory cannot explain the rapid expansion of new GD (an 4,000% to 20,000% increase?) cases as our genome is simply not changing that fast.

We should consider the "brain structures" theory of transgender identity. Yet there is only weak medical evidence to support this theory and the theory cannot explain the rapid expansion of new gender dysphoria cases as brain structures are not changing that fast.

We should consider the theory that increased social acceptance of the transgender lifestyle is leading many people who were transgender all along to come out. Yet this theory fails to explain why *males and older women are not coming out in the same huge numbers* and not coming out in "social peer group clusters" as adolescent females are reportedly doing.

We should consider the "immutable gender identity" theory. Yet this theory fails to explain the rapid expansion of patients. In addition, the "immutable" theory fails to explain the rapid expansion of "Rapid Onset Gender Dysphoria" reports — newly "trans" adolescent girl patients who reportedly showed no indication of gender dysphoria previously.

Having considered alternative theories -- to avoid confirmation bias – it appears that another alternative theory might well be the most applicable, rational theory to explain the extreme, recent increases in the GD patient population. This is the Social Contagion hypothesis. Social contagion effects are also reportedly responsible for the massive, rapid increase in "recovered repressed memory" cases and also the extraordinary expansion of "multiple personality disorder" cases in the 1990s. I also note the alternative investigative hypothesis that ***social contagion effects would appear to be psychological/psychiatric problems and NOT physical medical problems requiring hormonal or surgical "treatments"***.

70. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: ADOLESCENT FEMALE PSYCHOLOGY RESEARCH SHOWS WELL-DOCUMENTED PEER INFLUENCES on ANOREXIA, BULIMIA, DRUG ABUSE, and now GENDER DISCORDANT ("TRANSGENDER") SYMPTOMS:

The Social Contagion theory for the large increase in reported Rapid Onset Gender Dysphoria in adolescent girls appears to be the most rational explanation for the reportedly dramatic (rapid, media related, hundreds of times increase, YouTube influenced, Peer Group influenced) explosion of Gender Discordant ("transgender") patients among adolescent female friend groups.

Adolescent female social contagion effects in psychiatric illness are well-known and well documented. Consider, for example, Bulimia and Anorexia — both of which spread rapidly in adolescent female friend groups. See, Allison S, Warin M, Bastiampillai T. Anorexia nervosa and social contagion: clinical implications. Aust N Z J Psychiatry. 2014 Feb;48(2):116-20. doi: 10.1177/0004867413502092. Epub 2013 Aug 22. PMID: 23969627.

It has been known for decades that adolescent females are highly prone to social contagion effects spreading psychiatric symptoms — e.g. Anorexia, Bulimia, Drug Abuse, etc) are well known to be subject to "cluster" and "friendship" contagions as teens girls (and especially troubled teen girls) co-ruminate and share feelings at very high rates and with emotional depth. See, e.g., Crandall CS. Social contagion of binge eating. J Pers Soc Psychol. 1988 Oct;55(4):588-98. doi: 10.1037//0022-3514.55.4.588. PMID: 3193348.

For example, Prof. Amanda Rose at the University of Missouri has conducted research to understand why adolescent girls show such susceptibility to social contagion with psychiatric symptoms — "Teenage girls share symptoms via social contagions because their friendship

processes involve "co-rumination", that is, taking on the emotional pain and concerns of their friends." See, R. Schwatz-Mette and A. Rose, Co-Rumination Mediates Contagion of Internalizing Symptoms Within Youths 'Friendships, Developmental Psychology 48(5):1355-65, February 2012, DOI: 10.1037/a0027484 Developmental Psychology, Vol. 48, No. 5, 1355–1365 0012-1649/12/$12.00 DOI: 10.1037/a0027484. This could be one explanation for why we are hearing increasing reports of" clusters" and "friend groups" of teen girls who are adopting a "transgender identity" and "transitioning" as friends together.

71. INVESTIGATING ALTERNATIVE HYPOTHESES: THE SOCIAL CONTAGION THEORY: SCHOOL ENVIRONMENT SOCIAL CONTAGION: Observers including journalists have reported that schools in America — 1st grade through College — during the past few years have been aggressively teaching that a "non-binary" identity is the real "norm" and far better than traditional gender roles. Such school programs present Male and Female roles in a very rigid, highly stereotyped manner then teach children (even 1st graders) that if they do or feel anything different than narrow binary sex roles (girls enjoying football, boys enjoying art) they are surely "non-binary" and should receive much social support, reinforcement, and encouragement for "transitioning".

The rapid and historic transformation of the Gender Transition Industry patient pool has been widely noted by researchers, journalists, and providers. This transformation from early onset, chronically dysphoric male patients to rapid onset adolescent female patients has occurred in just the last few years. The patient transformation from 3 to 1 males (for decades) to 7 to 1 females (just in the last few years) is not easily explained by any of the Gender Transition Industry theories such as "genetics" or "brain structures" or the mysterious and tautalogical "immutable characteristics" theory. It has been reported that during this enormous increase in "Rapid Onset

Gender Dysphoria" a growing set of YouTube Transgender "influencers" teach and entertain millions of followers daily as they aggressively sell gender transitioning as a quick and effective cure for Depression, Anxiety, Loneliness, and confusion about life.

For example, journalist Abigail Shrier's book, *Irreversible Damage* about the social contagion theory of why patient demographics changed so very rapidly and expansively. Shrier's book was reportedly named a "Book of the Year" by The Economist and "one the Best Books of 2021" by The Times (of London) and The Sunday Times (of London). Many famed scientists of various fields have praised Shrier's work in highlighting A) the lack of competent scientific research supporting "gender affirmation" interventions and B) the political contamination including censorship and "cancel culture" attacks on academics that make gender affirmation investigation ("transgender science") such a controversial field. For example, several highly credible and deeply respected members of the relevant scientific and public policy-ethics communities have reportedly posted positive reviews of Shrier's analysis on the Amazon bookseller site including:

"In *Irreversible Damage*, Abigail Shrier provides a thought-provoking examination of a new clinical phenomenon mainly affecting adolescent females—what some have termed rapid-onset gender dysphoria—that has, at lightning speed, swept across North America and parts of Western Europe and Scandinavia. In so doing, Shrier does not shy away from the politics that pervade the field of gender dysphoria. It is a book that will be of great interest to parents, the general public, and mental health clinicians."— Kenneth J. Zucker, Ph.D., adolescent and child psychologist, multi-publication scientist in this field, and *Chair* of the American Psychiatric Association DSM-5 Work Group on Sexual and Gender Identity Disorders.

Similarly, "Abigail Shrier's book is thoroughly researched and beautifully written." —**Ray Blanchard, Ph.D.,** head of Clinical Sexology Services at the Centre for Addiction and Mental Health from 1995–2010.

Similarly, "For no other topic have science and conventional wisdom changed—been thrown away—more rapidly than for gender dysphoria. For a small but rapidly growing number of adolescent girls and their families, consequences have been tragic. This urgently needed book is fascinating, wrenching, and wise. Unlike so many of the currently woke, Abigail Shrier sees clearly what is in front of our faces and is brave enough to name it. Irreversible Damage will be a rallying point to reversing the damage being done." —**J. Michael Bailey**, Ph.D. professor of psychology at Northwestern University. All quotes from the Amazon bookseller site at https://www.amazon.com/Irreversible-Damage-Transgender-Seducing-Daughters/dp/1684510317 These quotes are offered to demonstrate the breadth and depth and international scope of the raging controversies regarding the Transgender Treatment Industry.

72. THE SOCIAL CONTAGION HYPOTHESIS - IDENTITY POLITICAL IDEOLOGY PROVIDES SOCIAL SUPPORT REWARDS FOR ADOLESCENTS TO ADOPT A GENDER DISCORDANT IDENTIFY ("TRANSGENDER"): Journalists have reported, "In many high schools, there is an "identity politics" victims sweepstakes where white middle and upper middle class girls are simply left out of any coveted "oppressed victim" status groups — thus the decision to become "transgender" brings instant social support and acclaim from teachers and coaches for their courage in coming out." Nobody questions such personal transformation, even if the teen is deeply troubled, and even if the teen has no history of gender dysphoria. To even ask questions or explore alternative explanations could get the teacher, counselor, therapist, or physician labelled as a "conversion therapist" and cancelled.

73. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: "CANCEL CULTURE" and IDEOLOGICAL-POLITICAL PRESSURE SEEKS TO INSTITUTIONALIZE THE SYSTEMATIC NEGLIGENCE and METHODOLOGICAL ERROR OF CONFIRMATION BIAS: Because of the efforts of apparently science illiterate and/or gullible legal and medical professionals and the intense activity of political trans activists — health providers (in many fields) are now NOT permitted to openly asks questions, properly investigate alternative diagnoses, or explore alternative hypotheses for the symptoms of Gender Dysphoria patients. They are compelled (sometimes under fear of employment termination or legal attacks) to adopt a patient's self-diagnosis and only support "transgender affirming" medical interventions. These providers are thus being pressured and/or compelled to commit the scientific and medical malpractice of Confirmation Bias. (See, detailed discussion above on confirmation bias.) Unexamined transgender affirming medical interventions — based on uncorroborated patient self-reports, assessed by mental health professionals with no methodology for discerning true from false patient reports, with no ability to decipher accurate from contaminated "memories", with no alternative treatments offered, and no alternative explanations (social contagion) explored — may thus be viewed as engaged in medical, psychological, surgical, and endocrinological negligence and a violation of the most basic, essential scientific and medical practices and methods requiring the generation and testing of alternative hypotheses. In sum, such a politically tainted system actually requires "confirmation bias" — one of the most serious of all methodological diagnostic failures. See, e.g. Mendel, R. et. al., Confirmation bias: why psychiatrists stick to wrong preliminary diagnoses, Psychological Medicine, Oxford University Press, 20 May 2011. ["*Diagnostic errors can have tremendous consequences because they can result in a fatal chain of wrong decisions*. Experts assume that physicians' desire to confirm a preliminary diagnosis

while *failing to seek contradictory evidence* is an important reason for wrong diagnoses. *This tendency is called 'confirmation bias'.*]; See also, Doherty, T.S. and Carroll, A.E., Believing in Overcoming Cognitive Biases, American Medical Association Journal of Ethics, 2020;22(9):E773-778. ["Like all humans, *health professionals are subject to cognitive biases* that can render diagnoses and treatment decisions vulnerable to error. Learning effective debiasing strategies and cultivating awareness of confirmation, anchoring, and outcomes biases and the affect heuristic, among others, and their effects on clinical decision making *should be prioritized in all stages of medical education*…. ***Confirmation bias is the selective gathering and interpretation of evidence consistent with current beliefs and the neglect of evidence that contradicts them***….]; See also, Hershberger PJ, Part HM, Markert RJ, Cohen SM, Finger WW. Teaching awareness of cognitive bias in medical decision making. *Acad Med*. 1995;70(8):661.

74. ALTERNATIVE INVESTIGATIONAL HYPOTHESES: GIVEN THE CURRENT LACK OF RELIABLE-VALID RESEARCH SUPPORT, IT IS A RECKLESS and EXPERIMENTAL INTERVENTION TO PERMIT CHILDREN TO ENGAGE IN SELF-DIAGNOSIS WHEN THE RESULTING "TREATMENTS" WILL LIKELY PRODUCE LIFE-LONG STERILIZATION and/or OTHER PERMANANT INJURIES TO NORMAL, HEALTHY ORGANS : In some jurisdictions in America now child or adolescent patients can — without parental permission or even parental notification -- receive hormones to begin the experimental treatment of "transitioning" with no competent diagnostic investigation or professional assessment of "Gender Dysphoria" and no competent medical investigation-testing-consideration of alternative hypotheses (there is no such reliable, objective assessment). Worst of all, providers can be coerced by law, collegial pressures, or "cancel culture" ideology to comply with the troubled child's/teen's/patient's amateur (potentially YouTube influenced) self-diagnosis or be faced with

potentially career ending allegations of "conversion therapy". Politically tainted, pseudo-science, experimental, unproven medical practices have caused grave harm to millions in the past (See the discussion of lobotomies, repressed memory therapy, multiple personality therapy, rebirthing therapy, etc above.) and unethical, politically driven, experimental medical errors should not be repeated today.

75. EXPERIMENTATION on SEX-GENDER DISCORDANT PATIENTS IS ESPECIALLY LIKELY TO CAUSE HARM TO MINORITY PATIENTS FROM HISTORICALLY MARGINALIZED COMMUNITIES — The development of effective strategies to impact long-term physical and psychological health in patients who experience sex-discordant gender identity should be undertaken with recognition of the disproportionate burden of this condition in a number of vulnerable minority populations of children. These include:

-- children with a prior history of psychiatric illness (See, e.g. Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and adolescent psychiatry and mental health*, *9*, 9. https://doi.org/10.1186/s13034-015-0042-y

-- children of color (See, e.g., G. Rider et al. (2018), Health and Care Utilization of Transgender/Gender Non-Conforming Youth: A Population Based Study, Pediatrics at 4, DOI: 10.1542/peds.2017-1683.

-- children with mental developmental disabilities (See, e.g. Bedard, C., Zhang, H.L. & Zucker, K.J. Gender Identity and Sexual Orientation in People with Developmental Disabilities. *Sex Disabil* **28,** 165–175 (2010). https://doi.org/10.1007/s11195-010-9155-7

- children on the autistic spectrum (See, e.g., de Vries, A. L., Noens, I. L., Cohen-Kettenis, P. T., van Berckelaer-Onnes, I. A. & Doreleijers, T. A. Autism spectrum disorders in gender

dysphoric children and adolescents. *J Autism Dev Disord* **40**, 930-936, doi:10.1007/s10803-010-0935-9 (2010).

-- children residing in foster care homes and adopted children (See, e.g. See e.g., D. Shumer et al. (2017), Overrepresentation of Adopted Adolescents at a Hospital-Based Gender Dysphoria Clinic, Transgender Health Vol. 2(1).

76. GENDER DYSPHORIA IS A VERY RARE PSYCHIATRIC CONDITION – THAT IS, RARE IN THAT IT IS TREATED WITH SURGERY THAT DAMAGES or DESTROYS WELL-FUNCTIONING, HEALTHY BODILY ORGANS LEADING TO LOSS OF ESSENTIAL BODILY FUNCTIONS (e.g. ***Medically Induced Sterilization***): Despite the fact that gender dysphoria represents a psychological condition (as catalogued in the DSM since the third edition of this publication), some conceptualize the condition as a medical illness similar to cancer. When considered from this viewpoint, the goal of "treatment" is to alter the appearance of the body to conform to a patient's perceived sexual identity, including the physical removal of unwanted "diseased" sexual organs. Since undesired body parts are fully formed and functional prior to hormonal or surgical intervention, the result of these "therapies" is injury to innate sexual ability. In particular, loss or alteration of primary sexual organs leads directly to impairment of reproductive potential. Recognition of this obvious consequence is the basis for the development of new arenas of medical practice where there is an attempt to restore what has been intentionally destroyed. See, e.g., Ainsworth AJ, Allyse M, Khan Z. Fertility Preservation for Transgender Individuals: A Review. Mayo Clin Proc. 2020 Apr; 95(4):784-792. doi: 10.1016/j.mayocp.2019.10.040. Epub 2020 Feb 27. PMID: 32115195. As correctly noted by Levine, gender dysphoria is unique in that it is "the only psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified

biological abnormality". See, e.g., S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law, 44, 236 at 238 ("Reflections"), at 240.)

77. A MULTI-DISCIPLINARY, COMPLEX, DEVELOPMENTAL MODEL PROVIDES ESSENTIAL ALTERNATIVE HYPOTHESES TO THE SIMPLE, UNEXAMINED "AFFIRMATON" TRANSITIONING MODEL OF TRANS ACTIVIST PROFESSIONALS and the GENDER TRANSTION INDUSTRY: The diagnosis of "gender dysphoria" encompasses a diverse array of conditions. While the etiologic contributors to sex discordant gender identity remain to be fully identified and characterized, differences both in kind and degree within individuals and across varied populations creates challenges in establishing specific approaches to alleviate associated suffering. For example, data from adults cannot be assumed to apply equally to children. Nor can data from children who present with sex discordant gender pre-pubertally be presumed to apply to the growing number of post-pubertal adolescent females presenting with this condition. Steven Levine, MD (Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine and Founder and Co-Director of the Case Western Reserve University Gender Identity Clinic) has described the developmental model — an alternative hypothesis of gender dysphoria conceptualization and treatment that is more in keeping with the known science and involves reduced costs and lowered risk of permanent physical harm (e.g., medically induced sterilization) to patients. Dr. Levine has written, "Gender dysphoria can be alternatively conceptualized in developmental terms, as an adaptation to a psychological problem that was first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans lives are not exceptions to this axiom. (See, e.g., S. Levine (2016),

Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy of Psychiatry and Law 44, 236 at 238). Mental Health Professionals (MHPs) who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self, and also to ameliorate suffering when the underlying problem cannot be solved. They work with the patient and (ideally) family to inquire what forces may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the fact that young children work out their psychological issues through fantasy and play." (See, Expert Report by Steven Levine, MD). A recent study documented "clustering" of new presentations in specific schools and among specific friend (peer) groups, pointing to social influences (See, the Littman study at Brown University discussed above). Both of these findings strongly suggest cultural factors. From the beginning of epidemiological research into this arena, there have always been some countries, Poland and Australia, for example, ***where the patient sex ratios were reversed*** as compared to North America and Europe, again demonstrating ***a powerful effect of cultural influences (e.g. social contagion)***. See, S. Levine (2018), Informed Consent for Transgendered Patients, J. of Sex & Marital Therapy, at 6, DOI: 10.1080/0092623X.2018.1518885 ; S. Levine (2016), Reflections on the Legal Battles Over Prisoners with Gender Dysphoria, J. American Academy Psychiatry and Law, 44, 236 at 238.

78. NO COMPETENT, SCIENTIFICALLY VALID-RELIABLE COST-BENEFIT ANALYSIS HAS BEEN DONE ON GENDER DISCORDANT "TRANSGENDER" TREATMENTS — When the FDA tests a drug, the safety analysis looks at all related risks. Specifically, the drug (treatment) must not only be effective, but it must not cause side effects that are more damaging than the proposed treatment. This is one of the key weaknesses of the Gender

Transition Industry. Not only have the treatments NOT been proven reliably effective compared in NO treatment, but the "transgender transitioning" interventions "treatments" are *DESIGNED with existing knowledge of well-documented, long-term health problems and damages* (e.g., testosterone use by transgender men increases the risk of fatal heart disease, estrogen use by transgender women increases risk of blood clots and strokes, Gender Transition Industry treatments — if completed — can cause life-long sterility, etc.).

79. LACK OF INTEGRATION OF CARE BY PROVIDERS IN THE GENDER TRANSITION INDUSTRY INCREASES DANGERS TO PATIENTS: It is too often the case in the Gender Transition Industry that "nobody is in charge" of a patient's care. The mental health professionals know little about the risks of surgery and the surgeons know little about the defects in mental health methodologies and the endocrinologists are only following the hormonal treatments and many are not aware of the serious methodological research defects in this field. Such disjointed care can increase dangers to patients. On cases showing such a lack of integration and uncertain chain of command in Gender Transition Industry healthcare cases, reliable measurements of the divergent, multi-disciplinary risks to patients of Gender Transition Industry treatments (e.g. hormones, incomplete therapy, or surgical side effects) are precluded and too often ignored. The Plaintiffs' expert witness reports in this case appear to ignore this issue.

80. ADDITIONAL OPINIONS TO BE DISCUSSED AT DEPOSITION OR TRIAL: There are additional relevant data and important considerations regarding existing understanding of the role of physicians and other healthcare workers in alleviating suffering in patients who experience gender dysphoria due to sex-gender identity discordance that are not fully discussed in this report. This includes:

-- the inherent complexity of human psychological and physical development from birth to adulthood

-- the relationship and differences between puberty and adolescence

-- the molecular mechanisms of steroid hormone action in regulating cellular gene expression

-- the physiology of sexual function including the hypothalamic-pituitary-gonadal axis in males and females and diseases that are associated with dysfunction of these processes

-- the expansive and growing field of sex-specific personalized medicine in relation to human health

-- the historical development and use of the scientific method (e.g. principles of hypothesis generation, testing of the null hypothesis, fundamentals of statistical analyses, differences between statistical and clinical significance)

-- the design and conduct of human clinical trials

-- the proper role of institutional review boards in the approval and supervision of clinical trials to mitigate risk

-- the National Institutes of Health (NIH) processes for establishment of research priorities (e.g. research funding announcements), procedures for scientists to apply for grant funding, peer review of research proposals, requirements for examining sex as a biological variable, safety monitoring, and requirements for sharing study results

-- the process for gaining FDA approval for new medications and new medical indications for existing medications including objective assessment of relative risk versus benefit as demonstrated from properly controlled clinical trials

These topics will be discussed, as needed, at deposition and trial to provide the court with the necessary scientific and medical information for proper litigation of this case.

81. NOTES: GENDER TRANSITION RESEARCH SHOWING METHODOLOGICAL DEFECTS, ERRORS, and the UNETHICAL MISREPORTING OF RESULTS.

In sum, THE GENDER TRANSITION INDUSTRY APPEARS TO HAVE IMPLODED IN RECENT YEARS as the relevant scientific community exposed the serious methodological and ethical errors in this highly controversial industry.

DR HRUZ's NOTES ON RESEARCH EVALUATIONS and METHODOLOGICAL ANALYSES:

TIMELINE NOTES DOCUMENT THE LOW QUALITY EVIDENCE FOR THE GENDER TRANSITION INDUSTRY'S EXPERIMENTAL TREATMENTS FOR DECADES FOLLOWED BY THE PUBLIC EXPOSURE of DEFECTS and MISCONDUCT and IMPLOSION OF THE GENDER TRANSITION INDUSTRY IN 2020-2021:

2016 - OLSON-KENNEDY ET AL - "CLINICALLY USEFUL TO PREDICT OUTCOMES IS LACKING" … "EXTENSIVE RESEARCH IS NEEDED" … GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH ARE BEING EXPOSED **See,** GROSS METHODOLOGICAL DEFECTS IN "TRANSGENDER" RESEARCH HAVE BEEN EXPOSED IN PUBLIC VENUES - Olson-Kennedy, J, et. al. listed a number of the serious defects in our current understanding of transgender patients. She noted:

—" ***Clinically useful information for predicting individual psychosexual development pathways is lacking.***" [Note: We can't predict outcomes because we don't understand the processes — thus "affirming" treatments are experimental].

— "Transgender youth are at high risk for poor medical and psychosocial outcomes." [Note: But we don't know why] …

— "Longitudinal data examining the impact of early social transition and medical interventions ***are sparse.***" [Note: Thus we don't know how to treat such patients.]

— "Existing tools to understand gender identity and quantify gender dysphoria ***need to be reconfigured*** to study a more diverse cohort of transgender individuals." [Note: For decades patients were uniformly males with early childhood onset, now most new patients are females with rapid onset in adolescence —are these even the same patient groups?].

Shared goals ***requiring much more research***: "Extensive research is needed to improve understanding of gender dysphoria, and transgender experience, particularly among youth. Recommendations include identification of predictors of persistence of gender dysphoria from childhood into adolescence [**the key research hasn't been done yet**], and a thorough investigation into the impact of interventions for transgender youth. **[the key research hasn't been done yet]** Finally, *examining the social environments of transgender youth is critical for the development of appropriate interventions necessary to improve the lives of transgender people*. [This kind of multi-disciplinary research, analysis of alternative hypotheses, and treatments for concomitant psychiatric-psychological symptoms is being tragically mislabeled and blocked as "conversion therapy" by political advocates.]

See, Olson-Kennedy, J, Cohen-Kettenis, P., et al., Research priorities for gender nonconforming/transgender youth gender identity development and biopsychosocial outcomes, Current Opinion in Endocrinology & Diabetes and Obesity: April 2016 - Volume 23 - Issue 2 - p 172-179, doi: 10.1097/MED.0000000000000236 [Note: Should compare once again the demonstrated ***lack of***

methodologically sound scientific support for the still-experimental gender affirmation "trans" interventions and the many unresearched missing questions in our understanding of these complex patients to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2016 - See, **Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58–69**.) **Activists and too many providers have used a fear of suicide *to push experimental unproven treatments*.** Activists and too many providers have attempted to manipulate parents and patients with the fearful maxim 'better a live daughter than a dead son'. In addition, parents, teachers and doctors are encouraged to affirm unquestioningly the alternative gender for fear of the implied consequences. ***There is a danger that poor-quality data are being used to support gender affirmation and transition without the strength of evidence that would normally determine pathways of care. A 20-year Swedish longitudinal cohort study showed persisting high levels of psychiatric morbidity, suicidal acts and completed suicide many years AFTER medical transition*.** **(**See also, Dhejne C, Lichtenstein P, Boman M, Johansson ALV, Långström N, Landén M. Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. Scott J, editor. **) PLoS ONE 2011; 6(2): e16885.** "***Such results are not reassuring*** and might suggest that more complex (untreated) intrapsychic conflicts remain, unresolved by living as the opposite sex."

2017 - LONG TERM STUDIES OF GENDER TRANSITION TREATMENT EFFECTS SHOW PERSISTENT PSYCHOLOGICAL-PSYCHIATRIC MORBIDITY INCLUDING ***HIGHER RISK OF SERIOUS SUICIDE ATTEMPTS*** AFTER TRANSITIONING TREATMENTS: Evidence often cited to support societal measures that promote or encourage gender transition, including the Plaintiffs' demand for use of multi-user sex-segregated restrooms corresponding with the Plaintiffs' gender identity, as a medically necessary treatment for gender dysphoria is limited. Recent studies reporting reductions in dysphoria following social transition of adolescent patients are small, poorly controlled and of insufficient duration to draw definitive conclusions regarding long-term efficacy. ***Long-term follow up of patients with gender dysphoria who have undergone social and hormonal transition with or without surgical intervention has shown persistent psychological morbidity far above non-transgendered individuals with suicide attempts 7-fold and completed suicides19-fold above the general population – AFTER "transition" interventions***. See, Adams, N., Hitomi, M. & Moody, C. Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature. Transgend Health 2, 60-75, doi:10.1089/trgh.2016.0036 (2017); See also, Dhejne, C. et al. Long-term Follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 6, e16885, doi:10.1371/journal.pone.0016885 (2011)).

2019 — SWEDEN NATIONAL REVIEW = GENDER AFFIRMATION STILL EXPERIMENTAL = NO RANDOMIZED TRIALS: results. See, Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 (https://www.sbu.se/307e **)**

SWEDISH REVIEW —"*No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."*

"This report was commissioned by the Swedish government and is a scoping review of the literature on gender dysphoria in children and adolescents. The report can be a basis for further evaluation of risk of bias and evidence.

Conclusions:

— We have *not found any scientific studies which explains the increase in incidence in children and adolescents who seek the heath care because of gender dysphoria*

— We have *not found any studies on changes in prevalence of gender dysphoria over calendar time, nor any studies on factors that can affect the societal acceptance of seeking for gender dysphoria*.

— There are few studies on gender affirming surgery in general in children and adolescents and only single studies on gender affirming genital surgery.

— *Studies on long-term effects of gender affirming treatment in children and adolescents are few, especially for the groups that have appeared during the recent decennium*.

— The scientific activity in the field seems high. A large part of the identified studies are published during 2018 and 2019.

— Almost all identified studies are observational, some with controls and some with evaluation before and after gender affirming treatment. *No relevant randomized controlled trials in children and adolescents were found.*

We have not found any composed national information from Sweden on: – the proportion of those who seek health care for gender dysphoria that get a formal diagnosis NOR – the proportion starting endocrine treatment to delay puberty NOR – the proportion starting gender affirming hormonal treatment NOR – the proportion subjected to different gender affirming surgery."

2016-2017 London GIDS Study
NO *evidence that hormones or surgery improve long-term psychological well-being*.
See, "GIDS referrals figures for 2016/17, Gender Identity Development Service, GIDS.NHS.uk (undated), http://gids.nhs.uk/sites/default/files/content uploads/referral-figures-2016-17.pdf

2017 - ENDOCRINE SOCIETY REVIEWS - ONLY *WEAK EVIDENCE* SUPPORTS GENDER TRANSITION INTERVENTIONS: Two systematic reviews commissioned by the US-based Endocrine Society in 2009 and 2017 concur with the finding of a ***the weak evidence base***, stating that ***the finding of benefits of hormonal interventions in terms of "psychological functioning and overall quality of life" comes from "low-quality evidence*** (i.e., which translates into ***low confidence in the balance of risk and benefits***)."

MISCONDUCT by the Endocrine Society: Despite this sober assessment, the Endocrine Society instructed clinicians to proceed with treating gender-dysphoric youth with hormonal interventions in its guidelines, which have now been broadly adopted by a number of medical societies. See, Transgender Health: An Endocrine Society Position Statement. December 15, 2020. Accessed January 6, 2021.https://www.endocrine.org/advocacy/position-statements/transgender-health

2017 - GENDER TRANSITION INTERVENTIONS REMAIN *EXPERIMENTAL* = The Society for Science Based Gender Medicine (SEGM)'s review, ***the "low confidence in the balance of risks and benefits" of hormonal interventions calls for extreme caution*** when working with gender-dysphoric youth, who are in the midst of a developmentally-appropriate phase of identity exploration and consolidation. While there may be short-term psychological benefits associated with the administration of hormonal interventions to youth, they must be weighed against the long-term risks to bone health, fertility, and other as yet-unknown risks of life-long hormonal supplementation.

Further, the irreversible nature of the effects of cross-sex hormones, and the potential for puberty blockers to alter the natural course of identity formation should give pause to all ethical clinicians. Studies consistently show that ***the vast majority of patients with childhood-onset gender distress who are not treated with "gender-affirmative" social transition or medical interventions grow up to be LGB adults.*** However, there is emerging evidence that socially-transitioned and puberty-suppressed children have much higher rates of persistence of transgender identification, necessitating future invasive and risky treatments. The trajectory of the novel, and currently the most common presentation of gender dysphoria, which emerges for the first time in adolescence following a gender-normative childhood is unknown, but the increasing voices of desisters and detransitioners suggest the rate of regret within this novel cohort will not be as rare as previously estimated.

It is The Society for Science Based Gender Medicine (SEGM)'s position that the significant uncertainties regarding the long-term risk/benefit profile of "gender-affirmative" hormonal

interventions call for noninvasive approaches (e.g. psychotherapy, social support, coping and resilience training, etc) as the first line of treatment for youth. If pursued, invasive and potentially irreversible interventions for youth ***should only be administered in clinical trial settings with rigorous study designs capable of determining whether these interventions are beneficial***.

In addition to undergoing ***rigorous psychological and psychiatric evaluations***, patients and their families should participate in a ***valid informed consent process.*** The latter must accurately disclose the limited prognostic ability of the gender dysphoria/gender incongruence diagnosis for young people, and ***the many uncertainties regarding the long-term mental and physical health outcomes of these poorly studied and largely experimental interventions***.

See, Spyridoula Maraka, Naykky Singh Ospina, Rene Rodriguez-Gutierrez, Caroline J Davidge-Pitts, Todd B Nippoldt, Larry J Prokop, M Hassan Murad, Sex Steroids and Cardiovascular Outcomes in Transgender Individuals: A Systematic Review and Meta-Analysis, The Journal of Clinical Endocrinology & Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3914–3923, https://doi.org/10.1210/jc.2017-01643

2017 Misleading, politically motivated-tainted Cornell University website's alleged "systematic literature review" was actually a form of misleading consumer manipulation. See, Anonymous. Cornell University, Public Policy Research Portal. "What does the scholarly research say about the effect of gender transition on transgender well-being?" Available: https://whatweknow.inequality.cornell.edu/topics/lgbt-equality/what-does-the-scholarly-research-say-about-the-well-being-of-transgender-people/ [accessed 20 November 2019] The relevant scientific community reacted to expose misinformation in the Cornell "Review".

See, Horvath, Hacsi. (2020). ***Activist-driven transgender research methods are reckless and will lead to harms***. 10.13140/RG.2.2.22455.55206. "In 2017, anonymous authors at Cornell University produced a document titled "What does the scholarly research say about the effect of gender transition on transgender well-being?". This document purports to be a "systematic literature review." In reality, it is simply a piece of "junk science", political propaganda, created by activists…. Horvath employed two instruments commonly used to assess the quality of systematic reviews. See, Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, et al. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008; and also Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097). ["The Cornell document fared poorly under examination with the AMSTAR 2 instrument. All questions answered with "No" or "Not reported" would optimally have been answered with 'Yes.' This review's methods appear to have been grossly inadequate.". The authors of the Cornell review failed to meet nearly every criterion of the PRISMA checklist. All items denoted as "Not done" would optimally have been answered 4 with "Done." Reporting of this review's methods and findings was very sloppy. Indeed, the review could hardly have been reported with less rigor].***Conclusions: The so-called "systematic literature review" produced at Cornell was nothing of the kind. Thus the "Findings" of this document should be ignored."***

The public should be warned regarding this kind of material misrepresentation of potentially dangerous, experimental treatments of vulnerable patients.

2018 AMSTERDAM RESEARCH DEBACLE : Deceptive Claims and Research Errors in the 2018 Amsterdam Cohort Study Debacle of (2018) See, Wiepjes CM, Nota NM, de Blok CJ, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972–2015): Trends in Prevalence, Treatment, and Regrets. The Journal of Sexual Medicine 2018; 15(4): 582-90.

These authors deceptively claimed: "The percentage of people who regretted gonadectomy remained small and did not show a tendency to increase."

Noting research limitations, errors, and/or deceptions:

— "***Not all data were available*** from the hospital registries, particularly older data or surgeries performed in other centers" (p.590)

— "A large number of transgender people…**were lost to follow-up**. Although transgender people receive lifelong care, ***a large group (36%) did not return to our clinic*** after several years of treatment" (page 589). (**How many were suicides or detransitioning? The researchers did not assess and thus cannot report.**)

— The "Regret" measure used was only tabulated for those who had gonadectomies and ALSO then requested hormone therapy consistent with biological sex "**and ALSO** expressed regret" (p.584); they also apparently ***improperly excluded any patient who died*** (are they hiding suicides?) (p.584)

— No uniform statistics were used to measure average follow-up time and variance = a **research error increasing the unreliability of the data**.

Admitted ***average time to regretting engaging in "transition" interventions was 130 months (10+ YEARS)***. Page 589 admission: "…it ***might be too early to examine regret rates in people who started with HT within the past 10 years."*** Many patients counted as "non-regret" are thus LIKELY to express REGRET beyond the study cut-off date. **Misreporting results in this manner is another unreliable research error indicative of deception or negligence**.

2018 - The Endocrine Society guidelines were published prior to the implosion of the Gender Transition Industry. These guidelines are already outdated and based on assumptions since demonstrated to be false (See, e.g. the recent Cochrane, British N.I.C.E. review, Swedish review, Finnish review, Turban's debunked studies, and the Branstrom Debacle debunked research). **None of the recent exposes of massive errors and/or misconduct in transgender medicine research field was known at the time of the Endocrine Society guidelines of 2009 and 2018.**

See, THE ENDOCRINE SOCIETY (ES) position(s) on the claims of the Gender Transition Industry is ***a political consensus-seeking process (voting)— not an evidence-seeking scientific research process —*** and should be reviewed with care. The Endocrine Society clearly states that its practice guidelines "cannot guarantee any specific outcome, nor do they establish a standard of care".

The 2009 ES guidelines noted the low quality (unreliable, invalid) of evidence in this field. E.g. "Evidence: This evidence-based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of evidence, which was low or very low."

See, Wylie C. Hembree, Peggy Cohen-Kettenis, Henriette A. Delemarre-van de Waal, Louis J. Gooren, Walter J. Meyer III, Norman P. Spack, Vin Tangpricha, and Victor M. Montori*Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, J Clin Endocrinol Metab. September 2009, 94(9):3132–3154. doi: 10.1210/jc.2009-0345.

First Corrected version: See, Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline [published correction appears in J Clin Endocrinol Metab. 2018 Feb 1;103(2):699]

Second corrected version: 2018 published correction appears in J Clin Endocrinol Metab. 2018 Jul 1;103(7):2758-2759]. J Clin Endocrinol Metab. 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

2019 TAVISTOCK DEBACLE — Professor Michael Biggs of Oxford - THE AFFIRMATION DRUGS ARE EXPERIMENTAL TREATMENTS - AFTER TREATMENT PATIENTS REPORTED *GREATER* SELF-HARM, *MORE* BEHAVIORAL and EMOTIONAL PROBLEMS and *GREATER* DISSATISFACTION WITH THEIR BODY…

Regarding the UK's Tavistock and Portman NHS Trust's Gender Identity Development Service's ***experimental trial*** of puberty blockers for early teenagers with gender dysphoria. Oxford's Professor Michael Biggs wrote, "To summarize, GIDS launched a study to ***administer experimental drugs to children suffering from gender dysphoria.***" "After a year on GnRHa [puberty blockers] ***children reported greater self-harm***, and ***girls experienced more behavioral and emotional problems and expressed greater dissatisfaction with their body—so puberty blockers actually exacerbated gender dysphoria***." (See,

Michael Biggs, "Tavistock's Experimentation with Puberty Blockers: Scrutinizing the Evidence," TransgenderTrend.com, March 5, 2019.)

2019 - IN GREAT BRITAIN, METHODOLOGICAL AND ETHICAL DEFECTS IN GENDER DISCORDANT "TRANSGENDER" RESEARCH and PRACTICES HAVE BEEN PUBLICLY EXPOSED, See, e.g. , The British Gids Clinic Controversies:

This reports noted below support my ongoing investigative hypothesis that the Gender Transition Industry is engaged in systemic, negligent, and/or unethical efforts to distribute misleading and/or incomplete information to patients, the scientific community, and the public. The Gender Transition Industry's systemic efforts appear to include multiple methods of deceptive misreporting including A) a failure to properly design research to search for key evidence, B) a misleading failure to properly report key evidence and methodological limitations and/or C) the improper minimizing of key evidence. The documented failures of the Gender Transition Industry with regard to informed consent, failures of scientific methodology, and the use of experimental treatments on unsuspecting patients-families appear to involve violations of standards of care and ethical requirements.]

E.G. : THE BBC REPORT of 2019: See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

"In 2019, England's only NHS youth gender clinic (Gids) lowered the age at which it offered children puberty blockers, partly based on research showing A) ***an increase in suicide risk following treatment*** and B) that virtually all young people who took the puberty blocker hormones went on to take cross-sex hormones (while ***80% or so of untreated children naturally grow out of their "gender dysphoria" phase by adulthood and accept their biological, natal gender***).

"Experts on clinical trials have criticized the design of the study, which they say makes it hard to tell if the reported effects were due to the puberty blockers or something else. But experts said they warranted further investigation."

[NOTE: An alternative hypotheses under investigation: Are the unusual methodological errors reported for Gender Transition Industry practices, research, and treatments the result of gross negligence, politically tainted pseudoscience, or something else?]

"Before 2011, the Gender Clinic (Gids) would give puberty blockers to children only once they had turned 16…. And in 2011, a medical study was approved through which younger children could access these drugs. "***Acknowledging the weak evidence for the use of these drugs (hormones),*** the research team, made up of Gids and University College Hospitals staff, set out to "evaluate the psychological, social and physical effects" of the blockers on a carefully selected group of young people.

Details about risks - such as potential adverse effects on bone strength, the development of sexual organs, body shape or final adult height - were provided in a patient information sheet. But ***BBC Newsnight found certain information had not been included*** . Previous research had suggested all young people who took the blockers went on to take cross-sex hormones - the next stage towards fully transitioning to the opposite gender. "But patients and parents were ***not*** told this in the information sheet." [***Note: This report appears to document a serious informed consent violation.]***

[NOTE: Are the unusual methodological-ethical errors reported for Gender Transition Industry practices and treatments the result of gross negligence, politically tainted pseudoscience, or something else?]

"I don't see that the parents and their children could really have given informed consent given the lack of information that was provided," said Michael Biggs, associate professor of sociology at Oxford University. Prof Biggs… added : "***They were not given the information they needed in order to take this momentous life-changing step***." He gave BBC Newsnight a series of documents relating to the research study he had obtained via freedom of information requests, which were independently looked at.

[NOTE: Such reported failures of informed consent, defects in methodology, and ***the use of experimental treatments on unsuspecting patients-families*** appear to be serious violations of ethical, practice, and/or licensing rules.]

Preliminary data for 30 of the 44 young people on the study was made available to the Tavistock's board in 2015. **It showed** that ***after*** a year on puberty blockers, ***there was a significant increase found in those answering the statement "I deliberately try to hurt or kill myself".*** See, Tavistock and Portman Foundation NHS Trust. Preliminary results from the early intervention research. In Tavistock and Portman Foundation NHS Trust, Board of Directors Part One: Agenda and Papers: Appendix 7; 50–55. Tavistock and Portman Foundation NHS Trust, June 2015 (https:// tavistockandportman.nhs.uk/about-us/governance/board-of-directors/ meetings/).

"Prof Susan Bewley (Emeritus Honorary Professor, King's College London Department of Obstetrics & Women's Health), who chairs Healthwatch, a charity for science and integrity in healthcare, ***is one of a number of doctors raising concerns about the lack of evidence in this area of medicine***. She said seeing any change around suicidal thoughts "is very worrying". "Good medical practice would normally be very reflective about an increase in harms," she added."

"Because of ***flaws [methodological defects] in how the study was set up***, it is not possible to infer cause and effect or even to say whether rates of suicidal thoughts are higher or lower in this group than in children with gender dysphoria who don't take puberty blockers. ***The study had no control group***, of children not taking the drugs, to compare with the observed results. In addition, the outcomes it was measuring were unclear. Nevertheless, experts say these observations should have given Gids pause for thought.

Gids told Newsnight: "All patients were seen regularly by mental health professionals. They concluded that there was no evidence of harms that could be directly attributed to the treatment and that continuation of the study was appropriate."

[**NOTE**: *This appears to be additional, publically exposed, documented evidence of Gender Transition Industry advocates* ***providing incomplete, misinformation to the public and patients***. Research has shown that mental health professionals have no relevant reliable-nor valid magical methods for deciphering the truth or falsity of patient reports of gender dysphoria and no reliable nor valid ways of predicting suicide in specific patients. They have no "lie detection" methodology better than flipping coins and they apply "clinical judgment" methods that are often no better than lay persons."(See a detailed discussion of the relevant science in this declaration.) For Gids to ward off responsibility for experimenting on children by assuring the public that "mental health professionals" were involved appears to be another example of not providing complete, accurate, proper information.]

The early data [showing an increase in suicidal ideation] was not shared with the Health Research Authority, despite its demands for updates on the study over a period of three years. In response to BBC Newsnight sharing this preliminary data and other concerns about the study, Teresa Allen, chief executive of the HRA, said: "The information that Newsnight has brought to our attention ***has not been raised with us before***. "We will therefore investigate further, which may include a review of the original ethics opinion."

[**NOTE**: This is apparently yet another public record of the Gender Transition Industry's deceptive misinformation and apparent unethical misconduct. Note that Dr Brown's expert declaration for the plaintiffs in this (Kadel v Folwell) case appears to be another example of this very same type of brazen misinformation — Dr Brown appears to claim there is no controversy in this field!**]**

BBC Newsnight's investigation comes amid growing concerns over the way Gids is operating. In an open letter, ***former Gids (Gender Clinic) clinician Dr Kirsty Entwistle raised concerns over the way puberty blockers were being presented to children as "fully reversible", when their long-term impact was unknown. She also said staff were unable to raise concerns without risking being branded transphobic. [politicized "cancel culture"]*** **See, open letter at [https://medium.com/@kirstyentwistle/an-open-letter-to-dr-polly-carmichael-from-a-former-gids-clinician-53c541276b8d].**

Tavistock and Portman Trust chief executive Paul Jenkins told BBC Radio 4's Today programme: "Puberty blockers are reversible."

[**NOTE**: This is apparently yet another public record - documented on BBC video — of Gender Transition Industry ***deceptive misinformation and unethical misconduct*** — a clear failure to provide

accurate information on risks and benefits of the treatment — providing such misinformation to a patient would be a serious violation of proper informed consent requirements.]

He said Gids was looking at processes to make it easier for clinicians to focus on their work, "rather than being swayed or influenced ***by the very heated debate"… (Note: This is the heated international medical, scientific, and ethical debate that Plaintiffs' expert Dr Brown apparently was not aware of or wishes to ignore.)*** See, Cohen, D. and Barnes, H., Transgender treatment: Puberty blockers study under investigation, BBC Newsnight 22 July 2019. https://www.bbc.com/news/health-49036145

2020 and 2021 - THE GENDER TRANSITION INDUSTRY IMPLODES — RESEARCH DEFECTS and UNETHICAL MISCONDUCT ARE WIDELY EXPOSED:

2020 - THE COCHRANE REVIEW - GENDER AFFIRMATION REMAINS EXPERIMENTAL: "INSUFFICIENT EVIDENCE" FOR "AFFIRMATION" INTERVENTIONS = STILL AN EXPERIMENTAL TREATMENT : The widely respected Cochrane review examined hormonal treatment outcomes for male-to-female transitioners over 16 years. ***They found "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition."***

It is remarkable that ***decades after the first transitioned male-to-female patient, quality evidence for the benefit of transition is still lacking***. See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.

2020 - GRIFFIN REVIEW In the Bulletin of the Royal College of Psychiatrists - PSYCHIATRIC DISORDERS PERSIST (after "transitioning") so use a SUPPORTIVE, EXPLORATORY APPROACH (not Mandated Affirmation) — In the Bulletin of the Royal College of Psychiatrists See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, ***the authors noted the hazardous error of mandating "affirmation treatments" — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice***. … As Griffin discussed, "***Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to 'conversion therapy'.*** Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. **As there is evidence that *many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory approach with gender-questioning patients should not be considered conversion therapy."*** … In addition, Griffin et al wrote: "Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, *although* **underlying causality has not been convincingly demonstrated**. **(See, Marshall E, Claes L, Bouman WP, Witcomb GL, Arcelus J. Non-suicidal self-injury and suicidality in trans people: a systematic review of the literature. Int Rev Psychiatry 2016; 28: 58–69.) Activists and too many providers have used a fear of suicide *to push experimental unproven treatments*.**

2020 – LONDON HIGH COURT: THE ETHICAL RISKS OF THE STILL EXPERIMENTAL GENDER AFFIRMATION INTERVENTIONS HAVE BEEN HIGHLIGHTED BY AN INTERNATIONALLY REPORTED LAWSUIT IN BRITAIN: See, Puberty blockers: Under-16s 'unlikely to be able to give informed consent', BBC, 1 December 2020 "Children under 16 with gender

dysphoria are unlikely to be able to give informed consent to undergo treatment with puberty-blocking drugs, three High Court judges have ruled…. "Given the long-term consequences of the clinical interventions at issue in this case, and given that ***the treatment is as yet innovative and experimental***, we recognise that clinicians may well regard these as cases where the authorization of the court should be sought prior to commencing the clinical treatment."… The judges have effectively split the issue into stages. They concluded a child under 13 is "highly unlikely" to be able to give informed consent and at 14 and 15 it is still "doubtful" they can fully understand the implications of the medication….Even for 16 and 17-year olds the ruling says it may be appropriate to involve the courts in the decision…. The judges point to the ***lack of evidence about the long-term effects of puberty blockers*** as adding to the difficulty of consent, but in effect, the courts will now play a much greater role in decisions, which are already highly emotionally charged… Paul Conrathe, the solicitor for both claimants, said the ruling was "an historic judgment that protects children who suffer from gender dysphoria". He said the judgment showed "that a culture of unreality has become embedded in the Tavistock". "This may have led to hundreds of children receiving this experimental treatment without their properly informed consent," he said. See, https://www.bbc.com/news/uk-england-cambridgeshire-55144148

2020 - D'ANGELO REVIEW OR TURBAN's DEFECTIVE RESEARCH … AN ONLINE "CONVENIENCE SAMPLE": D'Angelo, R., Syrulnik, E., Ayad, S. et al. One Size Does Not Fit All: In Support of Psychotherapy for Gender Dysphoria. Arch Sex Behav (2020). https://doi.org/10.1007/s10508-020-01844-2 …. ***"Turban used the 2015 USTS survey … a convenience sampling, a methodology which generates low-quality, unreliable data*** (Bornstein, Jager, & Putnick, 2013). Specifically, the ***participants were recruited through transgender political advocacy organizations*** and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but ***highly skewed politicized sample***."…." ***neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… "We call on the scientific community to ***resist the stigmatization of psychotherapy for GD and to support rigorous outcome research investigating the effectiveness of various psychological treatments aimed at ameliorating or resolving GD."***

2020 - THE TURBAN ONLINE SURVEY RESEARCH DEBACLE … PUBLIC EXPOSURE OF TURBAN's SERIOUS RESEARCH DEFECTS - Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research. … **See 2020 scathing D'ANGELO REVIEW….** ." ***neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… ***Turban used the 2015 USTS survey … a convenience sampling, a methodology which generates low-quality, unreliable data*** (Bornstein, Jager, & Putnick, 2013). Specifically, the ***participants were recruited through transgender political advocacy organizations*** and subjects were asked to "pledge" to promote the survey among friends and family. This recruiting method yielded a large but ***highly skewed politicized sample***."… Turban's defective project "does not differentiate between diagnostic evaluations or a specific therapeutic intervention. There is also no information about whether the focus of the encounter was gender dysphoria or another condition." … Turban's analysis is compromised by serious methodological flaws, including …. "***reliance on survey questions with poor validity***'… "Turban et al.'s (2020) finding of an association between the recall of GICE and scoring ≥ 13 actually suggests that ***the USTS participants recalling GICE were more likely to have a severe mental illnesses diagnosis*** than those not recalling GICE."… "Turban's ***failure to control for the subjects' baseline mental health makes it impossible to determine whether the mental health or the suicidality of subjects worsened, stayed the same, or potentially even improved after the non-affirming encounter.***"… "Another measure of psychological distress chosen by Turban et al.—substance misuse—was not significantly different between GICE and the non-GICE group. More importantly, there is a lack of consistency in the suicide measures. While lifetime suicide attempts were elevated among the GICE group, total suicide attempts in the prior 12 months, as well as suicide attempts requiring hospitalization, which generally indicate more serious attempts rather than non-suicidal self-injury, were

not significantly different between the two groups."… "Turban et al.'s choice to IMPROPERLY interpret the said association as evidence of harms of GICE ***disregards the fact that neither the presence nor the direction of causation can be discerned from this study due to its cross-sectional design***."… "Arguably, even more problematic than the flawed analysis itself is the simplistic "affirmation" versus "conversion" binary, which permeates Turban et al.'s (2020) narrative and establishes the foundation for their analysis and conclusions." … ***"at worst, it effectively mis-categorizes ethical psychotherapies (e.g., CBT) that do not fit the "affirmation" descriptor as conversion therapies***. Stigmatizing non-"affirmative" psychotherapy for GD as "conversion" will reduce access to treatment alternatives for patients seeking non-biomedical solutions to their distress."…

2020 - THE TURBAN PEDIATRICS RESEARCH ONLINE SURVEY DEBACLE: See, Turban JL, King D, Carswell JM, et al. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation, Pediatrics Feb 2020, 145 (2) e20191725; DOI: 10.1542/peds.2019-1725.

Multiple Letters to the Editor criticized Dr. Turban's 2020 study in Pediatrics for multiple methodological errors. https://pediatrics.aappublications.org/content/145/2/e20191725/tab-e-letters#re-pubertal-suppression-for-transgender-youth-and-risk-of-suicidal-ideation

Scott S. Field, Den A. Trumbull, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.

Patrick H Clarke, RE: Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation.

TURBAN used an Unreliable, biased sampling methodology: "Using a cross-sectional online survey of 20,619 transgender adults aged 18 to 36 years…" [2015 U.S Transgender Survey. Online survey of transgender and "genderqueer" adults recruited from trans-friendly websites. NO ID, NO evidence of identities, NO way to measure bogus subjects, NO medical diagnosis for entry.]… ***No causation can be determined from this retrospective, cross-sectional design***…. **("…cross-sectional design, does not allow for determination of causation.")**…. ***TURBAN failed to even assess Desisters and Regretters*** … **Turban claimed that** desisters and regretters would "not be likely" in this study group, which also only included adults, so his study "does ***not include outcomes for people who may have initiated pubertal suppression and subsequently no longer identify as transgender***." …. "Turban's misleading (deceptive?) claim of lower suicidal ideation for treated patients excluded the most seriously mentally ill patients that would have been DENIED affirmation treatment — "those who received treatment with pubertal suppression, when compared with those who wanted pubertal suppression ***but did not receive it***, had lower odds of lifetime suicidal ideation (adjusted odds ratio = 0.3; 95% confidence interval = 0.2– 0.6)."… … Turban appears to have "forgotten" to report that See, Table 3. Under "Suicidality (past 12 months)" reductions for suppressed group v non were seen for ideation (50.6% v 64.8%) and "ideation with plan" (55.6% v 58.2%). ***But suicidal "ideation with plan and suicide attempt" for the suppressed group INCREASED after treatment to 24.4% v 21.5% for the non-treatment group***."… The most clinically significant result in this study — that **"Affirmation Treatments *INCREASED SERIOUS SUICIDE ATTEMPTS* — was IGNORED BY THE AUTHORS** (i.e., not statistically significant but clinically significant) = **"Suicide attempts resulting in inpatient care" = 45.5% for suppression groups** v. 22.8% for non. [**This is clearly a very "UN-successful treatment" if 45% attempted suicide!**]. In sum, Turban et al. ignored their own finding that a history of puberty suppression was associated with an **INCREASE in recent serious suicide attempts.**"… In sum, the Turban 2020 Pediatrics study, **based on an unverified US Transgender Online Survey, tells us little** about the effects of puberty suppression on children with gender dysphoria. See, **Michael Biggs, Puberty Blockers and Suicidality in Adolescents Suffering from Gender Dysphoria. Archives of Sexual Behavior, accepted 14 May 2020, DOI: 10.1007/s10508-020-01743-6**

2020 - LONDON COURT RULING … "*given that the treatment is as yet innovative and experimental*"… CHILDREN HIGHLY UNLIKELY TO BE ABLE TO CONSENT TO "AFFIRMATION" INTERVENTIONS:

See, Dyer, C. , Children are "highly unlikely" to be able to consent to taking puberty blockers, rules High Court BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m4699 (Published 01 December 2020) Cite this as: BMJ 2020;371:m4699

Children under 16 cannot consent to the use of puberty blockers for gender dysphoria unless they can understand the immediate and long-term consequences of the treatment, which is unlikely, the High Court in London has ruled.

See, also Ruling on the application of Quincy Bell and A v Tavistock and Portman NHS Foundation Trust and others. [2020] EWHC3274 (Admin). https://www.judiciary.uk/judgments/r-on-the-application-of-quincy-bell-and-a-v-tavistock-and-portman-nhs-trust-and-others/.

The legal challenge was brought against the Tavistock and Portman NHS Trust, which runs the UK's only gender reassignment service for young people. Keira Bell, 23, who was treated as a teenager, and "Mrs A," the mother of a 15 year old with autism who was on the waiting list for treatment, challenged the service's policy and practice on the use of puberty blockers. They argued that children were unable to give informed consent for the treatment.

Victoria Sharp, president of the Queen's Bench Division, sitting with Lord Justice Lewis and Mrs Justice Lieven, said it was "highly unlikely" that a child aged 13 or under would be competent to give consent to the administration of puberty blockers. She said that the judges were "very doubtful" that a child aged 14 or 15 could understand and weigh the long term risks and consequences of the administration of puberty blockers.

For children of 16 and over there is a presumption that they have the ability to consent to medical treatment. But, "given the long term consequences of the clinical interventions at issue in this case, and ***given that the treatment is as yet innovative and experimental***, we recognise that clinicians may well regard these as cases where the authorisation of the court should be sought prior to commencing the clinical treatment," said Sharp.

Bell took puberty blockers at age 15 or16 and later was given male hormones and had her breasts removed. She has since "re-transitioned" back to living in accord with her female sex. Sharp said that puberty blockers had been prescribed to children as young as 10 years.

The trust, and other trusts to which it referred patients for treatment, had argued that taking hormone blockers and later cross sex hormones were entirely separate stages of treatment. Sharp concluded, "It is said therefore the child needs only to understand the implications of taking puberty blockers alone . . . in our view this does not reflect the reality. The evidence shows that the vast majority of children who take puberty blockers move on to take cross sex hormones, that stages 1 and 2 are two stages of one clinical pathway and, **once on that pathway, it is extremely rare for a child to get off it.**"

2020 -Schumm and Crawford Review SHOWING SEVERE DEFECTS IN AFFIRMATION RESEARCH BY Olson et al. 2016b; Durwood, McLaughlin, and Olson 2017 Schumm and Crawford asked the question: "Is good science being thrown under the bus for the sake of politically correct agendas?"

As Schumm and Crawford further noted: "The results should have been interpreted as evidence that ***even with high levels of parental support, transgender children have lower levels of mental health, especially with respect to higher levels of anxiety and lower levels of self-worth***…

Negligence, Fraud, or Political Ideology?: In the case of Olson et al. (2016b) and Durwood, McLaughlin, and Olson (2017), not only were there numerous statistical errors (Schumm et al. 2019), but ***a great deal of data and results, including some significant results, were not reported until the authors were queried***. Not reporting significant results may occur but when the apparent conclusion is that there were not any significant results, leaving out significant findings can be seen as self-serving to the idea of maintaining support for the null hypothesis regardless of the facts. Is good science being thrown under the bus for the sake of politically correct agendas? It's difficult to escape a sense that such is not an uncommon occurrence in areas of considerable political controversy. One has to wonder what other areas of controversial science may have been infected with this type of problem." (See, Schumm, WR and Crawford, DW, Is Research on Transgender Children What It Seems? Comments on Recent Research on

Transgender Children with High Levels of Parental Support, The Linacre Quarterly, 2020, Vol. 87(1) 9-24. DOI: 10.1177/0024363919884799

2020 - GREAT BRITAIN REVIEW OF GENDER AFFIRMATION INTERVENTIONS SHOWS "VERY LOW" QUALITY EVIDENCE: GB NICE REVIEW OF Oct 2020 - See, Deborah Cohen and Hannah Barnes for **BBC Newsnight - "Evidence for puberty blockers use *very low,* says NICE"**

The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding". **The assessment of the evidence into the drugs** was commissioned by NHS England. It is part of **a review into gender identity services** for children and young people. See, https://arms.nice.org.uk/resources/hub/1070905/attachment

NICE found it was ***difficult to draw conclusions from existing studies because of the way they had been designed.*** They were "all small" and ***didn't have control group***s, which are used to directly compare the effect of different treatments.

There were ***other issues with the studies too, such as not describing what other physical and mental health problems a young person may have alongside gender dysphoria***.

The review said there was ***"very little data" on any additional interventions*** - such as counselling or other drug treatments - the young people may have had alongside taking puberty blockers, and t***his could bias the results***.

The impact of puberty blockers on bone density has been raised as a potential concern by some experts previously. However, NICE found that without a "comparator group", it was not known whether any observed changes in bone density "are associated with GnRH analogues or due to changes over time".

Some argue that carrying out a controlled trial - which would provide better quality evidence - might be difficult because of the potential impact on mental health if treatment is withheld in one group. NICE accepted this, but said offering psychological support to compare puberty blockers ***"may reduce ethical concerns in future trials"***. The review found ***no evidence of cost-effectiveness of treatment.***

NICE also reviewed the evidence base for gender-affirming hormones - sometimes known as cross-sex hormones. See, https://arms.nice.org.uk/resources/hub/1070871/attachment

The review found the evidence of clinical effectiveness and safety of gender-affirming hormones *was also of "very low" quality*. "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria," NICE said. Both documents were prepared by NICE in October 2020 and will now help inform Dr Hilary Cass's independent review into NHS gender identity services for children and young people. See, https://www.bbc.com/news/health-56601386

2020 - THE MALONE, HRUZ, MASON and BECK et al. LETTER TO THE EDITOR DOCUMENTING RESEARCH DEFECTS IN THE GENDER TRANSITION INDUSTRY:

See, Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender-Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". The Journal of Clinical Endocrinology & Metabolism. **2020.**

Walch et al. endorse the ES Position that puberty suppression (PS), cross-sex hormones (CSH) and surgeries are "effective," "relatively safe," and have been "established as the standard of care" [2]. However, a growing body of evidence shows adverse effects on bone growth, cardiovascular health, and fertility, as well as transition regret.

Walch et al. also endorse the ES Position claiming there is an established "durable biological underpinning" to gender identity (GI) *2]. However, the first citation supplied by the ES for this position ***highlights contradictory studies*** and describes the biological origin of GD as simply ***a "current hypothesis"*** *7+. The other citation describes GI as a "complex interplay of biological, environmental, and cultural factors" *8+. Further, ***the concept of "durability" is challenged by the fact that most cases of GD in children naturally resolve by adulthood***. It is ***precisely this lack of durability that should give pause to***

administering potentially harmful and often irreversible medical interventions to young patients with GD.

The ES Position Statement also overlooks a key fact that the existing body of evidence regarding treatment outcomes for GD was not only **graded as "low quality"**, but has been ***derived from a vastly different population than the one presenting with GD today***. Currently, ***GD predominantly presents in adolescent females with no childhood history, in contrast to the prior population which was predominantly male with early onset of gender dysphoria***.

Walch A, Davidge-Pitts C, Safer JD, Lopez X, Tangpricha V, Iwamoto SJ. Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective. J Clin Endocrinol Metab. Jan 23 2021;106(2):305-308. doi:10.1210/clinem/dgaa816

Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. Nov 1 2017;102(11):3869-3903. doi:10.1210/jc.2017-01658

Rosenthal SM, Hembree WC, Cohen-Kettenis PT, et al. Response to Letter to the Editor: "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline". J Clin Endocrinol Metab. Nov 1 2019;104(11):5102-5103. doi:10.1210/jc.2019-00930

2020 - THE Branstrom DEBACLE - … EXPOSURE OF Branstrom et al's MULTIPLE, SERIOUS RESEARCH DEFECTS : Another example of the Gender Transition Industry's misleading and deceptive misreporting of incompetent research.

In 2020, Branstrom, et al, published a research report claiming that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." This research appeared to be an historic first — empirical evidence that gender transition surgeries demonstrated long-term benefits. (See, Branstrom, Pachankis: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734.)

Almost immediately, however, the relevant scientific community — including multiple MD, PhD methodology experts — exposed the Branstrom study ***as a series of methodological blunders and/or manipulative deceptions***. Multiple science experts concluded that, "These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender non-congruence based on the results presented in this article." They also noted evidence supporting the theory that these "errors" could well be purposeful and designed to support an ideological perspective when they noted, "people diagnosed with gender incongruence have a dramatically worse overall mental health outcome (after "transitioning" treatments) than the general population, which is, in fact, the answer to their stated aim and research question, but this (most essential) finding is not even referred to in the title or in the Conclusions section of the article."(See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:764; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

Additional methodology experts noted other serious flaws in the Branstrom study including : "For those whose last surgery was 10 or more years earlier, **how many completed suicide, died of other causes, or left Sweden prior to study initiation?***" The authors failed to find out (or hid negative results)*. The methodology experts also noted, "A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring. The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls."…"***The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality.*** In overlooking so much available data, ***this study lacks the evidence to support its pro gender-***

affirmation surgery conclusion." See, Van Mol, A., Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

Additional methodology experts noted that "The study confirms ***the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex***. However, ***the Branstrom study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity.*** It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors somehow ignored this most essential finding -*Note this appears to be more potential evidence of deception, research fraud, and/or licensing violations.]* …" See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

Still more reviewers concluded, "The data presented in Figure 1 in the article support findings from previous studies showing that ***transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress***."… "Because of the ***limitations in the study design***, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. (They failed to even measure increased suicides, etc) … "Therefore, the authors 'conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries ***cannot be supported***." See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149.

Finally, yet another (MD, PhD) reviewer noted in detail… "The Branstrom and Pachankis study on mental health treatment and suicide attempts … ***is misleading because the study design is flawed***." "The authors first found what was already known … ***the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning")***. The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but ***they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting HORMONAL treatment***. They somehow ***failed to publish this essential finding***. *[Note … more potential evidence of deception, research fraud, or licensing violations.]* In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate these negative outcomes to the number of years since surgery. ***Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question***. First, the authors include only persons who were alive in 2014. ***That means that those who died by SUICIDE before 2014—and hence were at highest risk for suicide attempt—are EXCLUDED from the data and confound the results***. *[Note …this appears to be still more potential evidence of deception, research fraud, and/or licensing violations.]* Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, *the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment;* it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, by definition, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors ' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and ***is not a proxy for improved mental health***. ***Because the authors do not present data prior to gender affirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity.*** Moreover, ***the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with HIGH risk for SUICIDE attempt***. *[Note … still more potential evidence of deception, research fraud, or licensing violations.]* ***Future research should use properly designed observational studies to answer***

the important question as to whether gender-affirming treatment affects psychiatric outcomes." See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165.

Yet another MD, PhD expert severely criticized the Branstrom, et. al. study noting : The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population. However, the title of the article implies that gender corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide gender affirming surgeries to transgender individuals who seek them." ***In my opinion, this conclusion is not supported by the data presented in the article***. *[Note ... more potential evidence of deception, research fraud, or licensing violations.]* The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not. Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment"). By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery. This corresponds to an odds ratio of 2.37 (95% CI= 1.01–5.56, p=0.047). ***Hence, among the individuals examined in the study, the risk of being hospitalized for a SUICIDE ATTEMPT was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not.*** *[Note this key finding was apparently hidden or not noticed by the authors ... more potential evidence of deception, research fraud, or licensing violations by the research authors.]* Whether these factors involve a causal relationship (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined from such a study. Nevertheless, ***the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria."*** See, Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170.

In addition, yet another pair of reviewers severely criticized the Branstrom study noting : " The qualitative approximation of this curve with the reduction described by Branstrom and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of INCREASED mental health treatment due to this surgery, fits *the data in the article and* ***OVERTURNS the authors stated conclusions***, *[Note ... more potential evidence of deception, research fraud, or licensing violations by the research authors.]* **suggesting that sex reassignment surgery is in fact associated with INCREASED mental health treatment.** See, Ring, A. (PhD) and Malone, W., Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

It should be noted, that after this very public exposure of **the Branstrom Debacle** by multiple expert reviews, ***the research authors admitted their conclusions were in error (confessed)*** and that ***"more research" is needed to answer the question of whether Gender Transition Industry treatments are helpful or harmful, long-term.*** The authors admitted, "**Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming**

care… (and)… When comparing the mental health treatment outcomes between the two groups (Table 1), we found ***no significant difference*** **in the prevalence of treatment for mood disorders and** ***no significant difference*** **in the prevalence of hospitalization-suicide attempts.** " and stunningly ***they admitted they had failed to note that "individuals diagnosed with gender incongruence who had received gender-affirming surgery were MORE likely to be treated for ANXIETY disorder compared with individuals diagnosed with gender incongruence who had NOT received gender-affirming surgery.*** 'and "While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, **like most extant research on the topic,** ***the design is incapable of establishing a causal effect*** **of gender affirming care on mental health treatment utilization**. This retreat and mea culpa was published as Branstrom, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals 'Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

[Underlines, italics, and emphases above are added]

In sum, like the Branstrom Debacle … too many ideologically tainted and methodologically defective research studies suffer from these kinds of ***serious errors, improper analyses and harmfully deceptive reports***. Such poorly designed and improperly conducted research studies continue to prevent gender transition "affirmation" treatments from being generally accepted by the relevant scientific community. Finally, the Error Rates for such unproven, experimental "treatments" as well as for the foundational politically-based transgender ideology, are unknown, un-peer-reviewed, and unpublished. [Note: Compare the multiple, scathing reviews by international scientist experts above to Dr Brown's and Dr Schechter's misleading and incomplete expert declarations for the plaintiffs in this case.]

2021 - The Singh, Bradley, and Zucker study — the largest sample to date - ***found support for the "watchful waiting" no affirmation treatment approach combined when needed with psychotherapy and coping-resilience training.***

This research supports the view that an aggressive, intrusive "affirmation" of the Gender Transition Industry's "transitioning treatments" is an unethical, experimental practice which brings an unnecessarily high risk of causing serious, lasting harm to most such children.

In a follow-up study reviewing data on **the largest sample to date of boys clinic-referred for gender dysphoria** (n = 139) with regard to gender identity and sexual orientation. At follow-up, gender identity/dysphoria was assessed via multiple methods with participants classified as persisters or desisters). Of the 139 participants, 17 (12.2%) were classified as persisters and the remaining 122 (87.8%) were classified as desisters**,** that is, patients who grew out of their gender dysphoric symptoms and came to accept their natal gender without further symptoms.

Clearly, given that the vast majority of these patients were on a natural developmental path to healthy adjustment without treatment, it would be unethical to engage in an intrusive "affirmation" treatment program using hormones and/or surgery that would be LIKELY to disrupt normal developmental processes producing iatrogenic (treatment caused injuries) harm to many patients. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021, Volume 12, Article 632784, www.frontiersin.org.

In addition, these authors discussed the previous 9 studies with sample sizes (excluding those lost to follow-up) ranging from 6 to 79 subjects (Mean age, 26 years). Most of these studies also provided the age at time of first evaluation in childhood, which ranged from a mean of 7 years (47) to a mean of 9 years (48), with an age range from 4 to 12 years. At the time of follow-up, using different metrics (e.g., clinical interview, maternal report, dimensional measurement of gender dysphoria, a DSM diagnosis of GID, etc.), **these studies provided information on the percentage of boys who continued to have gender dysphoria (herein termed "persisters") and the percentage of boys who did not (herein termed "desisters" of those who grew out of dysphoria).** Of the 53 boys culled from the relatively small sample size studies (Bakwin, Davenport, Kosky, Lebovitz, Money and Russo, Zuger), the percentage classified as persisters was 9.4% (age range at follow-up, 13–30 years). In Green (47), the percentage of persisters was

2% (total n = 44; Mean age at follow-up, 19 years; range, 14–24); in Wallien and Cohen-Kettenis (52), the percentage of persisters was 20.3% (total n = 59; Mean age at follow-up, 19.4 years; range, 16–28); and in Steensma et al. (51), the percentage of persisters was 29.1% (total n = 79; Mean age at follow-up, 16.1 years; range, 15–19). Across all studies, the percentage of persisters was 17.4% (total N = 235), with a range from 0 to 29.1%. See, Devita Singh1, Susan J. Bradley 2 and Kenneth J. Zucker, Frontiers in Psychiatry, March 2021 | Volume 12 | Article 632784, www.frontiersin.org,

These studies appear to support a "watchful waiting" treatment approach combined when needed with psychotherapy and/or coping-resilience training. An aggressive, intrusive "affirmation" of transitioning treatment model appears highly unethical and produces an unnecessarily high risk of causing serious, lasting harm to MOST of these patients.

2021-2020 CARMICHAEL STUDY (2020 also) — *HORMONE TREATMENTS DO NOT HELP CHILDREN WITH GENDER DYSPHORIA*… BUT DO STUNT GROWTH:

See, Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653; doi:https://doi.org/10.1101/2020.12.01.20241653 and Dyer, C. Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study. *BMJ* 372, n356, doi:10.1136/bmj.n356 (2021). **https://www.medrxiv.org/content/10.1101/2020.12.01.20241653v1 BBC summary: https://www.bbc.com/news/uk-55282113journal.pone.0243894. pmid:33529227**

Results 44 patients had data at 12 months follow-up, 24 at 24 months and 14 at 36 months. All had normal karyotype and endocrinology consistent with birth-registered sex. All achieved suppression of gonadotropins by 6 months. At the end of the study one ceased GnRHa and 43 (98%) elected to start cross-sex hormones…."**We identified *no changes in psychological function***. Changes in BMD were consistent with ***suppression of growth***. ***Larger and longer-term prospective studies using a range of designs are needed*** to more fully quantify the benefits and harms of pubertal suppression in GD."

Self-harm did NOT improve and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed."

"We found **no differences between baseline and later outcomes for overall psychological distress** as rated by parents and young people, nor for self-harm."

CONCLUSION: "We found ***no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm….***"**

Puberty blockers used to treat children aged 12 to 15 who have severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found.

However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

Media = See, Dyer, C. ***Puberty blockers: children under 16 should not be referred without court order, says NHS*** England. BMJ2020;371:m4717.doi:10.1136/bmj.m4717 pmid:33268453FREE Full TextGoogle Scholar

Media = See, Dyer, C., ***Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study***, BMJ 2021;372:n356 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021)

82. SUMMARY OPINIONS:

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

— A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

— A currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by a — peer group, social media, YouTube role modeling, and/or parental — social contagion and social pressure processes.

— Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

— It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any

patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmation" treatments.

— A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

— Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.

— NOT GENERALLY ACCEPTED: Affirmation medical treatments — hormones and surgery — for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc).

— NO KNOWN NOR PUBLISHED ERROR RATES: Gender transition "Affirmation" medical assessments and treatments — hormones and surgery — for gender dysphoria and "transitioning" have no known, peer reviewed and published error rates — the treatments and assessment methods lack demonstrated, reliable and valid error rates.

— POLITICS v. SCIENCE: Political activists, political activist physicians, and politically active medical organizations that operate by voting methodologies (e.g, WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and political ideologies (e.g., Critical Theory) rather than evidence-based scientific methodologies.

— ETHICAL RESTRICTIONS ON EXPERTS: Experts in legal cases have an ethical obligation to honestly, fairly, and accurately discuss the international controversy regarding the safety, effectiveness, reliability, and credibility of the Gender Transition Industry.

82. **LIMITATIONS ON EXPERT REPORTS:** My opinions and hypotheses in this matter are — as all expert reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to John Knepper (john@knepperllc.com), for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: 04/30/2021

Signed: Paul W Hruz

PAUL W. HRUZ, M.D., Ph.D.

THE END

Exhibit A

Curriculum Vitae

Date: 04/29/2021 09:26 AM
Name: Paul W. Hruz, M.D., Ph.D.

Contact Information

Office:	Phone: 314-286-2797 Fax: 314-286-2892
Mail:	Washington University in St. Louis School of Medicine Department of Pediatrics Endocrinology and Diabetes 660 South Euclid Avenue St Louis MO 63110
Email:	Office: Hruz_P@wustl.edu

Present Position

Associate Professor of Pediatrics, Endocrinology and Diabetes
Associate Professor of Pediatrics, Cell Biology & Physiology

Education

1987	BS, Chemistry, Marquette University, Milwaukee, WI
1993	PhD, Biochemistry, Medical College of Wisconsin, Milwaukee, WI Elucidation of Structural, Mechanistic, and Regulatory Elements in 3-Hydroxy-3-Methlyglutaryl-Coenzyme A Lyase, Henry Miziorko
1994	MD, Medicine, Medical College of Wisconsin, Milwaukee, WI
1994 - 1997	Pediatric Residency, University of Washington, Seattle, Washington
1997 - 2000	Pediatric Endocrinology Fellowship, Washington University, Saint Louis, MO
2017	Certification in Healthcare Ethics, National Catholic Bioethics Center, Philadelphia, PA

Academic Positions / Employment

1996 - 1997	Locum Tenens Physician, Group Health of Puget Sound Eastside Hospital, Group Health of Puget Sound Eastside Hospital, Seattle , WA
2000 - 2003	Instructor in Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2003 - 2011	Assistant Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2004 - 2011	Assistant Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO
2011 - Pres	Associate Professor of Pediatrics, Cell Biology & Physiology, Washington University in St. Louis, St. Louis, MO

2011 - Pres	Associate Professor of Pediatrics, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO
2012 - 2017	Division Chief, Endocrinology and Diabetes, Washington University in St. Louis, St. Louis, MO

Clinical Title and Responsibilities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

Teaching Title and Responsibilities

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

University, School of Medicine and Hospital Appointments and Committees

University

2012 - 2020	Disorders of Sexual Development Multidisciplinary Care Program

School of Medicine

2013 - 2020	Molecular Cell Biology Graduate Student Admissions Committee
2014 - Pres	Research Consultant, ICTS Research Forum - Child Health
2020 - Pres	WU ICTS Clinical and Translational Research Funding Program (CTRFP) Review Committee

Department/Division

2008 – 2016	Director, Pediatric Endocrinology & Diabetes Fellowship Program
2014 – 2017	Director, Pediatric Diabetes Research Consortium

Hospital

2000 - Pres	Attending Physician, St. Louis Children's Hospital

Medical Licensure and Certifications

1997 - Pres	Board Certified in General Pediatrics
2000 - Pres	MO State License #2000155004
2001 - Pres	Board Certified in Pediatric Endocrinology & Metabolism

Honors and Awards

1987	National Institute of Chemists Research and Recognition Award
1987	Phi Beta Kappa
1987	Phi Lambda Upsilon (Honorary Chemical Society)
1988	American Heart Association Predoctoral Fellowship Award
1994	Alpha Omega Alpha
1994	Armond J. Quick Award for Excellence in Biochemistry
1994	NIDDK/Diabetes Branch Most Outstanding Resident
1998	Pfizer Postdoctoral Fellowship Award
2002	Scholar, Child Health Research Center of Excellence in Developmental Biology at Washington University
2013	Julio V Santiago, M.D. Scholar in Pediatrics
2017	Redemptor Hominis Award for Outstanding Contributions to the Study of Bioethics
2018	Eli Lilly Outstanding Contribution to Drug Discovery: Emerging Biology Award
2018	Scholar-Innovator Award, Harrington Discovery Institute

Editorial Responsibilities

Editorial Ad Hoc Reviews

	AIDS
	AIDS Research and Human Retroviruses
	American Journal of Pathology
	American Journal of Physiology
	British Journal of Pharmacology
	Circulation Research
	Clinical Pharmacology & Therapeutics
	Comparative Biochemistry and Physiology
	Diabetes
	Experimental Biology and Medicine
	Future Virology
	Journal of Antimicrobial Chemotherapy
	Journal of Clinical Endocrinology & Metabolism
	Journal of Molecular and Cellular Cardiology
	Obesity Research
2000 - Pres	Journal of Biological Chemistry
2013 - Pres	PlosOne
2016 - Pres	Scientific Reports
2018 - Pres	Nutrients

Editorial Boards

2014	Endocrinology and Metabolism Clinics of North America

Community Service Contributions

2009 - 2017	Boy Scouts of America CPR Red Card Training

Professional Societies and Organizations

1992 - 2004	American Medical Association
1994 - 2005	American Academy of Pediatrics
1995 - 2014	American Association for the Advancement of Science
1998 - Pres	American Diabetes Association
1998 - Pres	Endocrine Society
1999 - Pres	Pediatric Endocrine Society
2004 - 2007	American Chemical Society
2004 - 2018	American Society for Biochemistry and Molecular Biology
2004 - 2020	Society for Pediatric Research
2005 - 2020	Full Fellow of the American Academy of Pediatrics
2013 - Pres	International Society for Pediatric and Adolescent Diabetes
2017 - Pres	Catholic Medical Association
2018 - Pres	American College of Pediatricians
2019 - Pres	Society of Catholic Scientists

Major Invited Professorships and Lectures

2002	Pediatric Grand Rounds, St. Louis Children's Hospital, St Louis, MO
2004	National Disease Research Interchange, Human Islet Cell Research Conference, Philadelphia, PA
2004	NIDA-NIH Sponsored National Meeting on Hormones, Drug Abuse and Infections, Bethesda, MD
2005	Endocrine Grand Rounds, University of Indiana, Indianapolis, IN
2005	The Collaborative Institute of Virology, Complications Committee Meeting, Boston, MA
2006	Metabolic Syndrome Advisory Board Meeting, Bristol-Meyers Squibb, Pennington, NJ
2007	American Heart Association and American Academy of HIV Medicine State of the Science Conference: Initiative to Decrease Cardiovascular Risk and Increase Quality of Care for Patients Living with HIV/AIDS, Chicago, IL
2007	Minority Access to Research Careers Seminar, University of Arizona, Tucson, AZ
2007	MSTP Annual Visiting Alumnus Lecture, Medical College of Wisconsin , Milwaukee, WI
2007	Pediatric Grand Rounds, St Louis Children’s Hospital, St Louis, MO
2008	Division of Endocrinology, Diabetes and Nutrition Grand Rounds, Boston University, Boston, MA
2009	Pediatric Grand Rounds, St Louis Children's Hospital, St. Louis, MO
2010	American Diabetes Association Scientific Sessions, Symposium Lecture Orlando, FL
2010	School of Biological Sciences Conference Series, University of Missouri Kansas City, Kansas City, MO
2011	Life Cycle Management Advisory Board Meeting, Bristol-Myers Squibb,, Chicago, IL
2013	Pediatric Grand Rounds, St Louis Children's Hospital, ST LOUIS, MO
2013	Clinical Practice Update Lecture, St Louis Children's Hospital, St Louis, MO
2014	Pediatric Academic Societies Meeting, Vancouver, Canada

2014	American Diabetes Association 74th Scientific Sessions, , San Francisco, CA
2017	Division of Pediatric Endocrinology Metabolism Rounds, University of Michigan, Ann Arbor, MI
2017	Catholic Medical Association National Conference, Denver, CO
2018	Obstetrics, Gynecology & Women's Health Grand Rounds, Saint Louis University, St. Louis, MO
2018	Medical Grand Rounds, Sindicato Médico del Uruguay, Montevideo, Uraquay
2018	Internal Medicine Grand Rounds, Texas Tech , Lubbock, TX
2019	Veritas Center for Ethics in Public Life Conference, Franciscan University, Steubenville, OH
2019	MaterCare International Conference, Rome, Italy
2019	Child Health Policy Forum, Notre Dame University, South Bend , IN
2021	Obstetrics & Gynecology Grand Rounds, University of Tennessee, Knoxville , TN

Consulting Relationships and Board Memberships

1996 - 2012	Consultant, Bristol Myers Squibb
1997 - 2012	Consultant, Gilead Sciences

Research Support

Completed Governmental Support

2001 - 2006	K-08 A149747, NIH Mechanism of GLUT4 Inhibition by HIV Protease Inhibitors Role: Principal Investigator
2007 - 2012	R01 Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $800,000.00
2009 - 2011	R01 Student Supp Mechanisms for Altered Glucose Homeostasis During HAART Role: Principal Investigator Total cost: $25,128.00
2009 - 2014	R01 Direct Effects of Antiretroviral Therapy on Cardiac Energy Homeostasis Role: Principal Investigator Total cost: $1,250,000.00
2017 - 2019	R-21 1R21AI130584 , National Institutes of Health SELECTIVE INHIBITION OF THE P. FALCIPARUM GLUCOSE TRANSPORTER PFHT Role: Principal Investigator Total cost: $228,750.00

Completed Non-Governmental Support

2015	Novel HIV Protease Inhibitors and GLUT4 Role: Principal Investigator

2008 - 2011 II
Insulin Resistance and Myocardial Glucose Metabolism in Pediatric Heart Failure
Role: Co-Investigator
PI: Hruz
Total cost: $249,999.00

2009 - 2012 Research Program
Regulation of GLUT4 Intrinsic Activity
Role: Principal Investigator
Total cost: $268,262.00

2010 - 2011 Protective Effect of Saxagliptin on a Progressive Deterioration of Cardiovascular Function
Role: Principal Investigator

2012 - 2015 II
Solution-State NMR Structure and Dynamics of Facilitative Glucose Transport Proteins
Role: Principal Investigator
Total cost: $375,000.00

2017 - 2020 Prevention And Treatment Of Hepatic Steatosis Through Selective Targeting Of GLUT8
Role: Co-Principal Investigator
PI: DeBosch
Total cost: $450,000.00

2018 - 2021 LEAP Innovator Challenge
Novel Treatment of Fatty Liver Disease
Role: Principal Investigator
Total cost: $68,500.00

Current Non-Governmental Support

2017 - 2021 Matching Micro Grant
Novel Treatment of Fatty Liver Disease (CDD/LEAP)
Role: Principal Investigator
Total cost: $68,500.00

2019 - 2021 Scholar-Innovator Award HDI2019-SI-4555 , Harrington Foundation
Novel Treatment of Non-Alcoholic Fatty Liver Disease
Role: Principal Investigator
Total cost: $379,000.00

Pending Non-Governmental Support

2015 Novel HIV Protease Inhibitors and GLUT4
Role: Principal Investigator

Trainee/Mentee/Sponsorship Record

Current Trainees

2019 Ava Suda, Other, Pre-med

Past Trainees

2002 - 2002 Nishant Raj- Undergraduate Student, Other
Study area: Researcher

2002 - 2010 Joseph Koster, PhD, Postdoctoral Fellow
Study area: Researcher

2003 - 2004 Johann Hertel, Medical Student
Study area: Research
Present position: Assistant Professor, University of North Carolina, Chapel Hill, NC

2003 - 2003 John Paul Shen, Medical Student
Study area: Research

2004 - 2005 Carl Cassel- High School Student, Other
Study area: Research

2004 - 2004 Christopher Hawkins- Undergraduate Student, Other
Study area: Researcher

2004 - 2004 Kaiming Wu- High School Student, Other
Study area: Research

2005 - 2005 Helena Johnson, Graduate Student

2005 - 2005 Jeremy Etzkorn, Medical Student
Study area: Researcher

2005 - 2005 Dominic Doran, DSc, Postdoctoral Fellow
Study area: HIV Protease Inhibitor Effects on Exercize Tolerance

2006 - 2006 Ramon Jin, Graduate Student
Study area: Research

2006 - 2006 Taekyung Kim, Graduate Student
Study area: Research

2007 - 2007 Jan Freiss- Undergraduate Student, Other
Study area: Researcher

2007 - 2008 Kai-Chien Yang, Graduate Student
Study area: Research
Present position: Postdoctoral Research Associate, University of Chicago

2007 - 2007 Paul Buske, Graduate Student
Study area: Research

2007 - 2007 Randy Colvin, Medical Student
Study area: Researcher

2008 - 2011 Arpita Vyas, MD, Clinical Fellow
Study area: Research
Present position: Assistant Professor, Michigan State University, Lansing MI

2008 - 2009 Candace Reno, Graduate Student
Study area: Research
Present position: Research Associate, University of Utah

2008 - 2012 Dennis Woo- Undergraduate Student, Other
Study area: Researcher
Present position: MSTP Student, USC, Los Angeles CA

2008 - 2008 Temitope Aiyejorun, Graduate Student
Study area: Research

2009 - 2009 Anne-Sophie Stolle- Undergraduate Student, Other
Study area: Research

2009 - 2009 Matthew Hruz- High School Student, Other
Study area: Research
Present position: Computer Programmer, Consumer Affairs, Tulsa OK

2009 - 2009	Stephanie Scherer, Graduate Student Study area: Research
2010 - 2014	Lauren Flessner, PhD, Postdoctoral Fellow Present position: Instructor, Syracuse University
2010 - 2010	Constance Haufe- Undergraduate Student, Other Study area: Researcher
2010 - 2011	Corinna Wilde- Undergraduate Student, Other Study area: Researcher
2010 - 2010	Samuel Lite- High School Student, Other Study area: Research
2011 - 2016	Thomas Kraft, Graduate Student Study area: Glucose transporter structure/function Present position: Postdoctoral Fellow, Roche, Penzberg, Germany
2011 - 2011	Amanda Koenig- High School Student, Other Study area: Research
2011 - 2012	Lisa Becker- Undergraduate Student, Other
2011 - 2011	Melissa Al-Jaoude- High School Students, Other
2014 - 2014	David Hannibal, Clinical Research Trainee

Bibliography

Journal Articles

1. Hruz PW, Narasimhan C, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase: affinity labeling of the Pseudomonas mevalonii enzyme and assignment of cysteine-237 to the active site. *Biochemistry*. 1992;31(29):6842-7. PMID:1637819
2. Hruz PW, Miziorko HM. Avian 3-hydroxy-3-methylglutaryl-CoA lyase: sensitivity of enzyme activity to thiol/disulfide exchange and identification of proximal reactive cysteines. *Protein Sci*. 1992;1(9):1144-53. doi:10.1002/pro.5560010908 PMCID:PMC2142181 PMID:1304393
3. Mitchell GA, Robert MF, Hruz PW, Wang S, Fontaine G, Behnke CE, Mende-Mueller LM, Schappert K, Lee C, Gibson KM, Miziorko HM. 3-Hydroxy-3-methylglutaryl coenzyme A lyase (HL). Cloning of human and chicken liver HL cDNAs and characterization of a mutation causing human HL deficiency. *J Biol Chem*. 1993;268(6):4376-81. PMID:8440722
4. Hruz PW, Anderson VE, Miziorko HM. 3-Hydroxy-3-methylglutaryldithio-CoA: utility of an alternative substrate in elucidation of a role for HMG-CoA lyase's cation activator. *Biochim Biophys Acta*. 1993;1162(1-2):149-54. PMID:8095409
5. Roberts JR, Narasimhan C, Hruz PW, Mitchell GA, Miziorko HM. 3-Hydroxy-3-methylglutaryl-CoA lyase: expression and isolation of the recombinant human enzyme and investigation of a mechanism for regulation of enzyme activity. *J Biol Chem*. 1994;269(27):17841-6. PMID:8027038
6. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 7 of the GLUT1 glucose transporter. *J Biol Chem*. 1999;274(51):36176-80. PMID:10593902
7. Murata H, Hruz PW, Mueckler M. The mechanism of insulin resistance caused by HIV protease inhibitor therapy. *J Biol Chem*. 2000;275(27):20251-4. doi:10.1074/jbc.C000228200 PMID:10806189
8. Hruz PW, Mueckler MM. Cysteine-scanning mutagenesis of transmembrane segment 11 of the GLUT1 facilitative glucose transporter. *Biochemistry*. 2000;39(31):9367-72. PMID:10924131
9. Hruz PW, Mueckler MM. Structural analysis of the GLUT1 facilitative glucose transporter (review). *Mol Membr Biol*. 2001;18(3):183-93. PMID:11681785

10. Murata H, Hruz PW, Mueckler M. Investigating the cellular targets of HIV protease inhibitors: implications for metabolic disorders and improvements in drug therapy. *Curr Drug Targets Infect Disord*. 2002;2(1):1-8. PMID:12462148
11. Hruz PW, Murata H, Qiu H, Mueckler M. Indinavir induces acute and reversible peripheral insulin resistance in rats. *Diabetes*. 2002;51(4):937-42. PMID:11916910
12. Murata H, Hruz PW, Mueckler M. Indinavir inhibits the glucose transporter isoform Glut4 at physiologic concentrations. *AIDS*. 2002;16(6):859-63. PMID:11919487
13. Koster JC, Remedi MS, Qiu H, Nichols CG, Hruz PW. HIV protease inhibitors acutely impair glucose-stimulated insulin release. *Diabetes*. 2003;52(7):1695-700. PMCID:PMC1403824 PMID:12829635
14. Liao Y, Shikapwashya ON, Shteyer E, Dieckgraefe BK, Hruz PW, Rudnick DA. Delayed hepatocellular mitotic progression and impaired liver regeneration in early growth response-1-deficient mice. *J Biol Chem*. 2004;279(41):43107-16. doi:10.1074/jbc.M407969200 PMID:15265859
15. Shteyer E, Liao Y, Muglia LJ, Hruz PW, Rudnick DA. Disruption of hepatic adipogenesis is associated with impaired liver regeneration in mice. *Hepatology*. 2004;40(6):1322-32. doi:10.1002/hep.20462 PMID:15565660
16. Hertel J, Struthers H, Horj CB, Hruz PW. A structural basis for the acute effects of HIV protease inhibitors on GLUT4 intrinsic activity. *J Biol Chem*. 2004;279(53):55147-52. doi:10.1074/jbc.M410826200 PMCID:PMC1403823 PMID:15496402
17. Yan Q, Hruz PW. Direct comparison of the acute in vivo effects of HIV protease inhibitors on peripheral glucose disposal. *J Acquir Immune Defic Syndr*. 2005;40(4):398-403. PMCID:PMC1360159 PMID:16280693
18. Hruz PW. Molecular Mechanisms for Altered Glucose Homeostasis in HIV Infection. *Am J Infect Dis*. 2006;2(3):187-192. PMCID:PMC1716153 PMID:17186064
19. Turmelle YP, Shikapwashya O, Tu S, Hruz PW, Yan Q, Rudnick DA. Rosiglitazone inhibits mouse liver regeneration. *FASEB J*. 2006;20(14):2609-11. doi:10.1096/fj.06-6511fje PMID:17077279
20. Hruz PW, Yan Q, Struthers H, Jay PY. HIV protease inhibitors that block GLUT4 precipitate acute, decompensated heart failure in a mouse model of dilated cardiomyopathy. *FASEB J*. 2008;22(7):2161-7. doi:10.1096/fj.07-102269 PMID:18256305
21. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. doi:10.1097/COH.0b013e3283139134 PMCID:PMC2680222 PMID:19373039
22. Flint OP, Noor MA, Hruz PW, Hylemon PB, Yarasheski K, Kotler DP, Parker RA, Bellamine A. The role of protease inhibitors in the pathogenesis of HIV-associated lipodystrophy: cellular mechanisms and clinical implications. *Toxicol Pathol*. 2009;37(1):65-77. doi:10.1177/0192623308327119 PMCID:PMC3170409 PMID:19171928
23. Tu P, Bhasin S, Hruz PW, Herbst KL, Castellani LW, Hua N, Hamilton JA, Guo W. Genetic disruption of myostatin reduces the development of proatherogenic dyslipidemia and atherogenic lesions in Ldlr null mice. *Diabetes*. 2009;58(8):1739-48. doi:10.2337/db09-0349 PMCID:PMC2712781 PMID:19509018
24. Guo W, Wong S, Pudney J, Jasuja R, Hua N, Jiang L, Miller A, Hruz PW, Hamilton JA, Bhasin S. Acipimox, an inhibitor of lipolysis, attenuates atherogenesis in LDLR-null mice treated with HIV protease inhibitor ritonavir. *Arterioscler Thromb Vasc Biol*. 2009;29(12):2028-32. doi:10.1161/ATVBAHA.109.191304 PMCID:PMC2783673 PMID:19762785
25. Vyas AK, Koster JC, Tzekov A, Hruz PW. Effects of the HIV protease inhibitor ritonavir on GLUT4 knock-out mice. *J Biol Chem*. 2010;285(47):36395-400. doi:10.1074/jbc.M110.176321 PMCID:PMC2978568 PMID:20864532

26. Gazit V, Weymann A, Hartman E, Finck BN, Hruz PW, Tzekov A, Rudnick DA. Liver regeneration is impaired in lipodystrophic fatty liver dystrophy mice. *Hepatology*. 2010;52(6):2109-17. doi:10.1002/hep.23920 PMCID:PMC2991544 PMID:20967828
27. Hresko RC, Hruz PW. HIV protease inhibitors act as competitive inhibitors of the cytoplasmic glucose binding site of GLUTs with differing affinities for GLUT1 and GLUT4. *PLoS One*. 2011;6(9):e25237. doi:10.1371/journal.pone.0025237 PMCID:PMC3179492 PMID:21966466
28. Vyas AK, Yang KC, Woo D, Tzekov A, Kovacs A, Jay PY, Hruz PW. Exenatide improves glucose homeostasis and prolongs survival in a murine model of dilated cardiomyopathy. *PLoS One*. 2011;6(2):e17178. doi:10.1371/journal.pone.0017178 PMCID:PMC3040766 PMID:21359201
29. Hruz PW, Yan Q, Tsai L, Koster J, Xu L, Cihlar T, Callebaut C. GS-8374, a novel HIV protease inhibitor, does not alter glucose homeostasis in cultured adipocytes or in a healthy-rodent model system. *Antimicrob Agents Chemother*. 2011;55(4):1377-82. doi:10.1128/AAC.01184-10 PMCID:PMC3067185 PMID:21245443
30. Remedi MS, Agapova SE, Vyas AK, Hruz PW, Nichols CG. Acute sulfonylurea therapy at disease onset can cause permanent remission of KATP-induced diabetes. *Diabetes*. 2011;60(10):2515-22. doi:10.2337/db11-0538 PMCID:PMC3178299 PMID:21813803
31. Aerni-Flessner L, Abi-Jaoude M, Koenig A, Payne M, Hruz PW. GLUT4, GLUT1, and GLUT8 are the dominant GLUT transcripts expressed in the murine left ventricle. *Cardiovasc Diabetol*. 2012;11:63. doi:10.1186/1475-2840-11-63 PMCID:PMC3416696 PMID:22681646
32. Vyas AK, Aerni-Flessner LB, Payne MA, Kovacs A, Jay PY, Hruz PW. Saxagliptin Improves Glucose Tolerance but not Survival in a Murine Model of Dilated Cardiomyopathy. *Cardiovasc Endocrinol*. 2012;1(4):74-82. doi:10.1097/XCE.0b013e32835bfb24 PMCID:PMC3686315 PMID:23795310
33. Hresko RC, Kraft TE, Tzekov A, Wildman SA, Hruz PW. Isoform-selective inhibition of facilitative glucose transporters: elucidation of the molecular mechanism of HIV protease inhibitor binding. *J Biol Chem*. 2014;289(23):16100-16113. doi:10.1074/jbc.M113.528430 PMCID:PMC4047383 PMID:24706759
34. Mishra RK, Wei C, Hresko RC, Bajpai R, Heitmeier M, Matulis SM, Nooka AK, Rosen ST, Hruz PW, Schiltz GE, Shanmugam M. In Silico Modeling-based Identification of Glucose Transporter 4 (GLUT4)-selective Inhibitors for Cancer Therapy. *J Biol Chem*. 2015;290(23):14441-53. doi:10.1074/jbc.M114.628826 PMID:25847249
35. Kraft TE, Hresko RC, Hruz PW. Expression, purification, and functional characterization of the insulin-responsive facilitative glucose transporter GLUT4. *Protein Sci*. 2015. doi:10.1002/pro.2812 PMID:26402434
36. Kraft TE, Armstrong C, Heitmeier MR, Odom AR, Hruz PW. The Glucose Transporter PfHT1 Is an Antimalarial Target of the HIV Protease Inhibitor Lopinavir. *Antimicrob Agents Chemother*. 2015;59(10):6203-9. doi:10.1128/AAC.00899-15 PMCID:PMC4576095 PMID:26248369
37. DeBosch BJ, Heitmeier MR, Mayer AL, Higgins CB, Crowley JR, Kraft TE, Chi M, Newberry EP, Chen Z, Finck BN, Davidson NO, Yarasheski KE, Hruz PW, Moley KH. Trehalose inhibits solute carrier 2A (SLC2A) proteins to induce autophagy and prevent hepatic steatosis. *Sci Signal*. 2016;9(416):ra21. doi:10.1126/scisignal.aac5472 PMID:26905426
38. Hresko RC, Kraft TE, Quigley A, Carpenter EP, Hruz PW. Mammalian Glucose Transporter Activity is Dependent upon Anionic and Conical Phospholipids. *J Biol Chem*. 2016. doi:10.1074/jbc.M116.730168 PMID:27302065
39. Kraft TE, Heitmeier MR, Putanko M, Edwards RL, Ilagan MX, Payne MA, Autry JM, Thomas DD, Odom AR, Hruz PW. A Novel Fluorescence Resonance Energy Transfer-Based Screen in High-Throughput Format To Identify Inhibitors of Malarial and Human Glucose Transporters. *Antimicrob Agents Chemother*. 2016;60(12):7407-7414. PMCID:PMC5119023 PMID:27736766

40. Mayer AL, Higgins CB, Heitmeier MR, Kraft TE, Qian X, Crowley JR, Hyrc KL, Beatty WL, Yarasheski KE, Hruz PW, DeBosch BJ. SLC2A8 (GLUT8) is a mammalian trehalose transporter required for trehalose-induced autophagy. *Sci Rep*. 2016;6:38586. PMCID:PMC5138640 PMID:27922102
41. Edwards RL, Brothers RC, Wang X, Maron MI, Ziniel PD, Tsang PS, Kraft TE, Hruz PW, Williamson KC, Dowd CS, John ARO. MEPicides: potent antimalarial prodrugs targeting isoprenoid biosynthesis. *Sci Rep*. 2017;7(1):8400. PMCID:PMC5567135 PMID:28827774
42. Wei C, Bajpai R, Sharma H, Heitmeier M, Jain AD, Matulis SM, Nooka AK, Mishra RK, Hruz PW, Schiltz GE, Shanmugam M. Development of GLUT4-selective antagonists for multiple myeloma therapy. *Eur J Med Chem*. 2017;139:573-586. PMCID:PMC5603412 PMID:28837922
43. Wei C, Heitmeier M, Hruz PW, Shanmugam M. Evaluating the Efficacy of GLUT Inhibitors Using a Seahorse Extracellular Flux Analyzer. *Methods Mol Biol*. 2018;1713:69-75. PMID:29218518
44. Heitmeier MR, Payne MA, Weinheimer C, Kovacs A, Hresko RC, Jay PY, Hruz PW. Metabolic and Cardiac Adaptation to Chronic Pharmacologic Blockade of Facilitative Glucose Transport in Murine Dilated Cardiomyopathy and Myocardial Ischemia. *Sci Rep*. 2018;8(1):6475. PMID:29691457
45. Zhang Y, Higgins CB, Mayer AL, Mysorekar IU, Razani BB, Graham MJ, Hruz PW, DeBosch BJ. TFEB-dependent Induction of Thermogenesis by the Hepatocyte SLC2A Inhibitor Trehalose. *Autophagy*. 2018. PMID:29996716
46. Emfinger CH, Yan Z, Welscher A, Hung P, McAllister W, Hruz PW, Nichols CG, Remedi MS. Contribution of systemic inflammation to permanence of K_{ATP}-induced neonatal diabetes in mice. *Am J Physiol Endocrinol Metab*. 2018;315(6):E1121-E1132. PMCID:PMC6336961 PMID:30226997
47. Heitmeier MR, Hresko RC, Edwards RL, Prinsen MJ, Ilagan MXG, Odom John AR, Hruz PW. Identification of druggable small molecule antagonists of the Plasmodium falciparum hexose transporter PfHT and assessment of ligand access to the glucose permeation pathway via FLAG-mediated protein engineering. *PLoS One*. 2019;14(5):e0216457. PMCID:PMC6508677 PMID:31071153
48. Hruz PW. Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria. *Linacre Q*. 2020;87(1):34-42. PMCID:PMC7016442 PMID:32431446
49. Zhang Y, Shaikh N, Ferey JL, Wankhade UD, Chintapalli SV, Higgins CB, Crowley JR, Heitmeier MR, Stothard AI, Mihi B, Good M, Higashiyama T, Swarts BM, Hruz PW, Shankar K, Tarr PI, DeBosch BJ. Lactotrehalose, an Analog of Trehalose, Increases Energy Metabolism Without Promoting Clostridioides difficile Infection in Mice. *Gastroenterology*. 2020;158(5):1402-1416.e2. PMCID:PMC7103499 PMID:31838076
50. Malone WJ, Hruz PW, Mason JW, Beck S. Letter to the Editor from William J. Malone: "Proper Care of Transgender and Gender Diverse Persons in the Setting of Proposed Discrimination: A Policy Perspective". *J Clin Endocrinol Metab*. 2021. PMID:33772300

Book Chapters

1. Henderson KE, Baranski TJ, Bickel PE, Clutter PE, Clutter WE, McGill JB. Endocrine Disorders in HIV/AIDS. In: *The Washington Manual Endocrinology Subspecialty Consult* Philadelphia, PA; 2008:321-328.
2. Paul W Hruz. Medical Approaches to Alleviating Gender Dysphoria In: Edward J Furton, eds. *Transgender Issues in Catholic Health Care* Philadelphia PA; 2021:1-42.

Invited Publications

1. Grunfeld C, Kotler DP, Arnett DK, Falutz JM, Haffner SM, Hruz P, Masur H, Meigs JB, Mulligan K, Reiss P, Samaras K, Working Group 1. Contribution of metabolic and anthropometric abnormalities to cardiovascular disease risk factors. *Circulation*. 2008;118(2):e20-8. PMCID: PMC3170411 PMID: 18566314
2. Hruz PW. HIV protease inhibitors and insulin resistance: lessons from in-vitro, rodent and healthy human volunteer models. *Curr Opin HIV AIDS*. 2008;3(6):660-5. PMCID: PMC2680222 PMID: 19373039
3. Hruz PW. Molecular mechanisms for insulin resistance in treated HIV-infection. *Best Pract Res Clin Endocrinol Metab*. 2011;25(3):459-68. PMCID: PMC3115529 PMID: 21663839
4. Hruz PW. HIV and endocrine disorders. *Endocrinol Metab Clin North Am*. 2014;43(3): xvii–xviii. PMID: 25169571
5. Hruz PW. Commentary. *Clin Chem*. 2015;61(12):1444. PMID: 26614228
6. Hruz PW, Mayer LS, and McHugh PR. Growing Pains: Problems with Pubertal Suppression in Treating Gender Dysphoria *The New Atlantis*. 2017;52:3-36.
7. Hruz, PW. The Use of Cross-Sex Steroids in Treating Gender Dysphoria *Natl Cathol Bioeth Q*. 2018;17(4):1-11.
8. Hruz, PW. Experimental Approaches to Alleviating Gender Dysphoria in Children *Nat Cathol Bioeth Q*. 2019;19(1):89-104.

Clinician Educator Portfolio

CLINICAL CONTRIBUTIONS

Summaries of ongoing clinical activities

	General Pediatrician, General Pediatric Ward Attending: 2-4 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Endocrinology Night Telephone Consult Service: Average of 2-6 weeks/per yr, St. Louis Children's Hosptial
2000 - Pres	Pediatric Endocrinologist, Inpatient Endocrinology Consult Service: 4-6 weeks per year, St. Louis Children's Hospital
2000 - Pres	Pediatric Endocrinologist, Outpatient Endocrinology Clinic: Approximately 50 patient visits per month, St. Louis Children's Hospital

EDUCATIONAL CONTRIBUTIONS

Direct teaching

Classroom

2009 - Pres	Lecturer, Markey Course-Diabetes Module
2020 - 2020	Facilitator, Reading Elective-Interdisciplinary/Miscellaneous Course #M80-800, Washington University School of Medicine

Clinical

2000 - Pres	Lecturer, Medical Student Growth Lecture (Women and Children's Health Rotation): Variable

2000 - Pres	Lecturer, Pediatric Endocrinology Journal Club: Presentations yearly
2009 - Pres	Facilitator, Medical Student Endocrinology and Metabolism Course, Small group
2016 - Pres	Facilitator, Medical Student Endocrinology and Metabolism Course, Small group

Other

	Facilitator, Cell Biology Graduate Student Journal Club, 4 hour/year
	Facilitator, Discussion: Pituitary, Growth & Gonadal Cases, 2 hours/year
2000 - Pres	Lecturer, Metabolism Clinical Rounds/Research Seminar: Presentations twice yearly
2009 - Pres	Facilitator, Biology 5011- Ethics and Research Science, 6 hours/year
2016 - Pres	Lecturer, Cell Signaling Course, Diabetes module, 3 hours/year

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Expert Witness Declaration of
Paul R. McHugh, MD
Baltimore, Maryland 21218

Knowledge Training and Experience :

1. Education and Training - Retention - Compensation : After graduating from Phillips Academy, Andover, in 1948, I received an A.B. degree from Harvard College in 1952 and an MD degree from Harvard Medical School in 1956. I completed my medical internship at the Peter Bent Brigham Hospital Boston, Massachusetts (1956-57) , my residency in neurology at the Massachusetts General Hospital (1957-60) and a Neuropathology Fellowship at the Massachusetts General Hospital (1958-59). I served as a Clinical Assistant in Psychiatry at the Maudsley Hospital, London, England (1960-61) with additional training as a Member of the Neuropsychiatry Division Walter Reed Army Institute of Research, Washington, D.C. (1961-64). My professional background, experience, and publications are further detailed in the updated copy of my curriculum vitae attached as Exhibit A to this declaration. I was retained as an expert

in this case by Attorney John Knepper. I have reviewed the case Complaint and Answer and will receive no compensation for my analysis-report-testimony in this matter.

2. **Board Certifications, License History, and Practice of Medicine :** I was qualified in both Psychiatry and Neurology by the American Board of Psychiatry and Neurology. National Board of Medical Examiners, Certified #35725; American Board of Psychiatry and Neurology, Certified #9508 ; Massachusetts Registration #26021 ; New York Registration #93799 ; Oregon Registration #8693 ; Maryland Registration #D-18666

3. **Medical Staff and Faculty Appointments :** I served as Asst. Professor, then Associate Professor, then Full Professor of Psychiatry at Cornell University Medical College (1964-1971). I also served as the Founder and First Director of Bourne Behavioral Research Laboratory, Westchester Division of the New York Hospital, Department of Psychiatry, Cornell Medical College (1967-68). I then served as Professor and Chairman: Department of Psychiatry at the University of Oregon Health Sciences Center (1973-75). From 1975 to 2001, I served as the Henry Phipps Professor of Psychiatry and the director of the Department of Psychiatry and Behavioral Science at the Johns Hopkins University School of Medicine. During this time period, I also served as the psychiatrist-in-chief at the Johns Hopkins Hospital and Professor in Department of The Johns Hopkins School of Hygiene and Public Health, Mental Health (1975 -). I also served as the Chairman of the Medical Board of the The Johns Hopkins Hospital, 1984-89. I continue to serve as the University Distinguished Service Professor of Psychiatry at Johns Hopkins University School of Medicine (1998 -).

4. **Publications and Editorial Work:** I have published many peer reviewed articles in scientific journals. (See attached Curriculum Vitae). I have also published a number of books including :

Author:

McHugh, P. R. (2006). Try to Remember: Psychiatry's Clash over Meaning, Memory, and Mind. New York: DANA

McHugh, P.R. (2008). The Mind Has Mountains: Reflections on Society and Psychiatry. Baltimore, MD: Johns Hopkins University Press.

Co-author:

— Hedblom, J. H., & McHugh, P. R. (2007). *Last Call: Alcoholism and Recovery*

— Fagan, P. J., & McHugh, P. R. Sexual Disorders: Perspectives on Diagnosis and Treatment.

— Neubauer, D. N., & McHugh, P. R. Understanding Sleeplessness: Perspectives on Insomnia.

— McHugh, P. R., & Slavney, P. R. (1998). *The Perspectives of Psychiatry,* 2nd ed. Baltimore, Maryland: Johns Hopkins University Press.

Editor:

— McHugh, P. R., & McKusick. Eds. (1990). *Genes, Brain, and Behavior.The Perspectives of Psychiatry (*1983 with Phillip R. Slavney)

I also served as an Editor or Reviewer for the following Journals:

Editorial Positions: 1. Associate Editor for the American Journal of Physiology: Regulatory, Integrative and Comparative Physiology, 1982 - 1996; President, Association for

Research in Nervous and Mental Disease (ARNMD), December 1989, “Genes, Brain and Behavior”

Editorial Boards: The Journal of Nervous and Mental Disease, Comprehensive Psychiatry, Medicine, Psychological Medicine, The Johns Hopkins University Press, International Review of Psychiatry, The American Scholar

Book Service Editorial Boards: The Handbook of Psychiatry, Cambridge University Press ; The Scientific Basis of Psychiatry, Cambridge University Press; Brill’s Studies in Epistemology, Psychology and Psychiatry ; The Handbook of Behavioral Neurobiology; and The Johns Hopkins Series in Contemporary Medicine and Public Health.

5. **Awards :** In 1992, I was elected to the Institute of Medicine (IOM) - National Academies of Science (now known as the National Academy of Medicine). In 2001, I was appointed by President George W. Bush to the President’s Council on Bioethics. I have received a number of Fellowships including those from the American College of Physicians, the American College of Psychiatrists, the American Psychiatric Association, and the Royal College of Psychiatrists. Other awards include:

William C. Menninger Award, American College of Physicians, 1987.

The Distinguished Achievement Award, The New York Hospital-Cornell Med. Center, Ctr. Alumni Council, 1988.

The Johns Hopkins University Alumni Association Excellence in Teaching Award, 1992.

Joseph Zubin Award of the American Psychopathological Association, 1995.

Distinguished Service Award, The American College of Psychiatrists, 2002.

Visiting Scholar, The Phi Beta Kappa Society, 2003-2004.

Distinguished Life Fellow, American Psychiatric Association, 2003.

Paul Hoch Award of the American Psychopathological Association , 2006.

Rhoda and Bernard Sarnat International Award in Mental Health of the Institute of Medicine, 2008.

Distinguished Career Award. Society for the Study of Ingestive Behavior, 2009.

Doctor Honoris Causa. University of Zaragoza, Spain, 2012.

6. Research Grants : Principal Investigator for research grants from the National Institutes of Health: A. Hormonal Studies in Depression. 1964 - 1968 ; B. Establishment of a primate research resource. 1967 - 1970 ; C. Hypothalamic studies in endocrinology. 1970 - 1974 ; D. #R01AM18554 Hypothalamus in Feeding Behavior. 1975- 1985 ; E. #R01AM19302 Gastrointestinal Integration and Feeding. 1985-95. (Became Co Principal Investigator in 1989, T.H. Moran became Principal Investigator). (See attached Curriculum Vitae).

7. **Psychiatric Misadventures *:*** In 1992, I published McHugh, P.R. *Psychiatric Misadventures*. The American Scholar, 61:497-510, 1992. This essay was selected and reprinted in The Best American Essays, 1993. ed. R. Atwan, Publisher, Ticknor & Fields, New York. An important part of my career has been engaged in observing and warning the public and mental health professions about Psychiatric Misadventures. I think this scientific, clinical, and health care system history will be helpful to the court in the Kadel v. Folwell case.

8. **The Psychiatric Misadventure of Lobotomies - a Tragic Psychiatric Misadventure that Damaged Tens of Thousands of Patients, Robbing Them of Their Emotions and Personality:**

A lobotomy, or leucotomy, is a form of psychosurgery, a neurosurgical treatment for mental disorders that involves severing severing prefrontal cortex connections in the patient's brain. The peak of the lobotomy era was earlier than my training, teaching, and practice but I learned much from the history of this bio-medical disaster. This "treatment" — received much attention, endorsement, and even awards as neurologist Antonioa Egas Moniz, shared the Nobel

Prize for Physiology or Medicine in 1949 for the "discovery of the therapeutic value of leucotomy in certain psychoses". By 1951, nearly 20,000 lobotomies had reportedly been performed in the United States and proportionally more in the United Kingdom. British psychiatrist Maurice Partridge, who conducted a follow-up study of 300 patients, reported that the treatment achieved its effects by "reducing the complexity of psychic life". Following the operation, "spontaneity, responsiveness, self-awareness, and self-control were reduced. The activity was replaced by inertia, and people were left emotionally blunted and restricted in their intellectual range." Many of these patients were left with with severe and disabling impairments. Proper informed consent was not obtained for these experimental "treatments". Surgeon Walter Freedman, who used the procedure widely, coined the term "surgically induced childhood" to refer to the results of lobotomy. [See, e.g., Partridge, Maurice. *Pre-frontal leucotomy:*. Oxford: Blackwell Scientific Publications; 1950.] Currently, the lobotomy era is viewed as an unethical psychiatric misadventure and an assault on the rights, health, and personalities of vulnerable patients. Like the infamous Tuskeegee research, and the horrific experiments of the Nazis and Imperial Japan in WWII, lobotomies are a textbook example of why informed consent protections are vital for patient safety and dignity.

7. **Early Warnings about the Methodological Limitations of a Psychiatric Dictionary — the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association — a Psychiatric Misadventure of Assessment and Diagnosis:**

In 1997, I testified in the *Rhode Island vs. Quattrochi* case Daubert hearing that the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association (DSM) was essentially a dictionary based on consensus-seeking voting methodologies rather

than evidence-seeking scientific methodologies. [See, Grove, W. M. and Barden, R.C. (2000) Protecting the Integrity of the Legal System : The Admissibility of Testimony from Mental Health Experts Under Daubert/Kumho Analyses, Psychology, Public Policy and Law, Vol 5, No. 1, 234-242.] In 2012, I published an essay in *The New England Journal of Medicine* (with co-author Phillip R. Slavney) seeking reforms to the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association which was soon to be published in its fifth edition. One of our main criticisms contended that the DSM used a top-down checklist approach to diagnosis rather than a thorough bottom-up approach. We compared the DSM to a field guide used by amateur birders to identify birds. It is important for legal professionals to understand that the DSM was created using a consensual, political process of committees and voting methodologies. Voting by committees is not a reliable-valid scientific, evidence-based process. The DSM was thus not built using uniformly valid and reliable scientific processes. In the DSM methodology, small groups of professionals, some with ideological or personal agendas, would form committees and create diagnoses to be "voted" into the DSM. The field has increasingly come to see the DSM as controversial and in need of reforms.

The limitations of the DSM methodology are now well known leading to calls for corrections from the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA*. Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the

American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be reorienting its research away from DSM categories."] ; See, also U.S. National Institute of Mental Health Director Thomas Insel on Transforming Diagnosis, April 29, 2013, See, https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure. In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, has been largely replaced in the past half century as we have understood that symptoms alone rarely indicate the best choice of treatment. Patients with mental disorders deserve better. NIMH has launched the Research Domain Criteria (RDoC) project to transform diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system."] In my opinion, the view that the DSM is insufficiently reliable and in need of methodological reforms is generally accepted by the relevant scientific community.

The unreliability of the DSM assessment process is important to understanding defects in transgender treatment methodologies. Patients are diagnosed with a DSM checklist for "gender dysphoria" and sent down a road towards potential sterility or other damages to normal, healthy organs based solely on unverified patient reports and the DSM checklist process. This inherently

unreliable process may explain in part why research in this field indicates an ongoing lack of understanding of how to help these vulnerable, suffering patients.

8. **Early Warnings to Protect Patients from the Predicted Iatrogenic Damages of the "Repressed Memory Therapy" and "Multiple Personality Disorder" Industries — a Psychiatric Misadventure that damaged tens of thousands of patients and families:**

In the early 1990s, I took the — very unpopular at the time — public position that "repressed childhood memories of trauma" , "recovered memory therapy" (RMT), and "multiple personality disorder" (MPD) were psychiatric misadventures employing unreliable, unscientific notions and methods that posed dangers to patients and to the integrity of the mental health system. See, McHugh, P.R., *Psychiatric Misadventures*, The American scholar, January 1993 ; McHugh, P.R. Resolved: Multiple Personality Disorder is an Individually and Socially Created Artifact. J. of the Amer. Academy of Child and Adolescent Psychiatry, 34:7 1995; McHugh, P.R. Witches, multiple personalties, and other psychiatric artifacts. Nature Medicine, 1:2 110-114, 1995 ; and McHugh, P.R. Multiple Personality Disorder—A Socially Constructed Artifact. J. of Practical Psychiatry and Behavioral Health, 1:3 158-166, 1995. By the end of the 1990s, after many dozens of research studies, dozens of civil malpractice lawsuits against "recovered memory" and "MPD" therapists, the closing of several RMT-MPD clinics, multiple media exposes, and several licensing revocations of RMT-MPD industry leaders, these treatments largely collapsed saving tens of thousands of patients and families from harm.

It is now well documented that the RMT-MPD misadventure was perhaps the worst disaster to befall the mental health system since lobotomies. See Pendergrast, M. (2017). *The repressed memory epidemic: How it happened and what we need to learn from it.* New York, NY: Springer ; See also, Barden RC: *Reforming the Mental Health System: Coordinated,*

Multidisciplinary Actions Ended "Recovered Memory" Treatments and Brought Informed Consent to Psychotherapy. Psychiatric Times. 2014;31(6): June 6, 2014. In sum, the field has come to agree that the RMT-MPD industries were indeed another Psychiatric Misadventure.

9. Early Warnings have not been Used to Protect Patients from the Documented Methodological Errors and Predicted Iatrogenic Damages of the Transgender Treatment Industry - yet another Psychiatric Misadventure :

Many years ago, our clinical experiences and research at Johns Hopkins led to the closing of the transgender clinic. Research showed insufficient benefits for the risks involved in such experimental, unproven treatments on vulnerable patients. Like lobotomies, the RMT-MPD industries, and over-reliance on the DSM, the Transgender Treatment Industry is a Psychiatric Misadventure based upon failures to apply proper scientific methodologies and patient protections. The DSM, the RMT-MPD industries and the Transgender Treatment Industries are all examples of failures to avoid confirmation bias, that is failures to properly generate and rigorously test alternative hypotheses without regard for ideological preconceptions. The key motivation of a psychiatrist and all physicians should be to develop, scientifically validate, and then apply the very best and most effective treatments to relieve the suffering of patients — not rapidly apply untested but "politically correct" treatments.

In recent years, this controversial field has faced increasing scrutiny as national research reviews in England, Sweden, and Finland as well a Cochrane Review and studies by multiple researchers have concluded that the evidentiary base for these experimental treatments is weak and demonstrates few benefits or actually shows this procedures can cause more harm than good. The rapid expansion in the number of patients and the rapid demographic shift in patients demonstrate how little we know about these troubles. Faced with overwhelming life problems

and chronic psychiatric illness, some patients seek a simple solution for their suffering. Whether its "recovered memories", "multiple personalities" or "transgender transitioning" such patient can pin their hopes upon this newly ascribed solution to complex life problems. This enormous increase in cases in the US and Europe cannot be explained and was not predicted by the movement's genetic, biological, "brain structure" or "immutable" theories of the etiology of gender discordance.

In contrast, the exponential growth in patients was indeed predicted and is readily explained by a social contagion theory — the same process by which adopting repressed memories and multiple personalities came to damage so many tens of thousands of lives. See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New Atlantis, Number 52, Spring 2017 pp. 3 -36; See also, Van Mol, A., Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765.

10. **The Transgender Treatment Industry Has Come Under Increasing Criticism In Recent Years as Methodological Errors and Systemic Failures have been publicly aired and debated including: (See Detailed Notes and Research-Review Citations attached).**

A) Current transgender theories failed to predict the widely reported exponential increase in cases (i.e. this is clearly not due to genetics, "brain structures", or "immutability"… social contagion seems more likely).

B) Current transgender theories failed to predict the rapid and unusual changes in patient demographics (from young boys with early onset-chronic dysphoria to adolescent females with rapid onset of gender dysphoria symptoms.

C) The Transgender Treatment Industry has failed to conduct competent randomized clinical trials to assess the safety and effectiveness of treatments despite offering "treatments" for 50 years.

D) The Transgender Treatment Industry has failed to conduct competent, rigorous long-term treatment outcome research despite having 50 years to do so.

E) The Transgender Treatment Industry has failed to conduct competent research on the social contagion theory in an attempt to understand the rapid increase in patients and demographic shift — in fact, they tried to suppress such research. This is true even though psychiatry has known for many years that some psychiatric disorders can be influenced by the peer group dynamics of adolescent girls. (e.g., eating disorders). See, e.g. L. Littman (2018), Parent Reports of Adolescents & Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria, PLoS ONE 13(8): e0202330.

F) The Transgender Treatment Industry has failed to properly and fully inform patients and the public of the serious risks, dangers, controversies, and methodological shortcomings of the current experimental treatments offered.

G) The Transgender Treatment Industry has tragically failed to acknowledge and properly learn from and adapt to the valid criticisms. The industry has yet to admit and advance beyond its scientific and clinician flaws, errors, and mistakes. Until it does, it will continue on as an example of a Psychiatric Misadventure.

11. **SUMMARY OPINIONS:** It is my opinion, to a reasonable degree of medical certainty that:

— There are currently no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are ***helped*** by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are ***injured or harmed*** by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of *assessing* gender identity by relying solely upon the unverified statements of a patient.

— A currently unknown number (but likely larger than 50%) of patients reporting gender dysphoria suffer from psychiatric illness(es) that can complicate and may distort their judgments and perceptions of gender identity.

— A currently unknown percentage and number of patients — many of them adolescent females — reporting gender dysphoria have been heavily influenced and/or manipulated by a source of social contagion — peer group, social media, YouTube influencers, therapists, and/or parents. Detailed psycho-social investigations of such patients — sometimes over a period of years — may be necessary to better understand the psychiatric-psychological-and neurological complexities of reported gender discordance.

— Patients suffering from gender dysphoria or related issues ***have a right to be protected*** from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

— Multiple research studies have shown that a large percentage of children (over 80% in some studies) who initially reported gender discordance will, ***if simply left alone***, develop a natural acceptance of their natal (biological) sex. Halting this natural healing process with hormones or surgery — when there are no reliable ways to predict which children will heal on their own — is an improper and experimental process that will produce lasting damage to many children.

— Medical treatments may differ significantly by sex according to chromosomal assessment but not by gender identity. ***Misinforming physicians of a patient's biological sex*** can have deleterious effects on treatment for a variety of medical conditions.

— Affirmation ("transgender transitioning") medical treatments — hormones and surgery — for gender dysphoria and "transitioning" remain unproven and have thus ***not been accepted by the relevant scientific communities*** (biology, genetics, neonatolgy, medicine, psychiatry, psychology, etc).

— Affirmation ("transgender transitioning") medical treatments — hormones and surgery — for gender dysphoria and "transitioning" remain unproven and poorly researched and thus ***have no known, peer reviewed and published error rates*** — these treatments methods lack demonstrated, reliable and valid error rates.

— Professional and political associations WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society, etc. are **not** the relevant scientific community, they are organizations that rely upon consensus-seeking methodologies including voting rather than careful, prudent, evidence-based, Popperian-testable scientific methodologies.

12. LIMITATIONS ON EXPERT WITNESS REPORTS: - RETENTION - COMPENSATION: My opinions and hypotheses in this matter are — as all expert reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to Attorney John Knepper (john@knepperllc.com) for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that my foregoing report in the Kadel v. Folwell case is true and correct.

Signed: _____ Date: _____
Paul R. McHugh, MD

12. LIMITATIONS ON EXPERT WITNESS REPORTS: My opinions and hypotheses in this matter are — as all expert reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to John Knepper (john@knepperllc.com), for distribution as consistent with the laws of the appropriate jurisdiction for this case.

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that my foregoing report in the Kadel v. Folwell case is true and correct.

Signed: Paul R. McHugh **Date:** 5/1/21

Paul R. McHugh, MD

Exhibit A

Curriculum Vitae

PAUL R. McHUGH, M.D.

Home address:	3707 St. Paul Street Baltimore, Maryland 21218
Born:	May 21, 1931
Place of Birth:	Lawrence, Massachusetts
Marital Status:	Married: Wife's name Jean, 3 children
Schooling:	Phillips Academy, Andover, 1948 Harvard College, A.B., 1952 Harvard Medical School, M.D., 1956
Medical Internship:	Peter Bent Brigham Hospital Boston, Massachusetts (1956-57)
Neurology Residency:	Massachusetts General Hospital (1957-60)
Neuropathology Fellow:	Massachusetts General Hospital (1958-59)
Teaching Fellow in Neurology and Neuropathology:	Harvard Medical School (1957-60)
Clinical Assistant in Psychiatry:	Maudsley Hospital, London, England (1960-61)
Member Neuropsychiatry Division:	Walter Reed Army Institute of Research, Washington, D.C. (1961-64)
Assistant Professor of Psychiatry and of Neurology:	Cornell University Medical College (1964-68)
Associate Professor of Psychiatry and of Neurology:	Cornell University Medical College (1968-71)
Professor of Psychiatry and of Neurology:	Cornell University Medical College (1971)
Director of Electroencephalography:	The New York Hospital (1964-68)

Founder and First Director:	Bourne Behavioral Research Laboratory, Westchester Division of the New York Hospital, Department of Psychiatry, Cornell Medical College (1967-68)
Clinical Director and Supervisor of Psychiatric Education:	Westchester Division of the New York Hospital, Department of Psychiatry (1968-73)
Professor and Chairman:	Department of Psychiatry University of Oregon Health Sciences Center (1973-75)
Henry Phipps Professor of Psychiatry and Director:	Department of Psychiatry and Behavioral Sciences, The Johns Hopkins University School of Medicine, 1975 - 2001
Psychiatrist-in-Chief:	The Johns Hopkins Hospital, 1975 - 2001
Professor in Department of Mental Health:	The Johns Hopkins School of Hygiene and Public Health, 1975 -
Director: Blades Center for Clinical Practice and Research in Alcoholism	The Johns Hopkins Medical Institutions, 1992 -2001
University Distinguished Service Professor of Psychiatry	The Johns Hopkins University, 1998 -

Qualified in both Psychiatry and Neurology by the American Board of Psychiatry and Neurology.
National Board of Medical Examiners, Certified #35725
American Board of Psychiatry and Neurology, Certified #9508
Massachusetts Registration #26021
New York Registration #93799
Oregon Registration #8693
Maryland Registration #D-18666

<u>Selective Administrative Responsibilities</u>

Chairman of the Associate Professor Promotions Committee:	The Johns Hopkins University School of Medicine, 1978-84
Chairman of the Medical Board:	The Johns Hopkins Hospital, 1984-89

Chairman of the Professorial Promotions Committee:	The Johns Hopkins University School of Medicine, 1985 - 1991
Member of Management Advisory Committee:	The Johns Hopkins Health System, 1989 - 1996
Board of Trustees/Advisors:	The Kennedy Krieger Research Institute, Inc., 1993 - 2001 The Johns Hopkins Hospital (ex-officio), 1984 – 1989 Association for Research in Nervous and Mental Disease, 1987 - The College of Notre Dame of Maryland, 1999 – 2005 False Memory Syndrome Foundation, 1993 – President, Johns Hopkins Chapter, Phi Beta Kappa, 2001 - 2002 President's Council on Bioethics, 2001 – 2008 United States Conference of Catholic Bishops National Review Board, 2002 - 2007
Fellowships:	American College of Physicians American College of Psychiatrists American Psychiatric Association Royal College of Psychiatrists
Memberships:	Alpha Omega Alpha American Academy of Clinical Psychiatrists American Association of Chairmen of Departments of Psychiatry American College of Neuropsychopharmacology American Medical Association American Neurological Association American Physiological Society Association for Research in Nervous and Mental Disease Baltimore City Medical Society Eastern Psychological Association Harvey Society International Society of Psychoneuroendocrinology Maryland Psychiatric Society Medical and Chirurgical Faculty of the State of Maryland New York Academy of Sciences Order of Malta Phi Beta Kappa The Pavlovian Society The Peripatetic Club Sigma XI Society of Biological Psychiatry Society for Neuroscience

Research Advisory Groups:	Bio-Psychology Study Section, NIH, 1985 - 86 Chairman, Bio-Psychology Study Section, 1986 - 89 American Federation for Aging Research (AFAR) Scientific Council of NARSAD (National Alliance for Research on Schizophrenia and Depression, 1986 - Scientific and Professional Advisory Board of FMS (False Memory Syndrome) Foundation, 1992 - Co-Chairman, Ethics Committee of American College of Neuropsychopharmacology (ACNP), 2001 - 2003
Editorial Positions:	1. Associate Editor *American Journal of Physiology* Regulatory, Integrative and Comparative Physiology, 1982 - 1996 2. President, Association for Research in Nervous and Mental Disease (ARNMD), December 1989, "Genes, Brain and Behavior"
Editorial Boards:	The Journal of Nervous and Mental Disease *Comprehensive Psychiatry* *Medicine* *Psychological Medicine* The Johns Hopkins University Press *International Review of Psychiatry* *The American Scholar*
Book Service Editorial Boards:	*The Handbook of Psychiatry*, Cambridge University Press *The Scientific Basis of Psychiatry*, Cambridge University Press *Brill's Studies in Epistemology, Psychology and Psychiatry* *Handbook of Behavioral Neurobiology* *The Johns Hopkins Series in Contemporary Medicine and Public Health*
Grants:	Principal Investigator from the United States Public Health Service, N.I.H. Training: 1. NIH Clinical Traineeship 1960 - 1963 2. Interdisciplinary Training Program in Psychiatry and Neuroscience (Director) 1990 – 1996

Principal Investigator for research grants from the National Institutes of Health:

1. Hormonal Studies in Depression. 1964 - 1968
2. Establishment of a primate research resource. 1967 - 1970
3. Hypothalamic studies in endocrinology. 1970 - 1974
4. #R01AM18554 Hypothalamus in Feeding Behavior. 1975-1985.
5. #R01AM19302 Gastrointestinal Integration and Feeding. 1985-95. (Became Co-Principal Investigator in 1989, T.H. Moran became Principal Investigator).

Awards and Honors:

William C. Menninger Award, Amer. College of Physicians, 1987.

The Distinguished Achievement Award, The New York Hospital-Cornell Med. Center, Ctr. Alumni Council, 1988.

Member, Institute of Medicine, National Academy of Sciences,1992.

The Johns Hopkins University Alumni Association Excellence in Teaching Award, 1992.

Joseph Zubin Award of the American Psychopathological Association, 1995.

Distinguished Service Award, The American College of Psychiatrists, 2002.

Visiting Scholar, The Phi Beta Kappa Society, 2003-2004.

Distinguished Life Fellow, American Psychiatric Association, 2003.

Paul Hoch Award of the American Psychopathological Association , 2006.

Rhoda and Bernard Sarnat International Award in Mental Health of the Institute of Medicine, 2008.

Distinguished Career Award. Society for the Study of Ingestive Behavior, 2009.

Doctor Honoris Causa. University of Zaragoza, Spain, 2012.

Representative Sample of Invited Lectures:

Distinguished Guest Lecturer at the Annual Meeting of The Royal College of Psychiatrists, London, England, July 5, 1978.

The Charles Getz, M.D. Memorial Lecture, The University of Maryland, School of Medicine, Baltimore, MD, March 6, 1979.

Dean's Lecture, The Johns Hopkins Medical Institutions Baltimore, MD, November 13, 1978.

Phineas J. Sparer Distinguished Visiting Professor, University of Tennessee, Memphis, TN, May 16, 1984.

Eastern Psychological Association Annual Meeting, New York, April 25, 1986.

Litchfield Lecturer, Univ. of Oxford, Oxford, England, June 1986.

Chairman, Symposium on Role of the Stomach in Regulation of Satiety. FASEB, Washington, D.C., March 31, 1987.

Telford Lecturer, Washington and Lee University, Lexington, Virginia, April 28, 1988.

Harvey Shein Memorial Lecturer. American Association of Directors of Psychiatric Residency Training, New Orleans, Louisiana, January 13, 1990.

Robert O. Jones Memorial Lecturer. Dalhousie University Medical School, Halifax, Nova Scotia, Canada, March 23, 1990.

Hasenbush Visiting Professor, Massachusetts Mental Health Center, Harvard Medical School, Boston, Mass., January 30, 1991.

Mapother Lecturer, Maudsley Hospital, Institute of Psychiatry, London, England, November 4, 1992.

William Paley Lecturer, Department of Medicine, Cornell Medical College, New York Hospital, February 4, 1993.

Theodore E. Woodward Lecturer, University of Maryland, April 15, 1993.

Sister Virgina Geiger Lecturer, College of Notre Dame of Maryland, Baltimore, Maryland, May 9, 1995.

Phi Beta Kappa Address, Washington & Lee University, Virginia, March 7, 1996.

Biele Lecturer, Thomas Jefferson University, Philadelphia, Pennsylvania, April 10, 1996.

Weniger Lecturer, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, April 26, 1996.

Taylor Lecturer in Neuropsychiatry, University of Maryland School of Medicine, Baltimore, Maryland, April 24, 1997.

Tumulty Lecturer, Johns Hopkins University School of Medicine, Baltimore, Maryland, May 14, 1997.

Mendelsohn Lecturer, New England Medical Center, Boston, Massachusetts, April 16, 1998.

Denny Brown Lecturer, Beth Israel Deaconess Hospital, Boston, Massachusetts, May 18, 2000.

Raymond D. Adams Honorary Lecture, Massachusetts General Hospital, Boston, Massachusetts, June 8, 2000.

Distinguished Psychiatrist Lecture, American Psychiatric Association, May 7, 2001.

PUBLICATIONS:

Books:

1. McHugh, P.R. and Slavney, P.R.: The Perspectives of Psychiatry, The Johns Hopkins University Press, Baltimore, MD, 1983.

   a. McHugh, P.R. and Slavney, P.R.: Perspectives de la Psiquiatria, Masson, Barcelona, Spain, 1985.

b. McHugh, P.R. and Slavney, P.R.: Psychiatriche Perspektiven, Springer-Verlag Berlin Heidelberg, Germany, 1984.

c. McHugh, P.R. and Slavney, P.R.: Les Perspectives de la Psychiatrie, Masson, Paris, France., 1986.

d. McHugh, P.R. and Slavney, P.R.: As Perspectivas da Psiquiatria, Artes Medicas, Porto Alegre, Brazil, 1988.

2. Slavney, P.R. and McHugh, P.R.: Psychiatric Polarities. The Johns Hopkins University Press, Baltimore, MD, 1987.

3. McHugh, P.R. and McKusick, V.A. (eds): Genes, Brain and Behavior. Assoc. Res. Nerv. Ment. Dis., Vol. 69, Raven Press, New York, 1990.

4. McHugh, P.R. and Slavney, P.R.: The Perspectives of Psychiatry, 2nd Edition, The Johns Hopkins University Press, Baltimore, MD, 1998.

5. McHugh, P.R.: The Mind Has Mountains: Reflections on Society and Psychiatry. The Johns Hopkins University Press, Baltimore, MD, 2006.

6. McHugh, P.R.: Try to Remember: Psychiatry's Clash Over Meaning, Memory, and Mind. Dana Press, 2008.

Papers:

1. Gibbons, J.L. and McHugh, P.R.: Plasma Cortisol in Depressive Illness. J. Psychiatr. Res., 1: 162, 1962.

2. Hays, R., McHugh, P.R., and Williams, H.: Absence of Thirst in Hydro-cephalus. New Engl. J. Med., 269: 277, 1963.

3. McHugh, P.R.: Occult Hydrocephalus. Quart. J. Med., 33: 297-308, 1964.

4. McHugh, P.R. and Smith, G.P.: Central Nervous System Control of Adreno-cortical Secretion. Symposium on Medical Aspects of Stress in the Military Climate. Walter Reed Army Institute of Research, 421-429, April 1964.

5. Smith, G.P., Boren, J. and McHugh, P.R.: Gastric Secretory Response to Acute Environmental Stress. Symposium on Medical Aspects of Stress in the Military Climate. Walter Reed Army Institute of Research, 353-365, April 1964.

6. McHugh, P.R., Black, W.C. and Mason, J.M.: Some Hormonal Responses to

Electrical Self Stimulation in the Macaca Mulatta. Am. J. Physiol., 210: 109-113, 1966.

7. McHugh, P.R.: Hydrocephalic Dementia. Bull. N.Y. Acad. Med., 42:907-917, 1966.

8. McHugh, P.R. and Smith, G.P.: The Plasma 17-OH-CS Response to Amygdaloid Stimulations With and Without After-Discharges. Am. J. Physiol., 212: 619-622, 1967.

9. McHugh, P.R. and Smith, G.P.: Negative Feedback in Adrenocortical response to limbic stimulation in Macaca Mulatta. Am. J. Physiol., 213: 1445-1450, 1967.

10. Smith, G.P. and McHugh, P.R.: Gastric Secretory Response to Amygdaloid or Hypothalamic Stimulation in Monkeys. Am. J. Physiol., 213: 640-644, 1967.

11. Reis, D.J. and McHugh, P.R.: Hypoxia as a Cause of Bradycardia During Amygdala Stimulation in Monkey. Am. J. Physiol., 214: 601-610, 1968.

12. McHugh, P.R.: Hypothalamic Controls in Feeding Behavior as Revealed by "Disconnection" Method. In: Transactions of the American Neurological Association, 95: 100-103, 1970.

13. McHugh, P.R. and Goodell, H.: Behavior of Patients with Sedative Poisoning Seen in a General Hospital. Archives of General Psychiatry, 25: 256-264, 1971.

14. Andersen, A. and McHugh, P.R.: Oat Carcinoma with Hyperadrenalism Manifesting Itself as a Suicide Attempt. Journal of Nervous and Mental Disease, 152: 6, 1971.

15. McHugh, P.R. and Gibbs, J.: Aspects of Subcortical Organization of Feeding Revealed by Hypothalamic Disconnections in Macaca Mulatta. Brain, 95: 279-293, 1972.

16. Folstein, M., Folstein, S., and McHugh, P.R.: Clinical Predictors of Improvement After Electroconvulsive Therapy of Patients with Schizophrenia, Neurotic Reactions, and Affective Disorders. Biological Psychiatry, 7: 147-152, 1973.

17. Slavney, P.R. and McHugh, P.R.: The Hysterical Personality: A Controlled Study. Archives of General Psychiatry, 30: 325-329, 1974.

18. Luria, R. and McHugh, P.R.: The Reliability and Clinical Utility of the Present

State Examination. Archives of General Psychiatry, 30: 866-871, 1974.

19. Sovner, R. and McHugh, P.R.: Lithium Treatment in Periodic Catatonia. The Journal of Nervous and Mental Disease, 158: 214-221, 1974.

20. Breakey, W.R., Goodell, H., Lorenz, P.L. and McHugh, P.R.: Hallucinogenic Drugs as Precipitants of Schizophrenia. Psychol. Med., 4: 255-261, 1974.

21. Robinson, R.G., McHugh, P.R. and Folstein, M.F.: Measurement of Appetite Disturbances in Psychiatric Disorders. J. Psychiat. Res., 12: 59-68, 1975.

22. Slavney, P.R. and McHugh, P.R.: The Hysterical Personality: An Attempt at Validation with the MMPI. Archives of General Psychiatry, 32: 186-190, 1975.

23. McHugh, P.R. and Folstein, M.F.: Psychiatric Syndromes of Huntington's Chorea: A Clinical and Phenomenological Study. Seminars in Psychiatry. In Psychiatric Aspects of Neurologic Disease. D. Frank Benson, M.D. and Dietrich Blumer, M.D., Ed. Grune & Stratton, New York, pp. 267-286, 1975.

24. Von Greif, H., McHugh, P.R., and Stokes, P.: The Familial History in Sixteen Males with Bipolar Manic-Depressive Illness. In Genetic Research in Psychiatry. R.R. Fieve, D. Rosenthal, and H. Brill, Ed. The Johns Hopkins University Press, 233-239, 1975.

25. Folstein, M., Folstein, S., and McHugh, P.R.: "Mini-Mental State": A Practical Method for Grading the Cognitive State of Patients for the Clinician. Journal of Psychiatric Research, 12: 189-198, 1975. **[CITATION CLASSIC, 1989]**.

26. Robinson, R.G., McHugh, P.R. and Bloom, F.E.: Chlorpromazine Induced Hyperphagia in the Rat. Psychopharmacology Communications, 1: 37-50, 1975.

27. Sovner, R. and McHugh, P.R.: Bipolar Course in Schizoaffective Illness. Biological Psychiatry, 11: 195-204, 1976.

28. McHugh, P.R., Gibbs, J., Falasco, J.D., Moran, T. and Smith, G.P.: Inhibitions of Feeding Examined in Rhesus Monkeys with Hypothalamic Disconnections. Brain, 98: 441-454, 1975.

29. Gibbs, J., Falasco, J. and McHugh, P.R.: Cholecystokinin Decreases Feeding in Rhesus Monkeys. Am. J. Physiol., 230: 15-18, 1976.

30. McHugh, P.R., Moran, T.H. and Barton, C.N.: Satiety: A Graded Behavioral Phenomenon Regulating Caloric Intake. Science, 190: 167-169, 1975.

31. McHugh, P.R. and Moran, T.H.: An Examination of the Concept of Satiety in Hypothalamic Hyperphagia. In: Anorexia Nervosa, R. Vigersky, Ed. Raven Press, New York, 1977, pp. 67-73.

32. Slavney, P.R., Rich, G.B., Pearlson, G.D. and McHugh, P.R.: Phencyclidine Abuse and Symptomatic Mania. Biol. Psychiat., 12: 697-700, 1977.

33. McHugh, P.R., Moran, T.H.: The Accuracy of the Regulation of Caloric Ingestion in the Rhesus Monkey: Caloric Regulation in Rhesus Monkeys. Am. J. Physiol., 235: R29-34, 1978.

34. Folstein, M.F., Maiberger, R. and McHugh, P.R.: Mood Disorder as a Specific Complication of Stroke. Journal of Neurology, Neurosurgery and Psychiatry, 40, 1018-1020, 1977.

35. Folstein, M.F. and McHugh, P.R.: Defective Long Term Caloric Regulation in Obesity. NIDA Research Monograph Studies, 20: 182-188, 1978.

36. McHugh, P.R. and Folstein, M.F.: Psychopathology of Dementia: Implications for Neuropathology: Res. Publ. Assoc. Res. Nerv. Ment. Dis. 57: 17-30, 1978

37 Folstein, M.F. and McHugh, P.R. Dementia Syndrome of Depression in Alzheimer's disease. In Senile Dementia and Related Disorders. Katzman, R. et al., Eds., New York: Raven Press, pp. 87-96, 1978.

38. Robinson, R.G., Folstein, M.F. and McHugh, P.R. Reduced Caloric Intake Following Small Bowel Bypass Surgery: A Systematic Study of Possible Causes. Psychol. Med., 9: 37-53, 1979.

39. McHugh, P.R.: Aspects of the Control of Feeding: Application of Quantification in Psychobiology. The Johns Hopkins Medical Journal, 144: 147-155, 1979.

40. McHugh, P.R., Moran, T.H.: Calories and Gastric Emptying: A Regulatory Capacity with Implications for Feeding. American Journal of Physiology, 236: R254-R260, 1979.

41. Folstein, S.E., Folstein, M.F., McHugh, P.R.: Psychiatric Syndromes in Huntington's Disease. Advances in Neurology, 23: 281-289, Raven Press, New York, 1979.

42. Robinson, R.G., Folstein, M.F., Simonson, M., McHugh, P.R.: Differential Antianxiety Response to Caloric Intake Between Normal and Obese

Subjects. Psychosomatic Medicine, 42: 415-427, 1980.

43. Moran, T.H., McHugh, P.R.: Distinctions Amongst Three Sugars in Their Effects on Gastric Emptying and Satiety. American Journal of Physiology, 241: R25-R30, 1981.

44. Rabins, P.V., Tune, L.E., McHugh, P.R.: Tardive Dyskinesia. The Johns Hopkins Medical Journal, 148: 206-211, 1981.

45. Tune, L.E., McHugh, P.R., Coyle, J.T.: Management of Extrapyramidal Side Effects Induced by Neuroleptics. The Johns Hopkins Medical Journal, 148: 149-153, 1981.

46. Pearlson, G.D., Veroff, A.E., McHugh, P.R.: The Use of Computed Tomography in Psychiatry: Recent Applications to Schizophrenia, Manic-depressive Illness and Dementia Syndrome. The Johns Hopkins Medical Journal, 149: 194-202, 1981.

47. Tune, L.E., McHugh, P.R., Coyle, J.T.: Drug Management in Chronic Schizophrenia. The Johns Hopkins Medical Journal, 150: 45-48, 1982.

48. Moran, T.H., McHugh, P.R.: Cholecystokinin Suppresses Food Intake by Inhibiting Gastric Emptying. American Journal of Physiology, 242: R491-R497, 1982.

49. McHugh, P.R., Slavney, P.R.: Methods of Reasoning in Psychopathology: Conflict and Resolution. Comprehensive Psychiatry, 23: 197-215, 1982.

50. Tune, L.E., Folstein, M., Rabins, P., Jayaram, G., McHugh, P.R.: Familial Parkinson's Disease: A Case Report. The Johns Hopkins Medical Journal, 151: 65-70, 1982.

51. McHugh, P.R., Moran, T.H., Wirth, J.B.: Post-Pyloric Regulation of Gastric Emptying in Rhesus Monkeys. American Journal of Physiology, 243: R403-R415, 1982.

52. Hunt, J.N., McHugh, P.R.: Does Calcium Mediate the Slowing of Gastric Emptying in Primates? American Journal of Physiology, 243: G200-G203, 1982.

53. Brener, W., Hendrix, T.R., McHugh, P.R.: Regulation of the Gastric Emptying of Glucose. Gastroenterology, 85: 76-82, 1983.

54. Wirth, J.B., McHugh, P.R.: Gastric Distension and Short-Term Satiety in the Rhesus Monkey. American Journal of Physiology, 245: R174-R180, 1983.

55. McHugh, P.R., Robinson, R.G.: The Two Way Trade—Psychiatry and Neuroscience. The British Journal of Psychiatry, 143: 303-305, 1983.

56. McHugh, P.R.: The Control of Gastric Emptying. Journal of Autonomic Nervous System, 9: 221-231, 1983.

57. Slavney, P.R., McHugh, P.R.: Life Stories and Meaningful Connections Reflections on a Clinical Method in Psychiatry and Medicine. Perspectives in Biology and Medicine, 27: 279-288, 1984.

58. Smith, G.T., Moran, T.H., Coyle, J.T., Kuhar, M.J., O'Donahue, T.L. and McHugh, P.R.: Anatomic Localization of Cholecystokinin Receptors to the Pyloric Sphincter. American Journal of Physiology, 246: R127-R130, 1984.

59. McHugh, P.R., Moran, T.H.: The Stomach: A Conception of its Dynamic Role in Satiety. Progress in Psychobiology and Physiological Psychology, 11: 197-232, Ed. A. Epstein and J. Sprague, Academic Press, Inc., 1985.

60. McHugh, P.R. Commentary on Charles Hanly's "Logical and Conceptual Problems of Existential Psychiatry". The Journal of Nervous and Mental Disease, 173: 278, 1985.

61. Slavney, P.R., McHugh, P.R.: The Life-Story Method in Psychotherapy and Psychiatric Education: The Development of Confidence. American Journal of Psychotherapy, 39: 57-67, 1985.

62. Moran, T.H., Robinson, P.H., McHugh, P.R.: The Pyloric Cholecystokinin Receptor: A Site of Mediation for Satiety. Annals of the New York Academy of Science, 448: 621-623, 1985.

63. Robinson, P.H., Moran, T.H., McHugh, P.R.: Gastric Cholecystokinin Receptors and the Effect of Cholecystokinin on Feeding and Gastric Emptying in the Neonatal Rat. Annals of the New York Academy of Science, 448: 627-629, 1985.

64. Folstein, M.F., Robinson, R., Folstein, S., McHugh, P.R. Depression and Neurological Disorders. New Treatment Opportunities for Elderly Depressed Patients. Journal of Affective Disorders, Supplement 1: S11-S14, 1985.

65. Nestadt, G., McHugh, P.R.: The Frequency and Specificity of Some "Negative" Symptoms. Weissnauer Symposium, Basisstadien endogener Psychosen und das Borderline-Problem. Ed. G. Huber, Schattauer, Stuttgart-New York, 1985.

66. Folstein, M., Romanoski, A., Nestadt, G., Chahal, R., Merchant, A., Shapiro, S., Kramer, M., Anthony, J., Gruenberg, E., McHugh, P.R.: Brief Report on the

Clinical Reappraisal of the Diagnostic Interview Schedule Carried Out at the Johns Hopkins Site of the Epidemiological Catchment Area Program of the NIMH. Psychological Medicine, 15: 809-814, 1985.

67. Moran, T.H., Robinson, P.H., Goldrich, M.S., McHugh, P.R.: Two Brain Cholecystokinin Receptors: Implications for Behavioral Actions. Brain Research, 362: 175-179, 1986.

68. McHugh, P.R., Moran, T.H. The Stomach, Cholecystokinin and Satiety. Federation Proceedings, 45: 1384-1390, 1986.

69. McHugh, P.R., Moran, T.H. The Stomach and Satiety. In: Interaction of the Chemical Senses with Nutrition. Ed. M.B. Kare, Academic Press, 167-180, 1986.

70. Notturno, M.A., McHugh, P.R.: Is Freudian Psychoanalytic Theory Really Falsifiable? Behavioral and Brain Sciences, 9: 250-252, 1986.

71. Robinson, P.H., Moran, T.H., McHugh, P.R.: Inhibition of Gastric Emptying and Feeding by Fenfluramine. American Journal of Physiology, 250: R764-R769, 1986.

72. McHugh, P.R., Moran, T.H.: The Inhibition of Feeding Produced by Direct Intraintestinal Infusion of Glucose: Is This Satiety? Brain Research Bulletin, 17: 415-418, 1986.

73. McHugh, P.R.: Commentary on Joseph H. Stephens, et al., "Inpatient Diagnoses During Adolf Meyer's Tenure as Director of The Henry Phipps Psychiatric Clinic, 1913-1940". The Journal of Nervous and Mental Disease, 174: 752-753, 1986.

74. Moran, T.H., Smith, G.P., Hostetler, A.M., McHugh, P.R.: Transport of Cholecystokinin (CCK) Binding Sites in Subdiaphragmatic Vagal Branches. Brain Research, 415: 149-152, 1987.

75. Robinson, P.H., Moran, T.H., Goldrich, M., McHugh, P.R. Development of Cholecystokinin Binding Sites in Rat Upper Gastrointestinal Tract. Am. J. Physiol., 252: G529-G534, 1987.

76. McHugh, P.R. Psychiatry and Its Scientific Relatives: "A Little More Than Kin and Less Than Kind." Journal of Nervous and Mental Disease, 175: 579-583, 1987.

77. Notturno, M.A., McHugh, P.R. Is Freudian Psychoanalytic Theory Really Falsifiable? Metaphilosophy, 18: 306-320, 1987.

78. McHugh, P.R. William Osler and the New Psychiatry. Annals of Internal Medicine, 107: 914-918, 1987.

79. Rabins, P., McHugh, P.R., Pauker, S., Thomas, J. The Clinical Features of Late Onset Schizophrenia. In: Schizophrenia and Aging, pp. 235-238, N.E. Miller/G.D. Cohen, ed., The Guilford Press, NY, 1987.

80. Romanoski, A.J., Nestadt, G., Chahal, R., Merchant, A., Folstein, M.F., Gruenberg, E.M., McHugh, P.R. Interobserver Reliability of a "Standardized Psychiatric Examination" (SPE) for Case Ascertainment (DSM III). J. Nerv. Ment. Dis., 176: 63-71, 1988.

81. Moran, T.H., McHugh, P.R. Gastric and Nongastric Mechanisms for Satiety Action of Cholecystokinin. Am. J. Physiol., 254:R628-R632, 1988

82. Moran, T.H., Moody, T.W., Hostetler, A.M., Robinson, P.H., Goldrich, M. McHugh, P.R. Distribution of Bombesin Binding Sites in the Rat Gastrointestinal Tract. Peptides, 9: 643-649, 1988.

83. Robinson, P.H., Moran, T.H., McHugh, P.R. Cholecystokinin Inhibits Independent Ingestion in Neonatal Rats. Am. J. Physiol., 255: R14-R20, 1988.

84. Moran, T.H., McHugh, P.R. Anatomical and Pharmacological Differentiation of Pyloric, Vagal and Brain Stem Cholecystokinin Receptors. In: Cholecystokinin Antagonists, Wang, R.Y., Schoenfeld, R., Ed., A.R. Liss, Inc., New York, 47: 117-132, 1988.

85. Moran, T.H., Shnayder, L., Hostetler, A.M., McHugh, P.R. Pylorectomy Reduces the Satiety Action of Cholecystokinin. Am. J. Physiol., 255: R1059-R1063, 1988.

86. Folstein, M.F., Warren, A., McHugh, P.R. Heterogeneity in Alzheimer's Disease: An Exercise in the Resolution of a Phenotype. In: Genetics and Alzheimer's Disease. Sinet, P.M., Lamour, Y., Christen, Y. (Eds.), Springer-Verlag, Berlin Heidelberg, 1988, pp. 5-12.

87. Robinson, P.H., McHugh, P.R., Moran, T.H., Stephenson, J.D. Gastric Control of Food Intake. J. Psychosomatic Res., 32: 593-606, 1988.

88. Margolis, R., Moran, T.H., McHugh, P.R. In Vitro Response of Rat Gastrointestinal Segments to Cholecystokinin and Bombesin. Peptides, 10: 157-161, 1989.

89. McHugh, P.R. Curt Richter and Johns Hopkins: A Union of Assets. Am. J.Physiol., 256: R1169-R1170, 1989.

90. Moran, T.H., McHugh, P.R. Effects of Pylorectomy in Cholecystokinin (CCK) Satiety: Evidence for Multiple and Separable Mechanisms. In: The Neuropeptide Cholecystokinin (CCK). J. Hughes, G. Dockray and G. Woodruff (eds.), Ellis Norwood Limited, Chichester, 1989, 227-231.

91. Hostetler, A.M., McHugh, P.R., Moran, T.H. Bombesin Affects Feeding Independent of a Gastric Mechanism or Site of Action. Am. J. Physiol., 257: R1219-R1224, 1989.

92. McHugh, P.R. The Neuropsychiatry of Basal Ganglia Disorders. A Triadic Syndrome and Its Explanation. Neuropsychiatry, Neuropsychology, and Behavioral Neurology, 2: 239-247, 1989.

93. McHugh, P.R., Moran, T.H., Killilea, M. The Approaches to the Study of Human Disorders in Food Ingestion and Body Weight Maintenance. Annals of the New York Academy of Sciences, 575: 1-12, 1989.

94. McHugh, P.R. The Basal Ganglia: The Region, the Integration of Its Systems and Implications for Psychiatry and Neurology. In: Function and Dysfunction in the Basal Ganglia. A.J. Franks, J.W. Ironside, R.H.S. Mindham, R.J. Smith, E.G.S. Spokes, W. Winlow (eds.), Manchester University Press, Manchester and New York, 1990, 259-269.

95. Nestadt, G., Romanoski, A.J., Chahal, R., Merchant, A., Folstein, M.F., Gruenberg, E.M., McHugh, P.R. An Epidemiological Study of the Histrionic Personality Disorder. Psychological Medicine, 20: 413-422, 1990.

96. Ladenheim, E.E., Jensen, R.T., Mantey, S.A., McHugh, P.R., Moran, T.H. Receptor Heterogeneity for Bombesin-line Peptides in the Rat Central Nervous System. Brain Research, 537: 233-240, 1990.

97. Moran, T.H., McHugh, P.R. Cholecystokinin Receptors. In: Handbook of Chemical Neuroanatomy, Vol. 9: Neuropeptides in the CNS. Part II. A. Bjorklund, T. Hokfelt and M. Kuhar (eds.), Elsevier Science Publishers, Amsterdam, pp. 455-476, 1990.

98. Moran, T.H., Norgren, R., Crosby, R.J., McHugh, P.R. Central and Peripheral Vagal Transport of Cholecystokinin Binding Sites Occurs in Afferent Fibers. Brain Research 526: 95-102, 1990.

99. McHugh, P.R. Clinical Issues in Food Ingestion and Body Weight Maintenance. Handbook of Behavioral Neurobiology, E.M. Stricker, ed., Volume 10, Plenum Publishing Corp., New York, 1990, 531-547.

100. McHugh, P.R. Explaining DSM-III-R in the '90s. ACP Psychiatric Update, 10: 1-11, 1990.

101. Schwartz, G.J., Moran, T.H., McHugh, P.R. Autoradiographic and Functional Development of Gastric Cholecystokinin Receptors in the Rat. Peptides, 11: 1199-1203, 1990.

102. Stephens, J.H., McHugh, P.R. Characteristics and Long-Term Follow-up of Patients Hospitalized for Mood Disorders in the Phipps Clinic, 1913-1940. J. Nerv. Ment. Dis., 179: 64-73, 1991.

103. McHugh, P.R., Moran, T.H. Pyloric CCK Receptors and the Afferent Vagal System Mediate CCK Satiety. In: Brain-Gut Interactions, Y. Tache, D. Wingate, Eds., CRC Press, Boca Raton, 1991, Chapter 22, 263-265.

104. Nestadt, G., Romanoski, A.J., Brown, C.H., Chahal, R., Merchant, A., Folstein, M.F., Gruenberg, E.M., McHugh, P.R. DSM-III Compulsive Personality Disorder: An Epidemiological Survey. Psychological Medicine, 21: 461-471, 1991.

105. Schwartz, G.J., McHugh, P.R., Moran, T.H. Integration of Vagal Afferent Responses to Gastric Loads and Cholecystokinin in Rats. Am. J. Physiol., 261: R64-R69, 1991.

106. Moran, T.H., Crosby, R.J., McHugh, P.R. Effects of Pylorectomy on Cholecystokin-induced Inhibition of Liquid Gastric Emptying. Am. J. Physiol., 261: R531-R535, 1991.

107. Schwartz, G.J., Netterville, L.A., McHugh, P.R., Moran, T.H. Gastric Loads Potentiate Inhibition of Food Intake Produced by a Cholecystokinin Analogue. Am. J. Physiol., 261: R1141-R1146, 1991.

108. Moran, T.H., Shnayder, L., Schwartz, G.J., McHugh, P.R. Pyloric Cholecystokinin Receptors. In: CCK Antagonists in Gastroenterology: Basic and Clinical Status, G. Adler and C. Beglinger (eds.), Springer-Verlag, Berlin Heidelberg, 1991, 159-164.

109. Moran, T.H., Schwartz, G.J., McHugh, P.R. Brain-Gut Interactions in Cholecystokinin (CCK) Satiety. In: Diabetes, H. Rifkin, J.A. Colwell, S.I. Taylor (eds.), Elsevier Science, 1991, 512-515.

110. Moran, T.H., Ameglio, P.J., Schwartz, G.J., McHugh, P.R. Blockade of Type A, not Type B, CCK Receptors Attenuates Satiety Actions of Exogenous and Endogenous CCK. American Journal of Physiology, 262: R46-R50, 1992.

111. Moran, T.H., Sawyer, T.K., Seeb, D.H., Ameglio, P.J., Lombard, M.A.,McHugh, P.R. Potent and Sustained Satiety Actions of a Cholecystokinin Octapeptide Analogue. Am. J. Clin. Nutr., 55: 286S-290S, 1992.

112. Schwartz, G.J., Netterville, L.A., McHugh, P.R., Moran, T.H. Gastric Loads Potentiate Inhibition of Food Intake Produced by a Cholecystokinin Analogue. Am. J. Physiol., 261: R1141-1146, 1992.

113. McHugh, P.R. A Structure for Psychiatry at the Century's Turn - The View from Johns Hopkins. Journal of the Royal Society of Medicine, 85: 483-487, 1992.

114. McHugh, P.R. Psychiatric Misadventures. The American Scholar, 61:497-510, 1992.
[Selected and Reprinted in THE BEST AMERICAN ESSAYS 1993, ed. R. Atwan, Publisher, Ticknor & Fields, New York].

115. Moran, T. H., McHugh, P.R.: Vagal Receptor Transport. In: Neuroanatomy and Physiology of Abdominal Vagal Afferents. S. Ritter, R.C. Ritter and C.D. Barnes, (eds) CRC Press, Boc Raton, pp. 157-178, 1992.

116. Nestadt, G., Romanoski, A.J., Samuels, J.F., Folstein, M.F., McHugh, P.R. The Relationship Between Personality and DSM-III Axis I Disorders in the Population: Results From an Epidemiological Survey. Am. J. Psychiatry, 149: 1228-1233, 1992.

117. Brown, C.H., Gruenberg, E. M., McHugh, P.R. The Epidemiology of Psychiatrist-ascertained Depression and DSM-III Depressive disorders. Psychological Medicine, 22: 629-655, 1992.

118. Moran, T.H., McHugh, P.R.: Gastric Mechanisms in CCK Satiety. In: Multiple Cholecystokinin Receptors in the CNS. C.T. Dourish, S.J. Cooper, S.D. Iversen and L.L. Iversen (eds), Oxford University Press, Oxford, pp. 183-205, 1992.

119. Lyketsos, C.G., Hanson, A.L., Fishman, M., Rosenblatt, A., McHugh, P.R., Treisman, G. Manic Syndrome Early and Late in the Course of HIV. Am. J. Psychiatry, 150: 326-327, 1993.

120. McHugh, P.R. Multiple Personality Disorder. The Harvard Mental Health Letter, 10: Number 3, 4-6, September 1993.

121. Treisman, G.J., Lyketsos, C.G., Fishman, M., Hanson, A.L., Rosenblatt, A., McHugh, P.R. Psychiatric Care for Patients with HIV Infection. The Varying Perspectives. Psychosomatics, 34: 432-439, 1993.

122. Schwartz, F.J., McHugh, P.R., Moran, T.H. Gastric Loads and Cholecystokinin Synergistically Stimulate Rat Gastric Vagal Afferents. Am. J. Physiol., 265: R1-5, 1993.

123. Moran, T.H., Ameglio, P.J., Schwartz, G.J., Peyton, H.J., McHugh, P.R. Endogenous Cholecystokinin in the Control of Gastric Emptying of Liquid Nutrient Loads in Rhesus Monkeys. Am. J. Physiol., 265:R371-375,1993.

124. Moran, T.H., Ameglio, P.J., Peyton, H.J., Schwartz, G.J., McHugh, P.R. Blockade of Type A, But Not Type B CCK Receptors, Postpones Satiety in Rhesus Monkeys. Am. J. Physiol., 265: R620-R624, 1993.

125. Schwartz, G.J., Berkow, G., McHugh, P.R., Moran, T.H. Gastric Branch Vagotomy Blocks Nutrient and Cholecystokinin-induced Suppression of Gastric Emptying. Am. J. Physiol., 264: R630-R637, 1993.

126. McHugh, P.R. Psychotherapy Awry. The American Scholar, 63: 17-30, 1994.

127. Schwartz, G.J., McHugh, P.R., Moran, T.H. Pharmacological Dissociation of Responses to CCK and Gastric Loads in Rat Mechanosensitive Vagal Afferents. Am. J. Physiol., 267: R303-R308, 1994.

128. Nestadt, G., Samuels, J.F., Romanoski, A.J., Folstein, M.F., McHugh, P.R. Obsessions and Compulsions in the Community. Acta Psychiatrica Scandinavica, 89: 219-224, 1994.

129. Cohen, B.J., Nestadt, G., Samuels, J.F., Romanoski, A.J., McHugh, P.R., Rabins, P.V. Personality Disorder in Later Life: A Community Study. British J. Psychiatry, 165: 493-499, 1994.

130. Nestadt, G., Eaton, W.W., Romanoski, A.J., Garrison, R., Folstein, M.F., McHugh, P.R. Assessment of DSM-III Personality Structure in a General Population Survey. Comprehensive Psychiatry, 35: 54-63, 1994.

131. Samuels, J.F., Nestadt, G., Romanoski, A.J., Folstein, M.F., McHugh, P.R. DSM-III Personality Disorders in the Community. Am. J. Psychiatry, 151: 1055-1062, 1994.

132. Pulver, A., Nestadt, G., Housman, D., Kazazian, H.H., McHugh, P.R., Manschreck, T., Childs, B., et al. Sequential Strategy to Identify a Susceptibility Gene For Schizophrenia: Report of Potential Linkage on Chromosome 22q12-q13.1. Part 1. American Journal of Medical Genetics, 54: 36-43, 1994.

133. Lyketsos, C., Hanson, A., Fishman, M., McHugh, P.R., Treisman, G. Screening for Psychiatric Morbidity in a Medical Outpatient Clinic for HIV Infection: The Need for a Psychiatric Presence. Int'l J. Psychiatry in Medicine, 24: 103-

113, 1994.

134. McHugh, P.R. A "Letter of Experience" about Faculty Promotion in Medical Schools. Academic Medicine, 69: 877-881, 1994.

135. McHugh, P.R. Suicide and Medical Afflictions. Medicine, 73: 297-298, 1994.

136. McHugh, P.R. What's the Story? The American Scholar, 64: 191-203, 1995.

137. McHugh, P.R. Resolved: Multiple Personality Disorder is an Individually and Socially Created Artifact. J. of the Amer. Academy of Child and Adolescent Psychiatry, 34:7 1995.

138. McHugh, P.R. Witches, multiple personalties, and other psychiatric artifacts. Nature Medicine, 1:2 110-114, 1995.

139. McHugh, P.R. Multiple Personality Disorder—A Socially Constructed Artifact. J. of Practical Psychiatry and Behavioral Health, 1:3 158-166, 1995.

140. Peyser, C.E., Folstein, M., Chase, G., Starkstein, S., Brandt, J., Cockrell, J., Bylsma, F., Coyle, J.T., McHugh, P.R., Folstein, S. Trial of d-a-Tocopherol in Huntington's Disease. Am J Psychiatry, 152:12 1771-1775, 1995.

141. McHugh, P.R. Hippocrates a la mode. Nature Medicine, 1:5 507-509, 1996.

142. McHugh, P.R. The Kevorkian Epidemic. The Amer Scholar, 66:1 15-27, 1997.

143. Stephens, J.H., Richard, P., McHugh, P.R. Long-Term Follow-up of Patients Hospitalized for Schizophrenia, 1913 to 1940. J Nerv Ment Dis, 185:12, 715-721, 1997.

144. McHugh, P.R. Dying Made Easy. Commentary, 107:2, 13-17, February, 1999.

145. Stephens, J.H., Richard, P., McHugh, P.R. Suicide in Patients Hospitalized for Schizophrenia, 1913 to 1940. J Nerv Ment Dis, 187, 10-14, 1999.

146. McHugh, P.R. How Psychiatry Lost Its Way. Commentary, 108:5, 32-38, December, 1999.

147. Stephens, J. H., Richard, P., McHugh, P.R. Long-Term Follow-up of Patients with a Diagnosis of Paranoid State and Hospitalized, 1913 to 1940. J Nerv Ment Dis, 188:4, 202-208, 2000.

148. McHugh, P.R. The Death of Freud and the Rebirth of Psychiatry. The Weekly Standard, 31-36, July 17, 2000.

149. McHugh, P.R. Beyond DSM-IV: From Appearances to Essences. Psychiatric

Research Report, 17:2, 2-3, 14-15, 2001.

150. McHugh, P.R. Romancing Depression. Commentary, 112:5, 38-42, December, 2001.

151. McHugh, P.R. A Psychiatrist Looks at Terrorism. The Weekly Standard, 21-24, December 10, 2001.

152. McHugh, P.R. Treating the Mind as Well as the Brain. The Chronicle Review, The Chronicle of Higher Education, Section 2, B14, November 22, 2002.

153. McHugh, P.R. Classifying Psychiatric Disorders: An Alternative Approach. Harvard Mental Health Letter, 7-8, November, 2002.

154. McCabe, O.L., Gwon, H.S., McHugh, P.R., et al. Academic Psychiatry and Health Care Reform: Strategic Initiatives for Sustaining the Clinical Mission. Psychiatric Services, 54:2, 236-239, February 2003.

155. McHugh, P.R. The End of a Delusion. The Psychiatric Memory Wars are Over. The Weekly Standard, 31-34, May 26, 2003.

156. McHugh, P.R. Zygote and "Clonote"-The Ethical Use of Embryonic Stem Cells. N Engl J Med, 351:3, 209-211, July 15, 2004.

157. McHugh, P.R., Lief, H.I., Freyd, P. and Fetkewicz, J.M. From Refusal to Reconciliation. Family Relationships After an Accusation Based on Recovered Memories. J Nerv Ment Dis, 192:8, 525-531, 2004.

158. McHugh, P.R. The Adventures of a "Different" Pair. Physiology and Behavior, 82: 171-174, 2004.

159. McHugh, P.R. The Substance of Style. The Weekly Standard, 31-33, August 30, 2004.

160. McHugh, P.R. Surgical Sex. First Things, 34-38, November 2004.

161. Caplan, A.L. and McHugh, P.R. Shall We Enhance? A Debate. Cerebrum, 6:4, 13-28, 2004.

162. McHugh, P.R. Teaching Darwin. The Weekly Standard, March 28, 2005, 23-26.

163. McHugh, P.R. Striving for Coherence. Psychiatry's Efforts Over Classification. JAMA, 293:20, 2526-2528, 2005.

164. McHugh, P.R. Annihilating Terri Schiavo. Commentary, June 2005, 27-32.

165. McHugh, P.R. A Nation of Crazy People? Overestimating Mental Illness in America. The Weekly Standard, June 27, 2005, 9-12.

166. McHugh, P.R. and Treisman, G. PTSD: A Problematic Diagnostic Category. Journal of Anxiety Disorders, 21: 211-222, 2007.

167. McCabe, O.L., Kaminsky, M.J., and McHugh, P.R. Clinical Assessment in Disaster Mental Health: A Logic of Case Formulation." American Journal of Disaster Medicine, 2(6): 297-306, 2007.

168. Rosen, G.M., Spitzer, R.L., and McHugh, P.R. Problems with the Post-traumatic Stress Disorder Diagnosis and its Future in DSM-V. British Journal of Psychiatry, 192: 3-4, 2008.

169. Hallett, M. and McHugh, P.R. Seeking Free Will in Our Brains: A Debate. In: **The Dana Foundation's Cerebrum: Emerging Ideas in Brain Science,** 109-124, 2008.

170. McHugh, P.R. Hysteria in Four Acts. Commentary, 126(5): 18-24, December, 2008.

171. McHugh, P.R. Psychiatry at Stalemate. In The **Dana Foundation: Cerebrum 2010: Emerging Ideas in Brain Science.** Updating the Diagnostic and Statistical Manual of Mental Disorders, pp. 93-102.

172. McHugh, P.R.: Leon Kass and the Poets. In: **Apples of Gold in Pictures of Silver. Honoring the Work of Leon R. Kass**. Edited by Y. Levin, T.W. Merrill, and A. Schulman, pp. 101-107, 2010.

173. Smith, C.N., Rascino, J.C., Kripke, D.L., McHugh, P.R., Treisman, G.J., Squire, L.R. Losing Memories Overnight: A Unique Form of Human Amnesia. Neuropsychologia, 2010.

174. Rosen, G.M., Lilienfeld, S.O., Frueh, C., and McHugh, P.R.,. Reflections on PTSD's Future in DSM-V. British Journal of Psychiatry 197: 343-344, 2010.

175. McHugh, P.R. and Slavney, P.R. Mental Illness – Comprehensive Evaluation or Checklist? ***N. Engl. J. Med***. 366:20, 1853-1855, 2012.

176.

Book Chapters:

1. McHugh, P.R.: Psychiatric Disturbances in Medical Patients. In Cecil-Loeb Textbook of Medicine, 12th tEdition. Beeson and McDermott (Ed.). W.B. Saunders, Philadelphia, 1448-1456, 1967.

2. McHugh, P.R.: Dementia. *
   McHugh, P.R.: The Concept of Disease in Psychiatry. *
   McHugh, P.R.: Functional Psychoses. *
   McHugh, P.R.: Personality Disorders and Neurotic Symptom. *
   McHugh, P.R.: Psychological Testing in Clinical Medicine. *
   - In Cecil-Loeb Textbook of Medicine, Ed. by P.B. Beeson and W. McDermott. 13th Edition, 102-128, 1970.

3. *Updated in: Cecil-Loeb Textbook of Medicine, Ed. by P.B. Beeson and W. McDermott. 14th Edition, 5580, 1975.

4. *Updated in: Cecil Textbook of Medicine, Ed. by P.B. Beeson, W. McDermott, and J.B. Wyngaarden, 15th Edition, 1979.

5. *Updated in: Cecil Textbook of Medicine, Ed. by J.B. Wyngaarden and L.H. Smith, Jr., 16th Edition, 1979-1997, 1982.

6. *Updated in: Cecil Textbook of Medicine, Ed. by J.B. Wyngaarden, L.H. Smith, Jr., and F. Plum, 17th Edition, W.B. Saunders Company, 1985.

7. Folstein, M.F. and McHugh, P.R.: Phenomenological Approach to the Treatment of Organic Psychiatric Syndrome. In: B.B. Wolman, (Ed.), The Therapist Handbook-Treatment Methods of Mental Disorders. Van Nostrand Reinhold Ltd., 279-286, 1976.

8. McHugh, P.R.: Education Control and the Hypothalamus. In: Scientific Approaches to Clinical Neurology. E.S. Goldensohn and S.H. Appel (Ed.), Philadelphia: Lea & Febiger, Vol. 2: 1786-1800, 1977.

9. Folstein, M.F. and McHugh, P.R.: The Neuropsychiatry of Some Specific Brain Disorders. In: Handbook of Psychiatry 2 - Mental Disorders and Somatic Illness. M.H.Lader, Ed.,Cambridge Univ. Press, Chapter 10, 107-118,1983

10. McHugh, P.R.: The Control of Gastric Emptying. In: Vagal Nerve Function: Behavioral and Methodological Considerations. J.G. Kral, T.L.Powley and Powley and C.M. Brooks, (Ed.), Elsevier Science Publishers, 221-

231,1983

11. McHugh, P.R.: Neuropsychiatry: The New Frontier. In: The 1984 Distinguished Visiting Professorship Lectures. J.E. Hamner III, (Ed.) The University of Tennessee Center for the Health Sciences (UTCHS), Memphis, 21-35,1985

12. McHugh, P.R. and Folstein, M.F.: Organic Mental Disorders. In: Psychiatry, Volume 1, Chapter 73, 1-21, J.B. Lippincott Company, Philadelphia, 1985.*

13. * Updated in: Psychiatry, 1987.

14. * Updated in: Psychiatry, 1-24, 1988.

15. McHugh, P.R.: Obesity, Eating, and Satiety Mechanisms. In: Diseases of the Nervous System, A.K. Asbury, (Ed.), W.B. Saunders Co., Philadelphia, 1985.

16. Teitelbaum, M.L. and McHugh, P.R.: Hysterical Behavior. In: Current Therapy in Neurologic Disease - 3. R.T. Johnson, Ed., B.C. Decker Inc., Philadelphia, 1990.

17. McHugh, P.R. Schizophrenia and the Disease Model. In: What is Schizophrenia, W.F. Flack, D.R. Miller, M. Wiener, (Ed.), Springer-Verlag, 73-80, 1992.

18. McHugh, P.R. Food Intake and Its Disorders. In: Diseases of the Nervous System. Clinical Neurobiology. A.K. Asbury, G.M. McKhann, W.I. McDonald (Ed.), W.B. Saunders, Philadelphia, 529-536, 1992.

19. Treisman, G.J., Fishman, M., Lyketsos, C.G. and McHugh, P.R. Evaluation and Treatment of Psychiatric Disorders Associated with HIV Infection. In: HIV, AIDS, and the Brain, New York: Raven Press, 1994.

20. Robinson, P.H. and McHugh, P.R.: A Physiology of Starvation that Sustains Eating Disorders. In: Handbook of Eating Disorders: Theory, Treatment and Research. C. Szmukler, C. Dare and J. Treasure, (Ed.), John Wiley & Sons, Chichester, England, 109-123, 1995.

21. McHugh, P.R. Emotional Disorders Associated with Dementing Illnesses. In: Progress in Alzheimer's Disease and Similar Conditions, L.L. Heston (Ed.), American Psychiatric Press, Inc., Washington, D.C., 1-8, 1997.

22. McHugh, P.R. Foreword (Genius in a Time , Place and Person) to the 1997 Edition of: General Psychopathology By Karl Jaspers, Johns Hopkins Press, Baltimore, MD 1997.

23. Treisman, G.J., Fishman, M., Schwartz, J.M., Lyketsos, C.G., McHugh, P.R. Treatment of Psychiatric Disorders in Patients Infected with HIV. In: Psychiatric Treatment of the Medically Ill, R.G. Robinson, W.R. Yates (Eds.), Marcel Dekker, Inc., New York, 181-205, 1999.

24. McHugh, P.R. Improving the Accuracy of Diagnosis. In: Alzheimer Disease: The Changing View, Katzman, R. and Bick K. (Ed.), Academic Press, San Diego, 211-224, 2000.

25. McHugh, P.R. and Slavney, Phillip R. The Education of Psychiatrists. In: New Oxford Textbook of Psychiatry, Gelder, M.G., Lopez-Ibor, J.J., Andreasen, N. (Eds.), Oxford University Press, 41-47, 2000.

26. McHugh, P.R. Resolved: Multiple Personality Disorder is an Individually and Socially Created Artifact. In: Taking Sides: Clashing Views on Controversial Issues in Abnormal Psychology, Halgin, R.P. (Ed.), Second Edition, McGraw Hill, 48-53, 2003.

27. McHugh, P.R. and Clark, M.R. Diagnostic and Classificatory Dilemmas. In: , Psychosomatic Medicine, Blumenfield, M., Strain, J.J. (Eds.), Lippincott Williams & Wilkins: Chapter 4, 39-45, 2006.

28. Treisman, G.J. and McHugh, P.R. Life Story as the Focus of Psychotherapy: The Johns Hopkins Conceptual and Didactic Perspectives. In: The Psychotherapy of Hope: The Legacy of Persuasion and Healing. Alarcon, R.D. and Frank, J.B. The Johns Hopkins University Press, Baltimore: Chapter 2, 22-33, 2012.

29. McHugh, P.R. Rendering Mental Disorders Intelligible: Addressing Psychiatry's Urgent Challenge. In: Philosophical Issues in Psychiatry II: Nosology. Kendler, K.S. and Parnas, J. (Eds.), Oxford University Press, Chapter 13, 269-279, 2012.

30/ McHugh, P.R. The Perspectives of Psychiatry: The Public Health Approach. In: Public Mental Health, Eaton, W.W. (Ed.), Oxford University Press, Chapter 2, 31-40, 2012.

Miscellaneous Writings:

1. McHugh, P.R. Living With Uncertainty: Issues of Responsibility in Informing the Individual. Huntington Review, I: 11-15, 1982.

2. McHugh, P.R. Reimbursement for Inpatient Psychiatry. The Psychiatric Times, III: No. 12, 1, December, 1986.

3. McHugh, P.R. Factitious Disorder. The Johns Hopkins Medical Grand Rounds. Vol. XIV, May, 1988.

4. McHugh, P.R. Foreword. In: DePaulo, J.R. and Ablow, K. Coping With Depression. McGraw Hill, New York, 1989.

5. McHugh, P.R. Book Review. The Medical Basis of Psychiatry, Winokur, G. and Clayton, P. W.B. Saunders, Philadelphia, 1986. J. Nerv. Ment. Dis. 177: 54-55, 1989.

6. McHugh, P.R. Obituary, Curt Paul Richter, Ph.D. JAMA, 261: 3174, 1989.

7. McHugh, P.R. Only the Myth of Freud is Tarnished. The New York Observer, 4: No. 15, 5, April 16, 1990.

8. McHugh, P.R. Does Psychiatry Whitewash Sex Offenders? The Baltimore Sun, June 16, 1990.

9. McHugh, P.R. The Professorial Promotions Committee at Johns Hopkins School of Medicine: A Letter of Experience, 1991.

10. McHugh, P.R. Reply to My Critics. The American Scholar, 62: 319-320, 1993.

11. McHugh, P.R. Further Reply to Critics.The American Scholar, 62:479-480,1993.

12. McHugh, P.R. Do Patients' Recovered Memories of Sexual Abuse Constitute a 'False Memory Syndrome'? Psychiatric News, XXVIII; 18, Dec. 3, 1993.

13. McHugh, P.R. Opinion: The Contemporary Witch-Craze: Remembered Sexual Abuse. Hopkins Medical News, 17: 56, 1994.

14. McHugh, P.R. Book Review. Suggestions of Abuse: True and False Memories of Childhood Sexual Trauma, Michael D. Yapko. New York Newsday, p. B8, June 30, 1994.

15. McHugh, P.R., et al. Controversy: Psychotherapy Awry. American Scholar, 63: 476-480, 1994.

16. McHugh, P.R. Book Review. An Anthropologist on Mars: Seven Paradoxical Tales. Sacks, O., Alfred A. Knopf, New York, 1995. Baltimore Sunday Sun, February 19, 1995.

17. McHugh, P.R. Answer to Critics to June, 1995, Witches, multiple personalities, and other psychiatric artifacts. Nature Medicine, Vol. 1, No. 6, 490-492, 1995.

18. McHugh, P.R. Book Review. The Jung Cult. Noll, R., Princeton Univ. Press, 1995. The American Scholar, Vol. 64, 617-622, 1995.

19. McHugh, P.R. Book Review. Emotional Intelligence: Why It Can Matter More Than IQ. Goleman, D., Bantam Books, New York. The Sun, September 10, 1995.

20. McHugh, P.R. Letter to the Editor. Commentary, Vol. 100, No. 6, 8, December 1995.

21. McHugh, P.R. The Argument: Legalize cocaine?--A prescription for disaster! The Sunday Sun, March 3, 1996.

22. McHugh, P.R. Book Review. The Creation of Dr. B: A Biography of Bruno Bettelheim. Pollak, R., Simon & Schuster. The Sun, January 19, 1997.

23. McHugh, P.R. Book Review. The Sexual Century. Person, E.S., Yale University Press, 2000. First Things, Vol. 107, 52-55, November, 2000.

24. McHugh, P.R. Book Review. New Oxford Textbook of Psychiatry and Contemporary Psychiatry. New England Journal of Medicine, Vol. 345, 299-300, 2001.

25. McHugh, P.R. A Report From the President's Council on Bioethics. American College of Neuropsychopharmacology Bulletin, Vol. 8, No. 2, 5, 2002.

26 McHugh, P.R. A Study on Minors Sexually Victimized by Catholic Priests is the Most Thorough Yet, But the Epidemic Raises More Questions. The Sunday Sun, February 29, 2004.

27. McHugh, P.R. Wrong Prescription: How the Emptying of State-Run Mental Hospitals Produced a Social Disaster. The Wall Street Journal, Book Review, June 14-15, 2008.

28 McHugh, P.R. Five Best: Paul McHugh on Books About the Factions and Follies of Psychiatry. The Wall Street Journal, W8, June 28-29, 2008.

29. McHugh, P.R. Children of Men. The Wall Street Journal, A15, December 18, 2012.

30. McHugh, P.R. A Manual Run Amok. The Wall Street Journal, C3, Saturday/Sunday, May 18-19, 2013.

31. McHugh, P.R. 'Death With Dignity' Claims Another Victim. The Wall Street Journal, A13, Saturday/Sunday, May 25-26, 2013.

32. McHugh, P.R. Transgender Surgery Isn't the Solution. The Wall Street Journal, A13, Friday, June 13, 2014.

Abstracts (Representative Sampling):

1. McHugh, P.R., Black, W. and Mason, J.M.: Some Hormonal Effects of Electrical Self Stimulation in the Lateral Preoptic Region. Physiologist, 6: 232, 1963.

2. McHugh, P.R. and Smith, G.P.: Brain Stimulation and Plasma 17-Oh Corticosteroid Control. Physiologist, 7: 204, 1964.

3. Smith, G.P. and McHugh, P.R.: Gastric Secretory Response to Amygdaloid Stimulation. Physiologist, 7: 259, 1964.

4. McHugh, P.R. and Smith, G.P.: Negative Feedback in Plasma 17-CH corti-costeroid Response to Amygdaloid Stimulation in Macaca Mulatta. Excerpta Medica, International Congress Series. 111: 710, 1966.

5. Reis, D.J. and McHugh, P.R.: The Role of Apnea in the Genesis of Bradycardia Following Stimulation in the Monkey. Fed. Proc., 25: 701, 1966.

6. McHugh, P.R. and Goodell, H.: The Diagnosis of Hydrocephalic Dementia. Neurology, 16: 299, 1966.

7. McHugh, P.R. and Gibbs, J.: Inhibitions on Feeding Revealed by Hypothalamic Disconnections in Macaca Mulatta. Federation Proceedings, 30: 375, 1971.

8. McHugh, P.R.: Inhibition of Feeding in Monkeys After Ventromedial Hypothalamic Disconnection. Federation Proceedings, 31: 397, 1972.

9. McHugh, P.R., Moran, T., Gibbs, J. and Falasco, J.: Intragastric Nutrient Infusions and Caloric Satiety in Monkeys. Federation Proceedings, 34: 374, 1975.

10. McHugh, P.R., Moran, T.H.: Caloric Assessment of Food Intake by Rhesus Monkeys. Federation Proceedings, 35: No. 3, March 1, 1976.

11. McHugh, P.R., Moran, T.H.: Gastric Emptying and Satiety for Food in Rhesus Monkeys. Federation Proceedings, 36: No.3, March 1, 1977.

12. Moran, T.H., McHugh, P.R.: Caloric Regulation of Gastric Emptying in Rhesus Monkeys. Federation Proceedings, 37: No. 3, 228, March 1, 1977.

13. Moran, T.H., McHugh, P.R.: Cholecystokinin: Gastric Emptying and Feeding in Macaca Mulatta. Federation Proceedings, 38: 1131, 1979.

14. McHugh, P.R., Moran, T.H.: Feedback Control of Nutrient Delivery From Stomach of Rhesus Monkeys. Federation Proceedings, 39: No. 3, March, 4, 1980.

15. McHugh, P.R., Moran, T.H., Wirth, J.B.: The Feedback Relationship Between Post Pyloric Glucose and Gastric Emptying Rate in Rhesus Monkeys. Federation Proceedings, 40: 576, 1981.

16. Wirth, J.B., McHugh, P.R. Interrelationship of gastric post-pyloric signals of satiety. Eastern Psychological Association, 52nd Annual Meeting, New York, April 22-25, page 90, 1981.

17. Brener, W., Hendrix, T.R., McHugh, P.R. Intraduodenal Glucose Calories Control Gastric Emptying in Man. Gastroenterology, 80: 1116, 1981.

18. Wirth, J.B., McHugh, P.R.: The Stomach in Satiety. Eastern Psychological Assn, 53rd Annual Meeting, Baltimore, MD, April 14, 1982, pg 168.

19. McHugh, P.R., Wirth, J.B.: The Small Intestine and Satiety. Eastern Psychological Association, 53rd Annual Meeting, Baltimore, MD, April14-17, 1982, page 169.

20. Wirth, J.B., McHugh, P.R.: Initial Emptying from the Stomach is Greater with Larger Gastric Volumes. Federation Proceedings, 41: No. 5, 1744, 1982.

21. McHugh, P.R., Goetz, K., Mearns, D., Wirth, J.B.: The Interrelations of Gastric Volume and Intestinal Glucose on Gastric Emptying in Rhesus Monkeys. Federation Proceedings, 42: No. 4, 1099, 1983.

22. Morton, D.A., McHugh, P.R., Hendrix, T.R.: Control of Gastric Emptying of Fructose in Man. Gastroenterology, 84: No. 5, Part 2, 1254, 1983.

23. Smith, G.T., Moran, T.H., Coyle, J.T., Kuhar, M.J., O'Donohue, T.L., McHugh, P.R.: Anatomical Localization of Cholecystokinin Receptors to the Pyloric Sphincter: Physiological Implications. The Physiologist, 26: No. 4, A-96, 1983.

24. Smith, G.T., Moran, T.H., Coyle, J.T., Kuhar, M.J., O'Donohue, T.L., McHugh, P.R: Autoradiographic Localization of Cholecystokinin Receptors to the Pyloric Sphincter of the Rat. Society for Neuro-science, 13th Annual Meeting, November 6-11, 1983, Boston, MA.Society for Neuroscience, 9: Part 1, page 172, 1983.

25. Moran, T.H., Robinson, P., Pronsky, C., McHugh, P.R. Localization andSpecificity of Pyloric Cholecystokinin Receptors. FASEB Meeting, April 1-6, 1984, St. Louis, MO, Federation Proceedings, 43: No. 4 page 1073, 1984.

26. Moran, T.H., Pronsky, C., McHugh, P.R. Localization and Specificity of Gastric Cholecystokinin Receptors. Volume 55: page 89, 1984.

27. Robinson, P.H., Moran, T.H., McHugh, P.R. Receptors for Cholecystokinin (CCK) and Effect of CCK on Independent Ingestion in Rat Pups. Annual Meeting of the Society for Neuroscience, page 1015, 1984.

28. Moran, T.H., Robinson, P.H., McHugh, P.R. Localization and Specificity of Pyloric CCK Receptors. Federation Proceedings, 42:1984.

29. Moran, T.H., Goldrich, M., Robinson, P.H., McHugh, P.R. Two Receptor Sites for the Mediation of CCK Satiety. Eastern Psychological Association, Boston, 56: 30, 1985.

30. Moran, T.H., Moody, T.W., Goldrich, M.S., Robinson, P.H., McHugh, P.R. Autoradiographic Localization of Bomesin Binding Sites Within the Gastrointestinal Tract. Society for Neuroscience, 11: 903, 1985.

31. Margolis, R.L., Moran, T.H., McHugh, P.R. The Contractility of Rat Gastrointestinal Tissue in Response to Bombesin and Cholecystokinin. The American Physiological Society's Annual Fall Meeting, October13-18, 1985, New York.

32. Speedie, L.J., Rabins, P., Pearlson, G., Moberg, P., McHugh P. Naming Deficits in Dementia of Depression. Journal of Clinical and Experimental Neuropsychology, 7, 645, 1985.

33. Moran, T.H., Smith, G.P., Hostetler, A.M., McHugh, P.R. Transport of CCK Receptors in Abdominal Vagal Branches. IXth International Conference on the Physiology of Food and Fluid Intake. Seattle, WA, July 7-11, 1986.

34. McHugh, P.R. The Stomach: A Conception of Its Dynamic Role in Satiety.Invited Address. Eastern Psychological Association, NY, 57:55, 1986.

35. Hostetler, A.M., Moran, T.H., McHugh, P.R. Bombesin: Gastric Emptying and Feeding. Eastern Psychological Association, New York, 57: 57, 1986.

36. Moran, T.H., Hicks, A., McHugh, P.R. Bombesin Inhibits Gastric Emptying in Rhesus Monkeys. FASEB 70th Annual Meeting, St. Louis, MO, Federation Proceedings, 45, 140. 1986.

37. Moran, T.H., McHugh, P.R. Examination of Pyloric Cholecystokinin (CCK) CCK Receptors. Society for Neuroscience, 12: Part 2, 1954, 1986.

38. Garcha, G.S., McHugh, P.R., Moran, T.H., Robinson, P.H., Stephenson, J.D. Development of Cholecystokinin Receptors and Suppression of Ingestion and Gastric Emptying. Proceedings of the Physiological Society, p.98P, 1987.

39. Moran, T.H., Sawyer, T.K., Jensen, R.T., Crosby, R.J., McHugh, P.R.Cholecystokinin (CCK) Analogs as Probes in Assessing the Site of Action of CCK Satiety. Society for Neuroscience, 14: Part 2, 1108, 1988.

40. Moran, T.H., McHugh, P.R. Effects of Pylorectomy on Cholecystokinin Satiety and Gastric CCK Receptors. CCK-88, Symposium on Cholecystokinin, Cambridge, 1988.

41. Crosby, R.J., Norgren, R., Moran, T.H., McHugh, P.R. Central and Peripheral Transport of CCK-A Receptors on Vagal Afferent Fibers. FASEB 73rd Meeting, New Orleans, LA, FASEB Jrnl, 3: A998, 1989.

42. Crosby, R.J., McHugh, P.R., Moran, T.H. Peripheral Transport of Vagal CCK Binding Sites Occurs Within Afferent Fibers. Proceedings of the Eastern Psychological Association, 60,: 38, 1989.

43. Seeb, D.H., Moran, T.H., McHugh, P.R. Inhibition of Feeding in Rhesus Monkeys by a Long Acting CCK Analog. Proceedings of the Eastern Psychological Association, 60, 39, 1989.

44. Robinson, R.G., Starkstein, S.E., Fedoroff, P., Berthier, M.L., Mayberg, H.S., McHugh, P.R. Bipolar Affective Versus Pure Manic Disorder After Brain Lesions. Society for Neuroscience, 15, Part 2, 1123, 1989.

45. Schwartz, G.T., Moran, T.H., McHugh, P.R. Effects of Sulfated and Non-Sulfated Cholecystokinin on Pyloric Contractility in the Developing Rat. Society for Neuroscience, 15, Part 2, 1279, 1989.

46. Moran, T.H., Crosby, R.J., McHugh, P.R. Effect of Pylorectomy on the Inhibition of Gastric Emptying by Cholecystokinin (CCK). Society for Neuroscience, 15, Part 2, 1280, 1989.

47. McHugh, P.R., Amgelio, P.J., Moran, T.H. Role of Endogenous Cholecystoknin (CCK) in the Regulation of Gastric Emptying of Liquid Glucose, Peptone and Intralipid Test Meals in Rhesus Monkeys. FASEB 75th Annual Mtg., Atlanta, GA, FASEB Journal, 5, Pt I, A386, 1991.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Case No.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.,	)
	)
Plaintiffs;	)
v.	)
	)
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al,	)
	)
Defendants.	)

Declaration of
Patrick W. Lappert, MD
Board Certified in Surgery and Plastic Surgery
Decatur, AL 35603

Knowledge Training and Experience :

1. Education and Training : I received my Bachelor of Arts in Biological Sciences at the University of California, Santa Barbara, 1979. There I was engaged in research in cell membrane physiology with Dr. Philip C. Laris, studying stoichiometry of the sodium: potassium ATPase pump. I received my M.D., Doctor of Medicine degree at the Uniformed Services University of the Health Sciences, 1983 at Bethesda, Md. I served my General Surgery Residency at the Naval Hospital Oakland/ UC Davis East Bay Consortium, 1987-1991 and served as Chief Resident, Department of Surgery, Naval Hospital Oakland, 1990-1991. I also served a Plastic Surgery Residency at the University of Tennessee- Memphis, 1992-1994. My

professional background, experience, and publications are described in more detail in my curriculum vitae. An updated copy of my CV is attached as Exhibit A to this declaration.

2. **Board Certifications in Medicine :** I have been Board Certified in Surgery (American Board of Surgery, 1992), in Plastic Surgery (American Board of Plastic Surgery, 1997; American Board of Plastic Surgery, 2008).

3. **Medical Staff Appointments : I served as the** Staff General Surgeon at the Naval Hospital Oakland, CA 1991-1992 and as Associate Professor of Surgery, UC Davis-East Bay, 1991-1992. I also served as a Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, VA 1994-2002 and as Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, VA 1996-2002. I later served as Clinical Assistant Professor, Department of Surgery, Uniformed Services University of the Health Sciences, 1995-2002 and as Founding Director, Pediatric Cleft Palate and Craniofacial Deformities Clinic, Naval Hospital Portsmouth, VA 1996-20002 also as the Founding Director, Wound Care Center, Naval Hospital Portsmouth, VA 1995-2002. I have also served as a Staff Plastic Surgeon in Nebraska, and Alabama.

4. **U.S. Surgeon General Service:** I served as a Specialty Leader, Plastic and Reconstructive Surgery, Office of the Surgeon General-USN, 1997-2002

5. **Faculty Appointments:** I served as Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery, 1995-2002

6. **Military Service :** I served as an Aviation Officer Candidate, Naval Aviation Schools Command, NAS Pensacola, 1978 and was Commissioned an Ensign, MC, USNR 1979 and Commissioned as a Lieutenant, MC, USN 1983 . I served as a Designated Naval Flight

Surgeon, Naval Aerospace Medical Institute, 1985 and was Assigned Marine Fighter/ Attack Squadron-451, serving as Flight Surgeon, and serving as 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. I served in the US Navy for 24 years, served in the USMC for 3 years. I retired with the rank of Captain, USN in 2002

7. **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 (6): 1048-53 ; Lappert P. Patch Esophagoplasty. J Plastic and Reconstructive Surgery. 1993; 91 (5): 967-8 ; Smoot E C III, Bowen D G, Lappert P, Ruiz J A. Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma. *J Craniofacial Surg.* 1995;6(4):327–331 ; 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.

8. **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

9. **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.

10. **Retained as an Expert Witness - Compensation - Bases for Opinions**: I have been retained as an expert witness by John G. Knepper, JD for the defense in connection with the Kadal, et al. vs. Folwell, et al litigation. I have actual knowledge of the matters stated in this declaration. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, travel, testimony, and consultation. My compensation does not depend on the outcome of this litigation. I am paid in advance for all written opinions or testimony to avoid any conflict of interest. To formulate opinions in this case I have reviewed

many scientific publications, the plaintiff's medical records, the Complaint and Answer, and all expert witness declarations.

11. **Affirmation Treatments are Currently *Experimental*** — as they have not been competently tested, not proven effective, are not generally accepted by the relevant scientific community, and have no documented error rates: Patients who experience a gender identity that is discordant with biological sex have an alarmingly high incidence of serious psychosocial morbidity including depression, anxiety, eating disorders, substance abuse, HIV infection, suicidality, and homelessness [Connolly, M. D., M. J. Zervos, C. J. Barone, C. C. Johnson, and 2nd C. L. Joseph. 2016. "*The Mental Health of Transgender Youth: Advances in Understanding.*" Journal of Adolescent Health 59:489–95. :10.1016/j.jadohealth.2016.06.012.] . While a need for effective treatment modalities is clear, ***there are currently significant deficiencies in our understanding the etiology of this condition, the risks and benefits of the current experimental (unproven, untested) medical interventions, and the long-term success of various affirmation experimental treatments in achieving the primary desired goal of reducing mental illness including reductions in suicide risk. M***ultiple recent studies and reviews including the recent national science summaries and guidelines from England-NICE, Sweden, Finland, the Cochrane Review, the British Royal College of Psychiatrists and others ***all document significant deficits in our current understanding of these complex disorders and signifigant defects in the existing science.*** As we strive to provide real, effective, and sustained treatment to patients who experience gender dysphoria within established ethical boundaries, it is essential that we properly and scientifically research the causes of gender dysphoria as well as conduct competent, properly conducted ***randomized clinical trials and long-term treatment***

outcome studies. These basic, foundational tasks — the tasks that make experimental procedures actual, proven treatments worthy of trust — have ***never been accomplished in the highly controversial field of the Transgender Treatment Industry***. Why? Suffering and vulnerable patients and their families continue to wait for this basic, foundational scientific work to be completed. Meanwhile, affirmation "treatments" must continue to be properly viewed as experimental.

The science and medical world have — in just the past few years — become increasingly aware of and deeply concerned about the glaring science and ethical defects of the Transgender Treatment Industry. For example, the very recently released 2020 Finland national science review and guidelines documented "***a lack of quality evidence*** to support the use of hormonal interventions in adolescents with gender dysphoria.". The new strict Finnish guidance prioritizes psychological therapy over treatment with hormones or surgery thus directly contradicting the non-science-based association protocols of WPATH]. The 2020 Finland national science review and guidelines also document the ongoing lack of scientific basis for the Transgender Treatment Industry stating "***Only limited research has been conducted on transgender identity and other gender identity conflicts, and comparative studies are very rare.***" In sum, the Finland National Science Review and Guidelines, like the new Sweden Review and Guidelines, and other reviews, and the collapse and recantation of the 2020 Branstrom long-term treatment outcome study claims under withering methodological criticisms, all appear contrary to the opinions of Drs Brown and Schechter and WPATH. See, e.g., https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/

Meanwhile, practitioners in this troubled field continue to offer defective research and politicized endorsements from politicized, union-like associations (WPATH, APA, ACP, etc) rather than competent, credible, valid and reliable, peer reviewed and published scientific evidence. As with the plaintiffs' experts in this case, they continue to refuse the serious defects and methodological limits of their data and experimental practices. 50 years of experimenting is enough! Its time for the Transgender Treatment Industry to come up with real, competently constructed scientific evidence that they are helping more people than they are hurting. As the recent recent national science reviews from England, Sweden, and Finland have all noted, its time to step back, slow down, and prudently investigate a range of approaches to vulnerable patients struggling with gender discordance issues.

12. **My Opinions regarding the Plaintiff's Expert Reports in this Case by Drs Schechter and Brown :**

As a physician and surgeon for decades, I have dedicated my life to helping the injured, the wounded, the sick, the vulnerable, and those in distress. As a physician and surgeon, I have a duty to carefully assess the available scientific research literature and determine what surgical procedures have been ***scientifically proven safe and effective for use on patients — and which procedures are still experimental***, potentially dangerous, and may well do more harm than good for patients. Such an assessment requires prudentialy reviewing scientific publications and being familiar with ***the ongoing methodological and scientific debates in the field***. In my opinion, the expert reports from Drs. Schechter and Brown in this case demonstrate little or no knowledge of the ongoing, raging scientific debates over the safety and effectiveness of "gender affirming" medical procedures. The reports of Drs. Schechter and Brown offer no disclosure and

demonstrate no awareness of the serious methodological defects and controversies exposing the lack of scientific foundations for the Transgender Treatment Industry (TTI). Over the past few years, scientific review after scientific review and multiple methodological exposes and national reviews in England, Sweden, Finland plus other reviews (e.g. Cochrane, Griffin, Carmichael, etc) have raised ***urgent warnings and serious questions about the quality and the integrity of the scientific foundation for this very controversial field.*** It it troubling that Drs Schechter and Brown appears to have financial and professional conflicts of interest as they appear to have admitted that much of their practices and income are derived from the experimental, unproven, potentially harmful methods and procedures of "affirmation" medical treatments. My review of the declarations of Drs Brown Schechter produced the following list of errors, omissions, and failures:

FAILURE TO DISCLOSE THE ONGOING CONTROVERSIES : Drs Schechter and Brown failed to properly disclose and discuss the international debates and controversies surrounding transgender affirmation methods and procedures. (See, the multiple journal articles, news reports, court cases, international reviews, etc cited below).

DEFECTIVE RESEARCH — Drs Schechter and Brown failed to properly disclose and discuss multiple peer-reviewed published exposes of significant methodological defects in research on transgender affirmation methods and procedures (e.g. the defective studies by Branstrom, Turban, and others discussed in detail below).

FAILURE TO DISCUSS CONTRARY STUDIES: Drs Schechter and Brown also failed to properly disclose and discuss recent scientific studies and reviews including the Cochrane Review, the Carmichael study, the Griffin review and the devastating scientific critiques of the

ill-fated and recanted Branstrom et al study including the many multiple, detailed, methodologically sophisticated letters to the editor.

TRANSGENDER, AFFIRMATION BREAST SURGERY IS EXPERIMENTAL and THUS NOT MEDICALLY NECESSARY: Drs Schechter and Brown failed to properly disclose and discuss the methodological and ethical controversies involving transgender breast surgery. The diagnostic process for such surgery is based soley on the patient's subjective report of dysphoria, but the medical necessity is based on the expectation that surgery will relieve the patient of the risk of, among other things, major depression, self-harm behaviors, and suicide. Competent , credible ressearch demonstrating such benefits does *not* yet exist. *None of the papers cited by Dr. Schechter (20, 21, 22, 23, 24, 25) address themselves to the question of medical necessity for either masculinizing surgery, or feminizing surgery*. They only address technical issues, management of complications, and subjective outcomes that employ precisely the same language that is used to assess cosmetic (not medically necessary) surgery of the breast. In summary, the medical necessity of transgender chest surgery is ***not supported by credible, competent, methodologically rigorous scientific evidence***, ***and appears to be firmly in the category of cosmetic (not medically necessary) surgery.***

THE ENGLAND-SWEDEN-FINLAND-COCHRANE-CARMICHAEL-GRIFFIN-BRANSTROM (Retraction) — NATIONAL SCIENCE REVIEWS and/or GUIDELINES ALL APPARENTLY CONTRADICT WPATH and the other ASSOCIATION NON-SCIENCE ENDORSEMENTS BASED ON VOTING PROCESSES : Drs Schechter and Brown also failed to properly disclose and discuss the internationally reported national reviews from England (NICE), Sweden, and Finland. These new science-based guidelines recommend different

methods, approaches, foci, and treatments than the controversial, unproven WPATH model supported by Drs. Schechter and Brown in this case. Where is the concern of WPTAH and Drs. Schechter and Brown for the suffering, vulnerable patients who deserve properly tested, proven, reliable, and efficacious treatments?

EXPERIMENTAL, UNPROVEN TREATMENTS ARE NOT "MEDICALLY NECESSARY" : Drs Schechter and Brown also failed to properly disclose and discuss the opinion of the relevant scientific community that all Transgender Transition affirmation "treatments" remain — after 50 years — controversial, untested, unproven, and thus clearly still experimental — and thus *cannot be medically necessary* — given the state of current research. (See, national reviews of England, Sweden, Finland, the Cochrance Review, the Griffin review, the Carmichael study, the Branstrom (recanted) study and others as cited in detail below).

THE ASSOCIATION VOTES CITED BY DRS BROWN and SCHECHTER ARE NOT THE PRODUCT OF A RELIABLE SCIENTIFIC METHOD, NOT ACCEPTED BY THE RELEVANT SCIENTIFIC COMMUNITY, HAVE NO KNOWN ERROR RATSE. SUCH METHODS HAVE NOTABLY PRODUCED SOME HISTORIC, DISASTROUS RESULTS : — Drs Schechter and Brown also failed to disclose and properly discuss the methodological defects in the ***non-scientific, unreliable, consensus-seeking, "voting" methodology*** of "associations" (e.g. WPATH, APA, ES, AAP, etc) in contrast to reliable-valid scientific research undergoing peer reivew, publication, then public review? Where is their concern for the suffering, vulnerable patients who deserve properly tested, proven, reliable, and efficacious treatments?

Professional associations and similar organizations have a tainted history of supporting unproven, controversial notions that were later shown to be improper, unreliable, and/or unethical. For example, it has been widely reported by historians that the American Medical Association supported (by voting) eugenic proposals to "improve the quality of the human stock" by coercive sterilization of "defective and undesirable Americans" and selective breeding. During the 1890s the renowned surgeon Albert Ochsner was invited to speak about his vasectomy procedure to the meeting of the American Medical Association. He recommended vasectomies to prevent the reproduction of "criminals, chronic inebriates, imbeciles, perverts, and paupers." (See, Oshsner, AJ, Surgical treatment of habitual criminals. JAMA, 1899:32:867-868). Similar to the political-policy-voting support of associations such as WPATH and APA for the Transgender Treatment Industry methods, the AMA's policy support for eugenics was a political not a scientific process. The unproven, political, experimental "treatments" of this movement were focused on "terminating the bloodlines" of the "submerged lower ten percent of the population with 'defective germ-plasm'". (See, Black, E. War Against the Weak, New York, NY, 2003). With the political-policy-voting support of the AMA, a Model Eugenics Sterilization Law was proposed to authorize sterilization of those supported in institutions or maintained at public expense. The model law encompassed the "feebleminded, insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent" — including "orphans, ne'er-do-wells, tramps, the homeless and paupers". Eighteen states passed laws based on the 1922 model legislation and ***sixty-four thousand people were forcibly sterilized.*** The lesson from the eugenics era is that associations can lend their weight and prestige to social movements believing that they are speaking from a foundation of science when

in fact they are articulating political or ideological concepts. Such pseudoscientific voting consensus processes are neither valid, reliable, nor evidence-based — whether they vote for experimental eugenics “treatments” or experimental transgender affirmation “treatments”. Suffering patients deserve more than political posturing they deserved competent, scientifically validated, tested and proven, effective and safe treatments. We are all still waiting for the politicized Transgender Treatment Industry to provide competent scientific support for their controversial, experimental methods and theories.

A similar methodological critique is relevant to the understanding of WPATH, the American Academy of Pediatrics, the American Endocrine Society, the American Psychiatric Association, the American Psychological Association and similar groups as they declare supportive policies that are not based on credible, reliable-valid science. These policies often do not acknowledge the glaring scientific deficiencies of proposed guidelines Beyond such policy voting statements is the absence of controlled studies, the absence of prospective follow up studies and no discussion nor proof of the error rates of interventions. It might be useful to examine what has been called the “Transgender Treatment Industry” (TTI). The TTI generates considerable income for hospitals, clinicians, and pharmaceutical companies. Members of the TTI have a vested interest in believing that science has already justified their existence. As sterilization is the expected adult outcome of endocrine and surgical treatments of the procedures undertaken in youth prior, the TTI must have developed strong rationalizations to justify creating infertility. Will one day the medical profession look at support for transitioning youth in the same manner the eugenics movement is now regarded? (See, Hruz, PW, Mayer, LS, and McHugh, PR, "Growing Pains: Problems with Puberty Suppression in Treating Gender Dysphoria," The New

Atlantis, Number 52, Spring 2017 pp. 3 -36 ; See also, McHugh, P., Psychiatric Misadventures, The American Scholar, Vol. 62, No. 2 (Spring 1993), pp. 316-320

Why did Drs Brown and Schechter fail to report this issue? Where is their concern for the suffering, vulnerable patients who deserve properly tested, proven, reliable, and efficacious treatments?

ANECDOTAL PATIENT STORIES ARE NOT DATA: — Drs Schechter and Brown also ***failed*** to disclose and properly discuss that Anecdotal Data unverified patient reports without control groups, randomized trials, or other scientific protections for the integrity of the medical system — are NOT reliable science. Tragically, much of the Transgender Treatment Industry support seems to come from personal patient stories claiming the "transitioning treatments" helped them. ***This is unreliable Anecdotal Data*** and it is not credible, ***scientific*** information. For example, for hundreds of years physicians/barbers would use "bleeding and leeching" to remove "unhealthy blood" as a "treatment" for a range of disorders including fevers. Many people were killed by such untested, unproven procedures but the patients who survived offered wonderful marketing by naively and unscientifically claiming that "bleeding and leeching" cured them.

PATIENTS SHOULD NOT RUN THE HOSPITAL — Drs Schechter and Brown also *failed* to disclose and properly discuss that surgeons are not permitted to give patients whatever they ask for (see e.g. Body Identity Disorder patients in the grip of a delusion demanding amputations) without credible research demonstrating safety and effectiveness Much of the Transgender Treatment Industry support comes from personal patient stories (unreliable anecdotal evidence) claiming the "treatments" will help them. Such patient stories are

Anecdotal Data. Such data if well known to be highly unreliable unscientific information. For example, for hundreds of years physicians/barbers would use “bleeding and leeching” to remove “unhealthy blood” as a “treatment” for a wide range of illnesses. Many people were killed by such procedures (including reportedly George Washington) but the ones who survived often offered wonderful marketing by naively and unscientifically believing and claiming that “bleeding and leeching” cured them. If the patient died during bleeding the physician could say “if she had only come in sooner so we could take more of the bad blood out” and alternatively if the patient recovered from the fever the physician could claim a treatment success. This failure to understand or apply fundamental scientific principles used in clinical trial research doomed millions to death and injury by quackery. It appears that the Transgender Treatment Industry is following in this destructive, unscientific footsteps.

CONFIRMATION BIAS — A POTENTIALLY DEADLY ERROR: — Drs Schechter and Brown also ***failed*** to disclose and properly discuss the wide spread foundational error of Confirmation Bias in the Transgender Treatment Industry. Providers in this troubled field apply a uni-causal hypothesis for very complex psychological disturbances, in spite of the fact that gender dysphoria can appear in different ways at different stages of development, and that the demographics show exponential growth and a radical switch in demographics. Whereas gender dysphoria historically affected boys 80% of the time, now the majority of new patients are adolescent females. In the politically tainted process of the Transgender Treatment industry the dangerous error of Confirmation Bias is built in to the system and institutionalized because the process of competent diagnosis and treatment — ***seeking and testing scientifically validated alternative theories, methods, and treatments*** — is demonized as “conversion therapy” when

actually such treatments are scientifically proven methods for reducing anxiety, depression, suicidality (e.g. Cognitive Behavioral Therapy that would ***not challenge*** any of the patients' beliefs regarding gender orientation or identity). In fact, an alternative hypothesis for investigation is that the "affirmation" providers want the patient to suffer depression and anxiety ***such untreated suffering motivates vulnerable patients*** to undergo the often painful and damaging experimental "transitioning" process. Once again, Drs. Brown and Schechter's defective expert reports somehow ignored all of these key issues. Where is their concern for the suffering, vulnerable patients who deserve properly tested, proven, reliable, and efficacious treatments?

THE DSM IS A DICTIONARY, NOT RELIABLE, VALID, PROVEN, METHODOLOGICALLY COMPETENT SCIENCE: — Drs Schechter and Brown also ***failed*** to disclose and properly discuss the ***fundamentally unreliable, defective and dangerous mis-diagnostic processes*** at the heart of the Transgender Treatment Industry. Basing life changing surgeries that damage and destroy the natural functions of perfectly healthy organs on nothing more than the ***unverified self-reports (conversations) of often disturbed patients*** as part of untested, unproven, experimental "treatments" that are "supported" by a methodologically defective research base when competent reviews have called such research "low quality" evidence and noted the "lack of any randomized clinical trials" — should be properly investigated as unethical, misconduct and an abuse of a vulnerable patient population. In addition, the reliance upon the DSM category of "gender dysphoria". It is important for legal professionals to understand that the DSM was created using a consensual, political process of small committees using ***voting methodologies***. ***Voting by DSM committees is not a reliable-***

valid scientific, evidence-based process. In the DSM methodology, small groups of professionals, often with ideological agendas and potentially with financial conflicts of interest, would form committees and create diagnoses to be "voted" into the DSM. The field has increasingly come to see the DSM as controversial and unreliable and in need of significant reform or retirement as a diagnostic methodology. The serious defects and limitations of DSM methodology are now well known leading to calls for reform by the relevant scientific community. See, e.g., Lee, C., *The NIMH Withdraws Support for DSM-5: The latest development is a humiliating blow to the APA.* Psychology Today News Blog at https://www.psychologytoday.com/us/blog/side-effects/201305/the-nimh-withdraws-support-dsm-5 ["Just two weeks before DSM-5 is due to appear, the National Institute of Mental Health, the world's largest funding agency for research into mental health, has indicated that it is withdrawing support for the APA's manual. In a humiliating blow to the American Psychiatric Association, Thomas R. Insel, M.D., Director of the NIMH, made clear the agency would no longer fund research projects that rely exclusively on DSM criteria. Henceforth, the NIMH, which had thrown its weight and funding behind earlier editions of the manual, would be "re-orienting its research away from DSM categories." See, NIMH Director Thomas Insel: Transforming Diagnosis, April 29, 2013, See, https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml The National Institute of Mental Health website documents the defects in DSM methodology. "Unlike our definitions of ischemic heart disease, lymphoma, or AIDS, the ***DSM diagnoses are based on a consensus about clusters of clinical symptoms, not any objective laboratory measure***. ***In the rest of medicine, this would be equivalent to creating diagnostic systems based on the nature of chest pain or the quality of***

fever. Indeed, symptom-based diagnosis, once common in other areas of medicine, ***has been largely replaced*** in the past half century as we have understood that ***symptoms alone rarely indicate the best choice of treatment***. ***Patients with mental disorders deserve better***. NIMH has launched the Research Domain Criteria (RDoC) project to transform diagnosis by incorporating genetics, imaging, cognitive science, and other levels of information to lay the foundation for a new classification system."] In my opinion, these views are generally accepted by the relevant scientific community and sound the death knell for the diagnostic practices of the experimental Transgender Treatment Industry. In sum, the field has come to agree that the DSM was indeed based upon a less than optimal process.

DRS BROWN AND SCHECHTER DID NOT REPORT RISKS AND DANGERS TO "TRANSGENDER TREATMENTS" INCLUDING: — Drs Schechter and Brown also ***failed*** to disclose and properly discuss serious risks with their experimental "treatments":

Sterilization. Sex Reassignment Surgery (SRS) that removes testes, ovaries, or the uterus is ***inevitably sterilizing and irreversible***. While by no means all transgender adults elect SRS, many patients do ultimately feel compelled to take this serious step in their effort to "live fully as the opposite sex". More immediately, practitioners recognize that the administration of cross-sex hormones, which is often viewed as a less radical measure, and is now increasingly done to minors, creates a risk of irreversible sterility. 31 These risks have never been properly studied nor quantified in a systematic manner. As a result, even when treating a child, the MHP, patient, and parents must consider ***permanent loss of reproductive capacity (sterilization)*** *to be one of the major risks of starting down the road*. The risk that supporting social transition may put the child on a pathway that leads to intentional or unintentional permanent sterilization is

particularly concerning given ***the disproportionate representation of minority and other vulnerable groups*** among children reporting a transgender or gender-nonconforming identity. *See* C. Guss et al., *TGN Adolescent Care* at 4 ("a side effect [of cross-sex hormones] may be infertility") and 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman et al., *Serving TG Youth* at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

Loss of sexual response. Puberty-blockers prevent maturation of the sexual organs and response. Some and perhaps many transgender individuals who transitioned as children and thus did not go through puberty consistent with their sex face significantly diminished sexual response as they enter adulthood, and are unable ever to experience orgasm. To my knowledge, data quantifying this impact has not been published. In the case of males, the cross-sex administration of estrogen limits penile genital function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine, *Informed Consent,* at 6.) (Perelman and Watters, 2016) Delayed Ejaculation in Handbook of Clinical Sexuality for. Mental Health Professionals 3rd edition, New York, Routledge**)**

The long-term health risks of this major alteration of hormonal levels ***have not yet been quantified*** in terms of exact risk *thus appropriate, ethical, complete informed consent* ***is not yet possible*** *for such experimental "treatments"*. However, a recent study found *greatly elevated levels of strokes and other acute cardiovascular events among male-to-female transgender individuals* taking estrogen. Those authors concluded, "it is critical to keep in mind that the risk for these cardiovascular events in this population must be weighed against the benefits of

hormone. *See* Tishelman et al., *Serving TG Youth* at 6-7 (Long-term effect of cross-sex hormones "is an area where ***we currently have little research to guide us***"). treatment." See, D. Getahun et al. (2018), *Cross-Sex Hormones and Acute Cardiovascular Events in Transgender Persons: A Cohort Study*, Annals of Internal Medicine at 8, DOI:10.7326/M17-2785.

Others similarly noted that administration of cross-sex hormones creates "an additional ***risk of thromboembolic events"—which is to say blood clots*** (Guss et al., *TGN Adolescent Care* at 5), ***which are associated with strokes, heart attack, and lung and liver failure***. The young patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view.

Health risks inherent in complex surgery. Complications of surgery exist for each procedure, and complications in surgery affecting the reproductive organs and urinary tract can have significant anatomical and functional complications for the patient's quality of life.

Disease and mortality generally. The MHP, the patient, and in the case of a child the parent, must also be aware of the wide sweep of strongly negative health outcomes among transgender individuals. ***Shortened life expectancy has been repeatedly documented*** in Sweden, US, and Denmark. See, Levine, Informed Consent, at 5 (citing T. van de Grift, G. Pigot et al. (2017), A Longitudinal Study of Motivations Before & Psychosexual Outcomes After Genital Gender-Confirming Surgery in Transmen, J. Sexual Medicine 14(12) 1621.).

Whatever the reason, transgender individuals including transgender youth certainly experience greatly increased rates of mental health problems. I have detailed this above with respect to adults living under a transgender identity. Indeed, Swedish researchers in a long- term study (up to 30 years since Sex Reassignment Surgery (SRS), with a median time since SRS of >

10 years) concluded that ***individuals who have SRS should have postoperative lifelong psychiatric care***. (Dhejne, Long Term, at 6-7.) With respect to youths a cohort study found that transgender youth had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services.

AFFIRMATION IGNORES MANY OTHER WAYS TO HELP THE SUFFERING— Drs Schechter and Brown also ***failed*** to disclose and properly discuss that th*e diagnosis of "gender dysphoria" encompasses a diverse and* ***controversial array of conditions***, with widely differing pathways and characteristics depending on age of onset, the complexities introduced by co-occurring mental illnesses, social contagion and other environmental factors, among other things. Data from one population (e.g. adults, those struggling with complex mental illnesses) should not naively be assumed to be easily applicable to others (e.g. children, those changed by social contagion) and other factors. The developmental and mental health patterns for of these groups are sufficiently different that data developed in connection with one of these populations ***cannot be assumed to be reliably applicable to another.*** See, K. Zucker (2018), The Myth of Persistence: Response to "A Critical Commentary on Follow-Up Studies & 'Desistance' Theories about Transgender & Gender Non-Conforming Children" by Temple Newhook et al., INT'L J. OF TRANSGENDERISM at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence").

NOT FDA APPROVED: — Drs Schechter and Brown also ***failed*** to disclose and properly discuss that the Food and Drug Administration has not approved the medications/ hormones used in the Transgender Treatment Industry for the treatment of gender dysphoria. The treatment research appears to document that such hormone treatments are of little if any benefit to patients and can cause severe damage to bone density and prevent normal psychological development during the key adolescent phase of life. (See, Carmichael, national science reviews of England-Sweden-Finland, and other publications cited in the Notes section of this declaration). Such off-label (not FDA approved) use of these powerful, permanently life-altering, medications is further evidence of the experimental nature of these scientifically unsupported treatments.

FAILURE TO DISCUSS THE FAILURE TO CONDUCT COMPETENT RESEARCH ON the ***UNKNOWN NUMBER AND PERCENTAGE of PATIENTS*** WHO DROP OUT OF TRANSITIONING OR REVERSE THE PROCESS (Detransitioners) : — Drs Schechter and Brown also ***failed*** to disclose and properly discuss — the phenomenon of desistance or regret experienced *later* than adolescence or young adulthood, or among older transgender individuals, has to my knowledge ***not been quantified or well-studied.*** However, it is a real phenomenon. I myself have worked with multiple individuals who have abandoned trans female identity after living in that identity for years, and who would describe their experiences as “regret”. More dramatically, a surgical group prominently active in the SRS field has published a report on a series of seven male-to-female patients requesting surgery to transform their surgically constructed female genitalia back to their original male form. See Djordjevic ML, Bizic MR, Duisin D, Bouman MB, Buncamper M. Reversal Surgery in Regretful Male-to-Female

Transsexuals After Sex Reassignment Surgery. J Sex Med. 2016 Jun;13(6):1000-7. doi: 10.1016/j.jsxm.2016.02.173. Epub 2016 May 4. PMID: 27156012. An increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. Given the rapid increase in the number of girls presenting to gender clinics within the last few years, the phenomena of regret and desistance by young women deserves careful attention and study by MHPs. As reported by one author in 2021, *60,000 testimonies of personal de-transition can be found on the Internet.* See, Pablo Exposito-Campos. A typology of gender detransition and its implications for health care providers J Sex & Marital Therapy 2020 https:..doi.org/101080/0092623x.2020.1869126); See also, reportedly one Reddit subthread [See, https://www.reddit.com/r/detrans/new/] for detransitioners currently has more than 17,000 members, and a facility in Sweden, the Lundstrom Gender Clinic, provides trauma therapy for detransitioners. [See, The Trans Train and Teenage Girls (Swedish documentary with English subtitles) at https://www.youtube.com/watch?v=oDV-ZL6-Gu0]

NOT GENERALLY ACCEPTED — Drs Schechter and Brown also ***failed*** to honestly and properly disclose that the A) underlying defective science, B) unreliable diagnostic methods, C) confirmation bias riddled treatment selection procedures, and the still unproven-experimental treatments of the Transgender Treatment Industry have never been generally accepted by the relevant scientific community.

NO ERROR RATES — Drs Schechter and Brown also ***failed*** to honestly and properly disclose that the A) underlying defective science, B) unreliable diagnostic methods, C) confirmation bias riddled treatment selection procedures, and the still unproven-experimental

treatments of the Transgender Treatment Industry have no known error rates thus more patients could be injured than helped by such methods and procedures as recent studies demonstrate (See Branstrom critiques, Carmichael study, etc.)

FAILURES TO DISCLOSE INFORMED CONSENT ERRORS: In the present treatment paradigm that is supported by Dr. Schechter, and applied to self-identified transgender persons, the diagnosis is made by the patient, and affirmed by counselors, primary care providers, pediatricians, and psychological services providers. Confirmation of the diagnosis amounts to the use of questionnaires that often are identical to questionnaires found on line. The questions, and their answers use highly rehearsed language that is the same whether asked by the school nurse, or the licensed psychologist. They are based upon the affirmation model of the condition, and assumes that the condition is biologically determined, even though there is little to no scientific evidence to support this hypothesis. No alternative hypotheses of causation of the patient's condition are permitted.

By the time the patient presents to the transgender surgeon, they have been the subject of affirmation processes that include everything from social transitioning, to hormonal manipulation. The surgical services provider does not question the diagnosis, nor investigate the science upon which it is based. Essentially the surgeon is performing permanently life-altering surgical interventions to cure a psychological condition that was diagnosed by the patient, and sometimes the patient made the diagnosis before they even entered puberty. ***Since the abandonment of frontal lobotomies in 1967, there has been no other psychological condition for which surgery is performed***, and there is no other area of surgical care where the

diagnostician is the patient themselves, and the surgeon has no means of confirming or rejecting the diagnosis.

Valid surgical consent requires that the surgeon is ultimately responsible for the accuracy of the diagnosis. For example, if an endocrinologist refers a patient for thyroidectomy because they have diagnosed a malignant thyroid nodule, the operating surgeon is still obliged to ensure the validity of the diagnosis. He has to entertain alternative diagnoses. Is it a benign nodule? Can it be treated with non-surgical means at lower risk to the patient. What do the scans show? What do the hormone levels show? Having evaluated all the alternative possibilities in the differential diagnosis, the surgeon can then counsel the patient and their family on the options of care, the likelihood of cure, and proper informed consent can be obtained.

The Transgender Treatment Industry, employing the scientifically unsupported WPATH guidelines, co-authored by Dr. Schechter, essentially excuse the surgeon from any responsibility for the diagnostic process or its consequences if the diagnosis is incorrect.

The 7th edition of the WPATH guidelines only requires two letters written by psychologists, and a period of social transition. There is no action taken to verify the diagnosis on the part of the surgeon. The surgeon has no means by which to anticipate who might benefit or who might be harmed by surgery.

Transgender surgeons like Dr. Schechter have no means of evaluating the diagnostic error rate because there is no= body of reliable scientific evidence that can be used to counsel the patient about what their risk of transgender regret is. The ever growing population of de-transitioning patients suggests that the error rate may be considerable, and the future medico-legal consequences may be proportionate.

In sum, in my opinion the expert reports of Drs Brown and Schechter — are misleading, un-scientific, advocacy statements of two providers that appear deeply embedded — politically, ideologically, and financially — in the Transgender Treatment Industry. It is currently not clear whether the "treatment" efforts of that industry and providers like Drs Schechter and Brown are causing more harm than benefit to the vulnerable, suffering patients we should seek to help and support with treatments proven safe and effective by validated, competent scientific research. ***After 50 years of experimental, unproven, treatments in this area, the vulnerable, suffering patients are still waiting for scientifically validated treatments.***

13. Review of Dr. Brown's Opinions Regarding the Plaintiff's Medical Records and My Review of the Plaintiff's Medical Records:

Dr Brown's updated (2nd) report on the plaintiff's medical records continued his avoidance of the many controversies, methodological defects, ongoing debates, and incongruous findings of the Transgender Treatment Industry. Once again, he failed to mention the significant hazards involved with these experimental treatments and the published reviews documents documented the lack of benefits and harms of "transitioning" treatments. My own review of the plaintiff's medical records found a demonstration of the errors in the industry described below including :

— *lack of appropriate informed consent* including failure to disclose and discuss the "low quality" of evidence this industry is based upon and the lack of randomized trial research and the lack of long-term research indicating such experimental treatments are more helpful than harmful to most patients.

— failure to carefully investigate the psychosocial alternative hypotheses regarding the etiology of the patient's disorder (See, new treatment guidelines from Sweden and Finland seeking psychological evaluations over years prior to intrusive medical "treatments" leading to harm to otherwise healthy organs

— failure to acknowledge that the "association" endorsements of these experimental treatments are based upon consensus-seeking (committee voting) and not evidence-seeking, scientific methodologies.

and the other errors and failures to disclose as discussed above.

14. **Why I Do Not Engage in *Experimental* Treatments Lacking Reliable, Credible Scientific Support with Gender Dysphoric (Transgender) Patients — or Any Other Patients:** As multiple national science reviews and multiple peer reviewed science publications demonstrate, the relevant scientific community has never accepted the reliability, validity, safety or effectiveness of "gender affirmation" treatment procedures — including surgical procedures. Significant medical, ethical, and potential legal problems are created when health care providers employ experimental, unproven, treatment including surgical procedures. As multiple national science reviews (e.g. Sweden, Great Britain, Finland), a Cochrane Review and multiple other published reviews of this controversial research field have recently noted, current Transgender Treatment Industry procedures are only supported by "low quality" methodologically flawed, research lacking general acceptance and lacking any published error rates. (See, eg. the Branstrom, et al study with accompanying multiple exposes of the researchers' serious methodological errors and failures to report the data accurately). For example, the current assortment of "gender affirmation" surgical procedures lack credible,

reliable and valid scientific support as there are currently no published randomized trials, nor and competent long-term research studies demonstrating safety, efficacy, and scientific validity for these currently controversial, unproven, experimental treatment protocols. Due to this well-documented lack of scientific support and only low quality evidence of efficacy and safety, I will not personally engage in the delivery of experimental gender affirming medical interventions to patients of any age. I will not consider doing such invasive, potentially harmful surgical procedures — that can lead to life-long sterilization of vulnerable patients — until reliable-valid, credible scientific research supports such methods.

15. **The biological basis of sex —** Sex is not "assigned at birth" but permanently "assigned" at conception by DNA. Medical technology can be used to determine a fetus's sex ***before birth***. It is thus not scientifically correct to talk of doctors "assigning" the sex of a child at birth; almost anyone can accurately and reliably identify the sex of an infant by genital inspection with approx 99.9% accuracy. Every nucleated cell of an individual's body is chromosomally identifiably male or female—XY or XX. Claims that patients can — via hormonal and surgical treatments — obtain a "sex change" or a "gender transition" process are ***misleading and scientifically impossible***. In reality, the typical "transgender" Gender Discordant patient has normal healthy sex organs but struggles with Gender Discordant ***feelings and perceived identity — a psychiatric and not a medical problem***.

16. ARE PATIENTS and PARENTS UNETHICALLY MISINFORMED BY PROVIDERS WHO FAIL TO DISCUSS THE KNOWN RISKS AND DANGERS OF "TRANSITIONING" TREATMENTS AND THE INTERNATIONAL CONTROVERSIES IN

THIS FIELD? : Putting a patient of any age on a pathway towards life as a transgender person puts that individual at risk of a wide range of long-term or even life-long harms, including:

— sterilization (whether chemical or surgical) and associated regret and sense of loss;

— inability to experience orgasm (for trans women);

— physical health risks associated with exposure to elevated levels of cross-sex hormones;

— surgical complications and life-long after-care;

— alienation of family relationships;

— inability to form healthy romantic relationships and attract a desirable mate;

— elevated mental health risks including increased depression, suicidality, and completed suicide.

Given that Drs Schechter and Brown failed to inform this court of the defects, uncertainties and controversies surrounding the entire field of Transgender Treatments, it seems difficult to imagine that they are properly informing patients of these defects, uncertainties and controversies.

17. VIRTUALLY ALL TRANSGENDER PATIENTS ARE BORN WITH HEALTHY NORMAL SEX ORGANS AND NO KNOWN BRAIN OR GENETIC ABNORMALITIES and NO SCIENTIFICALLY VALIDATED REASON TO SURGICALLY DAMAGE THEIR HEALTHY ORGANS - Transgender surgery is currently experimental and thus not medically necessary, as it seeks goals and benefits that have not yet been scientifically tested, validated, and proven. The long-term research on transgender surgical outcomes FAILED to show benefits and

suggested injuries from these experimental procedures (See Branstrom et al. research cited and discussed in the notes section of this declaration).

Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," ***this is not biologically attainable***. It is possible for some adolescents and adults to pass unnoticed as the opposite gender that they aspire to be—but with unknown levels of limitations, costs, and risks.

18. INDIVIDUAL PATIENTS and THE FIELD AS A WHOLE SHOULD CAREFULLY REVIEW AND CONSIDER THE POTENTIAL SURGICAL COMPLICATIONS and/or IATROGENIC INJURIES WITH EXPERIMENTAL TRANSGENDER SURGERY of UNKNOWN LONG-TERM SAFETY AND EFFECTIVENESS :

EXAMPLES OF SURGICAL RISKS: "Masculinizing" Female to "Male" - Complications:

"Transgender Procedures Metoidioplasty: Following hormonally induced clitoromegally, the clitoris is released so that it hangs dependently, mimicking a small phallus, the urethra is lengthened by the use of mucosal, and/ or cutaneous flaps and/or grafts so that the urinary stream emerges from the tip of the counterfeit phallus. Reported complications with varying degrees of frequency:

1. Urethral strictures producing varying degrees of urinary obstruction and retention. a. Requires re-operation to open or dilate the scar strictures, additional grafts, urinary diversion through the use of a bladder catheter through the lower abdominal skin (suprapubic catheter)

2. Urethral- cutaneous fistulae (urine leaking from holes in the neo-urethra caused by wound healing problems and obstruction as in 1. above) a. Requires re-operative procedures as in 1. a. above.

3. Recurrent lower urinary tract infections caused by 1, and 2 above.

4. Chronic cysto-cutaneous fistula (urine leaking from the bladder through the skin of the lower abdomen) caused by the need for suprapubic catheter to divert the urinary stream to protect the neo-urethra construct if chronic distal urinary obstruction results from original or subsequent re-operation.

5. **Life-long reproductive sterilization**, since metoidioplasty is often accompanied by previous or subsequent hysterectomy and oophorectomy.

Phalloplasty: The construction of a counterfeit "neo-phallus". Typically accomplished by the transplantation of a vascularized, sensate flap of skin and associated soft tissue from the non-dominant forearm (Sensate Radial Forearm Flap). Blood vessels and sensory nerves in the flap are connected to blood vessels and nerve in the area of the native genital structures. A highly technical procedure requiring microscopic assistance. ***Many published studies do NOT report complication rates***. *Overall,* ***the reported complication rate is above 50% for the most favored operation to construct counterfeit phallus*** *(1).* The most frequent complications involve stricture or leakage of urine, and occurs in approximately 40% of all patients (2, 3, 4), requiring surgical correction. Infectious complication rate of 9%, with associated complete flap loss in 2% of patients have been reported in a patient series by Leriche et al., as is cited in a comprehensive review of phalloplasty complications (5). One single center review of a 20 year experience shows that blockage of blood flow to the pseudo-phallus, requiring reoperation occurs 11% of

the time (6). This same review showed complete loss of the construct occurred in 3% of patients, and 17% of patients showed significant wound healing issues requiring re-operation and long term wound care. In a comprehensive review of the most common phalloplasty surgeries, published in Clinics of Plastic Surgery in 2018, the authors state, *"**Phalloplasty is known for its high rate of complication**"*. Their systematic review of the literature showed complete flap loss approaching 2%, partial loss of the flap in 5-7% of cases, opening of wounds (dehisence) in 11% of patients, and a high rate of blood clot formation in the patient's legs with risk of pulmonary embolization due to the long operative time, patient positioning for surgery, and the prolonged bed rest required (5). Similar complication rates have been reported in a review of 269 phalloplasties performed at a single center in Germany over a 22 year period. A review of patients whose phalloplasties included the use of prosthetic implants ***showed implant associated complication rate of 44%, including infection, extrusion, surgical replacement, and the need for surgical removal*** *(8).* There is also a high complication rate associated with the defect caused by harvesting the forearm tissue that is used in the construction of the counterfeit phallus. Kuran et al. in a 2019 article reviewing 940 radial forearm flap surgeries (730 of which were in transgender patients) showed an overall complication rate of 8%. **Infection in 16%, chronic pain in 10%,** loss of strength and sensation in the limb in 5%, contracture with loss of mobility requiring occupational therapy in 6.5%, and failure of the covering skin graft in 4.5%. (9) In addition to the cosmetic result, and the ability to urinate while standing, ***it would be expected that the transgender scientific literature would rigorously investigate the effects of these surgeries on erotic sensibility but they have not****. Human sexuality and gender identity discordance is at the heart of the justification for these very elaborate surgeries which carry high*

complication rates, however, ***a review of outcomes in this area shows the low quality of outcomes data, and thus the experimental nature of these operations.*** *In a 2019 literature review by Morrison et al. (10) the authors found that of 341 articles that had been published in peer reviewed journals, only 26 were found suitable for analysis.*

The authors summarize by saying, " Little data are available on genital sensibility outcomes after phalloplasty, and there are no standardized approaches for assessment of either sensibility or erogenous perception." They then conclude by confessing, " it is difficult to draw evidence-based conclusions." This is a remarkable finding given that the human genital apparatus has two basic functions, namely reproduction and erotic sensibility. We know that reproduction is irreversibly destroyed by these operations, and now we see that erotic sensibility is degraded if not destroyed as well. Having thus excluded the entirety of genital function, all that remains is a cosmetic result, which is not a scientifically quantifiable product. In summary, masculinizing female to "male" surgeries are highly complex procedures with a very high complication rate. The scientific literature in this area of medicine is largely of low quality, and evidences the experimental nature of these operations. The most scientifically rigorous long-term studies (11,) show that the stated goals of the surgeries, including decreased anxiety, decreased psychiatric hospitalization, decreased substance abuse, decreased self harm, and decreased suicide are not met. The long term cohort study from Sweden shows that persons who have completed all transition steps from female to "male", when compared with a population matched cohort, have a substance abuse rate that is 3.5 times higher, a psychiatric hospitalization rate that is 3.5 times higher, a rate of incarceration for violent crime that is 9.9 times higher, and a suicide rate that is 40 times higher than the control group. When the authors graphed these

findings over time, they show that any improvement in these markers begins to disappear within 6 to 8 years following completion of surgery. This largely explains the suggestion of improvement seen in the low quality data that is tainted by short follow-up, and self-selection bias. The best population based, cohort matched, longitudinal studies appear to show that all that is achieved by these surgeries is a cosmetic result, and reproductive sterilization.

COMPLICATIONS:

1. Complete loss of the microvascular flap. Typically caused by technical failure of the venous connection, may also result from clot formation in the blood vessels, or pressure of swelling that compresses the blood supply. a. Requires major re-operation to remove the dead flap, and placement or retention of urinary diversion with the use of a suprapubic bladder catheter.

2. Partial loss of the microvascular flap. Caused by transient or persistent insufficiency of blood flow, with similar etiologies as in 1 above. a. Requires re-operation to debride (remove) dead tissue, and chronic wound care involving daily dressing changes, wound care visits. b. Requires placement or retention of urinary diversion with suprapubic catheter to prevent urinary contamination of the chronic wound.

3. Urethro-cutaneous fistulae (urine leakage from the counterfeit phallus). Caused by wound healing problems within the construct that may result from inadequate blood flow, pressure, or distal urinary obstruction. a. Requires placement or long term retention of the suprapubic catheter, and surgical procedures to repair the wound openings.

4. Urethral strictures with associated urinary obstruction of varying degrees. a. Repeated urethral dilation and/ or catheterization, or re-operation to relieve chronic strictures, and will likely require urinary diversion as above.

5. Lower Urinary Tract Infections: resulting from any or the above complications of surgery. 6. Extrusion of erectile and or testicular prostheses. Cause by presence of bacteria on the implanted devices. Bacteria may have been introduced at time of surgical placement, or may result from above complications of partial flap loss or lower urinary tract infections that result from above complications.

7. Partial or complete loss of erotic sensibility. Native clitoris is typically placed at the base of the counterfeit phallus as part of the construct. Some degree of incidental surgical injury to sensory nerves is expected. Sensation from the shaft of the counterfeit phallus, provided by the surgical connection of the forearm nerve to the groin nerves, is considered successful if it provides any tactile sensation. It is not expected to produces the erotic provocation that the sensory apparatus of the native vagina produces.

8. Upper extremity complications. Common problems with the donor site can include: partial or complete loss of the skin grafts used to cover the exposed muscles and tendons that results from harvesting the forearm flap. Uncommon, but nonetheless possible, ischemic hand injury (inadequate blood flow to hand). a. Chronic wound care to achieve healing, and to protect exposed tendons. b. Scarring and tendon injuries from exposure may result in loss of range of motion. This is typically temporary, but may become permanent, depending on the age of the patient, and will require occupational therapy (OT). c. Chronic pain from harvest of the flap, or complications of healing as above.

9. Lifelong Reproductive Sterilization. These surgeries are typically preceded by or followed by hysterectomy and oophorectomy. An essential human function is being destroyed in order to produce a cosmetic result.'

Vaginoplasty - Complications :

Feminizing surgeries, performed on male persons, include the creation of external and internal structures that mimic the appearance and function of female genitalia. The most commonly performed surgery, called "inversion vaginoplasty" uses tissues from the patient's native genital structures to create neo-vaginal labia majora and minora, and a skin sleeve that is inverted into the pelvis to create a receptive passage capable of receptive copulation. In the process of this operation, the patient is castrated, the penis is opened, the erectile tissues removed, a portion of the glans is preserved while trying to preserve the erotic innervation so that it can be used to create a neo-clitoris, the skin of the penis is surgically closed and inverted into the pelvis, while preserving its native blood supply. The scrotal skin is used to construct the labia, and the urethra is shortened to an opening at the base of the neo-clitoris. Other vaginoplasty operations may involve the use of vascularized flaps from the thighs or abdomen to create the receptive neo-vaginal structure. Portions of the lower intestinal tract may be used to create the receptive sleeve of the neo-vagina. These operations are often used when prior surgeries have failed for a variety of reasons that will be presented below, or they may be a first choice if the patient has a poverty of genital tissue. Such poverty is a common result of prior use of puberty blockade and cross-sex hormones if the patient has been the subject of treatments that began in early adolescence.

As documented in the NOTES section of this declaration, The scientific literature offered in support of the efficacy, safety, and cost-effectiveness of these procedures is of low quality, and comprised almost entirely of case-series reports that lack controls, are of short duration, suffer from various biases including self-selection and confirmation bias. These problems are attested to by citations offered by Dr. Schechter in his expert testimony for the plaintiff. Dr. Schechter, in support of the efficacy of vaginoplasty surgery, cites a 2014 paper (20) which is typical. It reports outcomes on a consecutive case series of 254 male to "female" surgical patients. The data presented in support of the efficacy of surgery was in the form of a ***questionnaire*** that asked questions about satisfaction with the result (subjective data). The average follow up interval was 5 years, with the longest follow up in a single patient at 7 years (short follow-up), and ***only 46% of patients completed the questionnaire*** (self-selection bias). In another of Dr. Schechter's cited articles, the authors present a prospective study **of only 39 patients (a very small sample)**, who are given ***questionnaires*** about their quality of life (subjective data), and the final evaluation of outcomes is ***only 6 months post operation*** (very short follow up given that research shows deep regret often begins on average ***10 years after surgery***. Based upon such ***low quality data***, the authors conclude by claiming that their study result, "endorses sex reassignment surgery as a valuable option for these patients."

In his expert testimony, Dr. Schechter, having defined gender dysphoria, then goes on to justify surgical treatment based upon "medical necessity". He states, "Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide. Yet with only a single exception, ***no measure was made of the effects of surgery*** on what is claimed to constitute the "medical necessity" for these

procedures. The long term research — the Branstrom study cited in detail in the Notes Section of this declaration showed NO benefits for transgender surgery and NO reduction in succeed and an ***increase*** in serious suicide attempts requiring hospitalization in patients ***receiving*** the surgery. ***These recent, long-term, published, peer reviewed, credible research findings are quite contrary to the claims of Dr Schechter and Dr Brown — as are the National Science Reviews in this area from England-NICE, Sweden, and Finland (see Notes section in this declaration).***

Scientific rigor would demand an examination of such outcomes as: rates of substance abuse, psychiatric hospitalization, self-harm, or suicide, and how they were changed by surgery. The only paper in Dr. Schechter's list of citations that asks these crucial questions concerning efficacy is a very comprehensive, long term, longitudinal population cohort study (11) ***which actually shows the opposite*** of what Dr. Schechter claims for these patient outcomes. When followed beyond 8 years post operatively, this paper shows patients receiving Dr Schechter's treatments have ***the same alarmingly high rates of hospitalization, substance abuse, self-harm, and completed suicide as persons who have had no medical or surgical intervention***. The fact that the citation is included by Dr. Schechter, but never discussed in his opinion regarding efficacy is troubling. In summary, on the issue of the safety and efficacy of these surgeries, the scientific support is very weak, ***while the scientific evidence rejecting the hypothesis of efficacy is quite strong.***

BREAST SURGERY - COMPLICATIONS:

Mastectomy/ Chest Masculinization, Breast Augmentation/ Chest Feminization

The surgical removal of the breasts, and the re-contouring of the chest through liposuction is a common procedure for women who seek to present as men. These operations are

performed in both men and women, for a variety of reasons, are very safe, and typically performed in the outpatient setting. It is important to understand that the only way of distinguishing cosmetic breast surgery from "medically indicated" surgery is based upon the diagnosis of underlying pathology. For example, breast reduction may be cosmetic, or it may be medically indicated. In both cases, the patient presents with a complaint that her breast are too big. The distinction between cosmetic breast reduction, and medically indicated breast reduction, is based upon the presenting symptoms of orthopedic problems caused by the weight of the breasts, but even then, the weight of the removed tissue is factored into the objective verification that the surgery was "medically necessary".

The same issues are at stake in breast enhancement for men seeking to present as women. Cross-sex hormones will have caused varying degrees of gynecomastia (breast enlargement in men). Surgical enhancement procedures are exactly the same in both men and women. Medically necessary surgery in women is based upon the diagnosis of an objective medical condition, such as Poland's syndrome (congenital absence of a breast), surgical absence of the breast following cancer care. In men, the objective diagnosis of gynecomastia might warrant surgery based upon medical necessity, but it would be a removal of tissue. A rare diagnosis of breast cancer in a man might warrant chest wall reconstruction after cancer care. On the other hand, cosmetic surgery of the breast is entirely about the subjective feelings of the patient, and that is all that we have in the case of the self-identified transgender patient.

In the case of transgender chest surgery, the diagnosis is based on the patient's subjective report of dysphoria, but the medical necessity is based on the expectation that surgery will relieve the patient of the risk of, among other things, major depression, self-harm behaviors, and

suicide. None of the papers cited by Dr. Schechter (20, 21, 22, 23, 24, 25)address themselves to the question of medical necessity for either masculinizing surgery, or feminizing surgery. They only address technical issues, management of complications, and subjective outcomes that employ precisely the same language that is used to assess cosmetic surgery of the breast. In summary, the medical necessity of transgender chest surgery is not supported by scientific evidence, and appears to be firmly in the category of cosmetic surgery.

19**. SUMMARY OF OPINIONS:**

— There are no currently no competently conducted, long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

— A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

— A currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by a — peer group, social media, YouTube role modeling, and/or parental — social contagion and social pressure processes.

— Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

— It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmation" treatments.

— A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

— Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.

— NOT GENERALLY ACCEPTED: Affirmation medical treatments — hormones and surgery — for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc).

— NO KNOWN NOR PUBLISHED ERROR RATES: Gender transition "Affirmation" medical assessments and treatments — hormones and surgery — for gender dysphoria and

"transitioning" have no known, peer reviewed and published error rates — the treatments and assessment methods lack demonstrated, reliable and valid error rates.

— ASSOCIATION GUIDELINES AND ENDORSEMENTS ARE NOT SCIENCE : Political activists, political activist physicians, and politically active medical organizations that operate by voting methodologies (e.g, WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and political ideologies (e.g., Critical Theory) rather than evidence-based scientific methodologies.

— ETHICAL RESTRICTIONS ON EXPERTS - WILL THERE BE A PROPER INVESTIGATION OF MISINFORMATION? : Experts in legal cases have an ethical obligation to honestly, fairly, and accurately disclose and discuss the international controversies regarding the safety, effectiveness, reliability, and credibility of the Gender Transition Industry. It is astonishing that in their expert declarations, Drs Schechter and Brown ***failed*** to disclose and discuss the controversies, complex issues, debates, and contrary national science review recommendations in this field. Dr Brown even swore in his declaration that… "***Nor is there any uncertainty or dispute in the medical field regarding the medical necessity of this care***." It is difficult to imagine a more inaccurate summary of the state of the embattled, experimental Transgender Treatment Industry. Will such mis-information be properly investigated by the relevant authorities?

20. DR LAPPERT's RESEARCH NOTES: To assist in my testimony in this case. I include my notes, references and citations documenting the depth and breadth of the serious

controversies in this field. Over the past few years, the glaring defects in the research foundations of the Transgender Treatment Industry have been exposed for all the world to see.

> **Controversy -** 2015 Dutch Study by *Vrouenraets et al, Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,* Journal of Adolescent Health 57 (2015) 367e373. *…no consensus exists whether to use these early medical interventions.*….Results: Seven themes give rise to different, and even *opposing, views on treatment*: (1) *the lack of an explanatory model for GD*; (2) *the unknown nature of GD (normal variation?, social construct?, or mental illness?)*; (3) the role of physiological puberty in developing gender identity; (4) *the role of comorbidity [with severe mental illnesses]* ; (5) unknown possible *physical or psychological effects of (refraining from) early medical interventions*; (6) *child competence and decision making authority [to give truly informed consent to be sterilized for experimental procedures?]*; and (7) *the role of social context …how GD is perceived*. Strikingly, the guidelines are debated both for being too liberal and for being too limiting. Conclusions: As long as *debate* remains on these seven themes and *only limited long-term data are available, there will be* ***no consensus on treatment***. Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required. It is striking that Drs. Brown and Schechter somehow both failed to properly report this ongoing international debate within their claimed filed of expertise.

> **2011 - Dhejne** et al. **(2011)**, Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); See also, R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4). Swedish follow-up study of patients who underwent sex-reassignment surgery over a 30-year periodfound a ***suicide rate in the post-Sex Reassignment Surgery (SRS) population 19.1 times greater*** — after affirmation treatment — than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions.

> **2021-2020 Carmichael** P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653 … Self-harm did NOT improve and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed."… no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found… children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

> **See, 2020 Bränström and Panchankis long term surgical results NO benefit (data**

suggests and suggests an increased risk of serious suicide attempts) …See also See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:7 64; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

DEMOGRAPHICS… no biological explanation… The radical change in patient demographics from early onset in boys to teen girls with rapid onset— has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. "National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 See, Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." Adolescent Health, Medicine and Therapeutics Volume9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 See, Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." Pediatrics 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. See, Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." Archives of Sexual Behavior 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8.
and reportedly Australia.

2020 See National Review for Great Britain (NICE), Deborah Cohen and Hannah Barnes, Evidence for puberty blockers use very low, says NICE at https://www.bbc.com/news/health-56601386 [“The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding".;

See, Asscheman H, Giltay EJ, Megens JA, et al. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. *Eur J Endocrinol*. 2011;164:635-642. *"There is no evidence that transition reduces suicide when we look past 10 years, and there is some suggestion that suicide rates may actually increase after the transition honeymoon phase is over,*" says Malone, stressing the importance of providing proper evaluation and appropriate psychological treatment for any suicidal tendencies. (Supports the Branson conclusions after recantation and correction).

Sweden = Review of Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se,

English Proofreading: Project group and Jan Adolfsson, SBU [“ No relevant randomized controlled (treatment outcome) trials in children and adolescents were found.”] ; See, also e.g., FINLAND Issues Strict Guidelines for Treating Gender Dysphoria at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/. In 2020, Finland reportedly became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that there is a lack of quality evidence to support the use of hormonal interventions in adolescents with gender dysphoria…. they also issued the guideline ordering “No surgical interventions are allowed for children under the age of 18”.). As the ***methodological quality of the studies was already poor*** based on the type of study, thus no actual quality assessment or determination of the degree of evidence was performed.”] ;

See, Cochrane Review (See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.)

See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, the authors noted ***the hazardous error of mandating “affirmation treatments”*** — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice. … As Griffin discussed, “Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to ‘conversion therapy’. Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. ***As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity***. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory (psychotherapy) approach with gender-questioning patients should not be considered conversion therapy.”… In addition, Griffin et al wrote: “Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, although ***underlying causality has not been convincingly demonstrated.***

See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study BMJ 2021; 372 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021) Cite this as: BMJ 2021;372:n356 [Puberty blockers used to treat children aged 12 to 15 who have severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16]

See, e.g., Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170. [among the individuals examined in the Branstrom study, the risk of being hospitalized for a suicide attempt was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not…. the data presented in the Branstrom article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria."]
"Therefore, … the data in the article … ***OVERTURNS the authors' stated conclusions***, ***suggesting that sex reassignment surgery is in fact associated with INCREASED mental health treatment*** See, Ring, A. (PhD) and Malone, W. , Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

See, See, Van Mol, A., , Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765. "The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does NOT demonstrate that either hormonal treatment or surgery has ANY effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors some how ignored this most essential finding] …" See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149. "Bränström and Pachankis study on mental health treatment and suicide attempts … is misleading because the study design is flawed." "The authors first found what was already known … the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning"). The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting [gender affirmation] HORMONAL treatment. They somehow failed to publish this essential finding.
See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165. this conclusion is not supported by the data presented in the article.

See, Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

2020 - Sweden, following a national review of transgender science, published a new guideline that is NOT consistent with WPATH protocols nor the opinions of Drs Schechter and Brown in this case. [https://genderreport.ca/finland-strict-guidelines-

for-treating-gender-dysphoria/ The SWEDISH NATIONAL GUIDELINES appear quite contrary to the opinions of Drs Brown and Schechter and WPATH.

2020 - Finland following a review of transgender science, became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that *there is **a lack of quality evidence** to support the use of hormonal interventions in adolescents with gender dysphoria*. This new Finnish guidance *prioritizes psychological therapy over treatment with hormones or surgery* and suggests different care plans for early-onset vs late-onset childhood gender dysphoria.
The 2020 Finland guidelines state "***Only limited research has been conducted on transgender identity and other gender identity conflicts,** and comparative studies are very rare*."] The Finland National Guidelines appear quite contrary to the opinions of Drs Brown and Schechter and WPATH.

See, https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ Finland Clinical Guidelines and Conclusions Three reports were created by COHERE in Finland. The report "Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation" clarifies the roles of different healthcare providers in a situation where a minor is uncertain about their gender identity. They also produced general recommendations for the treatment of transgender people, which applies to adults. And interestingly, a third and separate set of recommendations for the treatment of gender dysphoria related to non-binary people and people with gender identities other than opposite-sex gender identities. The summaries are available for download here:
Summary-transgender_enDownload
Summary_minors_enDownload
Summary_non-binary_enDownload

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21. Expert Report Limitations: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. All opinions have been offered to a reasonable degree of medical certainty. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In

my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

CONFIDENTIAL INFORMATION SECTION BELOW

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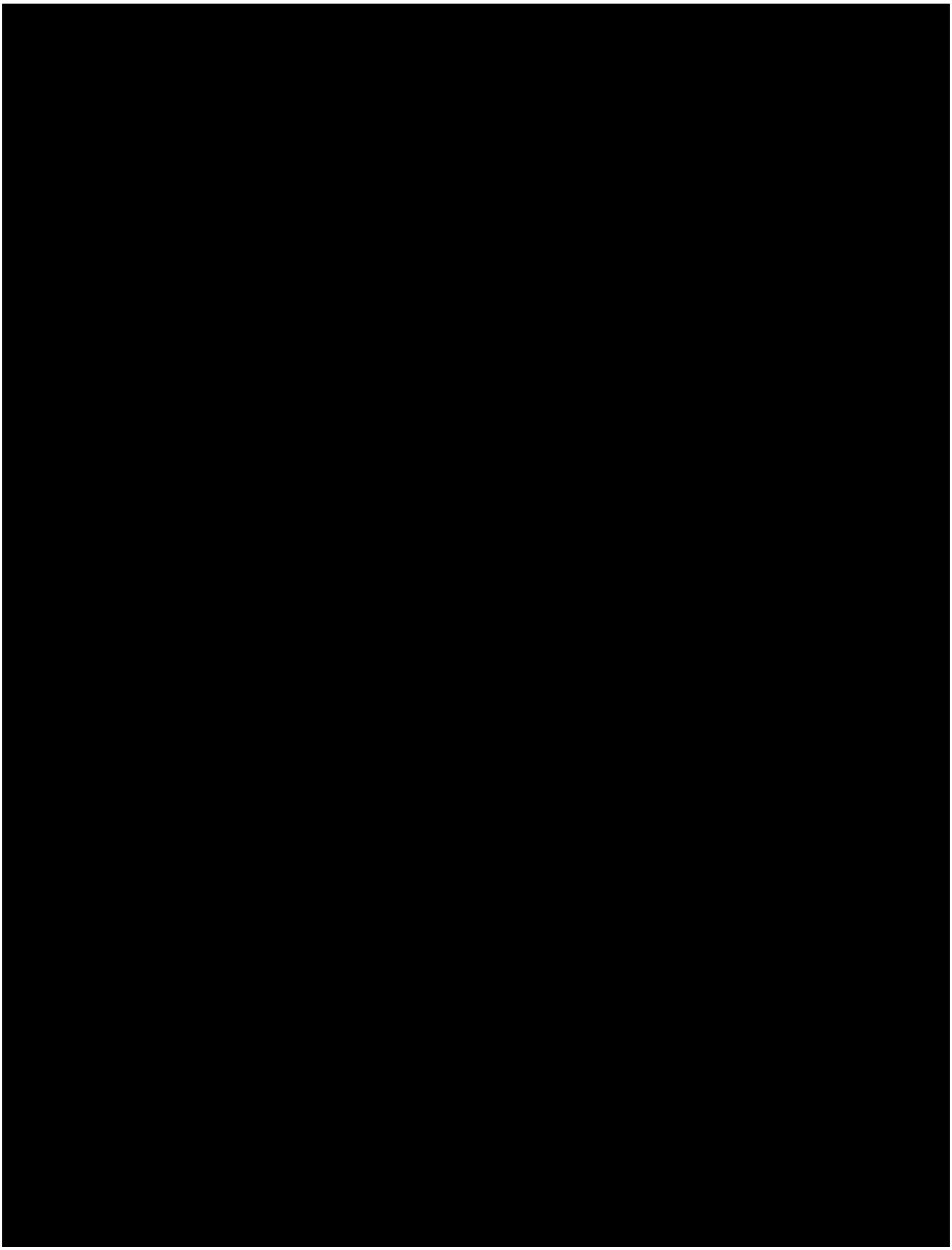

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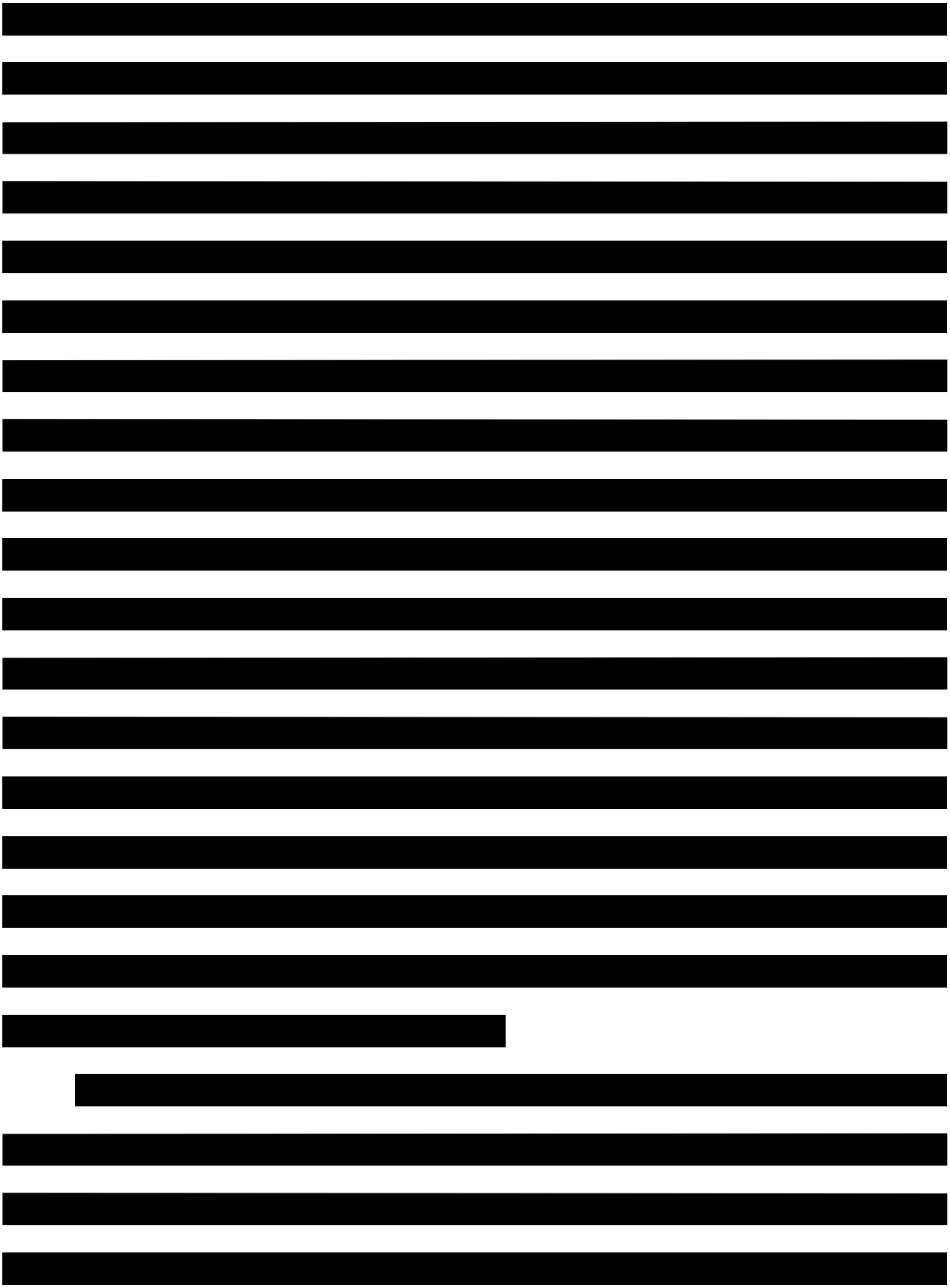

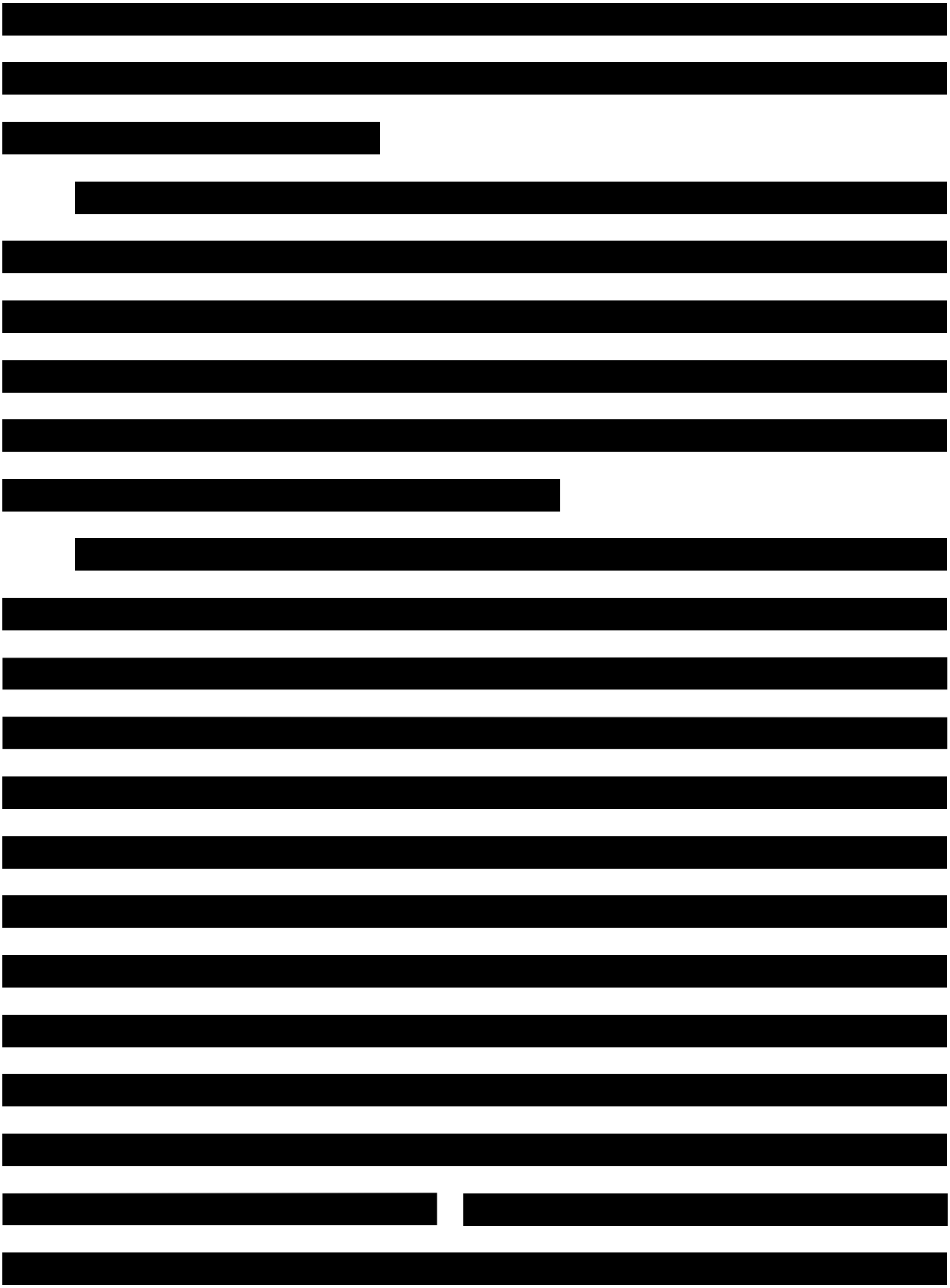

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Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____

Signed: _____ **May 1, 2021**

Patrick W. Lappert, MD

Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study

Richard Bränström, Ph.D., John E. Pachankis, Ph.D.

Objective: Despite professional recommendations to consider gender-affirming hormone and surgical interventions for transgender individuals experiencing gender incongruence, the long-term effect of such interventions on mental health is largely unknown. The aim of this study was to ascertain the prevalence of mood and anxiety disorder health care visits and antidepressant and anxiolytic prescriptions in 2015 as a function of gender incongruence diagnosis and gender-affirming hormone and surgical treatment in the entire Swedish population.

Methods: This study used the Swedish Total Population Register (N=9,747,324), linked to the National Patient Register and the Prescribed Drug Register. Among individuals who received a diagnosis of gender incongruence (i.e., transsexualism or gender identity disorder) between 2005 and 2015 (N=2,679), mental health treatment in 2015 was examined as a function of length of time since gender-affirming hormone and surgical treatment. Outcome measures were mood and anxiety disorder health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after a suicide attempt.

Results: Compared with the general population, individuals with a gender incongruence diagnosis were about six times as likely to have had a mood and anxiety disorder health care visit, more than three times as likely to have received prescriptions for antidepressants and anxiolytics, and more than six times as likely to have been hospitalized after a suicide attempt. Years since initiating hormone treatment was not significantly related to likelihood of mental health treatment (adjusted odds ratio=1.01, 95% CI=0.98, 1.03). However, increased time since last gender-affirming surgery was associated with reduced mental health treatment (adjusted odds ratio=0.92, 95% CI=0.87, 0.98).

Conclusions: In this first total population study of transgender individuals with a gender incongruence diagnosis, the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them.

Am J Psychiatry 2020; 177:727–734; doi: 10.1176/appi.ajp.2019.19010080

Numerous studies indicate that transgender individuals—that is, individuals who experience incongruity between their sex assigned at birth and their current gender identity—are at particular risk of psychological distress and associated impairment (e.g., suicidality) (1–3). This elevated risk is hypothesized to stem at least in part from transgender individuals' elevated exposure to stigma-related stress, also known as minority stress (4, 5), and it can also result from the stress associated with a lack of gender affirmation (i.e., the accurate recognition and validation of one's gender identity) (6). ICD-11 (7) specifies that individuals experiencing persistent discordance between their experienced gender and their assigned sex meet diagnostic criteria for gender incongruence.

To alleviate the stress of persistent discordance between experienced gender and assigned sex, an increasing number of transgender individuals who experience gender incongruence seek gender-affirming medical interventions, including hormone replacement therapy and gender-affirming surgeries (8). The World Professional Association for Transgender Health's *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* recommends consideration of these interventions for affirming transgender individuals' gender and alleviating gender-related stress (9).

Despite professional recommendations to consider gender-affirming medical interventions for transgender individuals who experience gender incongruence, the effect of such interventions on long-term mental health is largely unknown. Available evidence stems mainly from small samples utilizing cross-sectional designs and self-reported treatment exposures and mental health outcomes (2, 10, 11). A meta-analysis

See related feature: **Editorial** *by Dr. Mueller (p. 657)*

that aggregated data across nearly two dozen small-sample studies (10), mostly relying on cross-sectional designs, found positive associations between self-reports of receiving both hormone therapy and gender-affirming surgery and mental health. Several more recent uncontrolled studies of the effects of hormone replacement therapy on transgender individuals' mental health have found that transgender individuals' mental health improved for up to 24 months after initiating hormone therapy (11, 12).

Because of previous studies' limitations, including short assessment periods and the fact that existing probability-based surveys do not routinely assess transgender status or other aspects of gender diversity, insufficient evidence exists regarding associations between length of time since receiving gender-affirming interventions and treatment for psychiatric disorders among the transgender population. In fact, no probability-based evidence exists regarding even the prevalence of mood and anxiety disorder treatment among transgender individuals compared with the general population (1).

The limitations of previous research in terms of nonrepresentative sampling, self-reported measurement, and limited follow-up periods can be overcome with national health registry data sets that include clinician-derived assessment of gender incongruence and complete records of psychiatric and gender-affirming treatment and utilization data in an entire population. In the one known study to use a population-based design to investigate psychiatric morbidity among transgender individuals (N=324), individuals who had legally changed their gender and had a diagnosis of gender incongruence associated with an inpatient hospital visit in Sweden between 1973 and 2003 were at higher risk of suicide attempts, suicide-related mortality, and psychiatric hospitalization compared with age- and reassigned-gender-matched controls (13). The study did not report the prevalence of mood and anxiety disorder treatment among those receiving gender-affirming treatment compared with the total population or as a function of length of time since receiving gender-affirming treatment. Furthermore, the proportion of individuals receiving gender-affirming treatments in Sweden has increased nearly exponentially since 2003 (8, 14). Similar recent increases in referrals for gender-affirming treatments have been reported in other countries around the world (15–18).

In this study, we took advantage of the Swedish Total Population Register (19), linked to the Swedish National Patient Register and the Swedish Prescribed Drug Register, to ascertain the prevalence of mood and anxiety disorder health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after a suicide attempt among the entire Swedish population as a function of gender incongruence diagnosis, gender-affirming hormone and surgery utilization, and length of time since receiving gender-affirming treatments. This data set permitted identification of all individuals in Sweden seeking gender-affirming treatments between January 1, 2005, and December 31, 2015. Although not all transgender individuals seek gender-affirming treatments and not all treatment-seeking transgender individuals meet diagnostic criteria for gender incongruence, findings from this unique data opportunity have timely implications for documenting the mental health of transgender individuals seeking gender-affirmative treatment and ways in which the medical profession can support this increasingly visible population.

METHODS

This total population prospective study included all individuals living in Sweden on December 31, 2014, as identified in the Swedish Total Population Register. Using de-identified personal identification numbers (a unique number assigned to all Swedish residents), we linked sociodemographic information with National Patient Register information on health care usage between January 1, 2005, and December 31, 2015, and Prescribed Drug Register information on prescribed and purchased medication between July 1, 2005, and December 31, 2015. The study was approved by the Regional Ethics Committee in Stockholm (no. 2017/1736–31).

Gender Incongruence Diagnosis

Using the Swedish National Patient Register, we classified all individuals in Sweden according to whether they had received a diagnosis of gender incongruence, as defined by the diagnostic system applied in Sweden during the study period (i.e., a diagnosis of either transsexualism [ICD-10 code F64.0] or gender identity disorder [ICD-10 codes F64.8, F64.9]) during an inpatient or specialized outpatient visit between January 1, 2005, and December 31, 2015. The two diagnoses used to define gender incongruence at the time of the study are not fully equivalent but capture largely overlapping populations (20). In Sweden during the study period, a diagnosis of either transsexualism or gender identity disorder was required for accessing gender-affirming treatment (e.g., gender-affirming hormone treatment, hormone-suppressing or -blocking medication treatment, mastectomy with chest contouring, hair removal, vocal cord surgery, speech therapy, genital surgery) and was given after an approximately yearlong evaluation, following a national consensus program (14, 21). Adolescents could receive the same gender-affirming treatments as adults but could not receive genital surgery before age 18 (22).

Outcome Measures

This study's outcome measures were psychiatric outpatient health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after a suicide attempt between January 1, 2015, and December 31, 2015. Restricting the outcome assessment period to one year, 2015, the most recent available, removes potential confounding by secular trends in treatment utilization and transgender acceptance and visibility. Each psychiatric outpatient visit was coded by the treating physician with a primary diagnosis from ICD-10 (23)

and up to 20 supplementary ICD-10 diagnostic codes. Using these codes, we classified all individuals as having received treatment for any or no mood disorders (codes F30–F39) or anxiety disorders (codes F40–F42). Prescribed medication use was obtained from the Swedish Prescribed Drug Register, which contains information regarding all prescribed and purchased medications nationwide for all individuals. Individuals were categorized into any use or no use of antidepressant and anxiolytic medication according to the Anatomical Therapeutic Chemical (ATC) Classification system (codes N06A and N05B). All inpatient health care visits were similarly coded by the treating physician using ICD-10, indicating a primary cause of hospitalization and up to 30 supplementary causes. Using these codes, we classified all individuals as having been hospitalized after a suicide attempt (versus not) using the ICD-10 codes for intentional self-harm (codes X60–X84).

TABLE 1. Demographic characteristics of the Swedish population, by gender incongruence diagnosis, December 31, 2014

Measure	Individuals Diagnosed With Gender Incongruence (N=2,679)		General Population[a] (N=9,744,645)	
	Mean	SD	Mean	SD
Age (years)	31.5	14.0	40.7	23.8
Mean yearly household income (Swedish kronor, 000s)	298.4	301.0	464.8	800.6
	N	%	N	%
Legal gender				
Male	1,284	47.9	4,870,930	50.0
Female	1,395	52.1	4,873,715	50.0
University education	809	30.2	2,643,505	27.1
Urbanicity				
Larger city	1,102	41.1	3,364,003	34.5
Smaller city	867	32.4	3,238,223	33.2
Rural community	710	26.5	3,142,419	32.2
Country of birth				
Sweden	2,214	82.6	8,141,590	83.5
Other European country	164	6.1	801,227	8.2
Outside of Europe	301	11.2	800,800	8.2
No information about country of birth	0	0.0	1,028	0.01

[a] The N for general population excludes those with a diagnosis of gender incongruence.

Covariates

Sociodemographic information was drawn from the Swedish Total Population Register in December 2014 and included current legal gender, age, country of birth, level of education, urbanicity, and household income.

Gender-Affirming Treatment Utilization

For individuals with a gender incongruence diagnosis at any visit, we assessed the type and year of gender-affirming treatment, both hormone treatment and surgery. Information about hormone treatment, including androgen-suppressing and -blocking medication, was obtained from the Swedish Prescribed Drug Register between July 1, 2005, and December 31, 2015. All medications prescribed to individuals who had received a gender incongruence diagnosis were coded as gender-affirming if they were feminizing hormone medication (i.e., estrogens [ATC codes G03C, L02AA], progestogen [G03D]), masculinizing hormone medication (i.e., androgens [G03B]), or androgen-suppression or -blocking medication (i.e., testosterone-5-alpha reductase inhibitors [G04CB], antiandrogens [G03H], gonadotropin-releasing hormone analogues [G03GA, L02AE, H01CA], antigonadotropin-releasing hormones [H01CC], and spironolactone [C03DA01]). For each individual with a gender incongruence diagnosis who received prescriptions for any of these medications, we calculated the number of years since initiation.

Gender-affirming surgery was coded using information about all inpatient surgical procedures received by individuals with a gender incongruence diagnosis in the National Patient Register between January 1, 2005, and December 31, 2015. All surgical procedures associated with a gender incongruence diagnosis performed during this period were coded by type of surgery using the Nordic Medico-Statistical Committee Classification of Surgical Procedures (16): breast or dermatological chest surgery (codes H and QB), surgery of the reproductive organs (codes K and L), dermatological surgery (code Q), and laryngeal surgery (code DQ).

Statistical Analysis

We first examined sociodemographic differences between individuals with a gender incongruence diagnosis and the rest of the population in Sweden. We then compared the prevalence of any mood and anxiety disorder treatments (i.e., psychiatric outpatient health care visits and prescribed psychiatric medication) between individuals receiving gender-affirming treatments and the rest of the population in Sweden during 2015, using logistic regression. Among individuals with a gender incongruence diagnosis, we then investigated the odds of mood and anxiety disorder treatment and hospitalization following a suicide attempt (occurring in 2015) as a function of years since initiation of hormone or hormone-suppressing treatment and since last gender-affirming surgery. We examined years since *last* gender-affirming surgery because gender-affirming surgery is often a lengthy process involving several distinct procedures before gender affirmation is attained.

All analyses were conducted using SPSS, version 24 (IBM, Armonk, N.Y.), and adjusted for current legal gender, age, country of birth, level of education, urbanicity, and household income.

TABLE 2. Association between gender incongruence diagnosis and mood- and anxiety-related health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after suicide attempt in the total Swedish population, 2015[a]

	Individuals Diagnosed With Gender Incongruence (N=2,679)		General Population[b] (N=9,744,645)		Unadjusted		Adjusted	
Measure	N	%	N	%	Odds Ratio	95% CI	Odds Ratio	95% CI
Psychiatric outpatient visits, 2015								
Any mood disorder	250	9.3	95,137	1.0	10.44	9.16, 11.89	6.07	5.32, 6.93
Any anxiety disorder	197	7.4	63,200	0.6	12.16	10.52, 14.06	5.92	5.10, 6.86
Prescribed medication treatment, 2015								
Any antidepressant use	771	28.8	377,043	9.4	3.90	3.58, 4.24	3.95	3.62, 4.31
Any anxiolytic treatment	449	16.8	566,678	5.8	3.26	2.95, 3.61	3.43	3.09, 3.81
Inpatient visits, 2015								
Hospitalization after suicide attempt	22	0.8	7,104	0.1	11.35	7.46, 17.28	6.79	4.45, 10.35

[a] All analyses were conducted using logistic regression and adjusted for age, gender, education, income, urbanity, and country of birth.
[b] The N for general population excludes those with a diagnosis of gender incongruence.

RESULTS

Of the total Swedish population on December 31, 2014 (N=9,747,324), 2,679 had received a diagnosis of gender incongruence between January 1, 2005, and December 31, 2015 (Table 1). Those diagnosed with gender incongruence were significantly younger on average than the rest of the population (t=19.94, $p<0.001$), and they were more likely to have a current legal female gender than male gender ($\chi^2=4.54$, $p=0.03$). Individuals with a gender incongruence diagnosis were more likely to have a university education ($\chi^2=12.77$, $p<0.001$), to have a lower household income (t=30.61, $p<0.001$), to live in a larger city ($\chi^2=61.95$, $p<0.001$), and to have been born outside of Europe ($\chi^2=32.33$, $p<0.001$).

Mood and Anxiety Disorder Treatment Among Individuals Diagnosed With Gender Incongruence

Table 2 compares the prevalence of health care visits and medication treatment for mood and anxiety disorders between individuals diagnosed with gender incongruence and those not. In analyses adjusted for sociodemographic factors, those diagnosed with gender incongruence were about six times as likely to have had a health care visit due to a mood or anxiety disorder in 2015, more than three times as likely to have received prescriptions for antidepressant and anxiolytic medication in 2015, and more than six times as likely to have been hospitalized after a suicide attempt.

Gender-Affirming Treatments Among Individuals Diagnosed With Gender Incongruence

Just over 70% of individuals diagnosed with gender incongruence during the follow-up period (2005–2015) had received prescriptions for hormone treatment, including androgen-suppressing and -blocking medication, during this period. Half of those treated with hormones had initiated their hormone treatment within the past 5 years (Table 3).

Nearly 40% of those with a diagnosis of gender incongruence had received gender-affirming surgical treatments during the follow-up period. Table 3 presents the types of surgical treatments and the distribution of individuals by number of years since last gender-affirming surgery. The most common types of surgical procedures were mastectomy with chest contouring, surgery of the reproductive organs, dermatological surgeries, and laryngeal surgery.

Less than a third (29%) of those diagnosed with gender incongruence had received neither hormone treatment nor gender-affirming surgery. Among those who had received gender-affirming surgery, 97% had also been treated with hormones.

Changes in Likelihood of Mood and Anxiety Disorder Treatment After Gender-Affirming Hormone and Surgical Treatment

We examined the effect of years since hormone treatment initiation and years since last gender-affirming surgery on likelihood of having received mood or anxiety disorder treatment in 2015 among individuals with a diagnosis of gender incongruence. Among those with a gender incongruence diagnosis receiving hormone treatment, years since initiation of hormone treatment was not significantly related to likelihood of mental health treatment (i.e., psychiatric outpatient health care visits and prescribed psychiatric medication; adjusted odds ratio=1.01, 95% CI=0.98, 1.03). However, among those receiving gender-affirming surgical treatment, the risk of mental health treatment was significantly reduced with increased time since last surgical treatment (adjusted odds ratio=0.92, 95% CI=0.87, 0.97). Specifically, the likelihood of being treated for a mood or anxiety disorder was reduced by 8% for each year since last gender-affirming surgery. The number of individuals with a gender incongruence diagnosis who had been hospitalized after a suicide attempt in 2015 was low (N=22) but was also

reduced as a function of time since last surgical treatment. The association between time since gender-affirming hormone and surgical treatments and hospitalization after a suicide attempt did not reach significance (hormone treatment: adjusted odds ratio=1.12, 95% CI=0.97, 1.30; surgical treatment: adjusted odds ratio=0.87, 95% CI=0.61, 1.24). Figure 1 presents the prevalence of mental health treatment (either health care visits for depression and anxiety, antidepressant and anxiolytic prescriptions, or both) and hospitalization after a suicide attempt in 2015 by years since last gender-affirming surgical treatment.

To assess the potentially interrelated and therefore confounding effect of gender-affirming hormone and surgical treatments on each other, a sensitivity analyses was conducted, entering both years since initiation of hormone treatment and years since last surgical treatment simultaneously into the same model predicting odds of mood and anxiety disorder treatment (i.e., psychiatric outpatient health care visits and prescribed psychiatric medication). The results of this analysis were similar to those presented above, with a nonsignificant effect of time since initiation of hormone treatment (adjusted odds ratio=1.03, 95% CI=0.97, 1.08) and a significant effect of years since last gender-affirming surgical treatment (adjusted odds ratio=0.91, 95% CI=0.86, 0.97).

TABLE 3. Type of, and years since, gender-affirming hormone and surgery treatment in December 31, 2015, among individuals with a gender incongruence diagnosis in Sweden, January 1, 2005, to December 31, 2015

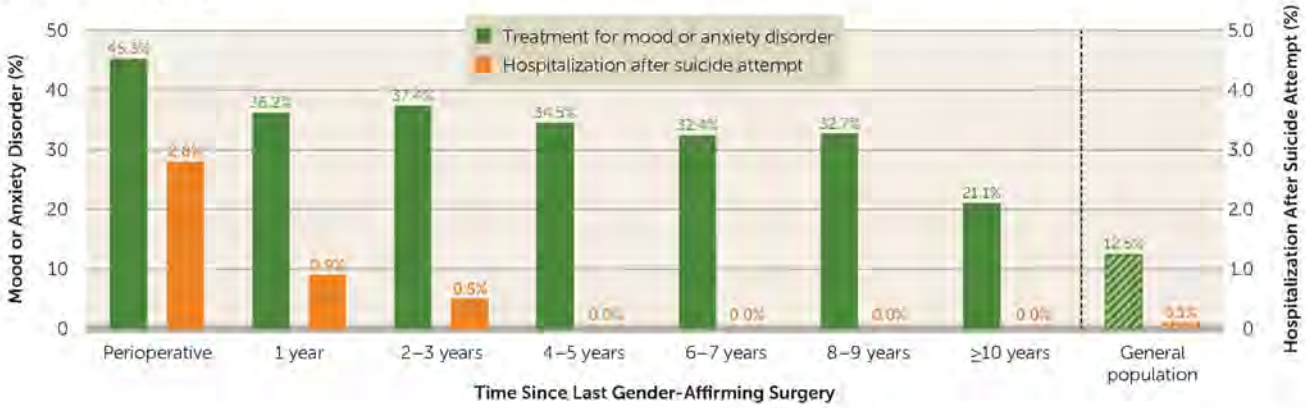
Measure	N	%
Time since first gender-affirming hormone treatment	Individuals with gender incongruence diagnosis (N=2,679)	
No hormone treatment	794	29.6
<1 year	359	13.4
1 year	226	8.4
2–3 years	367	13.7
4–5 years	330	12.3
6–7 years	176	6.6
8–9 years	193	7.2
≥10 years	234	8.7
Type of hormone treatment (more than one type is possible)	All individuals receiving gender-affirming hormone treatment (N=1,885)	
Estrogen or progesterone	1,066	56.6
Androgen	916	48.6
Androgen-suppressing or -blocking medication	808	42.9
Time since last gender-affirming surgical treatment	All individuals with gender incongruence diagnosis (N=2,679)	
No surgical treatment	1,661	62.0
<1 year	353	13.2
1 year	221	8.2
2–3 years	198	7.4
4–5 years	110	4.1
6–7 years	68	2.5
8–9 years	49	1.8
≥10 years	19	0.7
Type of surgical procedures (more than one type is possible)	All individuals receiving gender-affirming surgical treatment (N=1,018)	
Breast or dermatological chest surgery	788	77.4
Surgery of the reproductive organs	540	53.0
Dermatological surgery	315	30.9
Laryngeal surgery	70	6.9

DISCUSSION

Taking advantage of total population registers containing diagnoses of gender incongruence, gender-related hormone and surgical treatment codes, and mental health treatment utilization, we examined the potential impact of gender-affirming hormone and surgical treatment on later mental health treatment utilization. The results also present the first known population prevalence of mood and anxiety disorder treatment and suicide attempts among transgender individuals compared with the general population. Overall, our results show that transgender individuals, here defined as those with a diagnosis of gender incongruence, are about six times as likely as the general population to have had a health care visit for any mood or anxiety disorder, between three and four times as likely to have received prescriptions for antidepressant or anxiolytic medication, and more than six times as likely to have been hospitalized after a suicide attempt. Time since initiating gender-affirming hormone treatment was not associated with these mental health treatment outcomes, whereas time since receiving gender-affirming surgery was significantly associated with a decrease in mental health treatment.

These findings begin to answer the call for population-based documentation of transgender health (1) and extend earlier evidence of associations between gender-affirming treatment and improved mental health mostly derived from studies utilizing cross-sectional designs or short follow-up periods, self-reported exposures and outcomes, and small nonprobability samples (2, 10, 11). In addition to showing that transgender individuals are more likely to utilize mental health treatments than the general population, the results suggest that gender-affirming treatments may reduce this risk. Specifically, the odds of receiving mental health treatment in 2015 were reduced by 8% for every year since

FIGURE 1. Prevalence of treatment for mood or anxiety disorders (health care visit or antidepressant or anxiolytic prescription) and hospitalization after suicide attempt in 2015 among individuals with a gender incongruence diagnosis, by number of years since last gender-affirming surgery



receiving gender-affirming surgery over the 10-year follow-up period. Despite this linear decrease, even 10 years after receiving such treatments, the prevalence of mental health treatment utilization continued to exceed that of the general Swedish population (24), suggesting the need to address factors in addition to gender-affirming treatment availability that may strengthen transgender individuals' mental health. Such factors may include reductions in structural (e.g., economic inequality), interpersonal (e.g., victimization), and psychosocial (e.g., identity concealment) stressors to which transgender individuals are disproportionately exposed (4, 24). Ensuring access to transgender-affirming mental health care may also further reduce transgender individuals' persistent psychiatric risk (25). Although the prevalence of hospitalization after suicide attempt among those with a gender incongruence diagnosis was too small for statistical testing, the numbers who were treated after a suicide attempt decreased as a function of years since last gender-affirming surgery. Among those who received their last gender-affirming surgery more than 3 years ago, no suicide attempts were registered.

Despite the notable methodological strengths of utilizing data from a total population, the results should be interpreted in light of several limitations. First, the criterion used here to define the transgender population does not capture the full spectrum of those who identify as transgender. We specifically lacked information regarding gender assigned at birth, legal gender change, and gender identity at the time of data collection, preventing subgroup analyses of the transgender population (26). Recent estimates across five countries suggest that between 0.4% and 1.3% of the population may identify as transgender, including gender-nonconforming individuals who do not seek gender-affirming hormone or surgical treatment (18, 27–29). Although the transgender population in the present study is limited to individuals with a diagnosis of gender incongruence, this population is of particular concern to the medical community because of its high likelihood of seeking gender-affirming hormone and surgical treatments. Given the free availability of gender-affirming treatments in Sweden, our approach to ascertaining this particular population is likely highly sensitive. Our approach also did not include a comparison group of individuals who had sought but not yet received gender-affirming treatment. While this population might be able to serve as an important comparison group in future studies, without the ability to distinguish between those who had not received treatment because they are waiting for it and those not seeking it in the first place, the current data structure cannot provide this comparison. Longitudinal designs assessing within-person changes in treatment seeking, treatment receipt, and ultimate mental health outcomes would be essential for tracking mental health before and immediately after treatment. Because our approach could only ascertain suicide attempts among living individuals, longitudinal designs that allow for tracking completed suicide among decedents remains an important future direction.

Second, mental health treatment utilization is an imperfect proxy for mental health itself. Transgender people receiving treatment for gender incongruence are by definition exposed to treatment settings, which may disproportionately expose them to mental health treatment opportunities. Although the Swedish context of universal health care coverage removes financial barriers to treatment seeking, other unmeasured factors, such as general tendency toward treatment seeking or perceived discrimination in treatment settings, may influence the associations examined here. Third, because we derived information about outpatient psychiatric health care visits from national health care databases, we had limited information about the type of mental health treatment patients received, and we could not differentiate among individuals receiving psychotropic medication, psychotherapy, or both. Fourth, this study was conducted in a single high-income national context with legal protections for transgender individuals and universal health coverage, including for gender-affirming treatments. While this context makes the present study possible,

it also may constrain the generalizability of findings to low- and middle-income countries and to countries that lack transgender protections or universal health care coverage.

Overall, this study provides timely support for policies that ensure coverage of gender-affirming treatments. Although gender-affirming treatments are recommended as a medical necessity for appropriately selected individuals experiencing gender incongruence and are a covered health benefit in most developed countries, uncertainty exists, such as in the United States, regarding federal protections of transgender employees from transgender-related exclusions in employee benefits (30). In the context of such uncertainty, some U.S. states deny use of state funds to cover costs for gender-affirming treatments, and the Veterans Health Administration specifically prohibits gender-affirming surgery within Veterans Affairs (VA) facilities or use of VA funding for gender-affirming treatments (31, 32). To the extent that gender-affirmative medical interventions are interpreted as sterilization, many hospitals can refuse to provide such care, citing religious directives (33). Debates regarding the provision of gender-affirming health care are global, and in much of the world, such care is unavailable or largely unaffordable (29). Therefore, in many contexts around the world, lack of coverage for gender-affirming treatments drives the use of non–medically supervised hormones and surgeries, thereby exacerbating physical health risks (34) and the other epidemics disproportionately borne by the global transgender population, including suicide and HIV infection. The longitudinal association found in the present study between gender-affirming surgery and reduced mental health treatment utilization, combined with the physical and mental health risks of surgery denial, supports policies that provide gender-affirming surgeries to transgender individuals who seek such treatments.

ADDENDUM

After this article was published online on October 4, 2019, some letters containing questions on the statistical methodology employed led the *Journal* to seek statistical consultations. The results of these consultations were presented to us and we concurred with many of the points raised. The letters (35-41) and our response to them (42) appear in the Letters to the Editor section of the August 2020 issue of the *Journal*.

AUTHOR AND ARTICLE INFORMATION

Department of Social and Behavioral Sciences, Yale School of Public Health, New Haven, Conn. (Bränström, Pachankis); and the Department of Clinical Neuroscience, Karolinska Institutet, Stockholm (Bränström).

Send correspondence to Dr. Bränström (richard.branstrom@ki.se).

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REFERENCES

1. Reisner SL, Poteat T, Keatley J, et al: Global health burden and needs of transgender populations: a review. Lancet 2016; 388: 412–436
2. Dhejne C, Van Vlerken R, Heylens G, et al: Mental health and gender dysphoria: a review of the literature. Int Rev Psychiatry 2016; 28: 44–57
3. Connolly MD, Zervos MJ, Barone CJ 2nd, et al: The mental health of transgender youth: advances in understanding. J Adolesc Health 2016; 59:489–495
4. White Hughto JM, Reisner SL, Pachankis JE: Transgender stigma and health: a critical review of stigma determinants, mechanisms, and interventions. Soc Sci Med 2015; 147:222–231
5. Hatzenbuehler ML, Pachankis JE: Stigma and minority stress as social determinants of health among lesbian, gay, bisexual, and transgender youth: research evidence and clinical implications. Pediatr Clin North Am 2016; 63:985–997
6. Sevelius JM: Gender affirmation: a framework for conceptualizing risk behavior among transgender women of color. Sex Roles 2013; 68:675–689
7. World Health Organization: International Classification of Diseases, 11th Revision (ICD-11). Geneva, World Health Organization, 2018
8. Dhejne C, Öberg K, Arver S, et al: An analysis of all applications for sex reassignment surgery in Sweden, 1960–2010: prevalence, incidence, and regrets. Arch Sex Behav 2014; 43:1535–1545
9. Coleman E, Bockting W, Botzer M, et al: Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, 7th Version. Int J Transgenderism 2012; 13:165–232
10. Murad MH, Elamin MB, Garcia MZ, et al: Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes. Clin Endocrinol (Oxf) 2010; 72: 214–231
11. White Hughto JM, Reisner SL: A systematic review of the effects of hormone therapy on psychological functioning and quality of life in transgender individuals. Transgend Health 2016; 1:21–31
12. Fisher AD, Castellini G, Ristori J, et al: Cross-sex hormone treatment and psychobiological changes in transsexual persons: two-year follow-up data. J Clin Endocrinol Metab 2016; 101: 4260–4269
13. Dhejne C, Lichtenstein P, Boman M, et al: Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 2011; 6:e16885
14. Swedish National Board of Health and Welfare: Good Care of Adults With Gender Dysphoria. Stockholm, Swedish National Board of Health and Welfare, 2015
15. Torjesen I: Trans health needs more and better services: increasing capacity, expertise, and integration. BMJ 2018; 362:k3371
16. Wood H, Sasaki S, Bradley SJ, et al: Patterns of referral to a gender identity service for children and adolescents (1976–2011): age, sex ratio, and sexual orientation. J Sex Marital Ther 2013; 39:1–6
17. Chen M, Fuqua J, Eugster EA: Characteristics of referrals for gender dysphoria over a 13-year period. J Adolesc Health 2016; 58:369–371
18. Zucker KJ: Epidemiology of gender dysphoria and transgender identity. Sex Health 2017; 14:404–411
19. Ludvigsson JF, Andersson E, Ekbom A, et al: External review and validation of the Swedish national inpatient register. BMC Public Health 2011; 11:450
20. Drescher J: Queer diagnoses revisited: the past and future of homosexuality and gender diagnoses in DSM and ICD. Int Rev Psychiatry 2015; 27:386–395
21. Lundgren TK, Isung J, Rinder J, et al: Moving transgender care forward within public health organizations: inclusion of facial

feminizing surgery in the Swedish National Treatment Recommendations. Arch Sex Behav 2016; 45:1879–1880
22. The Swedish National Board of Health and Welfare: Good Care of Children and Adolescents With Gender Dysphoria. Stockholm, Swedish National Board of Health and Welfare, 2015
23. World Health Organization: International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10). Geneva, World Health Organization, 1993
24. Sundquist J, Ohlsson H, Sundquist K, et al: Common adult psychiatric disorders in Swedish primary care where most mental health patients are treated. BMC Psychiatry 2017; 17:235
25. Bockting WO, Knudson G, Goldberg JM: Counseling and mental health care for transgender adults and loved ones. Int J Transgenderism 2006; 9:35–82
26. Nieder TO, Herff M, Cerwenka S, et al: Age of onset and sexual orientation in transsexual males and females. J Sex Med 2011; 8:783–791
27. Flores AR, Herman JL, Gates GJ, et al: How many adults identify as transgender in the United States? Los Angeles, Williams Institute, June 2016
28. Collin L, Reisner SL, Tangpricha V, et al: Prevalence of transgender depends on the "case" definition: a systematic review. J Sex Med 2016; 13:613–626
29. Winter S, Diamond M, Green J, et al: Transgender people: health at the margins of society. Lancet 2016; 388:390–400
30. Baker KE: The future of transgender coverage. N Engl J Med 2017; 376:1801–1804
31. Kuzon WM Jr, Sluiter E, Gast KM: Exclusion of medically necessary gender-affirming surgery for America's armed services veterans. AMA J Ethics 2018; 20:403–413
32. Veterans Health Administration: Providing Health Care for Transgender and Intersex Veterans; Directive 1341. Washington, DC, Veterans Health Administration, 2018
33. United States Conference of Catholic Bishops: Ethical and Religious Directives for Catholic Health Care Services, 5th ed. Washington, DC, United States Conference of Catholic Bishops, November 17, 2009
34. Sanchez NF, Sanchez JP, Danoff A: Health care utilization, barriers to care, and hormone usage among male-to-female transgender persons in New York City. Am J Public Health 2009; 99:713–719
35. Anckarsäter H, Gillberg C: Methodological shortcomings undercut statement in support of gender-affirming surgery. Am J Psychiatry 2020; 177:764–765
36. Van Mol A, Laidlaw M, Grossman M, et al: Gender affirmation surgery conclusion lacks evidence. Am J Psychiatry 2020; 177: 765–766
37. Curtis D: Study of transgender patients: conclusions are not supported by findings. Am J Psychiatry 2020; 177:766
38. Malone W, Roman S: Calling into question whether gender affirming surgery relieves psychological distress. Am J Psychiatry 2020; 177:766–767
39. Landén M: The effect of gender-affirming treatment on psychiatric morbidity is still undecided. Am J Psychiatry 2020; 177: 767–768
40. Wold A: Gender corrective surgery promoting mental health in persons with gender dysphoria not supported by data presented in paper. Am J Psychiatry 2020; 177:768
41. Ring A, Malone M: Confounding effects on mental health observations after sex reassignment surgery. Am J Psychiatry 2020; 177: 768–769
42. Bränström R, Pachankis JE: Toward rigorous methodologies for strengthening causal inference in the association between gender-affirming care and transgender individuals' mental health. Am J Psychiatry 2020; 177:769–772

Correction to Bränström and Pachankis

After the article "Reduction in Mental Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study" by Richard Bränström, Ph.D., and John E. Pachankis, Ph.D. (doi: 10.1176/appi.ajp.2019.19010080), was published online on October 4, 2019, some letters containing questions on the statistical methodology employed in the study led the *Journal* to seek statistical consultations. The results of these consultations were presented to the study authors, who concurred with many of the points raised. Upon request, the authors reanalyzed the data to compare outcomes between individuals diagnosed with gender incongruence who had received gender-affirming surgical treatments and those diagnosed with gender incongruence who had not. While this comparison was performed retrospectively and was not part of the original research question given that several other factors may differ between the groups, the results demonstrated no advantage of surgery in relation to subsequent mood or anxiety disorder-related health care visits or prescriptions or hospitalizations following suicide attempts in that comparison. Given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and lower use of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" is too strong. Finally, although the percentage of individuals with a gender incongruence diagnosis who had received gender-affirming surgical treatments during the follow-up period is correctly reported in Table 3 (37.9%), the text incorrectly refers to this percentage as 48%. The article was reposted on August 1, 2020, correcting this percentage and including an addendum referencing the postpublication discussion captured in the Letters to the Editor section of the August 2020 issue of the Journal (1).

1. Kalin NH: Reassessing mental health treatment utilization reduction in transgender individuals after gender-affirming surgeries: a comment by the editor on the process (letter). Am J Psychiatry 2020; 177:765

Letters to the Editor

Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process

On October 4, 2019, we published an article by Bränström and Pachankis in which it was reported that observed reductions in mental health treatment utilization lent support to the decision to provide gender-affirming surgeries to those who seek them (1). After this article's publication, we received several letters calling into question the statistical analyses employed and the conclusions drawn from said analyses. These letters follow this comment (2–8).

We enlisted the services of a statistical reviewer to look again at the article as well as the letters we received. We then sent the letters we received and the results of this statistical review, which called for a matched-pairs analysis, to the original authors. The study authors complied with the request to perform an additional analysis, as presented in their letter response (9).

We sent the original letters, statistical review, and author response to a second statistical reviewer. The response from this consultation convinced us that, given that the study used neither a prospective cohort design nor a randomized controlled trial design, the conclusion that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them" was too strong. In the August 2020 issue of the *Journal*, we are publishing a correction to this effect and including an addendum to the article pointing to this postpublication discussion and process, both of which were composed with contributions and approval from the original article authors.

We thank the letter writers, statistical reviewers, and the original study authors—as well as the editorialist we invited to place this study's findings in context (10)—for helping us to make clear to our readers and for the literature what the article shows and what still remains to be investigated in future research.

REFERENCES

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734
2. Anckarsäter H, Gillberg C: Methodological shortcomings undercut statement in support of gender-affirming surgery (letter). Am J Psychiatry 2020; 177:764–765
3. Van Mol A, Laidlaw MK, Grossman M, et al: Gender-affirmation surgery conclusion lacks evidence (letter). Am J Psychiatry 2020; 177:765–766
4. Curtis D: Study of transgender patients: conclusions are not supported by findings (letter). Am J Psychiatry 2020; 177:766
5. Malone WJ, Roman S: Calling into question whether gender-affirming surgery relieves psychological distress (letter). Am J Psychiatry 2020; 177:766–767
6. Landén M: The effect of gender-affirming treatment on psychiatric morbidity is still undecided (letter). Am J Psychiatry 2020; 177:767–768
7. Wold A: Gender-corrective surgery promoting mental health in persons with gender dysphoria not supported by data presented in article (letter). Am J Psychiatry 2020; 177:768
8. Ring A, Malone WJ: Confounding effects on mental health observations after sex reassignment surgery (letter). Am J Psychiatry 2020; 177:768–769
9. Bränström R, Pachankis JE: Toward rigorous methodologies for strengthening causal inference in the association between gender-affirming care and transgender individuals' mental health: response to letters (letter). Am J Psychiatry 2020; 177:769–772
10. Mueller SC: Mental health treatment utilization in transgender persons: what we know and what we don't know (editorial). Am J Psychiatry 2020; 177:657–659

Ned H. Kalin, M.D.

Editor-in-Chief

The American Journal of Psychiatry

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Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery

TO THE EDITOR: The article by Bränström and Pachankis (1) has the stated aim "to ascertain the prevalence of mood and anxiety disorder health care visits and antidepressant and anxiolytic prescriptions in 2015 as a function of gender incongruence diagnosis and gender-affirming hormone and surgical treatment in the entire Swedish population." The authors conclude that "the longitudinal association between gender-affirming surgery and reduced likelihood of mental health treatment lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." In support of this claim, the authors report that the time since "last gender-affirming surgery" (in 2005–2014) was associated with reduced "mental health treatment" (a combined variable of outpatient visits with a diagnosis of a mood or anxiety disorder and/or prescriptions for antidepressants or anxiolytics) during 2015 (adjusted odds ratio=0.92, 95% CI=0.87–0.98). The authors have also

shown that the group of people diagnosed with gender incongruence have a dramatically worse overall mental health outcome than the general population, which is, in fact, the answer to their stated aim and research question, but this finding is not even referred to in the title or in the Conclusions section of the article.

In view of the claim that surgery was shown to be an efficient treatment for gender incongruence, the following issues have to be raised:

1. Variables, hypotheses, and analytical strategies were not described pre hoc. Adequate power analyses and corrections for multiple comparisons were not provided.
2. The article is vague or noninformative with respect to key aspects. Biological sex ratios are not provided. Surgeries for complications or even unrelated surgeries (e.g., in the skin or the larynx) may have been included. Lithium and atypical antipsychotic medications were not included as treatments for mood disorders, while a histamine blocker such as hydroxyzine, which is mainly used for non-mental health problems, was. Outpatient visits for mood and anxiety disorders were included as "mental health treatment" but not care for sleeping disorders, substance-related disorders, major mental disorders, or any inpatient psychiatric treatment.
3. The nonnormal distribution of data, known secular changes, age effects, or people who left Sweden and moved abroad, died from suicide or other causes, or had surgery to desist were not considered in the interpretation of the analyses.

As the article stands, we actually have no way of knowing whether the four reported analyses of purported treatment effects (time elapsed since start of hormones OR since last surgery BY outpatient mental health treatment OR suicide attempt–related hospitalization), one of which was statistically significant by a small margin, were the first analyses made or the final setup chosen for publication after a "fishing expedition" in the database.

These methodological shortcomings preclude any statement on the suitability of early surgery in persons seeking treatment for gender noncongruence based on the results presented in this article.

REFERENCE

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734

Henrik Anckarsäter, M.D., Ph.D.
Christopher Gillberg, M.D., Ph.D.

Centre for Ethics, Law and Mental Health (Anckarsäter), and Gillberg Neuropsychiatry Centre (Gillberg), University of Gothenburg, Gothenburg, Sweden

Send correspondence to Dr. Anckarsäter (henrik.anckarsater@neuro.gu.se).

The authors report no financial relationships with commercial interests.

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Gender-Affirmation Surgery Conclusion Lacks Evidence

TO THE EDITOR: We have concerns regarding severe shortcomings in the study by Bränström and Pachankis (1) that call into question the authors' conclusion that it "provides timely support for policies that ensure coverage of gender-affirming treatments."

This study covered outcomes only for calendar year 2015 for all individuals living in Sweden on December 31, 2014. The retrospective metric of "time since last gender-affirming surgery" in Figure 1 in the article is easily misinterpreted as a prospective 10-year follow-up that did not occur and leaves open the question of number and type of prior surgeries.

The 2,679 individuals diagnosed with gender incongruence in Sweden is a full order of magnitude below prevalence expectations from DSM-5. Table 3 in the article indicates that 38% of these individuals had any kind of gender-affirming surgery, but only 53% of those had surgery of reproductive organs. Given that such treatment in Sweden is free, ample loss to follow-up is implied.

Measured outcomes were limited to "mood and anxiety disorder health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after a suicide attempt." This selection excludes completed suicides, suicide attempts without subsequent hospitalization, health care visits and hospitalizations for other medical or psychological issues still related to gender-affirming surgeries, individuals refusing treatment, and individuals choosing self-medication with alcohol or illicit substances. Again, significant loss to follow-up must be considered before declaring success.

Dhejne's cohort study of 324 persons in Sweden undergoing sex-reassignment surgery used 30 years of data, population controls, and matching by birth year, birth sex, and reassigned sex (2). Through the Hospital Discharge Register, the authors evaluated discharge diagnoses, external causes of morbidity and mortality, and surgical procedure codes. Compared with the general population, patients who had sex reassignment surgery had 19 times the rate of completed suicide, almost three times the rate of all-cause mortality, nearly three times the rate of inpatient psychiatric care, and close to five times the rate of suicide attempts.

These important findings could have been updated to the current period, given the sharp rise in adolescent case presentations, use of puberty blockers, and changes in cross-sex hormones from agents like ethinyl estradiol to 17β-estradiol.

For those whose last surgery was 10 or more years earlier, how many completed suicide, died of other causes, or left Sweden prior to study initiation? A drop in hospitalizations for suicide attempts alone provides a very incomplete picture. When the data for such findings are accessible in the Swedish national registers, this omission is glaring.

The lack of control subjects, the limited 1-year time frame, and the avoidance of examining completed suicides and psychiatric hospitalizations are substantial study shortfalls.

The study supports only weak conclusions about psychiatric medication usage and nothing decisive about suicidality. In overlooking so much available data, this study lacks the evidence to support its progender-affirmation surgery conclusion.

REFERENCES

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734
2. Dhejne C, Lichtenstein P, Boman M, et al: Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 2011; 6:e16885

Andre Van Mol, M.D.
Michael K. Laidlaw, M.D.
Miriam Grossman, M.D.
Paul R. McHugh, M.D.

Family Practice, Dignity Health Medical Group North State, Redding, Calif. (Van Mol); Michael K. Laidlaw, M.D., Inc., Rocklin, Calif. (Laidlaw); Miriam Grossman, M.D., Psychiatry, New York (Grossman); Department of Psychiatry and Behavioral Sciences, Johns Hopkins University, Baltimore (McHugh).

Send correspondence to Dr. Laidlaw (docdrlaidlaw@gmail.com).

Dr. McHugh is listed as a coauthor of the Mini-Mental State Examination. The other authors report no financial relationships with commercial interests.

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Study of Transgender Patients: Conclusions Are Not Supported by Findings

TO THE EDITOR: The study of transgender individuals by Bränström and Pachankis claims to demonstrate a reduction in mental health treatment utilization after gender-affirming surgery but, in fact, demonstrates no such thing (1).

The only result they present that they claim is statistically significant is that there is an association between years since last gender-affirming surgery and recent mental health treatment (adjusted odds ratio=0.92, 95% CI=0.87–0.98). This result makes no sense as it stands because analysis of a quantitative measure against an outcome does not produce an odds ratio. Presumably, the authors must mean that each year since surgery is associated with an odds ratio of 0.92. There are also discrepancies between the data discussed in the text and in the tables. For example, the authors quote the percentage of patients with gender incongruence who received no treatment as 29% in the text but 29.6% in Table 3 and, more importantly, the percentage of patients who received surgery as 48% in the text but only 38.0% in the table. However, the key statistical criticism is that they have failed to carry out standard corrections for multiple testing. As they tested two interventions, hormone treatment and surgery, against two outcomes, mental health treatment and suicide attempts, they performed four tests. Because the upper confidence interval that they quote is very close to 1, it is obvious that if appropriate correction for multiple testing had been applied, then none of the results would have been deemed significant.

When one views the data on which these analyses are based, as presented in Figure 1 in the article, some very clear features emerge. First, there is obviously no general correlation between the outcomes and time since surgery. Rather, a spike in suicide attempts is seen in the year after surgery (in 2.8% of the patients), which falls off over the next 1–2 years, and to a lesser extent, there is also a spike in the proportion of patients receiving mental health treatment in the first year, going up to 45.3%. There is also a low rate of mental health treatment among patients who received surgery 10 or more years earlier. This may reflect the fact that in the past, patients with mental health problems would have been less likely to be offered surgery.

The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does not demonstrate that either hormonal treatment or surgery has any effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially high in the year after the completion of gender-affirming surgery and that increased support in this period might be indicated.

REFERENCE

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734

David Curtis, M.D., Ph.D.

UCL Genetics Institute, University College London, London; and Centre for Psychiatry, Queen Mary University of London, London.

Send correspondence to Prof. Curtis (d.curtis@ucl.ac.uk).

The author reports no financial relationships with commercial interests.

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Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress

TO THE EDITOR: The study by Bränström and Pachankis (1) shows a reduction in mental health treatments and hospitalization after suicide attempts with increased time after masculinizing or feminizing surgeries.

The data presented in Figure 1 in the article support findings from previous studies showing that transgender individuals have baseline mental health distress that is higher than that of the general population, but it is not possible to conclude from these data whether gender-affirming surgery relieves that distress.

According to the study, mental health utilization rates were highest in the perioperative period. However, the data also could be interpreted as showing that masculinizing or feminizing surgeries were the actual cause of increased mental health utilization. Surgery is a known risk factor for the development of depression (2) and may have caused a

deterioration in mental health in a population of individuals who already had more psychological distress, which abated with time since surgery. It is just as possible that mental health improved as individuals had fewer surgeries.

After the initial 11% drop in mental health visits in the first year after surgery, there was very little change in mental health visits (5.6% over 9 years), and there was a further 11% fall in the ≥10-year group. It is not clear what caused the reduction in the two markers for mental health distress past the 10-year mark. Loss to follow-up, death from suicide of the most psychologically distressed individuals, or death from cardiovascular disease, all known to be increased in the transgender population, could have falsely skewed the ≥10-year data. Comparisons with a control group would be best to answer these questions.

In addition, there are only 19 people in the ≥10-year group who underwent gender-affirming surgery. A total of 21.1% of them received mental health treatment, which is only four people. This means that a single mental health utilization event in either direction would change the calculated rate of utilization by 5%. However, the assertion that gender-affirming surgeries reduce mental health visits by 8% is highly dependent upon this sudden drop in rates in the ≥10-year group of only 19 people.

Finally, no information is given about the composition of the year 1 and ≥10-year groups, but given the changing epidemiology of gender dysphoria in Sweden (3), the year 1 group likely included a higher percentage of younger natal females than the ≥10-year group, which likely had more older natal males, making comparisons between the year 1 and ≥10-year groups problematic.

Because of the limitations in the study design, it is not possible to determine the cause of the differences in mental health service utilization or whether true reductions in psychological distress actually occurred. Therefore, the authors' conclusion that the results of their study should be interpreted to support policies that provide gender-affirming surgeries cannot be supported.

REFERENCES

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734
2. Wilson BR, Tringale KR, Hirshman BR, et al: Depression after spinal surgery: a comparative analysis of the California outcomes database. Mayo Clin Proc 2017; 92:88–97
3. Landén M: [Dramatic increase in adolescent gender dysphoria requires careful consideration.] Lakartidningen 2019; 116 (Swedish)

William J. Malone, M.D.
Sven Roman, M.D.

Idaho College of Osteopathic Medicine, Boise (Malone); Dr. Roman is in private practice in child and adolescent psychiatry in Stockholm.

Send correspondence to Dr. Malone (malone.will@gmail.com).

The authors report no financial relationships with commercial interests.

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The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided

TO THE EDITOR: In this issue of the *Journal*, Bränström and Pachankis study mental health treatment and suicide attempts in persons diagnosed with gender dysphoria in Sweden (1). Their claim that the study shows that gender-affirming treatment reduces the risk of mental health treatment and suicide attempts is misleading because the study design is flawed.

The authors first found what was already known (2): the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population. The authors then explored if the risk for mental health treatment changes as a function of years since starting hormonal treatment. They find no effect (odds ratio=1.0), but they do find a trend toward increased risk of suicide attempts as a function of years since starting hormonal treatment. In their key analysis, allegedly showing that gender-affirming surgery decreases risk for psychiatric treatment and suicide attempts, they relate these negative outcomes to the number of years since surgery. Contrary to what the authors repeatedly claim, they do not employ a longitudinal design but conduct a retrospective analysis unfit for their research question.

First, the authors include only persons who were alive in 2014. That means that those who died by suicide before 2014—and hence were at highest risk for suicide attempt—are excluded and confound the results. Second, any analysis starting with a negative event is bound to find a decreased risk for related negative outcomes with increasing time after the event. To exemplify this point, the rate of antidepressant treatment would decrease with time after a suicide attempt. This does not mean that suicide attempts cause a decrease in risk of antidepressant treatment; it is merely a case of regression toward the mean. Third, persons undergoing gender transition have, by definition, contact with mental health services in Sweden. After the transition, persons are followed up by endocrinologists and sometimes general practitioners; only those with persistent mental health issues are followed in psychiatric care. The authors' finding of lower rates of mental health treatment with increasing time after surgery is therefore not only a case of regression toward the mean, but it also follows from the standards of care and is not a proxy for improved mental health.

Because the authors do not present data prior to gender-affirming surgery, the study is uninformative with regard to the effects on psychiatric morbidity. Moreover, the authors miss the one conclusion that can be drawn: that the perioperative transition period seems to be associated with high risk for suicide attempt. Future research should use properly designed observational studies to answer the important question as to whether gender-affirming treatment affects psychiatric outcomes.

REFERENCES

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming

surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734
2. Dhejne C, Lichtenstein P, Boman M, et al: Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden. PLoS One 2011; 6:e16885

Mikael Landén, M.D., Ph.D.

Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; and Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm.

Send correspondence to Dr. Landén (mikael.landen@gu.se).

Dr. Landén has received lecture honoraria from Lundbeck.

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Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article

TO THE EDITOR: The article by Bränström and Pachankis (1) examines the psychiatric health of persons who have obtained a diagnosis of gender dysphoria between 2005 and 2015 compared with the general population. The variables examined were psychiatric diagnosis, prescription of psychiatric drugs (anxiolytics and antidepressants), and hospitalization for suicide attempt in 2015.

The results confirm what is already known, that is, that as a group, persons with gender dysphoria suffer from poorer psychiatric health than the general population.

However, the title of the article implies that gender-corrective surgery promotes mental health in this group, and the authors conclude in the Abstract section that the study "lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." In my opinion, this conclusion is not supported by the data presented in the article.

The most straightforward method to test whether surgery contributes to better psychological health would be to compare the health of those who underwent surgery with those who did not.

Of the persons diagnosed with gender dysphoria presented in the article, 1,018 had undergone surgery, while 1,661 had not. There were 22 individuals who were hospitalized in 2015 for a suicide attempt. The authors do not state how many of these individuals had received surgery, but this may be calculated by combining the data from Table 3 and Figure 1 in the article. Figure 1 shows the proportion of persons with gender dysphoria who were hospitalized for suicide attempt in 2015, grouped according to the time that had elapsed since the last gender-corrective surgery. Table 3 shows the number of individuals with gender dysphoria, grouped according to the time elapsed since last surgical operation ("Time since last gender-affirming surgical treatment").

By combining these data, we can calculate that 10 of the suicide attempts (2.8% of 353) occurred during the same year that the last surgical correction was made ("perioperative" group in Figure 1). Two cases occurred 1 year after the last surgical correction (0.9% of 221) and one case 2–3 years after the last surgical treatment (0.5% of 198), while none occurred more than 3 years after the last surgery. Thus, 13 individuals (10 plus two plus one) of the 22 persons who were hospitalized for a suicide attempt in 2015 had undergone gender-corrective surgery. Consequently, nine of them (22 minus 13) had not undergone any gender-affirmation surgery.

This corresponds to an odds ratio of 2.37 (95% CI=1.01–5.56, p=0.047). Hence, among the individuals examined in the study, the risk of being hospitalized for a suicide attempt was 2.4 times higher if they had undergone gender-corrective surgery than if they had not. Whether this is a causal relation (i.e., that surgery actually worsens the poor mental health in individuals with gender dysphoria) cannot be determined. Nevertheless, the data presented in the article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria.

REFERENCE

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734

Agnes Wold, M.D., Ph.D.

Department of Infectious Diseases, Institute of Biomedicine, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.

Send correspondence to Dr. Wold (agnes.wold@microbio.gu.se).

The author reports no financial relationships with commercial interests.

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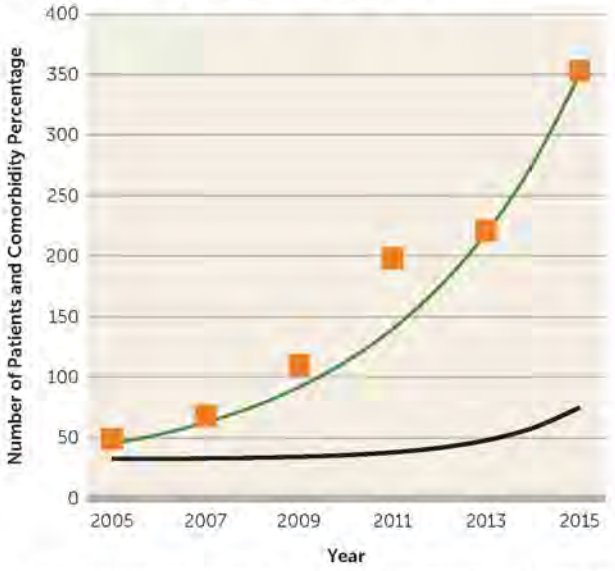
Confounding Effects on Mental Health Observations After Sex Reassignment Surgery

TO THE EDITOR: Bränström and Pachankis (1) report that Swedes with gender dysphoria who had undergone sex reassignment surgery in the decade to 2015 had a declining need for mental health treatment (as shown in Figure 1 in the article), leading them to consider that sex reassignment surgery improves mental health. However, the same data may be modeled in a way that leads to the opposite conclusion.

Except for a reduction after the perioperative year, Bränström and Pachankis found no further significant decrease in mental health treatment between the first and ninth years after surgery. They allowed for the increase in sex reassignment surgery from 2005 on but overlooked the increase in co-occurring mental health issues, which rose after 2005 but especially from about 2009 (2). A simple qualitative model illustrates how a dramatic change over time in mental health issues will affect the number of individuals accessing mental health treatment in 2015. In our Figure 1, the upper line depicts the rise in the number of sex reassignment surgeries, and the lower dark line depicts the rise in co-occurrence of mental health issues, assuming a final rise of 200% and a final co-occurrence of 75% (3).

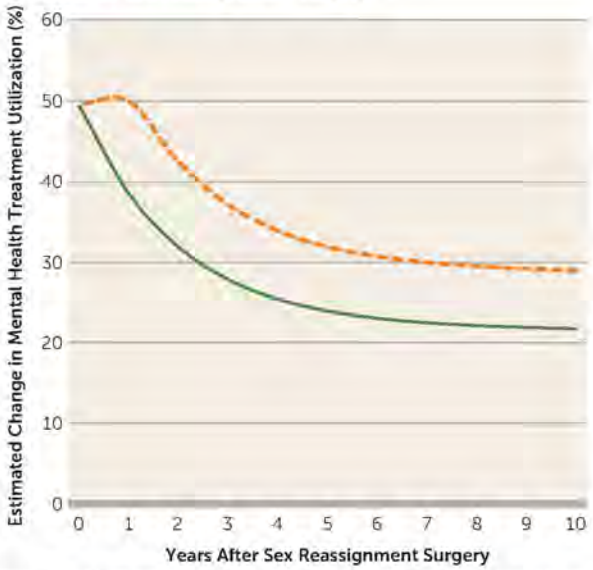
Because patients undergoing this surgery in the years closest to 2015 had higher rates of co-occurring mental health

FIGURE 1. Qualitative model of the number of sex reassignment surgeries and co-occurrence of mental health issues among individuals accessing mental health treatment[a]



[a] The orange boxes indicate the number of patients, the green line indicates the number of sex reassignment surgeries, and the dark line indicates the percentage of co-occurrence of mental health issues.

FIGURE 2. Estimation of mental health utilization by individuals in the years after sex reassignment surgery[a]



[a] The dotted line portrays projected mental health treatment utilization assuming aggravation of a mental health condition after sex reassignment surgery. The solid line portrays projected mental health treatment utilization assuming no aggravating effects after sex reassignment surgery.

issues than those whose surgery happened longer ago, we would expect the decline in mental health treatment to be pronounced (see the solid line in Figure 2), and with a beneficial effect of the surgery over time, the fall should be even more significant. Yet surprisingly, Bränström and Pachankis found only a very small decline over time.

However, if in fact this surgery aggravates a mental health condition by, say, 25%, then a more moderate fall in mental health utilization results (see the dashed line in Figure 2). The qualitative approximation of this curve with the reduction described by Bränström and Pachankis (in their Figure 1) is striking. Therefore, accounting for the increase in mental health issues from 2005, together with an assumption of increased mental health treatment due to this surgery, fits the data in the article and overturns the authors' conclusions, suggesting that sex reassignment surgery is in fact associated with increased mental health treatment.

REFERENCES

1. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177:727–734
2. Lukianoff G, Haidt J: The Coddling of the American Mind: How Good Intentions and Bad Ideas Are Setting Up a Generation for Failure. New York, Penguin, 2018
3. Kaltiala-Heino R, Sumia M, Työläjärvi M, et al: Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. Child Adolesc Psychiatry Ment Health 2015; 9:9

Avi Ring, Ph.D.
William J. Malone, M.D.

Pharmacy Department, University of Oslo, Oslo (Ring); and Idaho College of Osteopathic Medicine, Boise (Malone).

Send correspondence to Dr. Ring (avi.ring@gmail.com).

The authors report no financial relationships with commercial interests.

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Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters

TO THE EDITOR: Increasing attention has been paid to identifying the best way to support transgender individuals seeking gender-affirming care. This attention springs from the increasing number of individuals seeking such care in many countries worldwide, coupled with a lack of sufficient knowledge to provide evidence-based treatment recommendations. This attention is also reflected in the letters to the editor (1–7) submitted in response to our article in this issue in which we describe mental health treatment utilization among transgender individuals seeking gender-affirming care in Sweden compared with the general population, and as a function of time since last gender-affirming surgery (8).

The letter writers question our conclusion that our study "lends support to the decision to provide gender-affirming surgeries to transgender individuals who seek them." Their concerns about this conclusion can be summarized into three types:

Concern 1: The analysis focused on mental health treatment utilization during one specific year (i.e., 2015) rather than during a longer follow-up period, such as before and after provision of gender-affirming treatment.

Concern 2: The study did not employ an adequate comparison group.

Concern 3: The study did not sufficiently highlight the elevated mental health care needs of transgender individuals seeking gender-affirming care during the perioperative period.

Our study was motivated by two aims informed by the literature and the need for more knowledge in this field: first, to examine if transgender individuals seeking gender-affirming care have an increased risk of mental health treatment utilization compared with the general population; and second, to examine if mental health treatment utilization among transgender individuals who received gender-affirming care decreases as a function of number of years since receiving gender-affirming care.

In our article, we describe the background to our analytic decisions and discuss the limitations that our particular study design and analytic approach introduce. Many of the concerns raised by the letter writers are discussed at the conclusion of the article. In the article, we specifically call for further longitudinal studies that assess within-person changes in mental health treatment utilization before and after treatment. In the article, we also note that our approach was capable of ascertaining mental health only among those alive in 2015 and did not capture outcomes among the deceased. Several of the letter writers' concerns are drawn from assumptions about what our study methodology theoretically should have been or could have been but ultimately was not.

The letter writers suggest more ideal methodologies for identifying any causal impact of gender-affirming care on mental health treatment utilization, similar to what we wrote in our article. As outlined below, we join them in aspiring toward such methodologies capable of more rigorously establishing this impact. We also perform additional analyses permitted by our current data to start to move toward that goal.

Our Analytic Strategy

There is a great need for higher-quality studies using more representative samples of transgender individuals seeking gender-affirming care to better understand this population's mental and physical health care needs and the effects of gender-affirming care. Much current evidence derives primarily from small studies with cross-sectional designs, nonprobability samples, and self-reported treatment exposures and mental health outcomes. Our study does not. Although it is not capable of overcoming all threats to validity, our study design represents an improvement over much previous research.

Ours is an observational study based on registry data regarding mental health treatment utilization among individuals with a gender incongruence diagnosis. We focus on mental health treatment utilization during one specific year (the latest for which we had data), and we used the total Swedish population as a comparison group. First, to answer whether transgender individuals seeking gender-affirming care have an increased risk of mental health treatment utilization compared with the general population, we compared the prevalence of treatment for mood and anxiety disorders among those with and without a gender incongruence diagnosis among all individuals living in Sweden. Second, to answer whether odds of mental health treatment utilization among transgender individuals who received gender-affirming care are lower as a function of number of years since receiving gender-affirming care, we evaluated mental health treatment utilization in 2015 among those with a gender incongruence diagnosis as a function of time since the initiation of gender-affirming hormone treatment and the last gender-affirming surgical treatment.

As outlined below, although this design is capable of ruling out certain threats to validity (e.g., confounding by secular trends), it is incapable of ruling out others (e.g., loss to mortality).

Responses to the Letters

Response to concern 1. The first concern is that our analysis focused on mental health treatment utilization during one specific year (i.e., 2015) rather than during a longer follow-up period, such as before and after provision of gender-affirming treatment. This decision was made to control for several important factors. First, the situation for transgender individuals has changed rapidly in the past 10–15 years. In Sweden, legislation affecting transgender individuals (e.g., removal of sterilization as a requirement for change of legal gender; increased protection of transgender individuals in hate-speech legislation) has improved at the same time that population attitudes have become more accepting (9, 10). Second, the proportion of individuals in the population treated for mental health problems has increased over time. Third, access to gender-affirming care has also increased over time. By restricting our outcome assessment period to one year, 2015, the most recent year for which we had data, we were able to remove the influence of these secular trends in transgender acceptance, visibility, and treatment utilization (both gender-affirming treatment and mental health treatment).

Although our chosen strategy addressed many of the problems of these secular effects, it has several drawbacks. Because we looked at mental health treatment utilization in one specific year, we could not follow individuals over time. Our analysis of time since last gender-affirming surgical treatment compared groups of individuals with varying lengths of time since their last treatment. It is possible that other factors, such as age and a changing proportion of individuals of different legal genders who have sought gender-affirming care over time, could influence these comparisons. Therefore, we controlled for those sociodemographic

factors in our analyses. Another drawback to using only one year of mental health treatment utilization data is that our analysis contains a very small number of suicide attempts and no information about previous attempts and completed suicides. Studies employing prospective cohort designs are needed to better understand suicidality within this group and its associations with gender-affirming care. Any conclusion regarding suicidality in our present study should be interpreted with this limitation in mind. This limitation is reported in our article.

Response to concern 2. The second concern is that our study design lacked an adequate comparison group. To answer whether transgender individuals seeking gender-affirming care have an increased risk of mental health treatment utilization compared with the general population, we used the total population without a gender incongruence diagnosis as a comparison group. Because the total population differs in significant ways from the group diagnosed with gender incongruence, we adjusted our analysis for all available sociodemographic variables (i.e., age, legal gender, education, income, urbanicity, and country of birth). An alternative way of testing this aim would be to create a comparison group matched on important demographic variables, which we have now done. Specifically, we now compare individuals diagnosed with gender incongruence with an equally sized group without such a diagnosis matched by age, legal gender, education, and country of birth. The results are presented in Tables S1 and S2 in the online supplement, and they indicate a similar pattern of results as reported in our article, with only a slightly reduced disparity in the odds of mental health treatment utilization when individuals diagnosed with gender incongruence are compared with matched control subjects (instead of with the full population without gender incongruence, as was done in the original analysis).

To determine if mental health treatment utilization among transgender individuals receiving gender-affirming care decreases as a function of number of years since receiving gender-affirming care, we did not use a comparison group but tested the association between both year since initiation of gender-affirming hormone treatment and year since last gender-affirming surgical treatment with mental health treatment utilization in 2015. As a reference, we included the proportion of the general population treated for mental health conditions in 2015 in Figure 1 of our article. We have added the proportion of the matched control subjects treated for mental health problems in 2015 to Figure S1 in the online supplement.

Like some of the letter writers suggest, we also considered using a stronger comparison group but found the options unsatisfactory, if not impossible. Perhaps the most obvious comparison would have been individuals with a gender incongruence diagnosis who had not received surgical treatment. This would be a strong comparison group if all individuals diagnosed with gender incongruence are, in fact, seeking gender-affirming surgical treatment. However, this is not the case. Some individuals diagnosed with gender incongruence seek only gender-affirming hormonal treatment and not gender-affirming surgical treatment; others seek no treatment at all. The group diagnosed with gender incongruence not receiving surgery is a heterogeneous group, including those with no intention to seek surgery, that would be inappropriate as a comparison group for those receiving surgery. However, to be responsive to some of the letter writers' interest in comparing individuals with a gender incongruence diagnosis who received and did not receive gender-affirming surgery, we have created a matched group of individuals with a gender incongruence diagnosis who have not received surgery. These individuals were each matched to an individual with a gender incongruence diagnosis who had received gender-affirming surgery by age, legal gender, education, and country of birth. When comparing the mental health treatment outcomes between the two groups (Table 1), we found no significant difference in the prevalence of treatment for mood disorders and no significant difference in the prevalence of hospitalization after suicide attempt. However, individuals diagnosed with gender incongruence who had received gender-affirming surgery were more likely to be treated for anxiety disorders compared with individuals diagnosed with gender incongruence who had not received gender-affirming surgery. As reported in the article, the statistical test for hospitalization after suicide attempt must be interpreted with caution. As noted above, limited information can be drawn from this particular comparison.

Another comparison group could have involved individuals without a gender incongruence diagnosis undergoing a surgical treatment for which a thorough mental health assessment is required, as it is for gender-affirming surgery. However, we are unaware of any such surgical treatment. Such a comparison group would have, theoretically, enabled us to partially overcome two threats to the validity of our finding that odds of mental health treatment are lower as a function of time since final gender-affirming surgery. The first threat is that people are required to be screened for mental health problems before gender-affirming surgery and might therefore have particularly high odds of mental health treatment in the perioperative year because of their perhaps involuntary receipt of mental health services. These individuals might be less likely to voluntarily seek treatment for mental health problems with greater time since surgery. The second threat is that because we assessed only the mental health of individuals who were alive in 2015, individuals who died by suicide or migrated would not be included; greater time since last surgical treatment comes with greater time for suicide or migration to happen.

Response to concern 3. The third concern is that the study did not sufficiently highlight the elevated mental health care needs of transgender individuals seeking gender-affirming care during the perioperative period. The letter writers highlight this important finding of our study that we did not sufficiently emphasize originally. Specifically, regardless of the effect of gender-affirming care on mental health treatment

TABLE 1. Mood- and anxiety-related health care visits, antidepressant and anxiolytic prescriptions, and hospitalization after suicide attempt in 2015 among individuals diagnosed with gender incongruence in Sweden between 2005 and 2015, by gender-affirmative surgery status

	Individuals Diagnosed With Gender Incongruence Who Have Received Gender-Affirmative Surgery (N=1,018)		Individuals Diagnosed With Gender Incongruence Who Have Not Received Gender-Affirmative Surgery (N=1,018)[a]		Analysis	
2015 Treatment Outcome	N	%	N	%	Odds Ratio	95% CI
Psychiatric outpatient visits						
Any mood disorder	98	9.6	88	8.6	1.13	0.83–1.52
Any anxiety disorder	85	8.3	62	6.1	1.40	1.00–1.97
Prescribed medication						
Any antidepressant treatment	301	29.6	292	28.7	1.04	0.86–1.26
Any anxiolytic treatment	215	21.1	149	14.6	1.56	1.24–1.96
Inpatient visit (hospitalization after suicide attempt)	13	1.3	7	0.7	1.87	0.74–4.70

[a] Control group matched by age, gender, education, and country of birth.

utilization, our results show that the mental health care needs of this population are substantial in the year surrounding the last gender-affirming surgery. These results highlight the need for further research and clinical attention to be paid to the stressors and needed supports of this period (11).

In sum, the letter writers point out that although our study design addressed some threats to validity (e.g., confounding by secular trends), it introduced others (e.g., loss to mortality). While the design clearly establishes that individuals diagnosed with gender incongruence utilized more mental health care than the general population in 2015, especially during the perioperative period, like most extant research on the topic, the design is incapable of establishing a causal effect of gender-affirming care on mental health treatment utilization.

Should the Concluding Message of Our Study Have Been More Moderate?

Our conclusion based on the findings at hand in the article, which used neither a prospective cohort design nor a randomized controlled trial design, was too strong. However, given the urgent need for more knowledge about the mental health of transgender individuals and the potential consequences of gender-affirming care, this large-scale observational study serves an important purpose and fills an important knowledge gap. Specifically, this study highlights the substantially increased risk of mental health problems among individuals diagnosed with gender incongruence, and in particular, among those in the process of receiving gender-affirming surgery. The study also lends support for expecting a reduction in mental health treatment as a function of time since completing such treatment, at least among those who are still living in Sweden.

We thank the letter writers for their attention to this important topic and, recognizing the importance of approaching this topic with triangulated, rigorous methodologies, look forward to further collaborative research using even higher-quality methodologies to move closer to establishing the causal impact of gender-affirming care on the well-being of the transgender population.

REFERENCES

1. Anckarsäter H, Gillberg C: Methodological shortcomings undercut statement in support of gender-affirming surgery (letter). Am J Psychiatry 2020; 177:764–765
2. Van Mol A, Laidlaw MK, Grossman M, et al: Gender-affirmation surgery conclusion lacks evidence (letter). Am J Psychiatry 2020; 177:765–766
3. Curtis D: Study of transgender patients: conclusions are not supported by findings (letter). Am J Psychiatry 2020; 177:766
4. Malone WJ, Roman S: Calling into question whether gender-affirming surgery relieves psychological distress (letter). Am J Psychiatry 2020; 177:766–767
5. Landén M: The effect of gender-affirming treatment on psychiatric morbidity is still undecided (letter). Am J Psychiatry 2020; 177: 767–768
6. Wold A: Gender-corrective surgery promoting mental health in persons with gender dysphoria not supported by data presented in article (letter). Am J Psychiatry 2020; 177:768
7. Ring A, Malone WJ: Confounding effects on mental health observations after sex reassignment surgery (letter). Am J Psychiatry 2020; 177:768–769
8. Bränström R, Pachankis JE: Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. Am J Psychiatry 2020; 177: 727–734
9. Flores AR, Park A: Polarized Progress: Social Acceptance of LGBT People in 141 Countries, 1981 to 2014. The Williams Institute, UCLA School of Law, Los Angeles, 2018. https://williamsinstitute.law.ucla.edu/wp-content/uploads/Polarized-Progress-GAI-Mar-2018.pdf
10. Public Health Agency of Sweden: Hälsan och hälsans bestämningsfaktorer för transpersoner: en rapport om hälsoläget bland transpersoner i Sverige. Stockholm, 2015
11. Deutsch MB: Gender-affirming surgeries in the era of insurance coverage: developing a framework for psychosocial support and care navigation in the perioperative period. J Health Care Poor Underserved 2016; 27:386–391

Richard Bränström, Ph.D.
John E. Pachankis, Ph.D.

Department of Clinical Neuroscience, Karolinska Institutet, Stockholm (Bränström); and Department of Social and Behavioral Sciences, Yale School of Public Health, New Haven, Conn. (Pachankis).

Send correspondence to Dr. Bränström (richard.branstrom@ki.se).

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IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.	)	
	)	
Plaintiffs	)	
	)	Cause No.
vs.	)	1:19-cv-00272-
	)	LCB-LPA
DALE FOLWELL, et al.	)	
	)	
Defendants	)	

VIDEO ZOOM DEPOSITION OF DR. PAUL W. HRUZ

Taken on behalf of the Plaintiffs

September 29, 2021

Sheryl A. Pautler, RPR,
MO-CCR 871, IL-CSR 084-004585

(The proceedings began at 9:31 a.m. Eastern.)

THE VIDEOGRAPHER: Off the record at 6:00.

(Whereupon there was a short break.)

THE VIDEOGRAPHER: We are back on the record at 6:15. Excuse me.

[EXAMINATION]

QUESTIONS BY MR. KNEPPER:

Q. Dr. Hruz, in your testimony, you mentioned additional studies that reflect your understanding of the effect of hormone therapy in the patient outcomes. Are you referring to studies in addition to the study published by the American Journal of Psychiatry for Branstrom and Pachankis?

A. Yes, yes. I'm aware of actually very recently there's been another study. I may have mentioned it earlier but have not had the opportunity to go over those findings in detail. A study by Hisle-Gorman in the Journal of Sexual Medicine published very recently, which actually is in complete agreement with the retracted Branstrom paper showing that mental health utilization remains elevated.

In fact, in that paper, this is a population of children in the military and they actually had a control group which were siblings to

the effected children with sex discordant gender identity. And when they looked at after receiving cross-sex hormones their mental health utilization remained elevated. In fact, the use of psychotropic medications increased in that study.

I think that's really in line noting that the Branstrom paper the controversy surrounded the conclusions related to surgical interventions. But even before the retractions, it was acknowledged the cross-sex hormones themselves did not have any benefit. That was one of the original author's conclusions.

Q. So I'm going to ask for you to look at Exhibit 22.

A. Yes, I have that up.

(Whereupon Exhibit 22 was introduced for identification.)

Q. (By Mr. Knepper) Is that the Hisle-Gorman article you were referring to?

A. That is correct.

Q. And this article was published after the submission of your report to this court?

A. That is correct.

Q. But --

A. Yeah.

Q. But you -- you -- when you're referring to the science and recent studies, you're referring to the reports discussed -- the articles discussed in your report and also to this more recent article; is that correct?

A. That is correct.

Q. Okay. Dr. Hruz, at one point you mentioned the Dutch model and you mentioned -- let me start over. In this context, when it was referred to as the Dutch model, what are they discussing, what are -- what are providers and scientists discussing?

A. Yeah. So the original paper that came out and was published that is often referred to as the Dutch model was a group of predominantly males that presented with prepubertal onset of gender dysphoria and were followed over time. And many have drawn attention to the fact that at the time that study was done, the demographics of the people presenting for care were quite remarkably different than the current population. And indeed what was predominantly a condition that affected males over females is now reversed. And so females with male gender identity is now the largest group.

The other difference in the patients

Q. Dr. Hruz, you mentioned very briefly in response to plaintiff's counsel, the effect of sex hormones on brain development during puberty. Can you provide additional information about the state of scientific knowledge on -- on that?

A. Yes. So there are many --

MR. GONZALEZ-PAGAN: Form.

A. So I understand the question, you're asking me about whether there are any effects of GnRH agonists on the developing brain. And the answer to that is it's -- there -- it's an unsettled question. There's many -- like the effects on bone density are already known. There are many unknowns about the affect of suppressing normal timed puberty on brain development.

However, there is knowledge that it's based upon the effects of sex steroids themselves independent of suppressing it that have been studied for many years. The state of the science is often conflicting and unclear. The best data actually comes from several animal models, sheep in particular. But it involves the maturation of the brain in areas, for example, of decision-making, executive function.

And, you know, all of these features

are part of the whole adolescent process where an individual is able to overcome the adolescent impulsivity, the inability to see long-term consequences of their action, all of the reasons why in other areas adolescents are not allowed to make decisions, for example, to purchase and drink alcohol, to purchase and smoke cigarettes and to vote, are all based upon that developmental process that occurs.

Now, the science behind that is in its rudimentary stages right now. It includes structural studies. It includes functional studies. You know, functional magnetic resonance imaging. And really is put forward as a very important area of research.

So, again, this is why this is relevant, is that when we're talking about -- and this came up earlier in this deposition, about the differences between suppressing precocious puberty from suppressing puberty during the adolescent years. And that is the basis for the concern. There is emerging science and much more science that needs to be done.

So certainly the safest conclusion would be that there are many unknowns and many

THE JOURNAL OF
SEXUAL MEDICINE

ORIGINAL RESEARCH & REVIEWS

TRANSGENDER HEALTH

Mental Healthcare Utilization of Transgender Youth Before and After Affirming Treatment

Elizabeth Hisle-Gorman, MSW, PhD,[1] Natasha A. Schvey, PhD,[2] Terry A. Adirim, MD, MPH,[3] Anna K. Rayne, MD,[4] Apryl Susi, MS,[5] Timothy A. Roberts, MD, MPH,[6] and David A. Klein, MD, MPH[7]

ABSTRACT

Objective: Transgender and gender-diverse (TGD) adolescents experience increased mental health risk compared to cisgender peers. Limited research suggests improved outcomes following gender-affirmation. This study examined mental healthcare and psychotropic medication utilization among TGD youth compared to their siblings without gender-related diagnoses and explored utilization patterns following gender-affirming care.

Method: This retrospective cohort study used military healthcare data from 2010−2018 to identify mental healthcare diagnoses and visits, and psychotropic medication prescriptions among TGD youth who received care for gender dysphoria before age 18, and their siblings. Logistic and Poisson regression analyses compared mental health diagnosis, visits, and psychotropic prescriptions of TGD youth to their siblings, and compared healthcare utilization pre- and post-initiation of gender-affirming pharmaceuticals among TGD adolescents.

Results: 3,754 TGD adolescents and 6,603 cisgender siblings were included. TGD adolescents were more likely to have a mental health diagnosis (OR 5.45, 95% CI [4.77−6.24]), use more mental healthcare services (IRR 2.22; 95% CI [2.00−2.46]), and be prescribed more psychotropic medications (IRR = 2.57; 95% CI [2.36−2.80]) compared to siblings. The most pronounced increases in mental healthcare were for adjustment, anxiety, mood, personality, psychotic disorders, and suicidal ideation/attempted suicide. The most pronounced increased in psychotropic medication were in SNRIs, sleep medications, anti-psychotics and lithium. Among 963 TGD youth (M_{age}: 18.2) using gender-affirming pharmaceuticals, mental healthcare did not significantly change (IRR = 1.09, 95% CI [0.95 −1.25]) and psychotropic medications increased (IRR = 1.67, 95% CI [1.46−1.91]) following gender-affirming pharmaceutical initiation; older age was associated with decreased care and prescriptions.

Conclusion: Results support clinical mental health screening recommendations for TGD youth. Further research is needed to elucidate the longer-term impact of medical affirmation on mental health, including family and social factors associated with the persistence and discontinuation of mental healthcare needs among TGD youth.
Hisle-Gorman E, Schvey NA, Adirim TA, et al. Mental Healthcare Utilization of Transgender Youth Before and After Affirming Treatment. J Sex Med 2021;18:1444−1454.

Key Words: Transgender; Gender-Diverse; Mental Health; Adolescent; Youth

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[1]Department of Pediatrics, Uniformed Services University, Bethesda, MD; Department of Preventive Medicine and Biostatistics, Uniformed Services University, Bethesda, MD, USA;

[2]Department of Medical and Clinical Psychology, Uniformed Services University, Bethesda, MD, USA;

[3]Department of Preventive Medicine and Biostatistics, Uniformed Services University, Bethesda, MD; Department of Defense, Washington, DC, USA;

[4]Department of Family Medicine, Fort Belvoir Community Hospital, Fort Belvoir, VA, USA;

[5]Department of Pediatrics, Uniformed Services University, Bethesda, MD; Department of Preventive Medicine and Biostatistics, Uniformed Services University, Bethesda, MD, USA;

[6]Division of Adolescent Medicine, Children's Mercy Kansas City; Department of Pediatrics, University of Missouri-Kansas City School of Medicine, Kansas City, MO, USA;

[7]Department of Pediatrics, Uniformed Services University, Bethesda, MD; Department of Family Medicine, Uniformed Services University, Bethesda, MD, USA

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BACKGROUND

Transgender and gender-diverse (TGD) youth include those whose gender identity, expression, or behavior differs from that typically associated with their sex assigned at birth.[1] An estimated 0.7−2.7 percent of adolescents identify as TGD,[2−5] and TGD individuals are increasingly presenting for associated healthcare.[1,6−10]

While TGD individuals remain under-represented in medical research,[11−13] a growing body of literature suggests significant health disparities and poorer mental and physical health among TGD individuals as compared to cisgender peers.[2,3,14−21] In adult populations, large data studies of TGD Medicare recipients and Veterans indicate TGD adults use more mental healthcare, and experience increased disability, chronic conditions, substance abuse disorders, chronic pain, suicide, suicide related events, and disabling mental illness as compared to cisgender controls.[14−18] Health outcomes appear related to environment, with Veterans living in more accepting communities having fewer substance use and mental health comorbidities.[22,23]

In studies of children and adolescents, school and internet based surveys in the United States and other parts of the world, found self-identified TGD youth were less likely to report having a caring parent, and more likely to report depression, suicide attempts, suicidal risk, violence victimization, self-harm, substance use, unsafe sex, psychological distress, and bullying as compared to cisgender peers − outcomes likely related to stigma, family rejection, and victimization.[2,3,19,20,24−29] Parents of 105 adolescents with gender dysphoria reported 32% had a concurrent psychiatric disorder, including anxiety, mood, and disruptive disorders, and that multiple diagnoses were increased in those with transfeminine identities.[30] Larger studies using records from a community-based clinic and a 2-state integrated health system compared TGD youth to cisgender controls and found that the odds of multiple mental health diagnoses were increased 2 to several fold in TGD youth.[21,31]

However, some research indicates that mental health conditions in TGD youth and adults were not elevated, or were ameliorated in those with some level of medical or social affirmation (ie, those supported to live openly in their asserted gender identity).[32−43] Limited data, primarily using small samples, and self-report measures, indicate that mental health concerns and suicidality decreased, and well-being increased, following medical or social affirmation.[32−41,61] Small studies of youth who have completed social affirmation report improvement on psychological functioning and well-being and decreased gender dysphoria, but generally results rely on parent or child-report of symptoms.[35,36] Among adults, a meta-analysis of 1,833 TGD adults indicated self-reported improvement on gender dysphoria, psychological symptoms, quality of life, and sexual function following pharmaceutical affirmation.[44] One study in adults found that length of hormone treatment was not associated with changes in healthcare utilization for mood or anxiety disorders, but time from surgery was associated with decreases in care.[41,61]

Most TGD pediatric mental health research is limited by use of self- or parent-report, small sample size, limited geographic area, and lack of a non-TGD control group. While 2 studies have explored mental health diagnoses in larger samples,[21,31] neither examined patterns in mental healthcare utilization nor psychotropic medication prescriptions, which are important indicators of the severity of mental health conditions. Research specifically exploring effects of gender-affirming care on mental health have similar limitations, with few including adolescents or young adults.[32−41,61]

Given research indicating that TGD youth may be at increased risk for mental health conditions adequately powered studies are needed to better elucidate the mental healthcare needs of TGD youth, compared to matched controls, and to identify the trajectory of mental health comorbidities following gender affirmation. The current study examined mental healthcare and psychotropic medication utilization among TGD youth in a large healthcare administrative dataset, as compared to their siblings without a gender-related diagnosis, and explored mental health and psychotropic medication use in TGD adolescents following gender-affirming pharmaceutical care. We hypothesized that mental healthcare needs would be greater in TGD adolescents as compared to their siblings and that pharmaceutical affirmation would be associated with decreased treatment needs.

METHODS

We performed a retrospective cohort study examining mental healthcare utilization among TGD youth in the military healthcare system between October 2010 and September 2018 using the Military Healthcare Data Repository (MDR). The MDR includes records of all inpatient and outpatient care and outpatient prescriptions provided to military service members and retirees, and their family members domestically and abroad at military and civilian treatment facilities. The military provides no- to low-cost comprehensive care to these populations, including mental health and media (eg, pharmaceutical) care for gender dysphoria; active-duty members may also qualify for related surgical care. Access to care for gender dysphoria my differ geographically, however, the military attempts to address disparities through telemedicine and flying beneficiaries stationed overseas back to the United States, if needed, for specialized consultations. While generally reflective of the United States as a whole, the military tends to be more politically conservative, and more male, the proportion of African American individuals in the military is decreased, and the proportion of White individuals is increased as compared to the nation as a whole.[45]

TGD military dependent youth, <18 years of age at time of first contact, who received care in the military healthcare system were identified by 1 or more International Classification of Diseases (ICD) code (ICD-9 302.6, 302.85 302.50, 302.51, 302.52, 302.53, and ICD-10 F64.0, F64.1, F64.2, F64.8, F64.9, Z87.890) indicative of TGD status in their inpatient or outpatient record. This is a validated methodology.[8] ICD-9/10

codes are well-matched with clinical text notes in identification of TGD individuals.[46] We identified sibling controls in the MRD using the following criteria: shared a military sponsor (parent/guardian) with our TGD subjects; were <18 years old at their first encounter with the military health system during our study interval: and had no TGD diagnosis recorded, these siblings were considered cisgender controls, TDG youth and sibling were followed for the same time periods as care depended upon parental service.

We identified mental health care visits in the inpatient and outpatient care record by ICD-9/10 code using the Healthcare Cost and Utilization Project Clinical Classification Software system.[47] Mental health visits were sub-categorized by Healthcare Cost and Utilization Project categories for adjustment, anxiety, attention-deficit, conduct, developmental, mood, and cognitive disorders; disorders usually diagnosed in infancy or childhood (which includes autism), suicidal ideation/self-harm; alcohol use, substance use disorders; and miscellaneous mental health conditions (dissociative, eating and factitious disorders). The total number of mental health visits were counted overall, and by diagnosis sub-category; individuals were counted as having a given diagnosis if they had 1 or more visit for the diagnosis. Visits for TGD status, gender dysphoria, or mental health screening were not counted as mental health diagnoses. Children with one or more diagnosis for a mental health condition sub-category were categorized as having that mental health condition and having a mental health condition overall.

Psychotropic medications were identified by name in the outpatient pharmacy record, and included Bupropion, Selective Serotonin Reuptake Inhibitors (SSRI), Serotonin-Norepinephrine Reuptake Inhibitors (SNRI), other anti-depressants, sleep medication, benzodiazepines, antipsychotics, simulants, migraine medications, and lithium. Medications were classified by type and counted by day's supply. Gender affirming medications included puberty suppression (ie, implantable or injectable gonadotropin-releasing hormone agonists), masculinizing hormones and feminizing hormones, and were identified by name in the outpatient pharmacy record. Demographic data were extracted from the medical record and healthcare enrollment eligibility records; race/ethnicity data was not available.

Chi-squared analysis and Wilcoxon Rank sum test compared groups on demographics, logistic regression clustered by family compared groups on mental health diagnosis, and any psychotropic medication use overall and care/medication sub-category, and Poisson regression clustered by family compared mental healthcare visit rates and psychotropic medication days. Adjusted analyses controlled for sex assigned at birth, total healthcare contacts per year, age at study initiation, and parental rank. Parental rank was dichotomized as Junior Enlisted (enlisted ranks 1—4) vs more senior military ranks; Junior enlisted acted as a proxy for low income as Junior enlisted service member earn less than $35,000 a year.

Poisson regression clustered by individual compared mental healthcare visit rates and psychotropic medication days pre- and post- initiation of gender affirming pharmaceutical treatment, and logistic regression identified factors associated with decreased mental healthcare use and decreased psychotropic medications following initiation of gender-affirming medications. Adjusted models controlled for sex assigned at birth, total healthcare contacts per year, age at affirming medication initiation, type of initial gender affirming medication (puberty suppression vs gender-affirming hormones), and parental rank. Analyses were conducted using Stata Intercooled, version 13; P values <.05 was considered statistically significant. The study was reviewed and approved by the Uniformed Services University Institutional Review Board.

RESULTS

The research team identified a total of 3,754 TGD youths and 6,603 cisgender siblings who received Military Health System care between fiscal years 2010 and 2018. Both groups were tracked for a mean of 8.5 years. TGD youth were slightly older, less likely to be assigned male at birth, less likely to have Junior Enlisted parents, and utilized more outpatient healthcare overall as compared to their cisgender siblings (Table 1).

Mental Health Diagnosis

As compared to their cisgender siblings, TGD youth were more likely to have a mental health diagnosis and have a greater number of total mental health diagnoses (Table 1, 2). Looking at specific

Table 1. Demographics of included transgender and gender-diverse youth and their cisgender siblings

	TGD children N = 3,754	Cisgender siblings N = 6,603	Significance
Age at Study Initiation— Median [IQR]	10 [8-—13]	9 [4—14]	$P < .001$
Age at Study Completion— Median [IQR]	18 [16—21]	17 [11—21]	$P < .001$
Male Assigned Birth Sex	1,193 (31.8%)	3,312 (50.1%)	$P < .001$
Parent of Jr Enlisted Rank	1,524 (43.7%)	2960 (47.6%)	$P < .001$
Visits Per Year — Median [IQR]	18.7 [10.0—32.9]	9.5 [4.6—18.9]	$P < .001$
On psychotropic	2,820 (75.1%)	2,425 (37.7%)	$P < .001$
Years Tracked	8.5 [8.5—8.6]	8.5 [8.5—8.5]	$P < .001$
Median Mental Health Diagnoses	2 [1—4]	1 [0—2]	$P < .001$
Median Mental Health Visits Per Year	2.9 [0.8—7.0]	0.1 [0—2.0]	$P < .001$

TGD = transgender or gender-diverse.

Table 2. Mental health diagnoses and visits by transgender and gender-diverse status

	Mental health diagnosis			Visits per year		
	TGD Children N (%)	Cisgender Siblings N (%)	Adjusted* odds of mental health diagnosis or [95%CI]	TGD	Cisgender siblings	Adjusted* visit rate IRR [95%CI]
All Mental Health	3,352 (89.3)	3,308 (50.1)	5.45 [4.77–6.24]	5.5	3.1	2.22 [2.00–2.46]
Adjustment	1,687 (44.9)	1,191 (18.0)	1.09 [1.80–3.41]	0.74	0.29	2.49 [2.19–2.84]
Anxiety	1,908 (50.8)	1,216 (18.4)	3.30 [2.98–3.65]	0.77	0.28	2.49 [2.13–2.90]
ADHD	1,119 (29.8)	1,229 (18.6)	1.77 [1.59–1.97]	0.60	0.47	1.60 [1.37–1.88]
Cognitive	137 (3.7)	122 (1.9)	1.64 [1.26–2.14]	0.014	0.008	2.01 [1.39–2.89]
Developmental	189 (5.0)	429 (6.5)	1.11 [0.89–1.38]	0.10	0.30	0.97 [0.65–1.45]
First Diagnosed in Infancy	432 (11.5)	578 (8.8)	1.53 [1.30–1.79]	0.65	1.24	1.39 [0.86–2.26]
Impulse	60 (1.6)	45 (0.7)	2.18 [1.40–3.38]	0.013	0.009	1.55 [0.68–3.58]
Mood	2,413 (64.3)	1182 (18.9)	6.12 [5.51–6.80]	2.18	0.46	4.14 [3.64–4.71]
Personality	86 (2.3)	43 (0.7)	2.54 [1.71–3.78]	0.019	0.005	3.28 [1.53–7.00]
Psychotic	363 (9.7)	104 (1.6)	5.38 [4.20–6.88]	0.12	0.014	7.43 [4.72-–11.69]
Alcohol	57 (1.5)	66 (1.0)	1.25 [0.85–1.82]	0.011	0.010	0.93 [0.50–1.73]
Substance	237 (6.3)	209 (3.2)	1.61 [1.31–1.97]	0.053	0.032	1.77 [1.15–2.70]
Suicide	683 (18.2)	162 (2.5)	7.45 [6.11–9.08]	0.08	0.01	6.83 [5.03–9.26]
Miscellaneous	512 (13.6)	375 (5.7)	2.08 [1.77–2.45]	0.12	0.03	3.38 [2.20–5.18]

*Adjusted analysis, adjusts for sex assigned at birth, total healthcare contacts per year, age at study initiation, and parental rank.TGD = transgender or gender-diverse.

one-year periods, which is a more typical time period in which to access mental health diagnoses, TGD youth were more likely than their siblings to have a mental health diagnosis in a given year (eg, in 2010 [23.7% vs 13.9%, $P < .001$], 2015 [46.5% vs 18.8%, $P < .001$] and 2018 [42.7% vs 17.1%, $P < .001$]). The most common mental health diagnosis in TGD youth was mood/depressive disorder which impacted 64% of TGD youth at some point during the 8-year study period; followed by anxiety (51%) and adjustment disorders (44.9%; Table 2). For cisgender siblings, the most common mental health diagnoses were mood/depressive disorders (18.9%), ADHD (18.6%), and anxiety disorders (18.4%). After adjustment for age at study initiation, assigned sex at birth, parent rank, and number of outpatient visits per year, odds of having any mental health diagnosis were over 5 times higher in TGD youth as compared to their siblings (aOR = 5.45, 95% CI [4.77–6.24], $P < .001$). TGD youth were over 7 times as likely to have diagnosed suicidal ideation/self-harm (OR 7.45, 95%CI 6.11–9.08), over 6 times as likely to have a mood/depressive disorder (OR 6.12 95%CI [5.51–6.80]), over 5 times as likely to have a psychotic disorder (eg, schizophrenia) diagnosed (OR 5.38 95% CI [4.20–6.88]); and had similar odds of diagnosed developmental and alcohol use disorders (Table 2).

Mental Healthcare Use

TGD youth had an average of 5.5 mental healthcare visits per year over the course of the study as compared to 3.1 mental health visits per year for their cisgender siblings, and over twice as many visits in adjusted analysis (aIRR 2.22; 95% CI [2.00–2.46], $P < .001$). Mirroring diagnoses, mental healthcare visits for TGD youth were largely for mood/depressive, anxiety and adjustment disorders; however, care for cognitive, mood/depressive, personality, psychotic, and miscellaneous disorders, ADHD, substance use, and suicidal ideation/self-harm were all greater among TGD youth as compared to their siblings (Table 2). The most common diagnoses among siblings were disorders diagnosed in infancy and childhood, ADHD, and mood/depressive disorders. Care for development diagnoses, disorders usually diagnosed in infancy and childhood, impulse control disorder and alcohol use did not differ between the 2 groups (Table 2).

Psychotropic Medication Use

Over the full study period, 75% (2,820) of TGD youth were prescribed a psychotropic medication as compared to 38% (2,425) of their cisgender siblings ($P < .001$; Table 1). In adjusted analysis, TGD youth had over 2 and a half times as many medication days as their siblings (aIRR = 2.57; 95% CI [2.36–2.80], $P < .001$). SSRIs accounted for the most medication days in TGD youth, resulting in close to 3 times as many medication days for TGD youth; followed by stimulants, and antipsychotics. For siblings, stimulants accounted for the largest number of medication days followed by SSRIs, and anti-psychotics. In adjusted analyses TGD youth had over 3 times as many medication days for SNRIs, Lithium, anti-psychotics, and sleep medications as compared to their cisgender siblings (Table 3).

Impact of Gender Affirming Pharmaceutical Treatment

Of 3,754 included TGD youth, 963 (25.6%) initiated gender-affirming pharmaceutical treatment (puberty suppression or gender-affirming hormones) during the study period. The 963

Table 3. Psychotropic medication days by transgender and gender-diverse status

	Medication days per year		
	TGD children	Cisgender siblings	Adjusted[†] IRR [95% CI]
All Mental Health Meds	111.4	42.5	2.57 [2.36–2.80]
Wellbutrin	5.38	1.57	2.76 [2.12–3.60]
SSRI	37.25	11.18	2.96 [2.65–3.31]
SNRI	4.10	0.96	3.82 [2.64–5.54]
Other Antidepressant	7.93	2.50	3.01 [2.48–3.66]
Sleep Medications	5.82	1.61	3.28 [2.61–4.12]
Benzodiazepines	3.01	1.14	2.56 [1.85–3.56]
Anti-Psychotics	18.24	5.88	3.39 [2.83–4.07]
Stimulants	26.89	19.52	1.57 [1.39–1.77]
Migraine Medications*	0.92	0.42	1.69 [1.27–2.26]
Lithium	1.68	0.48	3.64 [2.02–6.55]

*Migraine Medications – Triptan.
†Adjusted analysis, adjusts for sex assigned at birth, total healthcare contacts per year, age at study initiation, and parental rank.TGD = transgender or gender-diverse.

pharmaceutically treated youth were tracked for a mean of 7.1 [IQR 5.5–7.8] years prior to pharmaceutical treatment initiation, and 1.5 [IQR 0.8–2.8] years following initiation of gender-affirming treatment. The median age of initiation of affirming medication was 18.2 [IQR 16.6–19.8] years, and the first gender affirming medications were: masculinizing hormones (61.4%, n = 591), feminizing hormones (28.7%, n = 276), and puberty suppression (10.0%, n = 96; Table 4). The median number of mental healthcare visits per years declined after starting gender affirming hormones (3.5 [IQR 1.2–7.5] vs 1.5 [0–7.8], Table 4). However, in adjusted Poisson regression analysis mental healthcare visits overall did not significantly change following gender-affirming pharmaceutical care (aIRR = 1.09, 95% CI [0.95–1.25], $P < .60$; 5.5 before vs 6.1 after) nor did care for most specific mental health diagnoses (Table 5). Of the youths who received gender-affirming pharmaceutical care, the majority (89%, n = 857) also used a psychotropic medication during the study period. Psychotropic medication use increased from mean of 120 days per year to a mean 212 days per year following gender affirming pharmaceutical care (aIRR = 1.67, 95%CI [1.46–1.91], $P < .001$]); medication use was increased in all classes explored except stimulants, migraine medications and lithium.

Factors Associated with Decreased Post-Affirming Mental Healthcare

Of youths receiving gender-affirming pharmaceutical care, 66.7% (642) had fewer mental healthcare visits following treatment. Decreased mental healthcare following gender-affirming care was associated with older age of medication initiation (aOR = 1.10, 95% CI [1.04–1.16]), and fewer overall visits per year over the study period (aOR = 0.99, 95%CI [0.99–0.99]), but was not associated with affirming medication type, sex assigned at birth, or parental rank. The median age of gender-affirming medication initiation of those with less mental healthcare use after initiation was 18.4 [IQR 17.0–19.8], and of those

Table 4. Demographics of 963 transgender and gender-diverse youth who initiated gender-affirming pharmaceutical treatment*

	TGD children N = 963		
	Before	After	*P*
Years Followed - Median	7.1 [5.6–7.9]	1.5 [0.7-2.7]	<.001
Mental Health Visits Per Year – Median [IQR]	3.5 [1.2–7.5]	1.5 [0-7.8]	<.001
Psychotropic Medication Days – Median [IQR]	69[17–157]	104[0-365]	.054
Fewer Mental Health Visits following Treatment	642 (66.7%)		
Fewer Medication Days Following Treatment	384 (44.8%)		
Age of First Affirming Medication	18.2 [16.6–19.8]		
First Medication Puberty Suppressant	96 (7.2%)		
First Medication Feminizing Hormone	276 (28.7%)		
First Medication Masculinizing Hormone	591 (61.4%)		
Male Sex Assigned at Birth	300 (31.2%)		
Parent of Jr Enlisted Rank	325 (33.8%)		
First Study Age – Median [IQR]	12 [10–14]		
Total Visits Per Year - Median[IQR]	48.9 [30.3–77.6]		

*Pharmaceutical treatment includes puberty suppression and gender-affirming hormonal therapy.TGD = transgender or gender-diverse.

Table 5. Transgender and gender-diverse youth mental healthcare and psychotropic medication use following initiation of gender affirming pharmaceutical treatment as compared to before initiation

Mental healthcare visits (N = 963)			
	Crude rate of visits per year		
	Before	After	Adjusted* IRR [95% CI]
All Mental Health Visits	5.50	6.10	1.04 [0.90-–1.20]
Adjustment	0.94	0.83	0.89 [0.67–-1.18]
Anxiety	0.98	1.04	1.07 [0.84–1.35]
ADHD	0.50	0.20	0.40 [0.27–-0.58]
Cognitive	0.02	0.02	0.83 [0.40–1.75]
Developmental	0.03	0.01	0.35 [0.16–0.78]
Infancy	0.37	0.53	1.02 [0.41–2.54]
Impulse	0.001	0.01	0.10 [0.02–0.53]
Mood	2.90	2.33	1.12 [0.94–1.35]
Personality	0.02	0.03	1.40 [0.44–-4.39]
Psychotic	0.13	0.16	0.99 [0.48–2.06]
Alcohol Abuse	0.13	0.06	0.66 [0.15–2.87]
Substance Abuse	0.05	0.12	1.39 [0.68–2.85]
Suicide	0.07	0.12	1.74 [1.18–2.56]
Miscellaneous	0.09	0.19	1.45 [0.56–3.60]

Medication days (N = 857)			
	Crude rate of medication days per year		
	Before	After	Adjusted* IRR [95% CI]
All Mental Health Meds	119.7	211.5	1.67 [1.46–1.91]
Wellbutrin	6.3	16.2	2.51 [2.71–3.69]
SSRI	44.8	73.9	1.72 [1.47–2.00]
SNRI	4.7	14.0	2.59 [1.52–4.38]
Other Antidepressant	9.2	18.9	1.61 [1.18–2.21]
Sleep Medications	6.4	16.2	2.23 [1.61–3.10]
Benzodiazepines	3.0	12.7	3.01 [1.95–4.65]
Anti-Psychotics	15.9	30.1	1.77 [1.34–2.35]
Stimulants	26.4	25.1	0.96 [0.72–1.26]
Migraine Medications	1.5	2.2	0.76 [0.37–1.53]
Lithium	1.3	2.3	1.11 [0.48–2.59]

*Adjusted analysis, adjusts for sex assigned at birth, total healthcare contacts per year, age at affirming medication initiation, and parental rank.

with more care was 17.9 [IQR 16.0–19.5]. Of included youth, 384 (44.8%) had decreased psychotropic medication prescription days following gender affirming pharmaceutical treatment. Decreased psychotropic medication use following gender affirming pharmaceutical treatment was associated with older age at time of affirming medication initiation (aOR = 1.09, 95% CI [1.03–1.16]) and male sex assigned at birth (aOR = 1.60 95% CI [1.18–2.17]).

DISCUSSION

Using a considerably larger population than previous studies, this research study found that TGD youth had greater mental healthcare use as compared to their cisgender siblings, with TGD youth more likely to have a mental health diagnosis, have multiple mental health diagnoses, use increased mental healthcare services, be prescribed a psychotropic medication, and use psychotropic medications for an increased number of days. For those TGD adolescents who initiated gender-affirming pharmaceutical care, mental healthcare and psychotropic medication needs were not reduced in the period following initiation after adjusting for confounders. Findings support previous research on a larger scale, control for family factors by comparing TGD youth to siblings, include psychotropic medication use as an additional mental health indicator, and document mental healthcare use rates as both an indicator of mental health severity and healthcare service need.

Over the 8.5-year course of the study's inclusion period, close to 90% of TGD youth had a mental health diagnosis, as compared to 50% of their cisgender siblings. For both TGD and cisgender youth, findings are higher than previously reported rates,[30,48] which likely relate to the study's extensive time period.

The median age of gender-affirming pharmaceutical treatment initiation was 18.2 years in this study which is substantially older than previous self- and parent-report studies of the initiation of medical and social transition (range 3−16 years).[32-37] Eighteen is the age at which youth can make their own medical choices; the fact that over half of included youth initiated gender-affirming pharmaceutical care after age 18 may suggest a lack of parental support or involvement in gender-affirming care among this study population. A lack of parental support may increase the need for new or ongoing mental health and/or psychotropic medication use which may also explain part of the increased rates of mental health diagnoses in our population. Yearly data from our study indicating that 23.7% to 46.5% of TGD youth had a mental health diagnosis in a given year is consistent with parental reports of mental health diagnoses in TGD youth at a given point in time.[29] Similarly, the yearly rate of mental health diagnoses among siblings (13.9%−18.8%) is comparable to published estimates.[48−50]

Findings of our study are consistent with adolescent and parent survey research, indicating that TGD youth have increased self- or parent-reported depression, suicide attempts/ideation, self-harm, substance use, and, emotional distress as compared to peers.[2,3,19,20,30] Results are also similar to large data research on adolescents and adults using clinic, healthcare provider, Medicaid, and veterans administration data which found increased mental health diagnoses in TGD individuals as compared to cisgender controls.[14,15,17,18,21,31] Our findings support current clinical recommendations to screen TGD youth for mental health concerns and address the underlying factors that increase risk in this population, and also suggest the importance of emphasizing mental health screening in future clinical recommendations.[51,52]

It is unclear why TGD youth were more likely to be diagnosed with psychotic conditions than their cisgender siblings, bur our findings are consistent with limited previous research in youth and adults.[31,52] Results may relate to lack of affirming care leading to depression with psychotic features.[53] Observed rates of increased provision of anti-psychotic medications among TGD youth may also be due to low dose prescriptions as an adjunct treatment for conditions such as severe depression and insomnia. The possible link between psychosis and TGD status warrants further exploration with well-validated psychiatric interviews.

While adjustment disorder, ADHD, cognitive, impulse control, personality, and miscellaneous diagnoses, substance use disorder, and conditions diagnosed in infancy or childhood (which includes autism) were significantly greater among TGD youth, differences were less pronounced. The finding of increased odds of conditions diagnosed in infancy and childhood, which includes autism, is consistent with previous research indicating increased odds of autism in TGD children and youth.[54,55] Developmental disorders and alcohol use disorders were not significantly increased among TGD youth.

Findings of increased psychotropic medication use (75% vs 38%) and medication days (111 vs 43 days per year) in TGD youth as compared to cisgender siblings are novel and corroborate prior studies indicating increased mental health needs in TGD youth.[2,3,14,15,17−21,30,31] Results are also consistent with findings that TGD adults were over 3 times as likely to use an antidepressant and/or anxiolytic,[41,61] but the current study is the first to examine psychotropic medications in youth, and include multiple medication classes. Consistent with increased care for anxiety, mood, and psychotic disorders; SSRIs, SNRIs, other antidepressants, Lithium, and anti-psychotics were all significantly increased in TGD youth (Table 3). TGD youth also had over 3 times as many sleep medication days as their cisgender siblings, results are consistent with research indicating a link between poor sleep duration/quality and depression/poor psychological well-being,[56,57] and suggests that screening for sleep concerns may be indicated in TGD care.

This study is among the first to analyze the associations of gender-affirming pharmaceutical treatment with mental health care patterns among TGD youth. Findings indicated that mental healthcare visits were not significantly changed and psychotropic medication use rose following gender-affirming pharmaceutical treatment after adjusting for potential confounders. Results are not consistent with adult and adolescent self-report survey research indicating improvements in mental health symptoms following gender-affirming care.[11,35−37,40,44] However, findings are consistent with one 10 year study which found visits for anxiety and mood disorders, and suicide attempt hospitalizations did not decrease following gender-affirming pharmaceutical care, but did decrease some following gender affirming surgery.[41,61] Findings that mental healthcare and psychotropic medications did not decrease after gender affirming care may be related to a number of factors. The median period following gender-affirming pharmaceutical care in the current study was relatively short (ie, 1.5 years), making it difficult to ascertain if the lack of a change in care patterns was related to continuing mental health problems, or represents the delivery of responsible mental healthcare that maintains a therapeutic relationship through a substantial life transition. Similarly, the period before initiation of gender affirming care was 7.1 years, making it possible that mental healthcare during the earlier portion of this period is not reflective of mental healthcare use patterns of youth with gender dysphoria, artificially deflating the rate of care in the period before gender affirming pharmaceutical care. Patients also age during the pretreatment period and mental health utilization may increase over time irrespective of gender affirming care.

Also, the sample in this study may differ from samples previously recruited from specialty transgender clinics. Military connected families are generally more conservative,[58] which may relate to the relatively low percentage receiving puberty blockers, and relatively older age of starting gender affirming pharmaceutical care. Military connected children and youth also have free mental healthcare and psychiatric medications through the age of 23, which may lower barriers to continued engagement in treatment of mental health conditions after gender transition. This

care would allow patients and clinicians to thoroughly address and treat all identified issues irrespective of gender-affirming treatment status, and maintain engagement in ongoing care even as symptoms begin to remit.[59]

The impact of access to high quality no-or low-cost mental healthcare available to the study population may impact mental healthcare and psychotropic medication trends, making results potentially less generalizable for adolescents and young adults in the United States. Although adults in the United States report some of the highest rates of mental health conditions, access to mental healthcare in the United States is reduced as compared to other high-income countries.[60]

Older age and fewer yearly visits were associated with decreased post-affirmation mental healthcare, and older age and male sex at birth were associated with decreased post-affirmation psychotropic medication prescriptions. Findings that older age was associated with decreased mental health and psychotropic care may suggest that parents were involved in scheduling and seeking mental healthcare and psychotropic medications for their younger children. Conversely, older youth who make their own medication decisions may have difficulties in scheduling care, or decide to reduce care they do not deem necessary. Alternatively, patients with higher levels of distress or engagement with mental health providers may be more likely to have parents that acknowledge their distress and consent for treatment.

Strengths of this study include the very large sample size, inclusion of data on psychiatric diagnoses, mental healthcare visits, and psychotropic medication use to assess mental health disparities, the extensive study period, the assessment of mental health care utilization following gender affirmation treatment, and the use of sibling controls. A sibling study group controls for household healthcare use, threshold for accessing mental healthcare, and gender socialization experience, but does not account for all differences between individuals. This study is limited by the use of healthcare data in the form of ICD-9/10 codes which cannot indicate the severity of diagnoses or the full breadth of complex TGD identities; however, the use of multiple indicators of mental health burden does mitigate this concern. The study is also limited by the short duration of care following gender-affirming pharmaceutical treatment, which may be insufficient to observe any clinically significant change. We were also unable to control for differing, regional, family level, and care provider acceptance, however within the military access to specialists can occur when requested. We also didn't distinguish puberty suppression from testosterone/estrogens as we were interested in pharmaceuticals as an indicator of treatment progression; however, it is possible that there are differences in outcomes for the 2 groups. Furthermore, the effect of affirming medical care may be confounded by increasing mental health disparities as TGD youth age (eg, due to increasing minority stress). Finally, results may have limited generalizability as military dependent youth face additional stressors, such as multiple moves and parental deployment, and benefit from high-quality free military healthcare until age 21 (or age 23 if in college), thereby potentially affecting post-affirming healthcare use patterns. The military population included in this study is likely substantially different than previous research which generally recruited youth from specialized TGD care clinics (which signals parental and family support). Available data did not allow for study of important intersections between cultural and ethnic factors which may predict outcomes such as healthcare utilization. While many adolescents included in this study received care for GD prior to age 18, many did not, and pharmaceutical affirmation was initiated after age 18 for over 50% of include youth. Therefore, results of this study may be more representative of the national population of TGD youth, some of whom receive parental support and some of whom self-report a lack of parental and family support, than the specialty clinic population used in many previous studies.

CONCLUSIONS

TGD youth have considerably greater mental health diagnoses, care, and psychotropic medication use across a range of diagnoses, as compared to their cisgender siblings. Results strongly support clinical recommendations for screening of mental health conditions in TGD youth and availability of healthcare for those in need. Additional research is needed to determine the long-term impact of gender-affirming care on psychiatric co-morbidities among TGD youth and young adults. While the need for mental health treatment appears to persist after the initiation of gender-affirming pharmaceutical treatment, longer term follow-up and care-specific analysis is needed to accurately understand changing care needs over time. Results may have policy implications as some states are currently considering limiting gender affirming care to adolescents.

DISCLAIMER

The contents of this article are solely the responsibility of the authors and do not necessarily represent the official views of the Uniformed Services University, the U.S. Air Force, the U.S. Navy, the U.S. Department of Defense, or the U.S. Government.

Corresponding Author: Elizabeth Hisle-Gorman, MSW, PhD, F. Edward Hébert School of Medicine - "America's Medical School", Uniformed Services University, Bethesda, MD 20814, USA. Tel: 301-221-7546/301-295-9726; Fax: 301-295-3898; E-mail: elizabeth.hisle-gorman.ctr@usuhs.edu

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STATEMENT OF AUTHORSHIP

Dr. Hisle-Gorman was responsible for conception and design of the study, analysis, and interpretation of results, drafting the article, and final approval of the paper.

Dr. Schvey was responsible for obtaining permission for data acquisition, assisting with the analysis plan, and revising the manuscript for intellectual content, and final approval of the paper.

Dr. Adirim was responsible for assisting with interpretation of results, revising the paper for critical content and final approval of the paper.

Dr. Rayne was responsible for helping to draft the paper, and approval of the final paper

Ms. Susi was responsible for acquisition of the data, and initial cleaning and analysis, revisiting the paper critically and approval of the final paper to be submitted.

Dr. Roberts was responsible for assisting with conception and design of the study, revising it critically for important intellectual content and approval of the final version to be submitted.

Dr. Klein was responsible for assisting with conception and design of the study, interpretation of results, revising the paper critically for important intellectual content, and final approval of the paper.

REFERENCES

1. Rafferty J, Committee On Psychosocial Aspects Of Child and Family Health Committee on Adolescence and Section on Lesbian, Gay, Bisexual and Transgender Health and Wellness. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. **Pediatrics 2018;142(4):1–16.**
2. Clark TC, Lucassen MF, Bullen P, et al. The health and well-being of transgender high school students: results from the New Zealand adolescent health survey (Youth'12). **J Adolesc Health 2014;55:93–99.**
3. Eisenberg ME, Gower AL, McMorris BJ. Risk and protective factors in the lives of transgender/gender nonconforming adolescents. **J Adolesc Health 2017;61:521–526.**

[4]. Herman JL, Flores AR, Brown TNT, et al. Age of Individuals who Identify as Transgender in the United States. Los Angeles, CA: UCLA School of Law; 2017.

5. Shields JP, Cohen R, Glassman JR, et al. Estimating population size and demographic characteristics of lesbian, gay, bisexual, and transgender youth in middle school. **J Adolesc Health 2013;52:248–250.**
6. Klein DA, Roberts TA, Adirim TA, et al. Transgender children and adolescents receiving care in the US military health care system. **JAMA Pediatr 2019;173:491–492.**
7. Zucker KJ. Epidemiology of gender dysphoria and transgender identity. **Sex Health 2017;14:404–411.**
8. Ewald ER, Guerino P, Dragon C, et al. Identifying medicare beneficiaries accessing transgender-related care in the era of ICD-10. **LGBT Health 2019;6:166–173.**
9. Handler T, Hojilla JC, Varghese R, et al. Trends in referrals to a pediatric transgender clinic. **Pediatrics 2019;144(5):1–9.**
10. Arnoldussen M, Steensma TD, Popma A, et al. Re-evaluation of the Dutch approach: are recently referred transgender youth different compared to earlier referrals? **Eur Child Adolesc Psychiatry 2020;29:803–811.**
11. Connolly MD, Zervos MJ, Barone 2nd CJ, et al. The mental health of transgender youth: advances in understanding. **J Adolesc Health 2016;59:489–495.**
12. Stall R, Matthews DD, Friedman MR, et al. The continuing development of health disparities research on lesbian, gay, bisexual, and transgender individuals. **Am J Public Health 2016;106:787–789.**
13. Adelson SL, American Academy of C, Adolescent Psychiatry Committee on Quality I. 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;51:957–974.**
14. Downing J, Conron K, Herman JL. Transgender and cisgender US veterans have few health differences. **Health Aff (Millwood) 2018;37:1160–1168.**
15. Dragon CN, Guerino P, Ewald E, et al. Transgender medicare beneficiaries and chronic conditions: exploring fee-for-service claims data. **LGBT Health 2017;4:404–411.**
16. Progovac AM, Cook BL, Mullin BO, et al. Identifying gender minority patients' health and health care needs in administrative claims data. **Health Aff (Millwood) 2018;37:413–420.**
17. Blosnich JR, Brown GR, Shipherd Phd JC, et al. Prevalence of gender identity disorder and suicide risk among transgender veterans utilizing veterans health administration care. **Am J Public Health 2013;103:e27–e32.**
18. Blosnich JR, Brown GR, Wojcio S, et al. Mortality among veterans with transgender-related diagnoses in the veterans health administration, FY2000-2009. **LGBT Health 2014;1:269–276.**
19. Lytle MC, Blosnich JR, Kamen C. The association of multiple identities with self-directed violence and depression among transgender individuals. **Suicide Life Threat Behav 2016;46:535–544.**
20. Veale JF, Watson RJ, Peter T, et al. Mental health disparities among Canadian transgender youth. **J Adolesc Health 2017;60:44–49.**
21. Reisner SL, Vetters R, Leclerc M, et al. Mental health of transgender youth in care at an adolescent urban community health center: a matched retrospective cohort study. **J Adolesc Health 2015;56:274–279.**
22. Blosnich JR, Marsiglio MC, Gao S, et al. Mental health of transgender veterans in US states with and without discrimination and hate crime legal protection. **Am J Public Health 2016;106:534–540.**

23. Bukowski LA, Blosnich J, Shipherd JC, et al. Exploring ural disparities in medical diagnoses among veterans with transgender-related diagnoses utilizing veterans health administration care. **Med Care 2017;55 Suppl 9(Suppl 2): S97–S103.**
24. Johns MM, Lowry R, Andrzejewski J, et al. Transgender identity and experiences of violence victimization, substance use, suicide risk, and sexual risk behaviors among high school students - 19 states and large urban school districts, 2017. **MMWR Morb Mortal Wkly Rep 2019;68:67–71.**
25. Olson J, Schrager SM, Belzer M, et al. Baseline physiologic and psychosocial characteristics of transgender youth seeking care for gender dysphoria. **J Adolesc Health 2015;57:374–380.**
26. Blosnich JR, Lehavot K, Glass JE, et al. Differences in alcohol use and alcohol-related health care among transgender and nontransgender adults: findings from the 2014 behavioral risk factor surveillance system. **J Stud Alcohol Drugs 2017; 78:861–866.**
27. Coulter RW, Blosnich JR, Bukowski LA, et al. Differences in alcohol use and alcohol-related problems between transgender- and nontransgender-identified young adults. **Drug Alcohol Depend 2015;154:251–259.**
28. Menino DD, Katz-Wise SL, Vetters R, et al. Associations between the length of time from transgender identity recognition to hormone initiation and smoking among transgender youth and young adults. **Transgend Health 2018;3:82–87.**
29. Wang Y, Yu H, Yang Y, et al. Mental health status of cisgender and gender-diverse secondary school students in China. **JAMA Netw Open 2020;3:e2022796.**
30. de Vries AL, Doreleijers TA, Steensma TD, et al. Psychiatric comorbidity in gender dysphoric adolescents. **J Child Psychol Psychiatry 2011;52:1195–1202.**
31. 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):1–13.**
32. Olson KR, Durwood L, DeMeules M, et al. Mental health of transgender children who are supported in their identities. **Pediatrics 2016;137:e20153223.**
33. Durwood L, McLaughlin KA, Olson KR. Mental health and self-worth in socially transitioned transgender youth. **J Am Acad Child Adolesc Psychiatry 2017;56:116–123.e2 116-123 e112.**
34. van der Miesen AIR, Steensma TD, de Vries ALC, et al. Psychological functioning in transgender adolescents before and after gender-affirmative care compared with cisgender general population peers. **J Adolesc Health 2020;66:699–704.**
35. de Vries AL, McGuire JK, Steensma TD, et al. Young adult psychological outcome after puberty suppression and gender reassignment. **Pediatrics 2014;134:696–704.**
36. Chew D, Anderson J, Williams K, et al. Hormonal treatment in young people with gender dysphoria: a systematic review. **Pediatrics 2018;141(4):1–20.**
37. de Vries AL, Steensma TD, Doreleijers TA, et al. Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. **J Sex Med 2011;8:2276–2283.**
38. Heylens G, Verroken C, De Cock S, et al. Effects of different steps in gender reassignment therapy on psychopathology: a prospective study of persons with a gender identity disorder. **J Sex Med 2014;11:119–126.**
39. Colizzi M, Costa R, Todarello O. Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: results from a longitudinal study. **Psychoneuroendocrinology 2014;39:65–73.**
40. Tucker RP, Testa RJ, Simpson TL, et al. Hormone therapy, gender affirmation surgery, and their association with recent suicidal ideation and depression symptoms in transgender veterans. **Psychol Med 2018;48:2329–2336.**
41. Branstrom R, Pachankis JE. Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: a total population study. **Am J Psychiatry 2020;177:727–734 appiajp201919010080.**
42. Kuper LE, Stewart S, Preston S, et al. Body dissatisfaction and mental health outcomes of youth on gender-affirming hormone therapy. **Pediatrics 2020;145(4):1–11.**
43. Turban JL, King D, Carswell JM, et al. Pubertal suppression for transgender youth and risk of suicidal ideation. **Pediatrics 2020;145(2):1–10.**
44. Murad MH, Elamin MB, Garcia MZ, et al. Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes. **Clin Endocrinol (Oxf) 2010;72:214–231.**
45. Branstrom R, Pachankis J. Reduction in mental health treatment utilization among transgender individuals after gender-affirming surgeries: A total population study - correction to branstrom and pachankis. **Am J Psychiatry 2020;177(8):734.**
46. Military One Source. 2019 Demographics Profile of the Military Community. 2019 Demographics Profile of the Military Community. Washington, DC: Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy; 2019 Department of Defense (DoD), Office of the Deputy Assistant Secretary fo Defense for Military Community and Family Policy.
47. Blosnich JR, Cashy J, Gordon AJ, et al. Using clinician text notes in electronic medical record data to validate transgender-related diagnosis codes. **J Am Med Inform Assoc 2018;25:905–908.**
48. HCUP Databases. Healthcare cost and utilization project (HCUP). Agency for healthcare reserach and quality published 2006-2009.
49. Hisle-Gorman E, Susi A, Gorman GH. Mental health trends in military pediatrics. **Psychiatr Serv 2019;70: 657–664.**
50. Perou R, Bitsko RH, Blumberg SJ, et al. Mental health surveillance among children—United States, 2005-2011. **MMWR Suppl 2013;62:1–35.**
51. Merikangas KR, He JP, Brody D. Prevalence and treatment of mental disorders among US children in the 2001-2004 NHANES. **Pediatrics 2010;125:75–81.**

52. Society for Adolescent Health and Medicine. Recommendations for promoting the health and well-being of lesbian, gay, bisexual, and transgender adolescents: a position paper of the society for adolescent health and medicine. **J Adolesc Health 2013;52:506–510.**
53. Coleman E, Bockting W, Botzer M, et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism; 2012. p. 165–232.
54. Smith WB, National LGBT Health Education Center A Program of the Fenway Institute. Caring for Transgender People with Severe Mental Illness. Caring for Transgender People with Severe Mental Illness. Boston, MA: The Fenway Institute; 2018.
55. Hisle-Gorman E, Landis CA, Susi A, et al. Gender dysphoria in children with Autism spectrum disorder. **LGBT Health 2019;6:95–100.**
56. Warrier V, Greenberg DM, Weir E, et al. Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals. **Nat Commun 2020;11:3959.**
57. Zhai K, Gao X, Wang G. The role of sleep quality in the psychological well-being of final year undergraduate students in China. **Int J Environ Res Public Health 2018;15 (12):2881–2893.**
58. Zhai L, Zhang H, Zhang D. Sleep duration and depression among adults: a meta-analysis of prospective studies. **Depress Anxiety 2015;32:664–670.**
59. Maniam S. U.S. veterans are generally supportive of Trump. **Pew Research Center 2017. https://www.pewresearch.org/fact-tank/2017/05/26/u-s-veterans-are-generally-supportive-of-trump/. Accessed June 29, 2021.**
60. Fraser L, Knudson G. Past and future challenges associated with standards of care for gender transitioning clients. **Psychiatr Clin North Am 2017;40:15–27.**
61. Tikkanen R, Fields K, Williams II R, et al. Mental health conditions and substance use: comparing U.S. needs and treatment capacity with those in other high-income countries. The commonwealth fund. Data brief web site. Available at: https://www.commonwealthfund.org/sites/default/files/2020-05/Tikkanen_-mental_hlt_intl_comparison_db.pdf. Accessed April 2, 2021.

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**TESTOSTERONE PRODUCTS (BRAND AND GENERIC)**
BRAND NAME (generic)	
	ANDRODERM (testosterone transdermal patch)
	ANDROGEL (testosterone topical gel)
	AXIRON (testosterone topical solution)
	DELATESTRYL (testosterone enanthate injection)
	DEPO-TESTOSTERONE (testosterone cypionate injection)
	FORTESTA (testosterone topical gel)
	NATESTO (testosterone nasal gel)
	STRIANT (testosterone mucoadhesive buccal system)
	TESTIM (testosterone topical gel)
	TESTOPEL (testosterone propionate implant pellets)
	(testosterone cream)
	(testosterone ointment)
	VOGELXO (testosterone topical gel)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Topical, buccal, nasal, implant, and injectable testosterone products are indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.
Primary hypogonadism (congenital or acquired) - testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter Syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range.
Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Limitations of Use
Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Safety and efficacy of topical, buccal, nasal, implant, and injectable testosterone products in males less than 18 years old have not been established.

Topical testosterone products may have different doses, strengths or application instructions that may result in different systemic exposure.

Delatestryl
Males
Delatestryl (Testosterone Enanthate Injection) is indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.
Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy.
Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. (Appropriate adrenal cortical and thyroid hormone replacement therapy are still necessary, however, and are actually of primary importance).
If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.
Safety and efficacy of Delatestryl in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
Delayed puberty - Delatestryl (Testosterone Enanthate Injection) may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.
Females
Metastatic Mammary Cancer - Delatestryl (Testosterone Enanthate Injection) may be used secondarily in women with advancing inoperable metastatic (skeletal) mammary cancer who are one to five years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or anti-estrogen therapy. This treatment has also been used in pre-menopausal women with breast cancer who have benefited from oophorectomy and are considered to a have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Testopel
Males
Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.
Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome: or orchiectomy.

Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.
If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.
Safety and efficacy of Testopel (testosterone pellets) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.
Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

COVERAGE CRITERIA

- Testosterone products will be covered with prior authorization when the following criteria are met:
  - The requested drug is being prescribed for primary or hypogonadotropic hypogonadism [Note: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
    AND
    - Before the start of testosterone therapy, the patient has at least two confirmed low testosterone levels according to current practice guidelines or your standard male lab reference values **OR**
    - For continuation of testosterone therapy: before the patient started testosterone therapy, the patient had a confirmed low testosterone level according to current practice guidelines or your standard male lab reference values

  OR
  - Delatestryl (testosterone enanthate injection) is being prescribed for inoperable metastatic breast cancer in a patient who is 1 to 5 years postmenopausal AND the patient had an incomplete response to other therapy for metastatic breast cancer

  OR
  - Delatestryl (testosterone enanthate injection) is being prescribed for a pre-menopausal patient with breast cancer who has benefited from oophorectomy and is considered to a have a hormone-responsive tumor

  OR
  - Delatestryl (testosterone enanthate injection) or Testopel (testosterone propionate implant pellets) is being prescribed for delayed puberty

REFERENCES

1. Androderm [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; July 2015.
2. Androgel 1% [package insert]. North Chicago, IL: Abbvie Inc; November 2016.
3. Androgel 1.62% [package insert]. North Chicago, IL: Abbvie Inc; October 2016.
4. Axiron [package insert]. Indianapolis, IN: Lilly USA, LLC; October 2016.
5. Delatestryl [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2015.
6. Depo-Testosterone [package insert]. New York, NY: Pharmacia and Upjohn Company; November 2016.
7. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; October 2016.
8. Natesto [package insert]. Malvern, PA: Endo Pharmaceuticals; July 2016.
9. Striant [package insert]. Malvern, PA: Endo Pharmaceuticals.; November 2016.
10. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc.; October 2016.
11. Testopel Pellets [package insert]. Malvern, PA: Auxilium Pharmaceuticals, Inc; October 2016.
12. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Labratories, Inc.; November 2016.
13. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 2016.
14. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed November 2016.
15. Petak S, Nankin H, Spark R, et al. American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hypogonadism in Adult Male Patients – 2002 update. *Endocrine Practice* 2002;8(6):439-456.

16. Bhasin S, Cunningham G, Hayes F, et al. Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism* 2010 95(6):2536-2559.

Reference number(s)
1973-A, 2078-A

SPECIALTY GUIDELINE MANAGEMENT

Supprelin LA (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Supprelin LA is indicated for the treatment of children with central precocious puberty (CPP).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

III. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Supprelin LA [package insert]. Malvern, PA: Endo Pharmaceuticals Solutions Inc.; May 2017.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.

3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.

Reference number(s)
1968-A, 2085-A

SPECIALTY GUIDELINE MANAGEMENT

TRELSTAR (triptorelin pamoate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Trelstar [package insert]. Parsippany, NJ: Watson Pharma; January 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.

Reference number(s)
2190-A, 2504-A

SPECIALTY GUIDELINE MANAGEMENT

TRIPTODUR (triptorelin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for the treatment of CPP in a female member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 8 years of age at the onset of secondary sexual characteristics.
2. Authorization up to age 13 may be granted for the treatment of CPP in a male member when all of the following criteria are met:
   a. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third generation LH assay.
   b. The assessment of bone age versus chronological age supports the diagnosis of CPP.
   c. The member was less than 9 years of age at the onset of secondary sexual characteristics.

III. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization up to age 12 may be granted for continuation of therapy for CPP in a female member if the member is currently less than 12 years of age.
2. Authorization up to age 13 may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age.

IV. REFERENCES

1. Triptodur [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; June 2018.
2. Kletter GB, Klein KO, Wong YY. A pediatrician's guide to central precocious puberty. *Clin Pediatr.* 2015;54:414-424.

3. Carel J, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123:e752-e762.
4. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics*. 2009;123:e1059-e1063.
5. Kaplowitz P, Bloch C, the Section on Endocrinology. Evaluation and referral of children with signs of early puberty. *Pediatrics*. 2016;137:e20153732.

Reference number(s)
1969-A, 2086-A

SPECIALTY GUIDELINE MANAGEMENT

VANTAS (histrelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Vantas [package insert]. Malvern, PA: Endo Pharmaceuticals; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.

Reference number(s)
1918-A, 1919-A

SPECIALTY GUIDELINE MANAGEMENT

ZOLADEX (goserelin acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Prostate cancer
   a. For use in combination with flutamide for the management of locally confined stage T2b-T4 (Stage B2-C) carcinoma of the prostate. Treatment with Zoladex and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.
   b. In the palliative treatment of advanced carcinoma of the prostate
2. Endometriosis
   For the management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with Zoladex for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months (Zoladex 3.6 mg strength only)
3. Endometrial thinning
   For use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding (Zoladex 3.6 mg strength only)
4. Advanced breast cancer
   For use in the palliative treatment of advanced breast cancer in pre-and perimenopausal women

B. Compendial Uses
1. Breast cancer
2. Prostate cancer

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions: Use of the 10.8 mg strength for diagnoses other than prostate cancer, breast cancer, and gender dysphoria (if applicable).

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer
Authorization of 12 months may be granted for the treatment of HR-positive breast cancer.

B. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

C. Endometriosis
Authorization of 6 months may be granted for treatment of endometriosis.

D. Endometrial-thinning agent
Authorization of 2 doses may be granted for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

V. REFERENCES

1. Zoladex 3.6mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2017.
2. Zoladex 10.8mg [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2017.
3. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 15, 2019.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: breast cancer. Version 3.2018. http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 15, 2019.
5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 2.2017. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.
6. Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in pre-menopausal women with estrogen receptor-positive advanced breast cancer. *Breast Cancer (Tokyo, Japan)*. 2016;23(5):771-779. doi:10.1007/s12282-015-0637-4.

Reference number(s)
1966-A, 2084-A

SPECIALTY GUIDELINE MANAGEMENT

ELIGARD (leuprolide acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
2. Metastatic androgen receptor positive salivary gland tumors

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

B. Salivary gland tumors
Authorization of 12 months may be granted for treatment of metastatic salivary gland tumors when the tumor is androgen receptor positive.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Eligard [package insert]. For Collins, CO: Tolmar Pharmaceuticals; February 2019.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.
3. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer. Version 4.2018. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed October 11, 2018.
4. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed October 11, 2018.

CVS caremark

5. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: head and neck tumors. Version 2.2018. http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed October 11, 2018.

UNITED STATES DISTRICT COURT
NORTH CAROLINA MIDDLE DISTRICT

MAXWELL KADEL, et al.,
Plaintiffs,
vs. Case No. 1:19-cv-00272-LCB-LPA
DALE FOLWELL, et al.,
Defendants.

THE DEPOSITION OF GEORGE R. BROWN, M.D.
September 23, 2021

PORTIONS ATTORNEYS' EYES ONLY

Reported by:
PATRICIA A. NILSEN, RMR, CRR, CRC
Licensed Court Reporter 717 for the State of Tennessee

Foundation. Object to the extent it's outside the scope of Dr. Brown's opinions.

A. So the short answer is no, but I also want to point out that the presence of symptoms is -- also has to be considered at a particular -- in a particular time frame. So it's not just a simple matter of, does the person experience gender dysphoria if they have transgender identity. They could have last year; they might have it next year; they don't have it today. It depends on where they are in time, and a variety of other parameters specific to the individual.

But it is true that there are transgender people who, sitting here today, if they were sitting here today, do not have gender dysphoria with little G, little D or big G, big D.

Q. Are there studies that identify the portion of -- the portion, prevalence, ratio of gender dysphoria, the diagnosis in transgender individuals?

MR. TISHYEVICH: Objection, to the extent it's beyond the scope of Dr. Brown's opinions.

A. The answer to that is, no one knows the answer to that.

of training.

So on a practical level, that's how it is often done in systems.

Q. Sure.

A. I can -- I can speak from my -- my system in the VA, in that what I've listed under 37 in the VA is -- is the case that all of our patients who are referred for hormonal interventions or surgical interventions have been evaluated by at least one qualified mental health professional.

Q. Sure. And I guess my -- my follow-up question is, is that required under the WPATH Version 7 Standards of Care?

MR. TISHYEVICH: Objection.

A. "Required" in the sense that they're flexible clinical guidelines, recognizing that they may not be met in all environments and in all countries -- because, again, this is international -- or in all states or in all sections of all states. So ...

Q. Leaving aside other countries, is -- is the flexibility you identify in the -- see if I can get this -- you made the statement that the -- that there is flexibility in the WPATH standard 7 -- Standards of Care; is that correct?

A. Correct.
Q. Is that flexibility identified in the specific recommendation that -- that an assessment can -- can occur after the -- the beginning of -- of hormone treatment or surgery, or is the assessment located in sort of the overall nature of the guidelines?
A. In -- in the beginning of the guidelines there's a -- there is verbiage to the effect that these are meant to be flexible standards, with the recognition that whatever standards you write on a specialty area, whether that's cardiology or interventional radiology or transgender healthcare, that there are going to be large swatches of -- of the world and the country, and given large states, that are not going to have what you might aspire to as the writer of a -- of a clinical practice guideline.

Which doesn't -- doesn't mean that the person isn't getting access to care and -- or access to competent care; it's just a recognition of the realities of scarcities of clinical resources, even in a country like the U.S.

Q. Sure.

COURT REPORTER: Just before we go

IN THE UNITED STATES DISTRICT COURT FOR
THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,)
)
Plaintiffs,)
) No. 1:19-cv-272-LCB-LPA
V.)
)
DALE FOLWELL, et al.,)
)
Defendants.)
)

DEPOSITION
OF
MICHAEL D. BUNTING

AUGUST 9, 2021

THIS TRANSCRIPT IS NOT COMPLETE
PORTIONS OF THIS TRANSCRIPT AND/OR EXHIBITS
MAY BE DESIGNATED CONFIDENTIAL/ATTORNEYS EYES ONLY
AFTER REVIEW OF TRANSCRIPT BY ATTORNEYS WITHIN 30
DAYS OF DATE OF DEPOSITION PER PROTECTIVE ORDER

PNC PLAZA DOWNTOWN
301 Fayetteville Street, Suite 1700
Raleigh, North Carolina

Reported by: Michelle Maar, RDR, RMR, FCRR

injection, this medication. The implant is a one-time, less painful procedure.

Q. Is that the only concern you had?

A. That is the only reason I can recall.

Q. Do you assert that the State Health Plan does not cover any of C[redacted]'s medical treatment?

MS. EVANS: Object to form.

THE WITNESS: Ask that again please -- make sure I understand you correctly.

BY MR. KNEPPER:

Q. Do you assert that the State Health Plan does not cover or pay for any of C[redacted]'s medical treatment?

MS. EVANS: Same objection.

THE WITNESS: No. I don't believe that.

BY MR. KNEPPER:

Q. Your concern and claim is that the State Health Plan does not cover treatment connected to C[redacted]'s gender dysphoria. Is that correct?

MS. EVANS: Object to form.

THE WITNESS: I believe I agree with that, yes.

BY MR. KNEPPER:

Q. Who is Echo Meyer?

A. A therapist.

Q. Who does Echo Meyer treat?

A. C[redacted]

UNITED STATES DISTRICT COURT
NORTH CAROLINA MIDDLE DISTRICT

MAXWELL KADEL, et al.,
Plaintiffs,
vs. Case No. 1:19-cv-00272-LCB-LPA
DALE FOLWELL, et al.,
Defendants.

THE DEPOSITION OF GEORGE R. BROWN, M.D.
September 23, 2021

PORTIONS ATTORNEYS' EYES ONLY

Reported by:
PATRICIA A. NILSEN, RMR, CRR, CRC
Licensed Court Reporter 717 for the State of Tennessee

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But it is true that there are transgender people who, sitting here today, if they were sitting here today, do not have gender dysphoria with little G, little D or big G, big D.

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So on a practical level, that's how it is often done in systems.

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Q. Sure.

COURT REPORTER: Just before we go

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, *et al.*,

Plaintiffs,

v.

No. 1:19-cv-272-LCB

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina; **DEE JONES,** in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees; **NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES**; and **STATE OF NORTH CAROLINA, DEPARTMENT OF PUBLIC SAFETY,**

Defendants.

DECLARATION OF BLUE CROSS BLUE SHIELD OF NORTH CAROLINA

I, AIMEE FOREHAND, on behalf of Blue Cross and Blue Shield of North Carolina ("BCBSNC"), state that to the best of my knowledge and based on a review of BCBSNC's records, the following is true and accurate:

1. BCBSNC is a non-profit medical services corporation, which is organized and existing under the laws of the State of North Carolina. BCBSNC is headquartered in Durham, North Carolina.

2. BCBSNC is the Third-Party Administrator ("TPA") of the North Carolina State Health Plan for Teacher and State Employees (the "State Health Plan" or the "Plan").

3. The State Health Plan is a self-funded customer of BCBSNC, which means that, in addition to deciding what benefits the Plan will provide to Plan participants each year, the Plan is also solely responsible for paying for all the benefits it has agreed to provide.

4. As TPA for the Plan, BCBSNC has a contract with the Plan to provide administrative services on behalf of the Plan. More specifically, after a participating, in-network healthcare provider provides a medical service to a Plan participant, the medical provider submits a claim to BCBSNC which processes the claim according to the terms of Plan and determines the amount of reimbursement that the healthcare provider will receive by the Plan for that service based on the terms of the Plan and the network participation agreement between BCBSNC and the participating provider.

5. The contract between the Plan and BCBSNC is an Administrative Services Only (hereafter "ASO") contract, which means that BCBSNC provides only administrative services that relate to the processing of the claims. BCBSNC has provided these services to the Plan for more than 30 years.

6. In addition to serving as a TPA for the Plan and other customers, BCBSNC also sells private health insurance to groups and individuals. BCBSNC uses its claims processing system and standards in the same manner for both its private health insurance business and its work as the TPA for the Plan. In both

circumstances, the BCBSNC operates in the manner accepted as the industry standard for the provision of healthcare benefits.

7. In accordance with industry practice, BCBSNC uses industry-standard procedural codes and diagnostic codes to determine whether a claim submitted to it by a healthcare provider for a specific medical treatment is compensable by the Plan. These diagnostic and procedural codes are not created by BCBSNC, but are uniform across the American health care, health benefits plan, and health insurance industries. Diagnostic codes are classification of diseases as provided by the ICD ("International Classification of Diseases"). Medical services and procedures are identified by a distinctive alphanumeric code known as CPT code ("Current Procedural Terminology"). Every medical service has its own unique CPT Code.

8. In order to request reimbursement for the medical service provided to a Plan participant, an in-network health care provider submits a claim to BCBSNC on an established industry form (either a CMS-1500 or UB-04 form depending on the type of provider; copies attached) or through an electronic billing agreement which requires the same information.

9. To receive reimbursement, a healthcare provider must submit a claim that contains both a diagnostic code and a corresponding procedural code (or, for facilities, a revenue code rather than a procedural code), among other information. This is the standard requirement across the national health insurance industry. Failure to submit both a diagnostic code and a corresponding procedural code results in denial of the claim.

10. When BCBSNC receives a claim for reimbursement from a provider, BCBSNC's automated claims systems reviews the claim to determine whether it is for a benefit covered by the Plan. If the medical treatment is a covered treatment, BCBSNC authorizes reimbursement to the healthcare provider by the Plan.

11. Each year, the State Health Plan creates a benefits booklet, which describes the benefits and reimbursement levels offered to eligible Plan participants. As TPA, BCBSNC receives and reviews the final Plan benefit booklet each year. BCBSNC is responsible for implementation of the benefits outlined in the benefit booklet. Because the benefits booklet does not contain or identify either procedural or diagnostic codes, BCBSNC—in consultation with the Plan staff—implements the coding for the benefits covered by the Plan.

12. When a healthcare provider performs a service for a Plan participant, the provider submits a claim to BCBSNC for reimbursement (as a benefit provided by the Plan). For more than 90% of claims submitted to BCBSNC for Plan beneficiaries, the process is automated, meaning it is processed electronically without being separately reviewed by a person.

13. As part of the claim submission, BCBSNC receives the name of the Plan participant, the name of the healthcare provider, the age and sex of the Plan participant, the ICD diagnostic code, and the CPT procedural Code, among other information. This is the industry-standard information required for claims submitted to insurance providers for reimbursement of expenses for medical services, and this information is submitted by the physician or other healthcare provider where the

physician or healthcare provider is a participating, in-network provider. BCBSNC has a publicly available manual for healthcare providers that advises them on what information must accompany a claim, and how to properly submit a claim.

14. As part of the claim submission process, BCBSNC does not request or require that the healthcare provider identify the transgender status of any person seeking medical care. The BCBSNC claim submission process does not include any method for the healthcare provider to submit this information, and the transgender status of any person is not recorded within the BCBSNC databases.

15. Certain claims require approval by BCBSNC before the medical service is provided to the Plan participant. BCBSNC and the State Health Plan jointly decide which claims will be subject to this preauthorization requirement. All inpatient surgical procedures require preauthorization. There is no separate or unique preauthorization requirement for claims submitted on behalf of individuals who identify as transgender.

16. Further, in determining whether to approve or deny a claim, BCBSNC does not consider whether the Plan participant identifies as transgender. More specifically, BCBSNC does not track whether any specific Plan participant identifies as transgender, cisgender, gender non-binary, etc. Thus, the transgender status of any person—or whether any person identifies as transgender—is not a fact that BCBSNC uses at any time to determine whether BCBSNC will approve a claim for benefits for State Health Plan participants.

17. BCBSNC processes claims for medical services provided to an individual who identifies as transgender in the exact same manner as BCBSNC processes claims for medical services provided to an individual who does not identify as transgender. BCBSNC process claims for medical services for gender non-binary individuals in the exact same manner as BCBSNC processes claims for medical services for an individual who identifies as neither transgender nor gender non-binary.

18. As noted above, in excess of 90% of submitted claims are approved by BCBSNC's claims-processing software. Claims not approved in this fashion because, for example, the software has identified a potential duplicate bill, are manually processed by BCBSNC employees. After this employee review, claims are approved or denied. Reasons to deny a claim include: incorrect coding (diagnosis or procedure), duplicative billing, failure to obtain prior authorization when required, or other reasons.

19. BCBSNC will not approve a claim, or preauthorization, for a service not covered by the Plan.

20. To the best of my knowledge, prior to January 1, 2017, in its implementation of the Plan Benefit Booklet, BCBSNC denied preauthorization for 4 specific surgeries, regardless of the diagnostic code.

Table 1

CPT Code	Description of Surgery
55970	Intersex Surgery, Male to Female
55980	Intersex Surgery, Female to Male

57335	Vaginoplasty for Intersex State
56805	Clitoroplasty for Intersex State

21. To best of my knowledge, prior to January 1, 2017, BCBSNC either denied preauthorization or reimbursement for claims for the following procedures when the procedural code is for treatment of one of two diagnostic codes: F64.0 (Transsexualism) or Z87.890 (Personal history of sex reassignment):

Table 2

CPT Code	Description of Surgery
54400	Insertion of Penile Prosthesis; non-inflatable (semi-rigid)
C1813	Prosthesis, Penile, Inflatable
54401	Insertion of Penile Prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of multi-component Inflatable Penile
54408	Repair Components(s) multi-component, Inflatable Penile
54410	Removal and replacement of all components(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal non-inflatable (semi-rigid) /inflatable
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of a non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54660	Insertion of Testicular Prosthesis (separate procedure)
55175	Scrotoplasty (simple)
55180	Scrotoplasty (complicated)
56800	Plastic Repair of Introitus
57291	Construction of artificial vagina (without graft)
57292	Construction of artificial vagina (with graft)
19316	Mastopexy
19318	Breast Reduction
57295	Revision (including removal) of prosthetic vaginal graft

57296	Revision (including removal) of prosthetic vagina graft
19325	Breast Augmentation with implant
17380	Electrolysis Epilation, each .5 hour

22. Although the industry-standard medical claim form requires a healthcare provider to identify the sex of the Plan participant, BCBSNC does not use the sex of the Plan participant to evaluate whether claims for the benefits identified above are covered by the Plan. This is true whether the claim is processed automatically or manually. Approval or denial of a claim is based solely on the procedural and diagnostic codes identified above.

23. Beginning on January 1, 2017, the Plan directed BCBSNC to approve claims when submitted with the procedures listed in Table 1—without regard to the diagnostic code—and in Table 2, when submitted with the two identified diagnostic codes.

24. Beginning on January 1, 2018, at the direction of the Plan, BCBSNC returned to its 1990-2016 claims processing rules, and thereafter denied claims for the above-referenced procedures because they were not included as benefits provided by the Plan.

25. BCBSNC would not approve a claim for cosmetic procedures for any Plan participant, regardless of the diagnostic code. The State Health Plan benefit booklet defines cosmetic services as not covered, and the Plan does not cover cosmetic surgeries. Accordingly, the following procedures, which, under the 1990-2016 claims processing rules described above, are considered cosmetic procedures, are not covered: shoulder shaping, chin contouring and implants, face lifts (unless as a

medically necessary part of other facial procedures), facial bone osteoplasty, forehead reduction and contouring, mandible reduction, mandible contouring or mandible augmentation, and chondrolaryngoplasty (tracheal shave).

26. BCBSNC does not process claims for the vast majority of pharmaceuticals or hormones, although it does process claims for the administration of some pharmaceuticals, e.g. intravenous infusions.

27. BCBSNC has never implemented the portion of the Plan's benefit booklets that excludes "surgery for psychological or emotion reasons." More specifically, BCBSNC does not have diagnostic codes or procedural codes connected to this language from the Plan's benefits book that would prevent any claim from being approved, without regard to whether the Plan participant identified as cisgender, transgender, gender non-binary, or otherwise.

28. BCBSNC processes all claims for behavioral health treatment to be potentially reimbursed by the Plan. For behavioral health treatment, healthcare provider payment requests are not screened by diagnosis. Rather, notwithstanding the language contained in the Plan's benefits book, BCBSNC authorizes payment for all behavioral health services, if they are otherwise within the Plan's benefits, regardless of the submitted diagnosis code. This has been true since at least 1990. BCBSNC claims processing does not distinguish between an individual diagnosed with gender dysphoria or another psychiatric diagnosis. Plan participants with claims for behavioral health treatment are not denied because the submitted claim identified gender dysphoria as the diagnosis.

29. BCBSNC, as TPA of the State Health Plan does not code or track whether Plan participants identify as transgender, cisgender, gender non-binary, or otherwise, and BCBSNC's implements the benefit booklets of the State Health Plan without denying coverage for any healthcare service on the basis of a Plan participant's identification as transgender, cisgender, gender non-binary, or otherwise.

I declare and verify under penalty of perjury that the foregoing is true and correct. Executed on November 30, 2021.

Aimee Forehand (Nov 30, 2021 12:14 EST)

Aimee Forehand
Director, State Health Plan
Blue Cross and Blue Shield of North Carolina

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

PICA

CARRIER

1. MEDICARE ☐ (Medicare#) MEDICAID ☐ (Medicaid#) TRICARE ☐ (ID#/DoD#) CHAMPVA ☐ (Member ID#) GROUP HEALTH PLAN ☐ (ID#) FECA BLK LUNG ☐ (ID#) OTHER ☐ (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M ☐ F ☐

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self ☐ Spouse ☐ Child ☐ Other ☐

7. INSURED'S ADDRESS (No., Street)

CITY | STATE

8. RESERVED FOR NUCC USE

CITY | STATE

ZIP CODE | TELEPHONE (Include Area Code) ( )

ZIP CODE | TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) ☐ YES ☐ NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M ☐ F ☐

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? ☐ YES ☐ NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? ☐ YES ☐ NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? ☐ YES ☐ NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below

SIGNED _____

PATIENT AND INSURED INFORMATION

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? ☐ YES ☐ NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24 A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1									NPI	
2									NPI	
3									NPI	
4									NPI	
5									NPI	
6									NPI	

PHYSICIAN OR SUPPLIER INFORMATION

25. FEDERAL TAX I.D. NUMBER SSN ☐ EIN ☐

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) ☐ YES ☐ NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. b.

33. BILLING PROVIDER INFO & PH # ( )

a. b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

BECAUSE THIS FORM IS USED BY VARIOUS GOVERNMENT AND PRIVATE HEALTH PROGRAMS, SEE SEPARATE INSTRUCTIONS ISSUED BY APPLICABLE PROGRAMS.

NOTICE: Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties.

REFERS TO GOVERNMENT PROGRAMS ONLY

MEDICARE AND TRICARE PAYMENTS: A patient's signature requests that payment be made and authorizes release of any information necessary to process the claim and certifies that the information provided in Blocks 1 through 12 is true, accurate and complete. In the case of a Medicare claim, the patient's signature authorizes any entity to release to Medicare medical and nonmedical information and whether the person has employer group health insurance, liability, no-fault, worker's compensation or other insurance which is responsible to pay for the services for which the Medicare claim is made. See 42 CFR 411.24(a). If item 9 is completed, the patient's signature authorizes release of the information to the health plan or agency shown. In Medicare assigned or TRICARE participation cases, the physician agrees to accept the charge determination of the Medicare carrier or TRICARE fiscal intermediary as the full charge and the patient is responsible only for the deductible, coinsurance and non-covered services. Coinsurance and the deductible are based upon the charge determination of the Medicare carrier or TRICARE fiscal intermediary if this is less than the charge submitted. TRICARE is not a health insurance program but makes payment for health benefits provided through certain affiliations with the Uniformed Services. Information on the patient's sponsor should be provided in those items captioned in "Insured"; i.e., items 1a, 4, 6, 7, 9, and 11.

BLACK LUNG AND FECA CLAIMS

The provider agrees to accept the amount paid by the Government as payment in full. See Black Lung and FECA instructions regarding required procedure and diagnosis coding systems.

SIGNATURE OF PHYSICIAN OR SUPPLIER (MEDICARE, TRICARE, FECA AND BLACK LUNG)

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete, 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law), 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI license #, or SSN) of the primary individual rendering each service is reported in the designated section.For services to be considered "incident to" a physician's professional services: 1) they must be rendered under the physician's direct supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of non-physicians must be included on the physician's bills.

For TRICARE claims, I further certify that I (or any employee) who rendered services am not an active duty member of the Uniformed Services or a civilian employee of the United States Government or a contract employee of the United States Government, either civilian or military (refer to 5 USC 5536). For Black-Lung claims, I further certify that the services performed were for a Black Lung-related disorder.

No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations (42 CFR 424.32).

NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.

NOTICE TO PATIENT ABOUT THE COLLECTION AND USE OF MEDICARE, TRICARE, FECA, AND BLACK LUNG INFORMATION (PRIVACY ACT STATEMENT)

We are authorized by CMS, TRICARE and OWCP to ask you for information needed in the administration of the Medicare, TRICARE, FECA, and Black Lung programs. Authority to collect information is in section 205(a), 1862, 1872 and 1874 of the Social Security Act as amended, 42 CFR 411.24(a) and 424.5(a) (6), and 44 USC 3101,41 CFR 101 et seq and 10 USC 1079 and 1086; 5 USC 8101 et seq; and 30 USC 901 et seq; 38 USC 613; E.O. 9397.

The information we obtain to complete claims under these programs is used to identify you and to determine your eligibility. It is also used to decide if the services and supplies you received are covered by these programs and to insure that proper payment is made.

The information may also be given to other providers of services, carriers, intermediaries, medical review boards, health plans, and other organizations or Federal agencies, for the effective administration of Federal provisions that require other third parties payers to pay primary to Federal program, and as otherwise necessary to administer these programs. For example, it may be necessary to disclose information about the benefits you have used to a hospital or doctor. Additional disclosures are made through routine uses for information contained in systems of records.

FOR MEDICARE CLAIMS: See the notice modifying system No. 09-70-0501, titled, 'Carrier Medicare Claims Record,' published in the Federal Register, Vol. 55 No. 177, page 37549, Wed. Sept. 12, 1990, or as updated and republished.

FOR OWCP CLAIMS: Department of Labor, Privacy Act of 1974, "Republication of Notice of Systems of Records," Federal Register Vol. 55 No. 40, Wed Feb. 28, 1990, See ESA-5, ESA-6, ESA-12, ESA-13, ESA-30, or as updated and republished.

FOR TRICARE CLAIMS: PRINCIPLE PURPOSE(S): To evaluate eligibility for medical care provided by civilian sources and to issue payment upon establishment of eligibility and determination that the services/supplies received are authorized by law.

ROUTINE USE(S): Information from claims and related documents may be given to the Dept. of Veterans Affairs, the Dept. of Health and Human Services and/or the Dept. of Transportation consistent with their statutory administrative responsibilities under TRICARE/CHAMPVA, to the Dept. of Justice for representation of the Secretary of Defense in civil actions, to the Internal Revenue Service, private collection agencies, and consumer reporting agencies in connection with recoupment claims; and to Congressional Offices in response to inquiries made at the request of the person to whom a record pertains. Appropriate disclosures may be made to other federal, state, local, foreign government agencies, private business entities, and individual providers of care, on matters relating to entitlement, claims adjudication, fraud, program abuse, utilization review, quality assurance, peer review, program integrity, third party liability, coordination of benefits, and civil and criminal litigation related to the operation of TRICARE.

DISCLOSURES: Voluntary; however, failure to provide information will result in delay in payment or may result in denial of claim. With the one exception discussed below, there are no penalties under these programs for refusing to supply information. However, failure to furnish information regarding the medical services rendered or the amount charged would prevent payment of claims under these programs. Failure to furnish any other information, such as name or claim number, would delay payment of the claim. Failure to provide medical information under FECA could be deemed an obstruction.

It is mandatory that you tell us if you know that another party is responsible for paying for your treatment. Section 1128B of the Social Security Act and 31 USC 3801-3812 provide penalties for withholding this information.

You should be aware that P.L. 100-503, the "Computer Matching and Privacy Protection Act of 1988", permits the government to verify information by way of computer matches.

MEDICAID PAYMENTS (PROVIDER CERTIFICATION)

I hereby agree to keep such records as are necessary to disclose fully the extent of services provided to individuals under the State's Title XIX plan and to furnish information regarding any payments claimed for providing such services as the State Agency or Dept. of Health and Human Services may request.

I further agree to accept, as payment in full, the amount paid by the Medicaid program for those claims submitted for payment under that program, with the exception of authorized deductible, coinsurance, co-payment or similar cost-sharing charge.

SIGNATURE OF PHYSICIAN (OR SUPPLIER): I certify that the services listed above were medically indicated and necessary to the health of this patient and were personally furnished by me or my employee under my personal direction.

NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1197. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. This address is for comments and/or suggestions only. DO NOT MAIL COMPLETED CLAIM FORMS TO THIS ADDRESS.

1	2	3a PAT. CNTL #	4 TYPE OF BILL
		b. MED. REC. #	
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM THROUGH
			7

8 PATIENT NAME	a	9 PATIENT ADDRESS	a
b		b	c d e

10 BIRTHDATE	11 SEX	ADMISSION 12 DATE	13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	CONDITION CODES 18	19	20	21	22	23	24	25	26	27	28	29 ACDT STATE	30

	31 OCCURRENCE CODE	DATE	32 OCCURRENCE CODE	DATE	33 OCCURRENCE CODE	DATE	34 OCCURRENCE CODE	DATE	35 OCCURRENCE SPAN CODE	FROM	THROUGH	36 OCCURRENCE SPAN CODE	FROM	THROUGH	37	
a																a
b																b

38		39 VALUE CODES CODE	AMOUNT	40 VALUE CODES CODE	AMOUNT	41 VALUE CODES CODE	AMOUNT
	a						
	b						
	c						
	d						

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1									1
2									2
3									3
4									4
5									5
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23		***PAGE ____ OF ____***	***CREATION DATE***		***TOTALS***				23

	50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI		
A							57		A
B							OTHER		B
C							PRV ID		C

	58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.	
A						A
B						B
C						C

	63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME	
A				A
B				B
C				C

66 DX	67	A	B	C	D	E	F	G	H	68
	I	J	K	L	M	N	O	P	Q	

69 ADMIT DX		70 PATIENT REASON DX	a	b	c	71 PPS CODE		72 ECI	a	b	c	73

74 PRINCIPAL PROCEDURE CODE	DATE	a. OTHER PROCEDURE CODE	DATE	b. OTHER PROCEDURE CODE	DATE	75
c. OTHER PROCEDURE CODE	DATE	d. OTHER PROCEDURE CODE	DATE	e. OTHER PROCEDURE CODE	DATE	

80 REMARKS	81CC			
	a			
	b			
	c			
	d			

76 ATTENDING	NPI	QUAL	
LAST		FIRST	
77 OPERATING	NPI	QUAL	
LAST		FIRST	
78 OTHER	NPI	QUAL	
LAST		FIRST	
79 OTHER	NPI	QUAL	
LAST		FIRST	

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

UB-04 NOTICE: **THE SUBMITTER OF THIS FORM UNDERSTANDS THAT MISREPRESENTATION OR FALSIFICATION OF ESSENTIAL INFORMATION AS REQUESTED BY THIS FORM, MAY SERVE AS THE BASIS FOR CIVIL MONETARTY PENALTIES AND ASSESSMENTS AND MAY UPON CONVICTION INCLUDE FINES AND/OR IMPRISONMENT UNDER FEDERAL AND/OR STATE LAW(S).**

Submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete. That the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts. The following certifications or verifications apply where pertinent to this Bill:

1. If third party benefits are indicated, the appropriate assignments by the insured /beneficiary and signature of the patient or parent or a legal guardian covering authorization to release information are on file. Determinations as to the release of medical and financial information should be guided by the patient or the patient's legal representative.
2. If patient occupied a private room or required private nursing for medical necessity, any required certifications are on file.
3. Physician's certifications and re-certifications, if required by contract or Federal regulations, are on file.
4. For Religious Non-Medical facilities, verifications and if necessary re-certifications of the patient's need for services are on file.
5. Signature of patient or his representative on certifications, authorization to release information, and payment request, as required by Federal Law and Regulations (42 USC 1935f, 42 CFR 424.36, 10 USC 1071 through 1086, 32 CFR 199) and any other applicable contract regulations, is on file.
6. The provider of care submitter acknowledges that the bill is in conformance with the Civil Rights Act of 1964 as amended. Records adequately describing services will be maintained and necessary information will be furnished to such governmental agencies as required by applicable law.
7. For Medicare Purposes: If the patient has indicated that other health insurance or a state medical assistance agency will pay part of his/her medical expenses and he/she wants information about his/her claim released to them upon request, necessary authorization is on file. The patient's signature on the provider's request to bill Medicare medical and non-medical information, including employment status, and whether the person has employer group health insurance which is responsible to pay for the services for which this Medicare claim is made.
8. For Medicaid purposes: The submitter understands that because payment and satisfaction of this claim will be from Federal and State funds, any false statements, documents, or concealment of a material fact are subject to prosecution under applicable Federal or State Laws.
9. For TRICARE Purposes:

   (a) The information on the face of this claim is true, accurate and complete to the best of the submitter's knowledge and belief, and services were medically necessary and appropriate for the health of the patient;

   (b) The patient has represented that by a reported residential address outside a military medical treatment facility catchment area he or she does not live within the catchment area of a U.S. military medical treatment facility, or if the patient resides within a catchment area of such a facility, a copy of Non-Availability Statement (DD Form 1251) is on file, or the physician has certified to a medical emergency in any instance where a copy of a Non-Availability Statement is not on file;

   (c) The patient or the patient's parent or guardian has responded directly to the provider's request to identify all health insurance coverage, and that all such coverage is identified on the face of the claim except that coverage which is exclusively supplemental payments to TRICARE-determined benefits;

   (d) The amount billed to TRICARE has been billed after all such coverage have been billed and paid excluding Medicaid, and the amount billed to TRICARE is that remaining claimed against TRICARE benefits;

   (e) The beneficiary's cost share has not been waived by consent or failure to exercise generally accepted billing and collection efforts; and,

   (f) Any hospital-based physician under contract, the cost of whose services are allocated in the charges included in this bill, is not an employee or member of the Uniformed Services. For purposes of this certification, an employee of the Uniformed Services is an employee, appointed in civil service (refer to 5 USC 2105), including part-time or intermittent employees, but excluding contract surgeons or other personal service contracts. Similarly, member of the Uniformed Services does not apply to reserve members of the Uniformed Services not on active duty.

   (g) Based on 42 United States Code 1395cc(a)(1)(j) all providers participating in Medicare must also participate in TRICARE for inpatient hospital services provided pursuant to admissions to hospitals occurring on or after January 1, 1987; and

   (h) If TRICARE benefits are to be paid in a participating status, the submitter of this claim agrees to submit this claim to the appropriate TRICARE claims processor. The provider of care submitter also agrees to accept the TRICARE determined reasonable charge as the total charge for the medical services or supplies listed on the claim form. The provider of care will accept the TRICARE-determined reasonable charge even if it is less than the billed amount, and also agrees to accept the amount paid by TRICARE combined with the cost-share amount and deductible amount, if any, paid by or on behalf of the patient as full payment for the listed medical services or supplies. The provider of care submitter will not attempt to collect from the patient (or his or her parent or guardian) amounts over the TRICARE determined reasonable charge. TRICARE will make any benefits payable directly to the provider of care, if the provider of care is a participating provider.

SEE http://www.nubc.org/ FOR MORE INFORMATION ON UB-04 DATA ELEMENT AND PRINTING SPECIFICATIONS

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

MAXWELL KADEL, et al.,
Plaintiffs,
vs.
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,
Defendants.

VIRTUAL ZOOM VIDEOTAPED DEPOSITION OF PETER ROBIE, M.D.
(Taken by Plaintiffs)
Winston-Salem, North Carolina
Wednesday, September 22, 2021

Reported by Andrea L. Kingsley, RPR

center for a long time. We are the biggest center for the poor in the state of North Carolina. I think I mentioned that earlier. So not only an urgent care, minor emergency room setting, but to primary care office, we deal with the issues of diagnosing all kinds of problems, cancer diagnosis, I just did that two days ago, making the appropriate arrangements. So I'm very much a part of the day-to-day medical world is the point I want to make. I just want that to be -- everyone to be aware that I'm in the trenches a lot these days because of COVID treating very sick people.

Q. Earlier Ms. Ravi was asking questions about -- I'm going to sneak up here so I can get in the camera -- Ms. Ravi was asking you questions about when it's necessary to determine or to confirm a patient or potential patient's chromosomal sex. I would like for you talk about as a treating physician when you're diagnosing a patient, for the entirety of your career, is it true that it has been important to know whether the person you are treating, that person's gender, whether it was ultimately confirmed on a chromosomal level or not?

A. Well, one issue that comes to mind is heart disease, vascular disease, cardiovascular

disease. The American Heart Association has five risk factors for vascular disease, heart attacks if you will, male sex, biological male sex, smoking, diabetes, hypertension, high cholesterol, you can also throw in family history in the mix if you want. Obviously, if a trans female comes in and they're biologically male and we don't know that, we might not be preventively treating them for a heart attack because we're not aware their chromosomal sex is male which increases their risk of cardiovascular death. Blood pressure readings and the cholesterol readings for a biological male are stricter given the number of risk factors they have compared to the female.

Q. Would you agree with the statement that as a physician who has been practicing internal medicine for over 40 years, that part of diagnosing the problems of a patient includes knowing whether that person is biological male or female?

A. Yes. With regards to cardiovascular disease which is the number one killer in the United States, in terms of preventing that cardiovascular disease, that would be important to know. That's the American Heart Association recommendations.

transgender care. To me the upsetness is equal. But the plan is trying to be financially solvent.

When I became a trustee, my goal was not to limit increases in cost, my goal was trying to cut the cost of healthcare for our state workers, especially our teachers, some of these individuals are paying 20, 25 percent of their monthly income on healthcare on the State Health Plan that they choose, and I would like to see the cost go down, not be stationary or go up to cover things like transgender. I'm looking for ways we can do all we can do and reduce the amount of charge to the State Health Plan member. Trying to help our teachers out. I think, again, that gets back to the fiduciary duty, do the best you can to be prudent but to help our state teachers and workers, state workers as much as we can so they get the best healthcare they can without financially really being a burden on them like we are now.

Q. As a board member making the difficult decision that you have to make individually and collectively as a member of the board because the factor of the potential number of State Health Plan members who you can reach with an added benefit, does that factor into your decision making process?

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

MAXWELL KADEL, et al.,	)	
	)	
Plaintiffs,	)	
	)	
-vs-	)	Civil Action No.
	)	1:19-cv-00272
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,	)	
	)	
Defendants.	)	

The videotaped videoconference deposition of RANDI C. ETTNER, Ph.D., reported remotely by JUNE M. FUNKHOUSER, CSR, RMR, and Notary Public, pursuant to the Federal Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, commencing at 9:35 a.m. on October 15, 2021.

dysphoria?

A First I'd like to correct the statement that the specific study done at the University of Minnesota is upcoming.

Q Okay.

A It's already been published. It was actually spoken about on Good Morning America. I'm not an epidemiologist, so I cannot really give an answer about prevalence or incidence of any medical condition.

Q Do all transgender individuals suffer from gender dysphoria?

A No.

Q Are all individuals suffering from gender dysphoria transgender?

A Yes.

Q Is there an article that you would cite to support that conclusion?

A Well, gender dysphoria by definition includes a portion of the transgender or gender-nonconforming population.

Q So we've used a couple of terms, and I just would like you to define them as you used them. So what does it mean to be -- the

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

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MAXWELL KADEL, et al.,

Plaintiffs,

vs. Case No. 1:19-cv-272-LCB-LPA

DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,

Defendants.

~~~~~~~~~~~~~~~~~~~~

Video Deposition of
STEPHEN B. LEVINE, M.D.

September 10, 2021
9:05 a.m.

Taken at:
Veritext Legal Solutions
1100 Superior Avenue
Cleveland, Ohio

Tracy Morse, RPR

substance abuse, they didn't distinguish between trans and -- statistically, but other studies have indicated that everything else, like suicide in the last thirty days, thinking about suicide in the last thirty days, making a suicide attempt, substance abuse, it's all higher in the trans community.

It's not low in sexual minority communities. Either is domestic violence in either of those communities, but it's much less in the trans -- in the lesbian and gay community than it is in the straight -- in the trans community. And it's even less in the straight community, but obviously we have these same problems in the straight community, the cis gender community.

Q. Return to the question. Do you consider surgery for the treatment of gender dysphoria to be experimental?

MR. CHARLES: I object to form.

A. I have the same answer that I had to the hormonal question and for the same reasons.

Q. Do all transgender people suffer from a gender dysphoria?

A. No.

Q. Are there any studies or scientifically valid research that indicates what percentage of transgender people suffer from gender dysphoria?

MR. CHARLES: Object to form.

A. What percentage of transgender people suffer from gender dysphoria? I don't think -- I can't recall a study that asks that question and use -- and had numbers to explain the answer. People like myself get to see individuals who are transgender but not dysphoric or who are dysphoric but not transgender.

Q. That was going to be my followup question. Are there people who are dysphoric who are not transgender?

A. Oh, yes. Oh, yes. Many years ago, before I ever got involved with any lawyer about these issues, I remember recommending to a group of alcohol specialists that they ought to look at the gender identity -- they ought to ask questions about the sexual identity of the people being treated for substance abuse and alcoholism. Because in my limited clinical

experience, I've run into -- I keep running into people who presented with substance abuse and really dangerous degrees of substance abuse that would get them hospitalized.

And then when I talked to them, they tell me stories about their hidden gender dysphoria or their struggles about -- let me just take a man, for example -- the struggles about the sense that they have that they're feminine and they can't -- they have feminine interests, they have feminine interests but social -- and they have a sense of themselves as more feminine than masculine and yet they are too afraid to show it and then they drink themselves into hepatitis or whatever.

Q. But you would not consider those individuals to be transgender?

A. Well, they don't call themselves transgender. They present themselves as cis gender people.

MR. KNEPPER: That's all I have. Carl, do you have any follow up?

MR. CHARLES: What time is your flight?

MR. KNEPPER: 7:15.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

MAXWELL KADEL, et al.,
Plaintiffs,
vs.
DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, et al.,
Defendants,

DEPOSITION OF DAN H. KARASIC, M.D.

Remote
September 20, 2021
9:00 a.m. Pacific Time

Prepared by:
Vicki L. O'Ceallaigh Champion, CR
Certificate No. 50534

Prepared for:

(Certified copy)

actually a question. I think you were characterizing his testimony, which I don't know if that's a question or you were going to ask a question after --

MR. KNEPPER: Hold on. Hold on. I stopped, because I wanted to let Dr. Karasic speak.

MR. HASKEL: Okay.

MR. KNEPPER: I absolutely will finish my question, but I want to give the Witness -- when he raised his finger and said he wanted to say something, I wanted to give him an opportunity to make sure that I was saying something correctly.

BY MR. KNEPPER:

Q. So go ahead, Dr. Karasic.

A. So on that last answer, I was saying in the example I was giving was a "no" to the question of do all transgender people also have a diagnosis of gender dysphoria, and I was giving an example that related to the difference between gender dysphoria and gender incongruence of ICD-11, so just to clarify my answer --

Q. Thank you. That does -- that does clarify for me.

I'm going to ask you the converse question now. Do all individuals -- are all individuals who

suffer from gender dysphoria, the psychiatric DSM-5 diagnosis, transgender?

MR. HASKEL: Objection to form, foundation.

A. So being transgender is an identity. So there are -- you know, there are different ways to define it. I think we tend to think about people who identify as transgender and then to look at that, you know, another -- if we are looking at differences between the term "transgender" and "gender dysphoria," that gender dysphoria is a symptom or a diagnosis. Transgender is a diagnosis -- I mean, an identity. I'm sorry -- an identity.

And so there may be people who have symptoms of gender dysphoria, but they personally don't identify as transgender. Similarly, to give an example, there can be people who have same-sex attraction, but don't identify as either lesbian or bisexual.

BY MR. KNEPPER:

Q. Are there any peer reviewed studies that attempt to quantify that distinction between the number of individuals who suffer from gender dysphoria and the number of individuals who claim a