NO. 22-1721

In The

United States Court Of Appeals

For The Fourth Circuit

MAXWELL KADEL; JASON FLECK; CONNOR THONEN-FLECK; JULIA MCKEOWN; MICHAEL D. BUNTING, JR.; C.B., by his next friends and parents; SAM SILVAINE; DANA CARAWAY,

Plaintiffs – Appellees,

v.

DALE FOLWELL, in his official capacity as State Treasurer of N.C.; DEE JONES, in her official capacity as executive Administrator of the N.C. State Health Plan for Teachers and State Employees,

Defendants – Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA AT GREENSBORO

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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

STATE HEALTH PLAN DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTIONS TO EXCLUDE EXPERT TESTIMONY

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I. Introduction

The State Health Plan, Dale Folwell, and Dee Jones ("Plan Defendants"), hereby provide this single Response in Opposition to Plaintiffs' multiple motions to Exclude expert testimony from Dr. Peter Robie, Dr. Paul W. Hruz, Dr. Paul R. McHugh, Dr. Patrick W. Lappert, and Dr. Stephen B. Levine. Docs. 202-09, 212-13.

Plaintiffs assert these doctors are not qualified to testify as experts; that their testimony is "irrelevant;" and/or that portions of their testimony would be "unreliable" or "patently false." *See*, *e.g.*, Doc. 205 at 4-23. In fact, these individuals are highly respected medical professionals with publications and practice experience in relevant fields. Plaintiffs' attempt to dismiss their qualifications—on the basis of ideological disagreement—misses the mark. Furthermore, opinions regarding the efficacy of certain medical treatments are directly relevant to the Plaintiffs' allegations of discrimination. Plaintiffs' criticism of these opinions' relevance and reliability not only misconstrues the facts but also seeks to usurp the role of the factfinder in weighing the importance and accuracy of those facts. The Plan Defendants ask this Court to deny the Plaintiffs' Motions to Exclude Expert Testimony.

II. Legal Standard

Rule 702 of the Federal Rules of Evidence provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to

understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. The Supreme Court has held that this requires the district court to determine that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993); *see Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995) (*Daubert* and Fed. R. Evid. 702 superseded *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).).

At the outset, the district court must consider the expert's qualifications to offer testimony, including his professional record and "full range of experience and training." *Belk, Inc. v. Meyer Corp.*, 679 F.3d 146, 162 (4th Cir. 2012). But expert testimony may rest on knowledge, skill, experience, training, or education. "These are disjunctive; an expert can qualify to testify on any one of the grounds." *Cooper v. Laboratory Corp. of America Holdings*, 150 F.3d 376, 380 (4th Cir. 1998) (citing *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). As a result, "although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert." *U.S. v. Young*, 916 F.3d 368, 381 (4th Cir. 2019) (citing *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017)).

In assessing reliability, the district court may consider (1) whether the expert's reasoning can be tested, (2) whether the expert's reasoning is subject to peer review and publications, (3) the rate of error, and (4) the level of acceptance of the expert's reasoning in the relevant professional community. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149-50 (1999); *see Daubert*, 509 U.S. at 593-94. However, the court has "broad latitude" to determine whether these factors are "reasonable measures of reliability in a particular case." *Kumho*, 526 U.S. at 153. The Fourth Circuit has emphasized that Rule 702 liberalizes the presentation of relevant expert testimony, so the reliability analysis need not determine the expert testimony is irrefutable or certainly correct. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). Instead, when expert testimony relies on experiential qualification, the court should consider "how [the expert's] experience leads to the conclusion reached, why [the expert's] experience is a sufficient basis for the opinion, and how [the expert's] experience is reliably applied to the facts." *U.S. v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007).

Under Rule 702, expert testimony is relevant if it has "a valid scientific connection to the pertinent inquiry" and helps "the trier of fact to understand the evidence or to determine a fact in issue." *Daubert*, 509 U.S. at 591-92. The Fourth Circuit has held that in a case where evidence is "complicated, touching by necessity on a wide variety of ideas, terms, people, and

organizations connected to" the topic at hand, expert testimony is relevant to help the factfinder understand evidence related to the motives of the relevant actors. *U.S. v. Benkahla*, 530 F.3d 300, 309 (4th Cir. 2008).

Significantly, the Supreme Court has instructed district courts, "as gatekeeper, [to] conduct[ ] a flexible inquiry, focusing on the principles and methodology employed by the expert rather than the conclusions reached." *Smith v. Wyeth-Ayerst Laboratories Co.*, 278 F.Supp.2d 684, 690 (W.D.N.C. Apr. 17, 2003) (citing *Daubert*, 509 U.S. at 594-95). After all, a district court's gatekeeping role "is not intended to serve as a replacement for the adversary system, and consequently, the rejection of expert testimony is the exception rather than the rule." *In re Lipitor Mktg.*, 892 F.3d 624, 631 (4th Cir. 2018).

III. Drs. Levine, McHugh, Hruz, Lappert, and Robie are highly qualified to testify as experts.

A. Plaintiffs seek to improperly constrain the scope of "knowledge, skill, experience, training, or education" under Rule 702.

Plaintiffs assert that the challenged experts lack the requisite "knowledge, skill, experience, training, or education," making their testimony inherently unreliable. Doc. 203 at 8; Doc. 207 at 6; Doc. 213 at 22. Plaintiffs' claim relies on their view that these experts have limited experience with providing direct medical treatment to transgender patients and publishing "original or peer-reviewed research about gender identity, transgender people,

or gender dysphoria." Doc. 207 at 6; *see generally* Doc. 203 at 8-10, Doc. 205 at 5-8, Doc. 209 at 6-8, Doc. 213 at 20-22.

But this assertion directly contradicts the Fourth Circuit's analysis for expert qualification. An expert's research work is straightforwardly not dispositive: "although publishing in a peer-reviewed publication is often a hallmark of expert witness reliability, that hallmark is a guidepost, not a mandatory prerequisite to qualification as an expert." *Young*, 916 F.3d at 381. Similarly, by focusing only on "experience" and "training," Plaintiffs ignore the Fourth Circuit's instructions that "an expert can qualify to testify on any one of the grounds." *Cooper*, 150 F.3d at 380 (emphasis added). Here, the challenged experts' knowledge, skill, and education—as summarized below—are more than adequate to establish specialized knowledge of the matters at hand.

Furthermore, Plaintiffs rely heavily on the purported principle that "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony," citing two federal district court decisions from Illinois and a single holding from a different court of appeals. *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362 at *2 (N.D. Ill. Aug. 30, 2007); *see also O'Conner v. Commonwealth Edison*, 807 F.Supp. 1376 (C.D. Ill. 1992); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352 (11th Cir. 2014). These cases are non-binding, of course, but Plaintiffs also

apply them in a misleading way. In claiming the challenged experts are not qualified simply because they have not performed narrowly-defined medical procedures or published in specific journals, Plaintiffs artificially constrain the "technical area" of the substantive issues at hand.

Instead, consistent with the inclusive approach mandated by Rule 702, this Court should recognize that a multitude of medical specialties—including, but not limited to, endocrinology, psychiatry, and plastic surgery—relate to the treatment of transgender individuals. Under this view, the challenged experts clearly have an extensive substantive basis to offer opinions on the relevant factual disputes, as summarized in the following subsections.

1. Dr. Levine

Dr. Levine is a licensed physician and, currently, Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. Dr. Levine maintains an active private clinical practice, and he specializes in treatment of sexual identity issues, sexual problems, and the relationship between love, intimacy, and mental health. Dr. Levine first encountered a patient with gender dysphoria in July 1973, and he founded the Case Western Reserve University Gender Identity Clinic in 1974. He still serves as Co-Director of that clinic, having evaluated and treated hundreds of patients with transgender identities. Dr. Levine was an early member of the Harry Benjamin International Gender Dysphoria Association (now known as

WPATH) and served as Chairman of the WPATH committee that developed the fifth edition of the Standards of Care. Dr. Levine is a Distinguished Life Fellow of the American Psychiatric Association and has lectured frequently to professional groups on transgender identity and other issues related to human sexuality. Exhibit 1, Declaration of Dr. Levine.

2. Dr. McHugh

Dr. McHugh is a licensed psychiatrist and tenured professor at the Johns Hopkins University School of Medicine. Dr McHugh was Chairman of Psychiatry at Johns Hopkins Medical School and psychiatrist in chief at the JH Hospitals for 30 years. Dr McHugh also served as the Chairman of the Medical Board of the entire Johns Hopkins University Hospital. He has published many peer-reviewed articles, books, and chapters in relevant areas including diagnosis, treatment efficacy, and the history of methodological errors in psychiatry. Dr. McHugh was elected to the Institute of Medicine of the National Academies of Science in 1992. Dr. McHugh is also a Distinguished Life Fellow of the American Psychiatric Association. Exhibit 2, Declaration of Dr. McHugh.

3. Dr. Hruz

Dr. Hruz is an M.D./Ph.D specialist in pediatric endocrinology at Washington University School of Medicine in St. Louis, Missouri where he also serves as Associate Professor of Cellular Biology and Physiology in the Division

of Biology and Biological Sciences. At this institution, Dr. Hruz served as Chief of the Division of Pediatric Endocrinology and Diabetes from 2012 to 2017 and as Director of the Pediatric Endocrinology Fellowship Program from 2008 to 2016. Dr. Hruz has published sixty scholarly articles over his academic career, including peer-reviewed articles in leading journals on metabolism, cardiology, HIV, and ethics. Dr. Hruz has participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development, and he was a founding member of the school's multidisciplinary Disorders of Sexual Development program. Dr. Hruz has extensively studied the scientific literature related to the incidence, potential etiology, and treatment of gender dysphoria. Exhibit 3, Declaration of Dr. Hruz.

4. Dr. Lappert

Dr. Lappert is a licensed physician and, until his recent retirement from surgical practice, a board-certified plastic and reconstructive surgeon. Dr. Lappert has broad experience through his twenty-year career as a flight surgeon with the United States Navy. While serving in uniform, Dr. Lappert was Chairman of the Department of Plastic and Reconstructive Surgery at the Naval Hospital in Portsmouth, Virginia, and Specialty Leader for Plastic and Reconstructive Surgery for the Surgeon General of the Navy. As a physician and surgeon, Dr. Lappert has treated thousands of patients in seven states and four foreign countries. He has personal experience with the surgical

procedures performed as part of sex reassignment surgery, although he performed these surgeries for other purposes (such as reconstruction of the genitals after cancer) rather than for treatment of gender dysphoria. Exhibit 4, Declaration of Dr. Lappert.

5. Dr. Robie

Dr. Robie is a licensed primary care physician with more than forty-seven years of clinical experience. Dr. Robie has served as Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine for the Wake Forest School of Medicine since 1981. Exhibit 5, Disclosure of Dr. Robie.

Unlike the other experts for Plan Defendants, Dr. Robie does not seek to provide testimony on the efficacy of gender dysphoria treatment or the lack thereof. As a member of the Plan's Board of Trustees, and as a physician, Dr. Robie has contributed his medical knowledge to Board deliberations. Dr. Robie will testify to the medical knowledge he shared with other Board members. In addition, as an expert in the diagnostic process, he will testify that physicians must know the biological sex of patients to provide competent medical care. Exhibit 5.

B. Plaintiffs seek to exclude the challenged experts based on their conclusions rather than their qualifications and methodology.

Tellingly, Plaintiffs repeatedly suggest that the challenged experts are not qualified to testify because of their unfamiliarity or disagreement with the World Professional Association for Transgender Health's ("WPATH") standards of care for transgender individuals. Doc. 203 at 8-9, Doc. 205 at 13-14, Doc. 207 at 6-7, Doc. 209 at 14-15. If adopted, this principle would systematically exclude any testimony presenting an opinion that diverges from Plaintiffs' desired conclusions. For example, if an expert may not testify unless he or she has provided "gender-affirming surgery," then no expert with reservations about such procedures could ever be heard by this Court. Under Plaintiffs' approach, Rule 702 analysis would ask not whether the expert evidence would "assist the trier of fact to understand the evidence or to determine a fact in issue," but instead whether it would help the jury to adopt Plaintiffs' understanding of that fact.

This self-serving approach misunderstands the function of Rule 702 and the role of expert testimony. For the reasons outlined below, the lack of consensus among the medical community will play an important role in the factual resolution of Plaintiffs' equal protection claims. Plaintiffs observe this lack of consensus and conclude that any disagreement with their view of transgender medical treatment is inherently unreliable. But the very

existence of such disagreement highlights the need for the jury to consider the different expert perspectives in its assessment of the motives for Plan Defendants' coverage decisions.

IV. The testimony of Drs. Robie, Hruz, McHugh, Lappert, and Levine speaks directly to dispositive factual questions.

A. The challenged experts address the medical necessity of Plaintiffs' desired treatments.

Plaintiffs argue that their enrollment in the State Health Plan entitles them to coverage for all "medically necessary pharmacy benefits, mental health benefits, and medical care such as surgical benefits." Doc. 75 at 15. This is a faulty assumption, because medical necessity informs, but does not dictate, the Plan's coverage decisions. *See* Doc. 197 at 31-34. Regardless, Plaintiffs seek damages and injunctive relief for the denial of "medically necessary hormone therapy or gender-confirming surgical care," Doc. 75 at 21, and "medically necessary surgery," *id.* at 26. Plaintiffs assert "that gender-confirming health care can be medically necessary and even life-saving," *id.* at 2, to support their conclusion that the Plan discriminates by "categorically excluding all coverage for [this] medically necessary" treatment, *id.* at 37.

Accordingly, the medical necessity of Plaintiffs' desired treatments is a factual question at the core of their requests for relief. If Plaintiffs argue that the Plan necessarily discriminates by excluding coverage for "medically necessary" care, they must establish that the specific surgery and hormone

therapy they seek is medically necessary. Sweeping assertions about the "life-saving" value of these treatments, and conclusory reliance on the WPATH standards (which are now 10 years old and increasingly controversial), present only one perspective on this factual question, which the factfinder need not necessarily credit. The challenged expert testimony provides scientific information that will be essential to the jury's ultimate determination whether the Plaintiffs' desired treatments are "medically necessary." Thus, these experts will help "the trier of fact to understand the evidence or to determine a fact in issue," and their testimony is relevant and admissible pursuant to Rule 702 and *Daubert*, 509 U.S. at 591-92.

B. The challenged experts address the motives for the Plan Defendants' coverage decisions.

Plaintiffs seek to establish discrimination by claiming that "denying coverage for such health care necessarily discriminates against transgender people." Doc. 75 at 15. Plaintiffs also allege, however, that "NCSHP's actual motivations matter to the analysis" and present Plan policy documents and public statements. Doc. 179 at 26. In particular, Treasurer Folwell's most prominent statement regarding the Plan's coverage decision specifically points to "the legal and medical uncertainty of this elective, non-emergency procedure." Exhibit 6, Statement of the Treasurer. Accordingly, Plaintiffs' discrimination claims hinge in large part on whether this statement is

accurate. If there is "medical uncertainty" regarding Plaintiffs' desired procedures, then the Plan has presented a compelling alternative explanation to Plaintiffs' allegations of discrimination. The Fourth Circuit has held that expert testimony is relevant when it helps the jury to understand motive in scenarios with complex competing factors. *Benkahla*, 530 F.3d at 309. That is the case here.

V. Plaintiffs' challenges to the reliability of Drs. Robie, Hruz, McHugh, Lappert, and Levine are irrelevant and misleading.

A. The validity of and scientific basis for the WPATH Standards are matters of considerable dispute that must be resolved by the trier of fact.

Throughout their filings, Plaintiffs rely extensively upon the WPATH standards referenced above. *See, e.g.*, Doc. 213 at 9-10, 12-13. This reliance highlights a fundamental error in their motions to exclude expert testimony.

As noted by Dr. Levine, who was one of the early members of the organization now called WPATH, "[m]ost psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH" and "[m]any psychiatrists and psychologists who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH." Ex. 1 at 38. "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." *Id.* at 38-39. Put another way, the WPATH guidelines are not "the product of reliable principles and methods." Fed. R. Evid. 702(c). WPATH does not qualify as a scientific organization because it allows participation by lay members. Furthermore, the WPATH guidelines are adopted by a voting process, rather than a peer review process, and they do not follow the national guidelines intended to prevent adoption of standards that are tainted by financial conflicts of interest.

In response, Plaintiffs argue that this Court is required to defer to the WPATH guidelines, and accept their validity, as a matter of law. To support this, they most directly rely on *Grimm v. Gloucester County School Board*. 972 F.3d 586 (4th Cir. 2020). The panel opinion in *Grimm* states the WPATH standards "represent the consensus approach of the medical and mental health community" and "have been recognized by various courts, including this one, as the authoritative standards of care." *Id.* at 595.

These statements have no permissible effect, legal or otherwise, on the evidence before the Court in this proceeding. "Precedents wield authority and power only to the extent that they establish or reinforce a legal rule or principle." Bryan A. Garner, *et al*, THE LAW OF JUDICIAL PRECEDENT 382

(2016) (emphasis added). It is "clear error" to hold that "stare decisis or res judicata makes a finding of fact applicable to persons not parties to the action in which the finding is made." *Spector v. United States*, 193 F.2d 1002, 1006 (9th Cir. 1952). *Grimm*, like the other cases Plaintiffs cite, involved factual conclusions. For example, *Grimm* relied upon an amicus brief submitted by medical experts, 972 F.3d at 596; this brief, and any factual evidence in that brief, is not before this Court. *See also* Doc. 205 at 18 (citing to opinion on preliminary injunction in *Brandt v. Rutledge*, 2021 WL 3292057 (E.D. Ark. Aug. 2, 2021)).

More fundamentally, this approach to factual questions is antithetical to the Court's gatekeeping role under *Daubert*. Science should be expected to develop over time. Dr. Levine, one of the Plan Defendants' experts, summarized as follows:

> And I just need to tell you that one of the great advantages of being a professional is that one spends one's life learning and evolving and changing. And the fact that five years ago or ten years ago, I thought this and today I think this, it may be a problem in the legal profession, but it's not a problem in the medical profession. We expect doctor's concepts to evolve with clinical experience in advance of science.

Exhibit 7, Deposition of Dr. Levine at 188:21-189:5. When the U.S. Department of Health and Human Services considered the medical science underlying the treatment of gender dysphoria in 2020, the agency found "there

is, at a minimum, a lack of scientific and medical consensus" to support HHS's earlier conclusion that the effectiveness of hormone and surgical treatment for gender dysphoria was generally accepted. 85 Fed. Reg. 37187 (June 19, 2020).

Plaintiffs ask this Court to prejudge the scientific evidence by finding that the Plan Defendants' experts in psychiatry (Drs. Levine and McHugh), endocrinology (Dr. Hruz), and surgery (Dr. Lappert) are not qualified to testify about the methodological flaws and errors in the science and ethics of transitioning treatments because they themselves do not perform these experimental treatments on vulnerable patients. This Court cannot exclude the Plan Defendants' experts for failure to endorse or practice according to the WPATH guidelines when those guidelines lack scientific reliability, validity, and provide no reliable error rates for safety or efficacy.

B. The scientific justification for Plaintiffs' desired medical treatments has collapsed in the past three years.

As an initial matter, Plaintiffs misunderstand their burden of proof. The Plan Defendants have been clear and consistent in their explanation for Plan's decision. Treasurer Folwell stated in 2018 that "[t]he legal and medical uncertainty of this elective, non-emergency procedure has never been greater." Ex. 6. *See also* Doc. 75 at ¶ 62.

Plaintiffs argue that the Plan's failure to cover hormone prescriptions and surgical procedures for treatment of gender dysphoria violates the Equal

Protection Clause. They argue that the Plan's coverage scheme is inherently discriminatory because the Plan covers certain prescriptions and surgeries (such as mastectomies and breast reconstruction for individuals with cancer) but does not cover the same procedures for treatment of gender dysphoria. Doc. 179 at 21.

To prevail on an equal protection claim, however, Plaintiffs must also establish that the Plan Defendants have denied a benefit of value. As discussed above, this requires Plaintiffs to demonstrate not only that these denied treatments are medically necessary for them, but also that the treatments are "safe and effective for correcting or ameliorating their gender dysphoria." *Hennessy-Waller v. Snyder*, 529 F.Supp.3d 1031, 1042 (D. Ariz. 2021) (failure to prove reassignment surgery would be effective in treating gender dysphoria justified denial of motion for preliminary injunction). Unfortunately, the most recent scientific literature—peer-reviewed articles published in respected medical journals—has failed to demonstrate that hormonal and surgical treatments actually improve outcomes for patients suffering from gender dysphoria.

The importance of scientific research can be seen in one specific finding, noted by transgender advocates as well as Plan Defendants' experts: transgender individuals have high levels of psychiatric morbidity, suicidal acts and completed suicide many years after medical transition. Cecilia Dhejne, *et*

al., *Long-term follow-up of transsexual persons undergoing sex reassignment surgery: cohort study in Sweden*, PLoS ONE 2011 6(2): e16885 (2011). 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 seven times and completed suicides nineteen times above the general population even after transition interventions. *Id.* *See* Ex. 1 at 66-67 (citing Dhejne).

Some advocates argue that these terrible health outcomes indicate the need for the hormonal and surgical interventions that the Plaintiffs seek, but "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." Ex. 1 at 67. Theories that treatment for gender dysphoria will reduce suicidality are, at this point, only theories. Based on the current state of the science, it is equally possible that the treatments sought by Plaintiffs will create further psychological harm in some patients. No one knows.

In October 2019, the American Journal of Psychiatry published a 10-year follow-up study of thousands of Swedish patients diagnosed with gender dysphoria. Richard Branstrom & John E. Pachankis, *Reduction in Mental*

Health Treatment Utilization Among Transgender Individuals After Gender-Affirming Surgeries: A Total Population Study, AM. J. OF PSYCHIATRY 177(8), 727-34 (2019). Critiques of the article led to a third-party review of its methodology and its correction. The final conclusions, agreed to by the authors and international methodological experts, documented zero benefits to hormone and surgical treatment. Ned H. Kalin, M.D., *Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process*, AM. J. OF PSYCHIATRY 177(8), 764 (2020). Indeed, the raw number of suicides and hospitalizations for mental illness actually increased for transgender patients who underwent transitioning treatments. Agnes Wold, *Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article*, AM. J. OF PSYCHIATRY 177(8), 768 (2020) (noting the data shows "the risk of being hospitalized for a suicide attempt was 2.4 times higher if [the patient] had undergone gender-corrective surgery than if they had not," although the data set was not large enough to establish a causal relationship).

The findings in the Branstrom article were confirmed in 2021 by a study conducted in the United States. Elizabeth Hisle-Gorman, *et al., Mental Healthcare Utilization of Transgender Youth Before and After Affirming Treatment*, J. OF SEX. MED. 18, 1444–54 (2021). Like the Branstrom study,

the Hisle-Gorman article documented no benefits to gender transition treatments for hundreds of patients followed over many years. "Among 963 transgender and gender-diverse youth using gender-affirming pharmaceuticals, mental healthcare did not significantly change and psychotropic (psychiatric) medications increased following gender-affirming pharmaceutical initiation." *Id.*

The integrity of the legal process requires that experts be able to discuss and explain these scientific controversies to the jury. If the Plan Defendants' experts are excluded, Plaintiffs will do what their experts did in their reports: ignore the Branstrom findings and the multiple articles that reach similar conclusions. *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 (finding "insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition").

The scientific controversy over the efficacy of hormonal and surgical treatment for gender dysphoria is particularly significant in this case because it undermines the ethical basis for these treatments. The "notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan v. Dir., Mo. Dep't of Health*,

497 U.S. 261, 269 (1990). Informed consent requires the health care provider to "provide the patient with sufficient information about the proposed treatment and its attendant risks to conform to the customary practice of members of the same profession with similar training and experience situated in the same or similar communities." *Foard v. Jarman*, 387 S.E.2d 162, 164 (N.C. 1990). A "reasonable person" must have a "general understanding of both the treatment or procedure and the usual and most frequent risks and hazards" associated with it. *Id.*

When the risks and benefits of medical treatment are unknown, the treatment is experimental. This does not mean that the procedures or treatments should be prohibited, and the Plaintiffs have not—and cannot—show that the Plan has prohibited anything. The only decision made by the Plan is that it will pay for other treatments, such as counseling, but not the treatments that Plaintiffs desire.

C. Plaintiffs' motions erroneously assume that gaps in scientific knowledge and differing conclusions are a basis to exclude the Plan Defendants' experts.

For each of the Plan Defendants' experts, Plaintiffs seek to identify inconsistencies, other courts that have not agreed with the expert's testimony, or particular conclusions with which Plaintiffs disagree. These are not appropriate bases to exclude expert testimony, particularly without testimony or cross-examination in a formal *Daubert* hearing.

The Plaintiffs misunderstand the purpose of *Daubert* review. "Whether expert evidence is reliable [and therefore admissible] is primarily a question of the validity of the expert's methodology, not the quality of the data used or the conclusions produced." *Krakauer v. Dish Network, L.L.C.*, No. 1:14-cv-333, 2015 WL 5227693, at *5 (M.D.N.C. Sept. 8, 2015) (emphasis added). The Plan Defendants' conclusions are carefully explained and cited to peer-reviewed articles in extensive reports. None of them should be excluded.

1. Dr. McHugh

Dr. McHugh's expert testimony will expand on the research he has done for more than fifty (50) years to bring medical science—the testing of hypotheses based on biological processes—to the field of psychiatry. Plaintiffs argue that they are entitled to specific procedures to treat their psychiatric diagnoses of gender dysphoria. Dr. McHugh will explain precisely what such a diagnosis means, how the diagnostic categories are created, and why these categories can operate to create harm and prevent thoughtful scientific research. Dr. McHugh offers testimony to help the factfinder understand how the scientific method is applied to research the best treatment for psychiatric illnesses, to provide a framework for the factfinder to understand precisely why the medical treatments for gender dysphoria remain medically uncertain.

Dr. McHugh has testified previously that the Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association (DSM) is

"essentially a dictionary based on consensus-seeking voting methodologies rather than evidence-seeking scientific methodologies." Ex. 2 at 6-7. The DSM is, scientifically, similar to a field guide used by amateur birders to identify birds. *Id.* "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 reliably-valid scientific, evidence-based process. The DSM was thus not built using uniformly valid and reliable scientific processes." *Id.* "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." *Id.* at 8 (quoting a 2013 statement by Director of the National Institute of Mental Health (NIMH)).

As Dr. McHugh explained in his report, the "unreliability of the DSM assessment process is important to understanding defects in transgender treatment methodologies. Patients who have been diagnosed using the DSM checklist for 'gender dysphoria' are diagnosed solely on unverified patient reports." This is an inherently unreliable process—contrast the blood tests and other objective measures applied to diagnose the various types of heart

disease—indicates an ongoing lack of understanding of how to help these vulnerable, suffering patients. *Id.* at 8-9.

Dr. McHugh has extensive experience, throughout his career, with psychiatric diagnoses (and treatments) that are now widely recognized as harmful to the patients, such as lobotomies and "Repressed Memory Therapy." *Id.* at 9-10. These failed treatments arose from the same scientifically flawed diagnostic process as the current effort to treat gender dysphoria. Dr. McHugh does not dispute that patients diagnosed with gender dysphoria are suffering, but he has reviewed the scientific literature as it has developed over more than fifty years. Advocates have not produced any rigorous scientific research that proves these treatments will increase the wellbeing of patients. *Id.* at 11-12.

Some of the Plaintiffs' objections to Dr. McHugh are the generic ones described above, such as their argument that only treating physicians who use the WPATH guidelines—individuals with a clear financial conflict of interest in this case—are qualified to testify about medical treatment of gender dysphoria. Doc. 207 at 6-11. The Plaintiffs then proceed to attack opinions elicited during a deposition that are not within Dr. McHugh's report. *See, e.g.*, *id.* at 12 ("desistance"), 15-16 (stating, incorrectly, that Dr. McHugh supports "reparative therapy"). These opinions were not offered to this Court, and they do not provide a basis for challenging Dr. McHugh's methodology.

Plaintiffs also improperly argue that McHugh should be excluded because his views are inconsistent with the cherry-picked reports they cite, or because other courts have relied upon the DSM, Doc. 207 at 21-22, or because he has previously summarized these views in non-scientific journals, *id.* at 22-24. Finally, they argue that Dr. McHugh is biased. All of these may be appropriate arguments to a jury. None of them provide a basis to exclude an expert witness.

2. Dr. Levine

The Plaintiffs' objections to Dr. Levine's testimony are similar to those made against Dr. McHugh. Plaintiffs disagree with Dr. Levine's conclusions, but they do not offer meaningful objections to the scientific methodology or experience supporting his views.

Plaintiffs argue that some of Dr. Levine's opinions support their arguments, but this goes to the credibility of the witness, not his methodology. Plaintiffs argue the science underlying the treatment of gender dysphoria is irrelevant because "this is simply an insurance dispute" and the Court "need not resolve questions about the etiology of sex." Doc. 213 at 10. This objection misstates the foundation of Plaintiffs' case. The Plan cannot be constitutionally required to pay for medical treatments that are not proven to actually help the patients. As Dr. Levine will testify, among his other conclusions, that "[t]here are no long-term, peer-reviewed published, credible,

reliable and valid, research studies documenting or establishing:" (1) the "percentage of patients receiving gender transition procedures who are helped by such procedures according to well known criteria;" (2) the "percentage of patients receiving gender transition procedures who are harmed by such procedures according to well known criteria; (3) the "reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient"; or (4) the "mental health outcomes of trans behaving children who are either affirmed or not affirmed in childhood". Ex. 1 at 87-88. These conclusions are based on the current scientific literature, and they provide a basis for the jury to conclude that the Plan is justified in its decision not to cover Plaintiffs' desired medical procedures.

The remainder of Plaintiffs' objections speak to impeachment rather than any basis for exclusion. Doc. 213 at 13-21. The Plaintiffs no doubt strongly disagree with the conclusions that Dr. Levine has reached, based on the scientific peer-reviewed literature, but this is a basis on which to confront his opinions, not to exclude them entirely.

3. Dr. Hruz

Plaintiffs also seek to exclude Dr. Paul Hruz, even though he is the only expert in this case, on either side, who has specialized in the effect of hormones on the human body (*i.e.*, endocrinology). Given that hormone suppression and cross-sex hormones are two treatments that Plaintiffs seek, it is inaccurate to

state that Dr. Hruz lacks relevant scientific knowledge. Doc. 205 at 7-10. He has specifically studied the treatments that Plaintiffs seek. *See, e.g.*, Ex. 3 at 3-4. The fact that Dr. Hruz has concluded that these hormonal treatments are unethical does not render him inherently unqualified. *Id.* at 4-5.

The bulk of Plaintiffs' arguments reflect disagreement with Dr. Hruz's conclusions and statements about the existing scientific literature. Doc. 205 at 9-12. As one example, Plaintiffs argue Dr. Hruz should be excluded because he "has no view about what modality of treatment should be provided to transgender people suffering gender dysphoria." *Id.* at 12. But this is one of Dr. Hruz's key findings: "[d]espite 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." Ex. 3 at 16. The remainder ask this Court to exclude his opinions because they differ from that of other courts, various medical societies, or the Plaintiffs' experts. These are not a proper basis for exclusion. Nor are the Plaintiffs' unsubstantiated claims of bias, which would again be appropriate for cross-examination, but not this Court's analysis pursuant to *Daubert*.

4. Dr. Lappert

Plaintiffs' attacks on Dr. Lappert suffer the same flaws. Dr. Lappert has performed every procedure identified by Plaintiffs, but he has not done so for the purpose of treating gender dysphoria. Plaintiffs devote significant attention to Dr. Lappert's decision to retire from the practice of plastic surgery, and the fact that his decision not to renew his board certification was not accurately reflected in his expert report, Doc. 209 at 8-9, but Dr. Lappert did not conceal this accidental error, nor does this provide a basis to exclude his testimony. The remainder of the objections reflect the same attempts by Plaintiffs to ask this Court to defer to professional organizations or to other courts on the facts to be presented in this case. *Daubert* rejected this approach, and the Plaintiffs cannot renew it here. Plaintiffs have presented no valid basis to exclude Dr. Lappert's testimony.

5. Dr. Robie

Plaintiffs' motion to exclude Dr. Peter Robie is similarly flawed. Dr. Robie is an accomplished primary care physician in Winston-Salem and the Plan Defendants have been clear about his testimony. He has not prepared an expert report because he will testify about the information he provided to the Plan's board during its discussions. The expert views he has provided beyond this information deal with the diagnostic process followed by primary care physicians and the importance of accurate information about the patient's

biological sex during that process. These views are well within his forty-seven years of medical care and his education.

VI. Conclusion

Accordingly, the State Health Plan Defendants respectfully request that this Court deny Plaintiffs' motions to exclude expert testimony.

Respectfully submitted, this the 23rd day of February, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on the 23rd day of February, 2022, the foregoing was filed electronically with the Clerk of Court using the CM/ECF electronic filing system, which will send notification of such filing to all registered users.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that the State Health Plan Defendants' Response in Opposition to Plaintiffs' Motions to Exclude Expert Testimony (Docs. 202-09, 212-13) complies with the Court's word limit as calculated using the word count featureof the word processing software. Specifically, this singular Response contains less than 6,250 words, including the body of the Response and headings, but not including the caption, signature lines, this certificate, or the certificate of service.

This the 23rd day of February, 2022.

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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.

Exhibit A

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

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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

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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 Electroencephalo-graphy:	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.

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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.

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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
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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
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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
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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
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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.	)

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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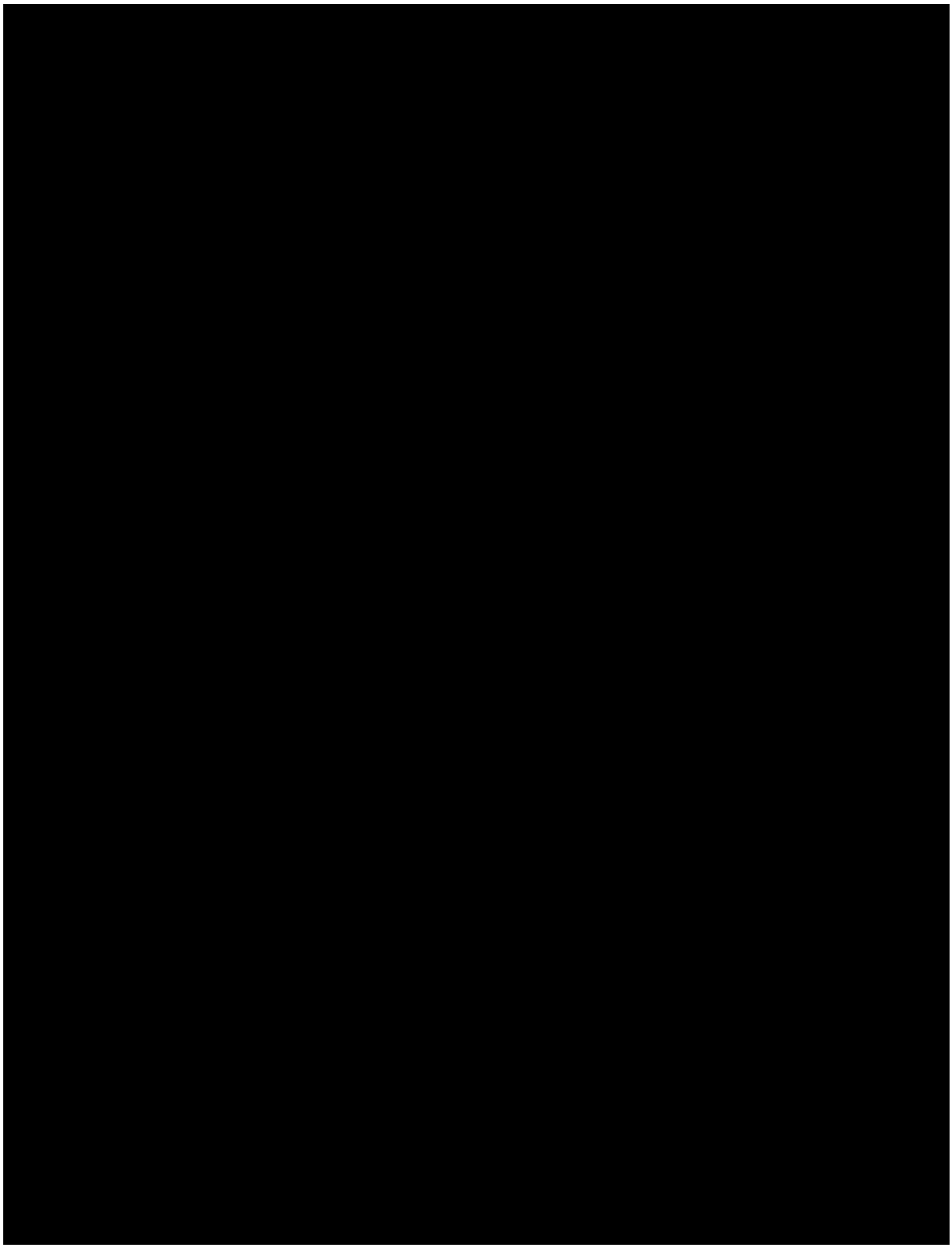
21. Expert Report Limitations: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. All opinions 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

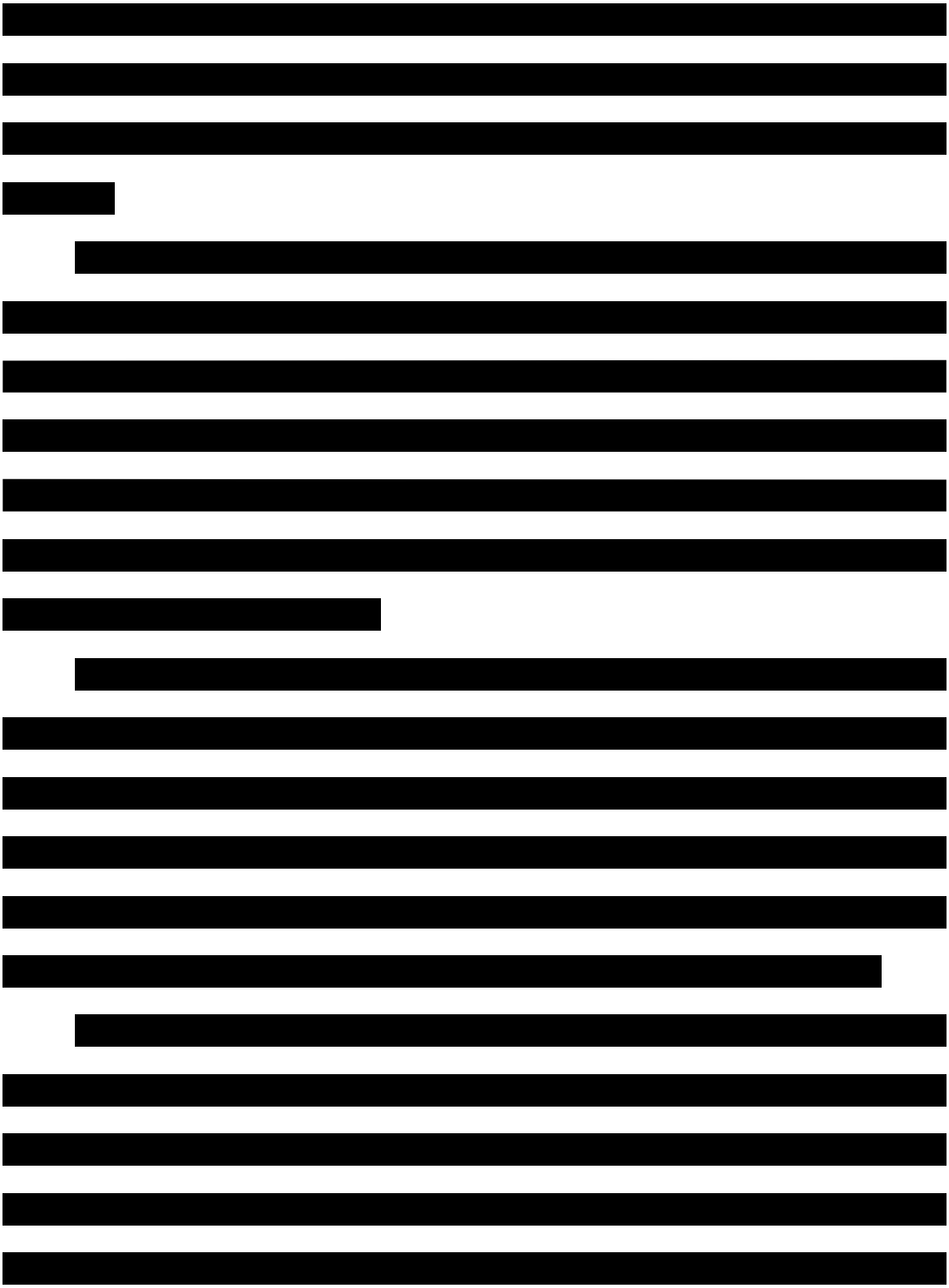
my opinion, a key role of an expert witness is to help the court, lawyers, parties, and the public understand and apply reliable scientific, technical, and investigative principles, hypotheses, methods, and information. I have transmitted this confidential expert report directly to attorney John G. Knepper, J.D. for distribution as consistent with the laws of the appropriate jurisdiction for this case.

CONFIDENTIAL INFORMATION SECTION BELOW

[redacted]

[redacted]





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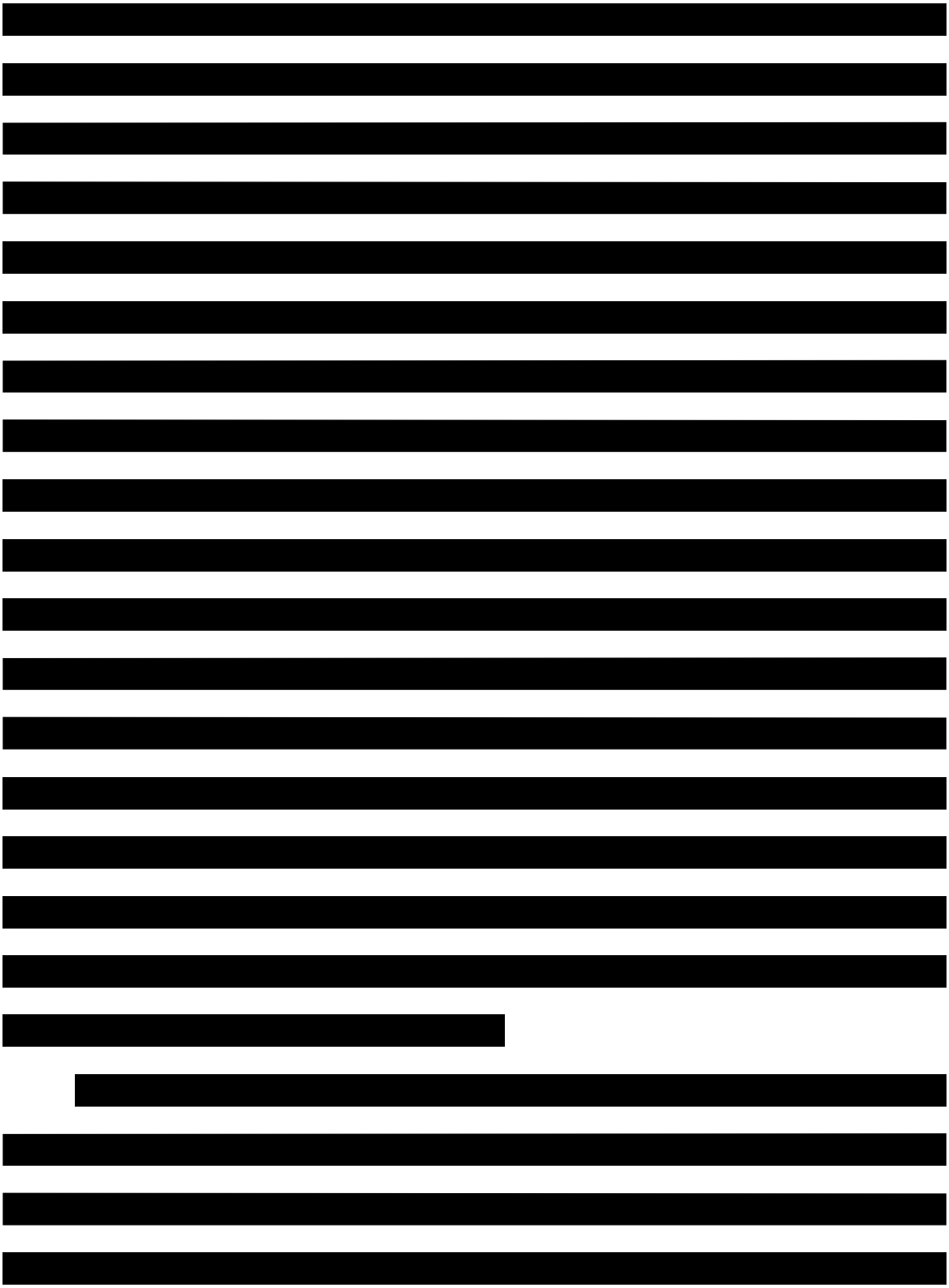

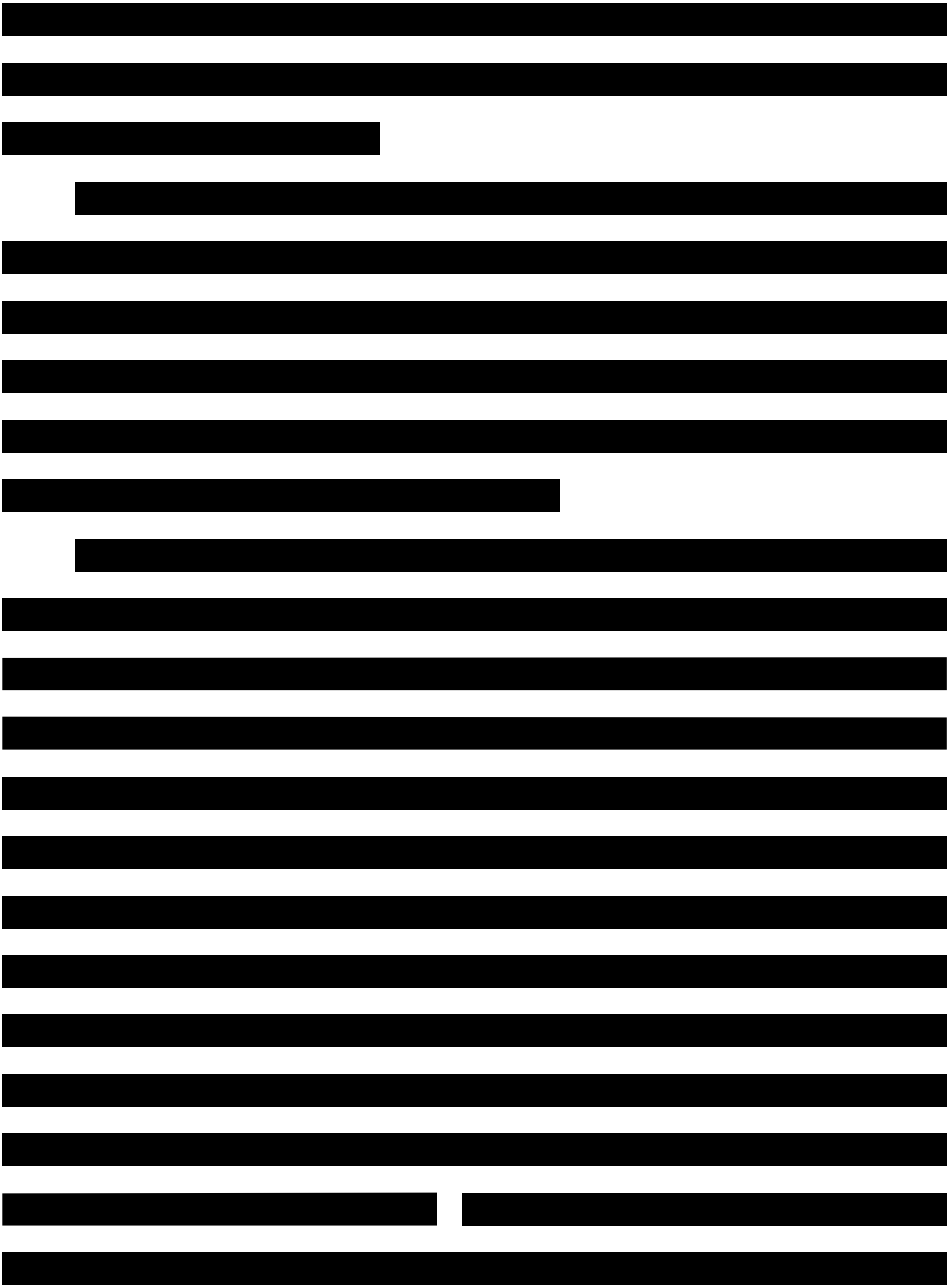

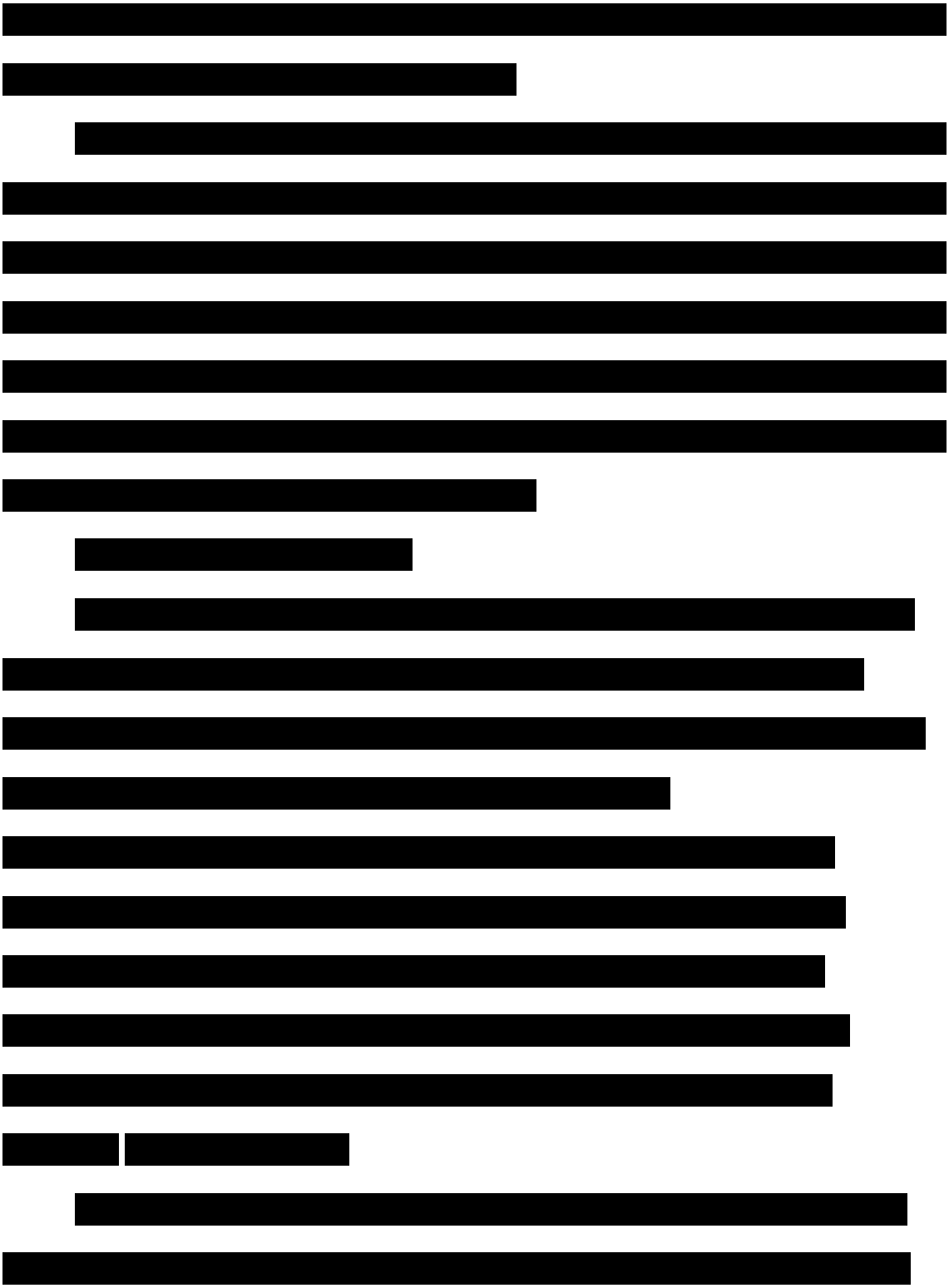

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____

Signed: _____ **May 1, 2021**

Patrick W. Lappert, MD

Statement on State Health Plan Coverage of Sex Change Operations
October 24, 2018

The State Health Plan's policy of not covering sex change operations as a benefit, is the same now as it was during the entire eight years of Treasurer Janet Cowell's administration and all previous North Carolina Treasurers.

The legal and medical uncertainty of this elective procedure has never been greater.

Until the court system, a legislative body or voters tell us that we "have to," "when to," and "how to" spend taxpayers money on sex change operations, I'm reluctant to make a decision that has the potential to discriminate against those who desire other currently uncovered elective procedures.

We empathize with all members' desires, but cannot provide them all with every service they want.

PLAN DEF0021499

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Civil Action No. 1:19-cv-00272

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; UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL; NORTH CAROLINA STATE UNIVERSITY; UNIVERSITY OF NORTH CAROLINA AT GREENSBORO; and NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES,	)
Defendants.	)

DISCLOSURE OF EXPERT WITNESSES WHO DO NOT PROVIDE A WRITTEN REPORT PURSUANT TO FED. R. CIV. P. 26(A)(2) BY DEFENDANTS DALE FOLWELL, DEE JONES, AND THE NORTH CAROLINA STATE HEALTH PLAN FOR TREACHERS AND STATE EMPLOYEES

(3) Peter W. Robie, M.D., FACP

Dr. Robie has served on the Board of Trustees for the State Health Plan since 2017. He also serves on the Pharmacy and Therapeutics Committee for the Plan. Dr. Robie will testify about the Board's consideration of requests that the Plan eliminate the current coverage exclusion for gender transition surgery and related hormone treatment.

Dr. Robie is not a specialist in the treatment of gender dysphoria, and the Defendants do not seek to qualify him as such. Dr. Robie is, however, a primary care physician with more than forty-seven years of experience. As a member of the Board of Trustees, and a physician, Dr. Robie has contributed his medical knowledge to Board deliberations. Dr. Robie will testify to the medical knowledge he has shared with other Board members. He will also testify that, in order to provide diagnostic and medical treatment that meets a professional standard of care, primary care physicians must know the chromosomal sex of patients.

Dr. Robie has served as a primary care physician for more than forty-seven years. He has treated patients as a physician in a small group/solo practice and as a member of a large primary care practice group affiliated with Wake Forest Medical Center. Dr. Robie earned his M.D. with honors from the Baylor College of Medicine in 1976. He has served as an Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine for the Wake Forest School of Medicine since 1981.

Dated this 1st day of May, 2021.

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.

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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

just looked at in December of 2020, which is not even a full year ago, you testified differently. So what has changed in nine months?

MR. KNEPPER: Objection, form.

A. What has changed in nine months? In nine months, I've reviewed a lot of the literature. I've heard the arguments. I've talked to pediatric endocrinologists. I've read articles, new articles. I've seen the lack of follow-up. I've seen the misinformation that puberty blocking hormones were entirely reversible, even in the face of the fact where people making those claims could not even conceptualize the psychosocial implications of remaining puerile. So a lot has changed in nine months. And I don't think nine months ago I was exactly gung-ho on these treatments, but I think I'm just a little more strong today.

And I just need to tell you that one of the great advantages of being a professional is that one spends one's life learning and evolving and changing. And the fact that five years ago or ten years ago, I thought this and

today I think this, it may be a problem in the legal profession, but it's not a problem in the medical profession. We expect doctor's concepts to evolve with clinical experience in advance of science. And we also know that politics affects a lot of things that happen in medicine. And certainly the politics has changed in this field.

And what is happening, we've had one direction of the politics of transgender life until the last two and half years, three years and suddenly the politics are changing again. And they're changing as a result of science, some of the things you've been -- in these exhibits, you see. And so we're -- I'm allowed to, in my view, without being embarrassed, I'm allowed to have an evolution in my views as certainly -- you know, if you quote one sentence here and one sentence here and another sentence out of context there, it appears that, oh, my god, I'm inconsistent, but what I am is in evolution, in developmental, professional evolution, which is an ideal thing both in a lawyer and in a physician.

Q. All right. Very quickly and then

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-00272-LCB-LPA

REPLY IN SUPPORT OF PLAINTIFFS' MOTIONS TO EXCLUDE EXPERT TESTIMONY OF DR. PETER ROBIE (ECF NO. 202), DR. PAUL W. HRUZ (ECF NO. 204), DR. PAUL R. MCHUGH (ECF NO. 206), DR. PATRICK W. LAPPERT (ECF NO. 208), AND DR. STEPHEN B. LEVINE (ECF NO. 212)

Defendants willfully ignore the Fourth Circuit's most recent and relevant reaffirmance of "the indispensable nature of district courts' Rule 702 gatekeeping function in all cases in which expert testimony is challenged." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021). The Court should disregard Defendants' plea for lax gatekeeping and instead should rigorously examine the challenged experts' qualifications and the relevance and reliability of their testimony.

ARGUMENT

"The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of proof." *Smith v. Wyeth-Ayerst Lab'ys Co.*, 278 F.Supp.2d 684, 691 (W.D.N.C. 2003). Defendants fail to meet this burden, however, even after specific challenges regarding each experts' qualifications and opinions. Defendants' failure to address specific arguments amounts to waiver, which is reason enough to exclude those opinions. *See, e.g.*, *Stenlund v. Marriott Int'l, Inc.*, 172 F.Supp.3d 874, 887 (D. Md. 2016) ("In failing to respond to this argument [in defendant's motion], Plaintiff concedes the point.").

I. DEFENDANTS' EXPERTS ARE NOT QUALIFIED TO OPINE ON THE DIAGNOSIS AND TREATMENT OF GENDER DYSPHORIA.

There is no such thing as a jack-of-all-trades expert. Accordingly, "any expert, including physicians, must have the specialized knowledge or skill *in the specific area in which the testimony is proffered*." *Smith*, 278 F.Supp.2d at 698 (emphasis added).

"Experience in a particular field is not enough to qualify an expert; *the expert must have experience with the issue before the court*." *Harvey v. Novartis Pharm. Corp.*, 895

F.Supp.2d 1206, 1209 (N.D. Ala. 2012) (emphasis added); *see also, e.g.*, *Zellers v. NexTech Ne., LLC*, 533 F.App'x 192, 197 (4th Cir. 2013) (neurologist not qualified to testify as an expert about toxicology because "she lacks specific training in th[at] field"); *Hubbard v. Rite Aid Corp.*, 433 F.Supp.2d 1150, 1161 (S.D. Cal. 2006) (dermatologist not qualified as expert in disability). Courts thus routinely recognize that an expert in a particular subspecialty is not *ipso facto* an expert in every other subspecialty within the same field—let alone in an entirely different field. *See, e.g.*, *Elegant Massage, LLC v. State Farm Mut. Auto. Ins. Co.*, 2022 WL 433006, at *9 (E.D. Va. Feb. 11, 2022) ("the Fourth Circuit has recognized that experience and expertise in one area does not automatically qualify someone as an expert in another similar area"); *Maldonado v. Apple, Inc.*, 2021 WL 1947512, at *17 (N.D. Cal. May 14, 2021) (chemical engineer not qualified to opine about "reliability engineering," because "slapping the label 'engineering' on an expert or opinion is insufficient to show expertise across that expansive field"); *Shreve v. Sears, Roebuck & Co.*, 166 F.Supp.2d 378, 392 (D. Md. 2001) ("an expert who is a mechanical engineer is not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering").

Defendants concede—as they must—that their experts cannot qualify based on scientific research and peer-reviewed writing in this area. Instead, Defendants argue that their experts are qualified based on their generalized knowledge, skill, and education in their fields of medicine. That is not enough, however, and Defendants cite no authority for their proposition that any physician may testify about gender dysphoria and its treatment

even if they have no specialized training, research experience, clinical experience, or peer-reviewed publications in the area.

Finally, Defendants conflate and misrepresent Plaintiffs' arguments regarding their experts' "unfamiliarity or disagreement with the … [WPATH] standards of care." Dkt. 215 at 16. If a challenged expert is unfamiliar with the WPATH Standards of Care, that calls into question both the expert's qualifications *and reliability*. Separately, a challenged expert's disagreement with what is otherwise the recognized medical and scientific consensus calls into question their *reliability* because general acceptance in the relevant scientific community is an important element of reliability. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017).

A. Dr. Robie

Defendants concede that Dr. Robie will not opine regarding "the efficacy of gender dysphoria treatment," Dkt. 215 at 15—not surprising, since Dr. Robie admitted he lacks experience with this area. Dkt. 202 at 8. Instead, Defendants say that Dr. Robie will testify to the medical knowledge he shared with other Board members. Dkt. 215 at 15. But that is a role of a fact witness, not an expert. Moreover, as he stated in his deposition, the knowledge he shared relates to coverage of continuous glucose monitors for diabetic patients, biological agents for cancer treatment, and COVID management, care, and status. Dkt. 203-1 at 23:11–25:12; 31:19–32:14. These issues are irrelevant to this dispute, and there is no need for purported expert testimony on them.

B. Dr. Hruz

Defendants argue Dr. Hruz is qualified to testify as an expert in this case because he has purportedly "extensively studied the scientific literature related to the incidence, potential etiology, and treatment of gender dysphoria." Dkt. 215 at 14; *but see* Dkt. 205 at 20-22 (noting misrepresentations about the nature of his study in the area). However, Dr. Hruz has no clinical, research, or scientific publication experience in this area. And the fact that Dr. Hruz has "read in the area" and "holds an opinion on the topic" "is not enough" to make him an expert on this topic. *United States v. Jacques*, 784 F.Supp.2d 59, 62 (D. Mass. 2011); *see also Zellers*, 533 F.App'x at 197 (neurologist not an expert on toxicology because she reviewed scientific literature on toxicology).

C. Dr. McHugh

In arguing that Dr. McHugh is qualified, Defendants do nothing other than recite his credentials. But "a proffered expert's professional qualifications are insufficient to support his testimony; he must also have sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case." *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012) (cleaned up). Here, Dr. McHugh has no clinical, research, or scientific publication experience regarding the diagnosis or treatment of gender dysphoria and is therefore unqualified to testify as to those issues. Dkt. 207 at 5-9.

D. Dr. Lappert

Defendants do not contend that Dr. Lappert is qualified to opine on topics other than plastic surgery (like endocrinology, psychiatry, mental health conditions, and development

of treatment guidelines)—again not surprising, since he conceded he is not an expert in those areas. Dkt. 209 at 9-10, 15-16; *e.g.*, *Scott v. Mid-Atlantic Cable Installation, LLC*, 2006 WL 2079373, at *3 (E.D. Va. July 25, 2006); *Nunez v. Coloplast Corp.*, 2020 WL 2315077, at *5-6 (S.D. Fla. May 11, 2020).

As to surgery, Defendants argue Dr. Lappert is qualified to testify based on his "personal experience with the surgical procedures performed as part of sex reassignment surgery," although not "for treatment of gender dysphoria." Dkt. 215 at 14-15. But that is not enough. Defendants do not explain how Dr. Lappert's experience performing these procedures for *other conditions* qualifies him to opine on the efficacy of these procedures to treat *gender dysphoria*. *See Harvey*, 895 F.Supp.2d at 1210–11; *Thomas v. Novartis Pharms. Corp.*, 443 F.App'x 58, 63 (6th Cir. 2011) (finding experienced maxillofacial surgeon who had treated patients with osteonecrosis of the jaw unqualified to opine on the causation of osteonecrosis of the jaw).

Finally, Defendants fail to respond to Plaintiffs' argument regarding the Code of Ethics of the American Society of Plastic Surgeons requiring plastic surgeons to have "performed the specific procedure in question within three (3) years of the date of being retained as an expert witness," which Dr. Lappert has not. Dkt. 209 at 8.

E. Dr. Levine

Plaintiffs have established that Dr. Levine is not qualified to offer opinions about the treatment of prepubescent transgender children. Dkt. 213 at 20-22. In response,

Defendants only recite Dr. Levine's credentials. But again, credentials alone are "insufficient to support [an expert's] testimony." *Belk, Inc.*, 679 F.3d at 162.

II. THE CHALLENGED EXPERTS' OPINIONS ARE IRRELEVANT AND UNRELIABLE.

"[T]he party seeking the admission of expert testimony must come forward with evidence from which the court can determine that the proffered testimony is … reliable and relevant." *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 2021 WL 781682, at *2 (D. Md. Mar. 1, 2021). Defendants fail to meet this burden.

A. Defendants do not refute that many of the challenged experts' opinions are irrelevant.

Relevancy "is a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F.Supp.3d 837, 846 (W.D.N.C. 2016) (cleaned up).

In asserting their experts' testimony is relevant, Defendants set up a strawman. Defendants claim that "medical uncertainty" exists around the treatment of gender dysphoria, based on a statement made by Treasurer Folwell. Dkt. 215 at 17-19. They fail to mention, however, that Treasurer Folwell's belief comes from Dr. Robie, who Defendants concede is not qualified to opine on the treatment of gender dysphoria. Dkt. 180 (Ex. 11 (Folwell Deposition) at 170:8-171:8 ("Q: … your belief that there was medical

uncertainty of this elective procedure was based on conversation you had with Dr. Robie? A: Generally speaking.")). The Plan cannot claim "uncertainty" exists and shoehorn expert testimony based on the speculation and conjecture of an individual who is not even qualified to opine on the subject.

Further, Defendants do not rebut Plaintiffs' challenges to the relevancy of certain opinions by their experts. Accordingly, the Court should exclude opinions related to

1. desistence (Dkt. 205 at 9-10; 207 at 10-11; 209 at 18-19);
2. supposed controversies in other countries (Dkt. 205 at 10-11);
3. hypotheses about the causation of gender dysphoria (Dkt. 205 at 11; 207 at 12; 209 at 18-19);
4. the validity and reliability of the DSM, which does not set forth treatment (Dkt. 207 at 11);
5. Dr. Levine's opinions about the etiology and immutability of sex (Dkt. 213 at 8-9); and
6. Dr. Robie's opinions about the supposed need for physicians to know the chromosomal makeup of their patients (Dkt. 203 at 13-14).

B. The challenged experts' opinions are unreliable.

Expert testimony should only be admitted if it is reliable and "proffered evidence that has a greater potential to mislead than to enlighten should be excluded." *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018) (cleaned up). Moreover, "where a party seeks to qualify a

witness as an expert based upon experience, the district court must require the experiential witness to explain how his experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion, and how his experience is reliably applied to the facts." *Jackson v. United States*, 2010 WL 2228378, at *6 (D.S.C. May 28, 2010) (cleaned up).

Here, again, Defendants fail to meet their burden and have not contended with many of Plaintiffs' arguments regarding reliability. Where Defendants do not address a particular argument, they should be deemed to have conceded the point.

1. Dr. Robie

Defendants now contend Dr. Robie's opinions are limited to (1) medical knowledge he shared with other Board members;[1] (2) the diagnostic process primary care physicians follow; and (3) the importance of accurate information about a patient's chromosomal sex during that process. Dkt. 215 at 34-35; Dkt. 215-5.[2]

But Dr. Robie does not inquire about his patients' chromosomal makeup normally, Dkt. 203 at 13-14, and therefore cannot explain how such knowledge is important to the diagnostic process. Moreover, he only formed this opinion in 2019 in connection with this litigation. Accordingly, his opinion on this should be excluded as unreliable. *See Kiessling v. Kiawah Island Inn Co. LLC*, 2019 WL 331176, at *8 (D.S.C. Jan. 25, 2019).

[1] As noted above, to the extent Defendants say that Dr. Robie will testify to the medical knowledge he shared with other Board members, that is the role of a *fact* witness, not an expert.

[2] The Court should exclude any other expert opinions by Dr. Robie beyond these three, including those regarding costs (*see* Dkt. 203 at 15-17).

2. Dr. Hruz

Defendants do not refute that all of Dr. Hruz's opinions are based on hypotheses and not *facts*. Dkt. 205 at 11-13. "Speculation, guesswork and conjecture are not acceptable substitutes for facts and data, and an opinion based on speculation is not founded on reliable methodology." *Samuel v. Ford Motor Co.*, 112 F.Supp.2d 460, 470 n.11 (D. Md. 2000). And because "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record," *Tyger Const. Co. Inc. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994), all of Dr. Hruz's opinions should be excluded.

Defendants also fail to rebut Plaintiffs' arguments about the misleading nature of some of Dr. Hruz's opinions. Dkt. 205 at 13-17. Defendants portray these arguments as mere disagreements, but there are no "alternative facts" in court. *See Old White Charities, Inc. v. Bankers Ins., LLC*, 2018 WL 8622359, at *6 n.10 (S.D.W. Va. Aug. 28, 2018). "Facts must be facts and truth must be truth." *Id.* at *6. Dr. Hruz is untruthful when he says gender-affirming care has not been accepted by relevant scientific communities, or when he says no medical care is provided to adolescents and adults with gender dysphoria under the "watchful waiting" model. Dkt. 205 at 13-14, 15. His opinions are more likely to mislead than to enlighten.

In addition, Dr. Hruz has conducted no scientific research or study with regards to gender dysphoria, rather he has read some articles and talked with other professionals. *Id.* at 6-7. But not only does he misrepresent the nature of his conversations, *see id.* at 20-22,

conversations with others health care professionals do not make him an expert. *See Jackson*, 2010 WL 2228378, at *7.

Finally, Defendants do not address Plaintiffs' argument that Dr. Hruz's testimony is unreliable because it is permeated by unscientific views and bias. Dkt. 205 at 19-23.

3. Dr. McHugh

Defendants' assertion that Plaintiffs' challenge opinions by Dr. McHugh not in his report strains credulity. The desistence opinions that Dr. McHugh offered at his deposition are rooted in his report. *See* Dkt. 207-4 at 14. Likewise, Dr. McHugh's opinions about reparative therapy are connected to his opinions that gender-affirming care is harmful and/or experimental. His belief in reparative therapy (widely considered harmful and unethical) as the proper mode of treatment for gender dysphoria underscores the unreliability of his opinions. Defendants also do not refute that the foundation of Dr. McHugh's opinions is that transgender people are supposedly "disordered" because they suffer from a "disorder of assumption" or "overvalued idea." Dkt. 207 at 13-14.

Defendants argue that Plaintiffs deem Dr. McHugh's views unreliable solely because he disagrees with the WPATH Standards of Care. Not true. Dr. McHugh's opinions conflict with those of *every* major medical or health organization in the United States. *Id.* at 14-17. This includes the U.S. Department of Health and Human Services ("HHS"), which just last week, proclaimed that, "[HHS] and all leading national medical and pediatric associations confirm that providing gender-affirming medical care is in the best interest of children and youth who need it." Ex. A.

Defendants also do not refute that Dr. McHugh's opinions are based on speculation and untested theories, Dkt. 207 at 17-18, and thus should be excluded because "speculation is unreliable evidence and is inadmissible." *Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003). Nor do Defendants refute that Dr. McHugh's opinions about the provision of care in other countries are both unreliable and misleading. Dkt. 207 at 18.

Defendants argue the Court should permit Dr. McHugh's opinions about the DSM, but aside from being irrelevant, those opinions are highly misleading, and Dr. McHugh's proposed alternative to the DSM "has been able to attract only minimal support within the community." Dkt. 207 at 19-20.

Finally, Defendants do not even attempt to negate that Dr. McHugh's opinions are so tainted by bias and prejudice that they are unreliable. *Id.* at 22-24.

4. Dr. Lappert

Ignoring their burden, Defendants do not respond to Plaintiffs' arguments that Dr. Lappert's non-surgery-related opinions are unreliable. Dkt. 207 at 9-10, 15-20. Whatever the reason for Defendants' failure to respond, they have not carried their burden to demonstrate that these opinions satisfy Rule 702.

Dr. Lappert's opinions on risks of surgical procedures are also unreliable. In particular, he opines about the supposed risks of these procedures when used to treat gender dysphoria. But that is a specific application of these procedures to a particular population with which Dr. Lappert admittedly has no first-hand experience whatsoever, and for which

he therefore has no basis to offer expert testimony. *See, e.g.*, *SDM Software, Inc. v. EMove, Inc.*, 945 F.Supp.2d 628, 639 (E.D.N.C. 2013).

5. Dr. Levine

Defendants summarize some of what Dr. Levine will say but do not explain "how his experience leads to the conclusion reached" or "how his experience is reliably applied to the facts." *Jackson*, 2010 WL 2228378, at *6 (cleaned up). Dr. Levine's opinions are not relevant and reliable just because Defendants deem it so. Defendants cannot explain how Dr. Levine's testimony will enlighten the factfinder, because it will not. And here, where Dr. Levine testified that he follows and applies the WPATH Standards of Care in his own practice, Dkt. 213 at 6-8, 12-13, his testimony against coverage of this care has a greater potential to mislead than to enlighten.

Ultimately, Defendants argue that Dr. Levine's testimony about a purported lack of studies is based on his review of scientific literature and provides a basis for a factfinder to conclude the Exclusion is justified. But what Dr. Levine and Defendants fail to do explain how the alleged lack of long-term studies somehow proves that gender-affirming treatment is not medically necessary and effective, particularly given the multitude of cross-sectional, observational, and longitudinal studies demonstrating the efficacy of such treatment.[3]

[3] The Court should disregard Defendants' arguments about what certain studies show. Not only do Defendants misrepresent those studies (*e.g.*, Dkt. 207 at 18 n.5; 213 at 13-14), but legal argument from Defendants' counsel is not expert testimony.

CONCLUSION

It is Defendants' burden to prove that the challenged experts are qualified and that their opinions are relevant and reliable; they have failed to do so. Defendants do not explain how their experts' experience leads to their conclusions, why their experience is a sufficient basis for their opinions, and how their experience is reliably applied to the facts of this case. To the contrary, the challenged experts' opinions are based on conjecture.

The Court should grant Plaintiffs' motions to exclude expert testimony.

Dated: March 9, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 3,125 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: March 9, 2022

/s/ Omar Gonzalez-Pagan

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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

SUPPLEMENTAL DECLARATION OF OMAR GONZALEZ-PAGAN

Pursuant to 28 U.S.C.§ 1746, I, Omar Gonzalez-Pagan, do hereby declare as follows:

1. I am over 18 years of age.

2. I am Counsel at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the stated herein, except those stated on information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Reply in support of Plaintiffs' Motions to Exclude Expert Testimony of Dr. Peter Robie (ECF No. 202), Dr. Paul W. Hruz (ECF No. 204), Dr. Paul R. McHugh (ECF No. 206), Dr. Patrick W. Lappert (ECF No. 208), and Dr. Stephen B. Levine (ECF No. 212).

5. Attached as **Exhibit A** is a true and correct copy of Information Memorandum Log No. ACYF-CB-IM-22-01 issued by the Administration of Children, Youth and Families of the U.S. Department of Health and Human Services on March 2, 2022.

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

Dated this 9th day of March, 2022.

/s/ Omar Gonzalez-Pagan
Omar Gonzalez-Pagan

Exhibit A

Kadel v. Folwell, No. 1:19-cv-00272-LCB-LPA (M.D.N.C.)
Reply in Support of Plaintiffs' Motions to Exclude Experts

ACF Administration for Children and Families	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Administration on Children, Youth and Families	
	1. Log No: ACYF-CB-IM-22-01	**2. Issuance Date: 03-02-2022**
	3. Originating Office: Children's Bureau	
	4. Key Words: Title IV-E and Title IV-B; LGBTQI+; John H. Chafee Foster Care Program for Successful Transition to Adulthood; Training; Foster Care	

INFORMATION MEMORANDUM

TO: State, Tribal, and Territorial Agencies Administering or Supervising the Administration of Titles IV-E and IV-B of the Social Security Act (the Act); Indian Tribes and Indian Tribal Organizations

SUBJECT: Titles IV-B and IV-E of the Act program requirements that state, county, and tribal child welfare agencies and their federally funded contractors (collectively, title IV-B and IV-E agencies, unless otherwise noted) can use to guide their work when determining how best to serve lesbian, gay, bisexual, transgender, queer or questioning, and intersex (LGBTQI+[1]) children and youth, including those with non-conforming gender identity or expression who are involved with the child welfare system.

LEGAL AND RELATED REFERENCES: Titles IV-B and IV-E of the Act

PURPOSE: Research and best child welfare practices clearly demonstrate that every child and youth in foster care should be affirmed and supported, including children and youth who are LGBTQI+ or who have a non-conforming gender identity or expression. Supporting and affirming LGBTQI+ children and youth in foster care is an overarching equity issue for each title IV-B and IV-E agency and for the Children's Bureau, and we encourage each agency to approach serving these children and youth through both a programmatic and an equity lens.

[1] Throughout the Information Memorandum, we use the term "LGBTQI+" as inclusive of individuals who have non-conforming gender identity or expression.

This Information Memorandum (IM) offers guidance to title IV-B and IV-E agencies when serving LGBTQI+ children and youth who are involved with the child welfare system. It also encourages agencies to consider the many provisions in titles IV-B and IV-E of the Act that agencies can use to help guide their work with families at risk, and when creating case plans for LGBTQI+ children and youth in foster care.

SUMMARY: Children and youth who are LGBTQI+ and are involved with the child welfare system historically and currently are particularly vulnerable and often are underserved. Many are at high risk for varying degrees of family rejection, neglect, exploitation, and hostility. Many other children and youth, especially transgender youth, are unable to access necessary and affirming medical care for a variety of reasons, including as a result of intentionally erected systemic barriers. These include policies that discourage, penalize, or otherwise impede providing such care and policies that falsely seek to characterize gender-affirming care, both of which present a severe risk of creating further barriers to access to such care. The Department of Health and Human Services and all leading national medical and pediatric associations confirm that providing gender-affirming medical care is in the best interest of children and youth who need it. Such children, youth, and their families can require specific support in order to ensure that a child or youth can remain at home in an emotionally and physically safe environment. As such, each title IV-B and IV-E agency should consider how best to provide services and supports to each LGBTQI+ child and youth who is at risk of entering or is in foster care. These services and supports should be tailored to their individual needs, including those related to their sexual orientation, gender identity, or gender expression.

Entities that accept title IV-B and IV-E federal funding must comply with the title IV-B and IV-E plan requirements associated with the funding, as well as with all other applicable federal laws. Title IV-B and IV-E agencies and their federally funded grantees and contractors are encouraged to apply the title IV-B and IV-E requirements in ways that are intentional, creative, and responsive to the needs of each LGBTQI+ child and youth who is involved with the child welfare system.

For example, title IV-B and IV-E agencies must consider and address the needs of children and youth in their care as part of their case plan. This includes placing them in safe, permanent placements that support the whole of each child and youth's well-being. This also should include addressing needs that a child or youth may have as a result of their sexual orientation, gender identity, or gender expression. Agencies also must consult with youth age 14 and older on various aspects of their case plans and provide services that are appropriate for older youth and young adults. Such services should address LGBTQI+ issues as needed. See generally section 475(1) of the Act. This IM delineates the title IV-B and IV-E program provisions that each agency should consider when serving LGBTQI+ children and youth who are in care or whose families are at risk of a child or youth entering foster care.

I. Background Research: LGBTQI+ Children and Youth

Studies demonstrate that children and youth who are LGBTQI+ are over-represented in the child welfare system. The Williams Institute published "Sexual and Gender Minority Youth in Foster Care," which was the result of a multi-year study that examined the experiences of sexual and gender-minority youth in the Los Angeles, California foster care system (the LAFYS Study). The LAFYS Study found that LGBTQI+ youth are 1.5 to 2 times more likely than their peers to be living in foster care.[2] They also experienced increased rates of physical violence and emotional harm both prior to being involved with, and while in, the child welfare system.[3] The LAFYS Study also found that 12.9% of LGBTQI+ children and youth reported poor treatment by the foster care system, compared to 5.8% of non-LGBTQI+ children and youth in foster care.[4] LGBTQI+ children and youth were found to be more than 2.5 times more likely than their non-LGBTQI+ counterparts to be placed in congregate care placements, such as group homes.[5] There is consensus across multiple stakeholders that most children and youth are best served in a family setting. Stays in congregate care should be based on a child or youth's specialized behavioral and mental health needs or clinical disabilities,[6] not on a child or youth's sexual orientation or gender identity.

Additionally, many LGBTQI+ children and youth enter foster care as a result of familial conflict, neglect, exploitation, or hostility about their sexual orientation, gender identity, or gender expression.[7] These youth also experience homelessness at disproportionately high rates, sometimes before entering foster care. These traumatic experiences correlate with increased rates of suicide and depression.[8] This underscores the need for child welfare agencies to work with families of LGBTQI+ children and youth to address family conflict related to sexual orientation and gender identity prior to a crisis that necessitates the need for the child or youth to be removed from the home.

Every child and youth who is unable to live with their parents should be provided a safe, loving, and affirming foster care placement, regardless of the young person's sexual orientation, gender

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[2] Cooper, K., Katsinas, A., Nezhad, S., & Wilson, B. (2014, August). *Sexual and gender minority youth in foster care: Assessing disproportionality and disparities in Los Angeles*, p. 37. Retrieved from http://williamsinstitute.law.ucla.edu/research/safe-schools-and-youth/lafys-aug-2014/

[3] *Id*. at 11.

[4] *Id*. at 40.

[5] *Id.* at *7*.

[6] The Children's Bureau. (2015, May 13). *A national look at the use of congregate care in child welfare*. Retrieved from http://www.acf.hhs.gov/cb/resource/congregate-care-brief

[7] Cooper, K., Kastanis, A., Nezhad, S., & Wilson, B. (2014, August). *Sexual and gender minority youth in foster care: Assessing disproportionality and disparities in Los Angeles*, p. 40. Retrieved from http://williamsinstitute.law.ucla.edu/research/safe-schools-and-youth/lafys-aug-2014/

[8] *Id*.

identity, or gender expression.[9] Evidence is clear that LGBTQI+ children and youth in foster care are most likely to thrive in safe, affirming environments without risk of physical or emotional harm on the basis of their sexual orientation or gender identity, and regardless of the type of placement in which the child lives.

II. Titles IV-B and IV-E: Provisions that Support LGBTQI+ Children and Youth

ACF recognizes that several existing federal laws, including title IV-B, title IV-E and their implementing regulations are intended to ensure the safety and well-being of children and youth in foster care, including the LGBTQI+ children and youth that child welfare agencies serve. These laws also provide funds for agencies to provide prevention and support services to families who are struggling to accept that the child or youth is LGBTQI+ or otherwise are not providing a safe environment for the child or youth. Similarly, title IV-E provides agencies with training funds to assist foster parents, kinship caregivers, and agency staff understand issues related to LGBTQI+ identities that are particularly relevant to children and youth in foster care.

This IM describes provisions in title IV-B and IV-E that child welfare agencies can use to support, encourage, and care for LGBTQI+ children and youth across the child welfare continuum. Similarly, this IM describes provisions that agencies can use to educate families, foster caregivers, and caseworkers.

A. Title IV-B Prevention and Family Preservation Services

Title IV-B of the Act provides funding to states and eligible tribes to provide "family preservation services," which are defined as "services for children and families designed to help families (including adoptive and extended families) at risk or in crisis." These services include preventive services, such as intensive family preservation programs that are designed to help children at risk of foster care placement remain safely with their families. Title IV-B funding also can be used to help parents identify where they need to develop or learn additional parenting skills, and to help parents build capacity to effectively parent an LGBTQI+ child or youth. See generally section 431(a)(1) of the Act.

[9] *See* ACYF-CB-IM-11-03. Retrieved from http://www.acf.hhs.gov/cb/resource/im1103

Research is clear that children and youth who are LGBTQI+ enter foster care at disproportionate rates.[10] Agencies should consider how to use family preservation funds and services to support families who are grappling with how to embrace an LGBTQI+ child or youth. For example, an agency could focus on parent education and building skills that will help the parent understand how best to support and parent the child in a safe and affirming manner that does not threaten the child's safety or well-being.

B. Title IV-B Adoption and Post-Adoption Support Services

Additionally, title IV-B provides funding to states and eligible tribes for "adoption promotion and support services." Section 431(a)(8) of the Act defines "adoption promotion and support services" as those services "designed to encourage more adoptions out of the foster care system when adoptions promote the best interests of children, including such activities as pre and post adoptive services and activities designed to expedite the adoption process and support adoptive families." Accordingly, title IV-B and IV-E agencies should consider what types of practices and services would best support families who have adopted LGBTQI+ children. These services can and should be intentional and highly personalized to address the needs of each family, child, and youth and can serve to support adoptive families whose adoptions may be at risk of disrupting because a child or youth is LGBTQI+. For example, an agency may assist a family in accessing gender affirming health care for their child or youth; connect the family with local supportive services; or update legal documents to reflect the child or youth's gender identity.

C. Title IV-E Reasonable Efforts to Prevent Removal

When determining whether a child should be removed from home, the title IV-E agency must ensure that it has made reasonable efforts to prevent the need for a child to be removed from home prior to being placed in foster care. Similarly, it must make reasonable efforts to reunify families when a child has been removed. See section 471(a)(15)(B) of the Act. Finally, once a child has been in foster care for 12 months, and every 12 months thereafter while in foster care, the agency must obtain court validation that it has made reasonable efforts to finalize the child's permanency plan. It also must ensure that when it makes reasonable efforts to prevent removal, reunify a family, or finalize the permanency plan, "the child's health and safety shall be the paramount concern." See 45 C.F.R. § 1356.21; section 471(a)(15)(A) of the Act.

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[10] Cooper, K., Katsinas, A., Nezhad, S., & Wilson, B. (2014, August). *Sexual and gender minority youth in foster care: Assessing disproportionality and disparities in Los Angeles*, p. 37. Retrieved from http://williamsinstitute.law.ucla.edu/research/safe-schools-and-youth/lafys-aug-2014/.

Reasonable efforts are specific to each family's circumstances and needs. In the case of a family who is at risk or whose child or youth has been removed from home as a result of conflicts related to the child or youth being LGBTQI+, these efforts might include, but are not limited to working with a family to provide family preservation services around the issues with which the family is struggling. It might include parent outreach or education. It might include working closely with kinship supports to determine whether a kinship placement might be the most supportive and affirming for the child or youth. Similarly, reasonable efforts to finalize the permanency plan might include the agency's efforts to assist a parent complete longer term or ongoing parent education on parenting a child or youth who is LGBTQI+.

D. Title IV-E Case Review System

Each title IV-B and IV-E agency must have a case review system, which is a procedure for assuring various protections for each child and youth in foster care, including a case plan for each child and youth. The case plan must be individualized and designed to achieve placement in a "safe setting that is the least restrictive (most family like) and most appropriate setting available and in close proximity to the parents' home, consistent with the best interest and special needs of the child" or youth. See section 475(5)(A) of the Act. In addition, the case plan must address a variety of issues, including the child or youth's safety, services that facilitate reunification, and services that support the child or youth's needs while in foster care. See section 475(1)(A) and (B) of the Act. When developing and implementing the child's case plan, states and tribes must consider all of a child or youth's needs, including those related to their sexual orientation and gender identity. See sections 471(a)(16) and 475(1) of the Act.

The Children's Bureau recognizes that a safe and appropriate placement setting is one in which a child or youth's LGBTQI+ identity is supported and affirmed, and their individualized needs are considered and addressed, including those related to being LGBTQI+. Moreover, Children's Bureau acknowledges that a placement in which so called "conversion therapy," or any other attempt to undermine, suppress, or change the sexual orientation or gender identity of a child or youth in foster care is utilized, is neither safe nor appropriate. As such, there are no circumstances under which an LGBTQI+ child or youth should be subjected to so called "conversion therapy," including a child or youth in foster care. This practice has been widely discredited as both ineffective and harmful by the mental health, psychological, and medical fields. In fact, in 2015, the United States Substance Abuse and Mental Health Services Administration (SAMHSA) published a report that outlined research, clinical expertise, and expert consensus on therapeutic practices related to children's and adolescent's sexual

orientation and gender identity that made clear that so-called "conversion therapy" should not be used among this population.[11]

Additionally, when considering a prospective foster care placement, including one for an LGBTQI+ child or youth, the title IV-E agency must consider whether the prospective environment will be physically and emotionally safe. This includes that the child or youth's whole development will be supported and affirmed in the placement that the agency determines is most appropriate for the child or youth. Similarly, as part of the child or youth's case plan, the title IV-E agency must provide services to facilitate a child or youth's reunification with their parents, if that is the plan for the family. Specifically, the case plan must include how the agency is working to improve the conditions in the family such as any underlying issues or conflicts with the child or the youth's parents that impede reunification, including those that relate to the child or youth's sexual orientation or gender identity/expression.

E. Developmentally Appropriate Activities for Children and Youth in Foster Care

A title IV-E agency must ensure that children and youth in its care have caregivers who are trained in understanding developmentally appropriate activities for such children and youth, including the reasonable and prudent parenting standard. The reasonable and prudent parenting standard is the standard characterized by "careful and sensible parental decisions that maintain the health, safety and best interests of a child, while at the same time encouraging the emotional and developmental growth of the child…when determining whether to allow a child in foster care under the responsibility of the State to participate in extracurricular, enrichment, cultural, and social activities." See sections 471(a)(10)(A) and 475(10) of the Act.

For example, as part of its title IV-E plan licensing requirements, the agency must ensure that each child-care institution has an onsite authority who is trained and authorized to apply the reasonable and prudent parenting standard for children and youth who are placed in the child-care institution. See section 471(a)(10) of the Act. Similarly, before placing a child or youth in a foster family home, a title IV-E agency must ensure that the foster parents have been prepared adequately to provide for the child or youth, including appropriate activities, knowledge, and skills relating to the developmental stages of the cognitive, emotional, physical, and behavioral capacities of the child or youth. See section 471(a)(24) of the Act.

[11] Substance Abuse and Mental Health Services Administration. (2015, November). *Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth.* Also accessible at: http://store.samhsa.gov/shin/content//SMA15-4928/SMA15-4928.pdf

This means, among other things, that an agency should consider a child or youth's sexual orientation and gender identity when determining how to facilitate their "extracurricular, enrichment, cultural, and social activities." See section 471(a)(24) of the Act. In order to ensure that children and youth have the opportunity to engage in age or developmentally appropriate activities, the title IV-E agency must consider the circumstances of each child and youth, which should include their sexual orientation and gender identity or expression. See section 475(11) of the Act. For example, participating in a school-based club could be a "developmentally appropriate" activity.

Each agency should also ensure that it does not prohibit LGBTQI+ children or youth from participating in such activities solely on the basis of the child or youth's sexual orientation or gender identity. Additionally, as appropriate or requested, agencies should help to provide LGBTQI+ children or youth with opportunities to participate in activities such as mentoring programs, peer support groups, or other community activities that affirm and support their identities in an age-appropriate manner. See sections 471(a)(10) and (24) of the Act; see also sections 475(5)(B) and (11)(A) of the Act. For example, if a youth in foster care wanted to participate in a Gender and Sexualities Alliance club within their high school, or attend faith-based youth groups, the title IV-E agency should not deny them the opportunity to do so solely because of their perceived or expressed sexual orientation and gender identity. Similarly, the title IV-E agency should provide individualized, intentional services to assist LGBTQI+ older youth and young adults transition to adulthood, including those related to their sexual orientation or gender identity, and including those related to their religious or spiritual beliefs and faith life.

Each agency should familiarize itself and partner with community and local LGBTQI+ affirming entities that parents, kinship providers, prospective parents, and child-care institution authorities can access to assist them to support and care for an LGBTQI+ child or youth. We also encourage each title IV-E agency to consider how it can ensure that each LGBTQI+ child and youth has the ability to participate in a wide variety of activities, including those that may affirm or support their identity.

F. John H. Chafee Foster Care Program for Successful Transition to Adulthood (Chafee Program)

The Chafee program provides funding for services and support to children and youth who have experienced foster care at age 14 or older to transition to self-sufficiency. See section 477 of the Act. These funds are used to assist youth to engage in age or developmentally appropriate activities; positive youth development; and experiential learning that reflects what their peers in intact families experience. See section 477(a)(3) of the Act. It also provides funding for a variety of services and supports to former foster care recipients who are between 18 and 21 years of

age (or 23 years of age, at state option). These services and supports should complement the youth/young adult's own efforts to achieve self-sufficiency and assist young adults to accept responsibility for transitioning from adolescence to adulthood. See section 477(a)(4) of the Act. States and eligible tribes that receive Chafee funds must use objective criteria for determining eligibility for benefits and services under the programs, and for ensuring that Chafee recipients, including those who are LGBTQI+, receive fair and equitable treatment. See section 477(b)(2)(E) of the Act.

G. Title IV-E Administrative and Training Funds

In accordance with an approved cost allocation plan, a title IV-E agency may use and claim title IV-E training and administrative funds to train agency staff and foster and adoptive parents in competencies related to bolstering protective factors and parenting LGBTQI+ children and youth. The types of training courses that may be allowable include, but are not limited to: courses that address the particular health care needs of LGBTQI+ children and youth; particular child development issues that are common to LGBTQI+ children and youth, such as emotional support or support for trauma related to violence that a child or youth has experienced that is related to sexual orientation or gender identity/expression; resources that are available to support such children within an under-served community; trainings related to uncovering or addressing bias against LGBTQI+ individuals and other such issues.

In addition, an agency may claim title IV-E training funds to support prospective adoptive or foster parents' attendance at conferences that have training components or that include discussions of significant issues covering the needs of LGBTQI+ children and youth in foster care or who have been adopted. See generally section 474(a) of the Act; 45 C.F.R. § 1356.60; Child Welfare Policy Manual (CWPM) at § 8.1H, including Question and Answer (QA) #21. We strongly encourage each title IV-E agency to consider how to use title IV-E administrative and training funds to bolster its capacity and skill to train its foster and adoptive parents and care for LGBTQI+ children and youth.

III. **Enforcement**

A. Fair Hearings

Federal regulations require the agency responsible for the title IV-E and title IV-B programs to provide an opportunity for a fair hearing to any individual whose claim for benefits or services is denied or is not acted upon with reasonable promptness. See section 471(a)(12) of the Act; 45 C.F.R. § 205.10 (through cross reference at 45 C.F.R. § 1355.30). This includes an opportunity

for complainants to have access to the fair hearing process for LGBTQI+ related service disputes, including not providing age or developmentally appropriate services or services identified in the case plan to the youth on the basis of sexual orientation or gender identity. See CWPM §8.4G, QA #1.

Each state or tribal title IV-E agency's fair hearing process differs slightly. However, the hearing process always requires, among other things, that applicants and recipients be advised of their right to a hearing, that they may be represented by an authorized representative, and that there be a timely notice of the date and place of the hearing. See 45 C.F.R. § 1355.30 (p) and § 205.10. To the extent that a state or tribe's fair hearing process does not include appeals for service-related issues for LGBTQI+ children and youth, we strongly encourage the agency to consider ensuring that its fair hearing process can address such issues as needed.

B. Partial Reviews

The regulations at 45 C.F.R. § 1355.32(d) regarding partial reviews of title IV-E or IV-B plans allow ACF to conduct a partial review appropriate to the nature of the concern if ACF becomes aware of a title IV-B or IV-E compliance issue outside the scope of the Child and Family Services Review (CFSR). As part of the partial review, ACF will conduct an inquiry and require the title IV-E agency to submit additional data as may be necessary. If the inquiry demonstrates that the agency is not in compliance with its title IV-B or IV-E plan, the agency must enter into a program improvement plan (PIP) that is designed to bring the agency into compliance with its plan and relevant requirements. If, after the PIP process, the agency still fails to comply with the applicable requirements, the agency will be subject to a penalty related to the extent of the noncompliance. See 45 C.F.R. § 1355.32(d)(4). The partial review process applies to title IV-B and IV-E plan compliance issues that involve children and youth who are LGBTQI+.

Conclusion

The Children's Bureau stands solidly in support of LGBTQI+ children and youth who are involved with the child welfare system. Each agency should be intentional about assessing each LGBTQI+ child and youth's individualized needs, including those related to the child or youth being LGBTQI+. LGBTQI+ children and youth experience higher rates of violence prior to and while in foster care than their non-LGBTQI+ peers. Too often, systemic barriers and practices are created to deny such children and youth gender affirming medical care, especially to transgender and gender nonconforming children and youth. The Children's Bureau does not support these barriers and practices, and we are unequivocal that they are counter to children and youth's best interests. As such, each title IV-E agency should be particularly vigilant about placing LGBTQI+ children and youth in homes and child-care institutions where they are supported, safe, and can develop as a whole person. But the agency's responsibility does not stop there: each agency

also should provide LGBTQI+ children and youth with opportunities to participate in activities that further support their identity, resilience, and development, including activities related to being LGBTQI+.

Additionally, we strongly encourage agencies to take advantage of opportunities to work internally to develop the capacity to identify, understand, and address some of the issues that often confront LGBTQI+ children and youth at different points in the child welfare continuum. An agency also should consider whether its data can inform appropriate services to LGBTQI+ children, youth, and families, including when a family is at risk of a child or youth entering foster care, once a child is in foster care, or after the child has been adopted. The agency must be prepared and competent to address trauma-related issues that have occurred as a result of the child or youth facing rejection, discrimination, or harassment because they are LGBTQI+, especially in their family of origin. Children's Bureau also strongly encourages agencies to focus attention on ensuring that each LGBTQI+ child has access to affirming medical care. This includes working with and providing services and training opportunities to parents who are struggling to accept that their child or youth is LGBTQI+ or has a non-conforming gender identity, especially when that is either the cause of the child or youth being removed or a barrier to a safe, healthy reunification.

Finally, the Children's Bureau has resources to help each agency develop the capacity to serve LGBTQI+ children and youth, as well as their foster parents, adoptive parents, and kinship caregivers. Consider partnering with community organizations that can provide additional or specialized support to LGBTQI+ children, youth, and families who are involved with your agency. We also encourage each agency to take advantage of the wide variety of resources accessible on the Child Welfare Information Gateway. The Children's Bureau's Regional Program Managers also stand ready to assist each agency to support, affirm, encourage, and lift up the voices and experiences of each LGBTQI+ child and youth in its care.

INQUIRIES TO:

Children's Bureau Regional Program Managers

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

MAXWELL KADEL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:19CV272
DALE FOLWELL, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER

LORETTA C. BIGGS, District Judge.

Before the Court is a Motion for Leave to File Brief of *Amici Curiae* the American Medical Association and Seven Additional Health Care Organizations in Support of Plaintiffs. (ECF No. 131). Proposed Amici "are eight leading medical, mental health, and other health care organizations" who "represent hundreds of thousands of physicians and mental-health professionals, including specialists in family medicine, mental health treatment, internal medicine, endocrinology, obstetrics and gynecology, and thousands of nurses." (*Id.* at 1–2.) Proposed Amici filed their motion on November 30, 2021, in support of Plaintiffs' Motion for Summary Judgment, (ECF No. 178), which is currently before the Court.[1]

[1] Plaintiffs originally filed two summary judgment motions simultaneously with Proposed Amici's motion on November 30, 2021. (ECF Nos. 138; 152.) The Court struck these motions on December 10, 2021 and allowed Plaintiffs to file a single dispositive motion with an accompanying memorandum not to exceed 9,000 words. (ECF No. 176.) Plaintiffs subsequently filed their Motion for Summary Judgment on December 20, 2021. (ECF No. 178.)

"The decision of whether to grant [a motion for leave to file an amicus brief] is left to the discretion of the trial judge." *Finkle v. Howard Cty.*, 12 F. Supp. 3d 780, 783 (D. Md. 2014); *Am. Humanist Ass'n v. Md.-Nat'l Cap. Park & Plan. Comm'n*, 303 F.R.D. 266, 269 (D. Md. 2014); *see* LR 7.5(b). Participation of an amicus brief "may be less appropriate" at the trial level, "where the issues of fact as well as law predominate, . . . than at the appellate level where such participation has become standard procedure." *Finkle*, 12 F. Supp. 3d at 783. "The aid of amici curiae has been allowed at the trial level where they provide helpful analysis of the law, they have a special interest in the subject matter of the suit, or existing counsel is in need of assistance." *Bryant v. Better Bus. Bureau of Greater Md., Inc.*, 923 F. Supp. 720, 728 (D. Md. 1996) (Davis, J.). Ultimately, the question is one of utility: "a motion for leave to file an amicus curiae brief should not be granted unless the court deems the proffered information timely and useful." *Finkle*, 12 F. Supp. 3d at 783 (internal quotations and alterations omitted).

The Fourth Circuit recently relied on an amicus brief filed by several of the Proposed Amici here concerning substantially similar subject matter. *See Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586 (4th Cir. 2020). *Grimm* concerned "whether equal protection and Title IX can protect transgender students from school bathroom policies that prohibit them from affirming their gender." *Id.* at 593. After acknowledging that "many of us carry heavy baggage into any discussion of gender and sex," the Fourth Circuit began its discussion by "developing a fact-based understanding of what it means to be transgender, along with the implications of gendered-bathroom usage for transgender students." *Id.* at 594. The court found an amicus brief highly similar to the one proposed by Proposed Amici invaluable in developing this background and cited to it approximately ten times. *Id.* at 594–613.

Here, the Court likewise finds Proposed Amici's perspective useful in developing a background understanding of what it means to be transgender and the implications of being unable to receive medical treatment for gender dysphoria. Proposed Amici have a special interest as representatives of a great number of medical providers in North Carolina who provide many of the medical services at issue in this suit.

Defendants argue that Proposed Amici's motion should be denied for failure to comply with requirements for expert testimony. (ECF No. 186 at 2–5.) However, Defendants do not cite, and this Court is not aware of any opinion requiring Amicus briefs to comply with the rules of Federal Rules of Evidence. *See Washington All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 518 F. Supp. 3d 448, 453 n.3 (D.D.C. 2021) ("[Plaintiff's] reliance on cases addressing the evidentiary standards for sworn testimony is misplaced, and [it] fails to provide a single example where those standards have been applied to amicus briefs." (internal quotations omitted)). While an amicus brief *itself* may not be considered as evidence on summary judgment if it would not be admissible at trial, *see Md. Highways Contractors Ass'n v. Maryland*, 933 F.2d 1246, 1251 (4th Cir. 1991) ("[H]earsay evidence, which is inadmissible at trial, cannot be considered on a motion for summary judgment."), it appears that evidence supplied by amici may be considered, so long as it would be admissible at trial and does not exceed the scope of the arguments properly raised by parties to the suit, *see Hirschfeld v. Bureau of Alcohol, Firearms, Tobacco & Explosives*, 5 F.4th 407, 441 (4th Cir.), *as amended* (July 15, 2021) (concluding that it was "unclear" whether it could rely on evidence submitted by amici that was "neither adopted nor relied on" by the parties), *vacated as moot*, 14 F.4th 322 (4th Cir. 2021), *cert. denied sub nom. Marshall v. Bureau of Alcohol*, No. 21-1155, 2022 WL 994369 (U.S. Apr. 4, 2022); *see,*

e.g., *Kluge v. Brownsburg Cmty. Sch. Corp.*, 548 F. Supp. 3d 814, 833 (S.D. Ind. 2021) ("In deciding whether to permit such a brief, courts should consider 'whether the brief will assist the judges by presenting ideas, arguments, theories, insights, *facts*, *or data* that are not to be found in the parties' briefs.'" (quoting *Voices for Choices v. Ill. Bell Tel. Co.*, 339 F.3d 542, 544 (7th Cir. 2003)) (emphasis added)). The Court therefore finds Defendants' opposition to Potential Amici's motion unpersuasive.

Thus, Potential Amici's motion will be granted.

For the reasons stated herein, the Court enters the following:

ORDER

IT IS THEREFORE ORDERED that the Motion for Leave to File Brief of *Amici Curiae* the American Medical Association and Seven Additional Health Care Organizations in Support of Plaintiffs, (ECF No. 131), is **GRANTED**.

IT IS FURTHER ORDERED that Proposed Amici shall file their amicus brief in the form of ECF No. 131-2 within seven days of entry of this Order.

This, the 7th day of April 2022.

/s/ Loretta C. Biggs
United States District Judge

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

MAXWELL KADEL, *et al.*; *Plaintiffs*, v. DALE FOLWELL, in his official capacity as State Treasurer of North Carolina, *et al.*, *Defendants*.	1:19-cv-00272-LCB-LPA

BRIEF OF *AMICI CURIAE* THE AMERICAN MEDICAL ASSOCIATION AND SEVEN ADDITIONAL HEALTH CARE ORGANIZATIONS IN SUPPORT OF PLAINTIFFS

AUTHORSHIP DISCLOSURE

Pursuant to LR 7.5(d), *amici curiae* certify that this brief was authored entirely by counsel for *amici curiae* and not by counsel for any party, in whole or part; no party or counsel for any party contributed money to fund preparing or submitting this brief; and apart from *amici curiae* and their counsel, no other person contributed money to fund preparing or submitting this brief.

SUMMARY OF ARGUMENT

Transgender individuals have a gender identity that is incongruent with the sex they were assigned at birth. The health care community's understanding of what it means to be transgender has advanced greatly over the past century. It is now understood that being transgender implies no impairment in a person's judgment, stability, or general social or vocational capabilities.

According to a 2016 report, approximately 1.4 million adults identify as transgender in the United States. Andrew R. Flores *et al.*, The Williams Institute, How Many Adults Identify as Transgender in the United States? 2 (June 2016), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Trans-Adults-US-Aug-2016.pdf. A similar study indicates that roughly 22,200 of 250,000 (*i.e.*, 0.3% of) adults in North Carolina who identify as lesbian, gay, bisexual, transgender, or queer ("LGBTQ") likely identify as transgender. Christy Mallory & Brad Sears, The Williams Institute, Discrimination, Diversity, and Development: The Legal and

Economic Implications of North Carolina's HB2 4, 7 (May 2016), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Legal-Economic-Implications-HB2-May-2016.pdf. Similarly, two probabilistic studies indicates that between 0.74% and 1.7%, or between 4,650 and 15,600 North Carolina youth identify as transgender. *Id.*; *see also* Jody L. Herman *et al.*, The Williams Institute, Age of Individuals Who Identify As Transgender in The United States 4 (Jan. 2017), https://williamsinstitute.law.ucla.edu/wp-content/uploads/Age-Trans-Individuals-Jan-2017.pdf. Growing acceptance and destigmatization from parents, doctors, and peers is allowing young people with gender dysphoria to become increasingly comfortable disclosing their transgender status and transitioning. Nick Lehr, *What's Behind the Rising Profile of Transgender Kids? 3 Essential Reads*, The Conversation (June 21, 2021, 8:24 AM), https://theconversation.com/whats-behind-the-rising-profile-of-transgender-kids-3-essential-reads-161962 ("[T]hanks to growing acceptance from parents, doctors and peers, young people with gender dysphoria are becoming increasingly comfortable coming out of the closet and transitioning."). However, such "population estimates likely underreport the true number of [transgender] people, given difficulties in collecting comprehensive demographic information about this group." Am. Psych. Ass'n, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70 Am.

Psychologist 832, 832 (2015), https://www.apa.org/practice/guidelines/transgender.pdf [hereinafter "Am. Psych. Ass'n *Guidelines*"].

Many transgender individuals experience a condition called gender dysphoria, which is characterized by clinically significant distress resulting from the incongruence between one's gender identity and the sex assigned to the individual at birth. The international consensus among health care professionals regarding treatment for gender dysphoria is to assist the patient to live in accordance with the patient's gender identity, thus alleviating the distress or impairment. Treatment may include any or all of the following: counseling, social transition (through, *e.g.*, use of a new name and pronouns, new clothes and grooming in order to allow the person to conform to social expectations and norms associated with his or her identity), hormone therapy and/or gender-confirming surgeries. The treatment for gender dysphoria is highly effective in reducing or eliminating the incongruence and associated distress between a person's gender identity and assigned sex at birth.

Barring coverage of gender-affirming care for state employees or their dependents effectively places such care out of reach for many North Carolina state employees and their dependents. Lack of treatment, in turn, increases the rate of negative mental-health outcomes, substance abuse, and suicide. Beyond exacerbating gender dysphoria and interfering with treatment, discrimination—including discrimination in health coverage—reinforces the stigma associated with

being transgender. Such stigma, in turn, leads to psychological distress and attendant mental-health consequences.

ARGUMENT

I. What It Means To Be Transgender And To Experience Gender Dysphoria.

All people have a "gender identity"—a "deeply felt, inherent sense" of their gender. Am. Psych. Ass'n *Guidelines*, *supra*, at 832, 834, 862; *see also* David A. Levine & Comm. on Adolescence, Am. Acad. of Pediatrics, Technical Report: Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth, 132 Pediatrics e297, e298 (July 2013), https://www.pediatrics.org/cgi/doi/10.1542/peds2013-1283 [hereinafter "AAP Technical Report"]. Transgender individuals have a gender identity that is not aligned with the sex assigned to them at birth.[1] Transgender people differ from cisgender (*i.e.*, non-transgender) individuals, whose gender identity aligns with the sex they were assigned at birth. Am. Psych. Ass'n *Guidelines*, *supra*, at 861. A transgender man is someone who is assigned the sex of female at birth, but is male and transitions to live in accordance with that male identity. A transgender woman is an individual who is assigned the sex of male at birth but is female and transitions

[1] Although most people have a gender identity that is male or female, some individuals have a gender identity that is "a blend of male or female[,] or an alternative gender." Am. Psych. Ass'n *Guidelines*, *supra*, at 834.

to live in accordance with that female identity. A transgender man is a man. A transgender woman is a woman. Gender identity is distinct from and does not predict sexual orientation. Transgender people, like cisgender people, may identify as heterosexual, gay, lesbian, bisexual, or asexual. Am. Psych. Ass'n *Guidelines*, *supra*, at 835-36; Sandy E. James et al., Nat'l Ctr. for Transgender Equality, The Report of the 2015 U.S. Transgender Survey 246 (Dec. 2016), http://www.transequality.org/sites/default/files/docs/usts/USTS%20Full%20Report%20-%20FINAL%201.6.17.pdf.

The medical profession's understanding of gender has advanced considerably over the past fifty years. Throughout much of the twentieth century, individuals who were not gender conforming were often viewed as "perverse or deviant." Am. Psych. Ass'n, Report of the APA Task Force on Gender Identity and Gender Variance 26-27 (2008), https://www.apa.org/pi/lgbt/resources/policy/gender-identity-report.pdf [hereinafter "Am. Psych. Ass'n *Task Force Report*"]. Much as our professions now recognize that homosexuality is a normal form of human sexuality—and that stigmatizing gay people causes significant harm—we now recognize that being transgender "implies no impairment in judgment, stability, reliability, or general social or vocational capabilities"—and that stigmatizing transgender people also causes significant harm. Jack Drescher *et al.*, Am. Psychiatric Ass'n, *Position Statement on Discrimination*, *supra*, at 1.

A. Gender Identity

"[G]ender identity" refers to a "person's internal sense" of being male, female, or another gender. Am. Psych. Ass'n, Answers to Your Questions About Transgender People, Gender Identity, and Gender Expression 1 (2014), http://www.apa.org/topics/lgbt/transgender.pdf [hereinafter "Am. Psych. Ass'n *Answers*"]. Every person has a gender identity. Caitlin Ryan, Family Acceptance Project, San Francisco State University, Supportive Families, Healthy Children: Helping Families with Lesbian, Gay, Bisexual, & Transgender Children 17 (2009), https://familyproject.sfsu.edu/sites/default/files/FAP_English%20Booklet_pst.pdf. A person's gender identity cannot be altered voluntarily. Colt Meier & Julie Harris, Am. Psych. Ass'n, Fact Sheet: Gender Diversity and Transgender Identity in Children 1, http://www.apadivisions.org/division-44/resources/advocacy/transgender-children.pdf; *see also* Jason Rafferty, Am. Acad. of Pediatrics, *Gender Identity Development in Children*, HealthyChildren.org (Sept. 18, 2018), https://healthychildren.org/English/ages-stages/gradeschool/Pages/Gender-Identity-and-Gender-Confusion-In-Children.aspx. Further, gender identity cannot necessarily be ascertained immediately after birth. Am. Psych. Ass'n *Guidelines*, *supra*, at 862.

Many children develop stability in their gender identity between ages three and four.[2] *Id*. at 841.

"[G]ender expression refers to the way a person communicates gender identity to others through behavior, clothing, hairstyles, voice or body characteristics." Am. Psych. Ass'n *Answers*, *supra*, at 1. There are many individuals who depart from stereotypical male and female appearances and roles, but who are not transgender. Ethan C. Cicero & Linda M. Wesp, *Supporting the Health and Well-Being of Transgender Students*, 33 J. Sch. Nursing 2 (2017). Indeed, most people who express their gender in a non-stereotypical or non-conforming manner are or become comfortable with the sex they were assigned at birth. The World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People 5 (7th Version, 2011), https://www.wpath.org/media/cms/Documents/SOC%20v7/Standards%20of%20Care%20V7%20-%202011%20WPATH.pdf?_t=1605186324 [hereinafter "WPATH *Standards of Care*"]. In contrast, a transgender boy or transgender girl "consistently,

[2] "Although gender identity is usually established in childhood, individuals may become aware that their gender identity is not in full alignment with sex assigned at birth in childhood, adolescence, or adulthood." Am. Psych. Ass'n *Guidelines*, *supra*, at 836.

persistently, and insistently" identifies as a gender different from the sex they were assigned at birth. *See* Meier & Harris, *supra*, at 1; *see also* Cicero & Wesp, *supra*, at 5-6.

While psychologists, psychiatrists, and neuroscientists are have not pinpointed why some people are transgender, research suggests there may be biological influences, including, for example, exposure of transgender men identified at birth as females to elevated levels of testosterone in the womb. *See* Jason Rafferty, Am. Acad. of Pediatrics, *Gender Diverse & Transgender Children*, HealthyChildren.org (June 7, 2021), https://healthychildren.org/English/ages-stages/gradeschool/Pages/Gender-Non-Conforming-Transgender-Children.aspx; Peggy T. Cohen-Kettenis *et al.*, *The Treatment of Adolescent Transsexuals: Changing Insights*, 5 J. Sexual Med. 1892, 1895 (2008); Arianne B. Dessens *et al.*, *Gender Dysphoria and Gender Change in Chromosomal Females with Congenital Adrenal Hyperplasia*, 34 Arch. Sexual Behav. 389, 395 (2005). Brain scans and neuroanatomical studies of transgender individuals may also support these biological explanations. *See, e.g.*, Francine Russo, *Is There Something Unique About the Transgender Brain?*, Sci. Am. (Jan. 1, 2016), https://www.scientificamerican.com/article/is-there-something-unique-about-the-transgender-brain/.

B. Gender Dysphoria

As noted above, being transgender "implies no impairment in judgment, stability, reliability, or general social or vocational capabilities." Am. Psychiatric Ass'n, *Position Statement on Discrimination*, *supra*, at 1. However, many transgender individuals are diagnosed with gender dysphoria, a condition that is characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex. Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 451-53 (5th ed. 2013) [hereinafter "*DSM-5*"]. As discussed in detail below, the recognized treatment for someone with gender dysphoria is medical support that allows the individual to transition from his or her birth assigned sex to the sex associated with his or her gender identity. WPATH *Standards of Care*, *supra*, at 9-10. These treatments are "effective in alleviating gender dysphoria and are medically necessary for many people." *Id.* at 5.

1. The Diagnostic Criteria And Seriousness Of Gender Dysphoria

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition codifies the diagnostic criteria for gender dysphoria in adults as follows: "[a] marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two" out of six criteria, and

"clinically significant distress or impairment in social, occupational, or other important areas of functioning." *DSM-5*, *supra*, at 452-53. The six criteria include (1) "[a] marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics"; (2) "[a] strong desire to be rid of one's primary and/or secondary sex characteristics"; (3) "[a] strong desire for the primary and/or secondary sex characteristics of the other gender"; (4) "[a] strong desire to be of the other gender (or some alternative gender . . .)"; (5) "[a] strong desire to be treated" as a gender different from one's assigned gender; and (6) "[a] strong conviction that one has the typical feelings and reactions" of a different gender. *Id.* at 452.

If untreated, gender dysphoria can cause debilitating distress, depression, impairment of function, self-mutilation to alter one's genitals or secondary sex characteristics, other self-injurious behaviors, and suicide. *See*, *e.g.*, *id*., at 455, 458; Stephanie A. Brill & Rachel Pepper, The Transgender Child: A Handbook for Families and Professionals 202 (2008) (discussing risk of self-mutilation). Like other minority groups, transgender individuals also are frequently subjected to prejudice and discrimination in multiple areas of their lives (*e.g.*, school, employment, housing, health care), which exacerbates these negative health outcomes and makes access to appropriate medical care all the more important. Michael L. Hendricks & Rylan J. Testa, *A Conceptual Framework for Clinical Work*

with Transgender and Gender Nonconforming Clients: An Adaptation of the Minority Stress Model, 43 Pro. Psych.: Research & Practice 460 (2012); Jessica Xavier *et al.*, Va. Dep't of Health, The Health, Health-Related Needs, and Lifecourse Experiences of Transgender Virginians (Jan. 2007), https://www.vdh.virginia.gov/content/uploads/sites/10/2016/01/THISFINALREPORTVol1.pdf.

2. **The Accepted Treatment Protocols For Gender Dysphoria**

In the last few decades, transgender people suffering from gender dysphoria have gained widespread access to gender-affirming medical and mental health support and treatment. Am. Psych. Ass'n *Guidelines*, *supra*, at 835; WPATH *Standards of Care*, *supra*, at 8-9. For over thirty years, the generally accepted treatment protocols for gender dysphoria[3] have aimed at alleviating the distress associated with the incongruence between gender identity and birth-assigned sex. Am. Med. Ass'n, Comm. on Human Sexuality, Human Sexuality 38 (1972). These protocols are laid out in the *Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (Version 7)* developed by the World Professional Association for Transgender Health ("WPATH"). WPATH

[3] Earlier versions of the *DSM* used different terminology, *e.g.*, "gender identity disorder," to refer to this condition. Am. Psych. Ass'n *Guidelines*, *supra* note 6, at 861.

Standards of Care, *supra*. The major medical and mental health groups in the United States expressly recognize the WPATH Standards of Care as representing the consensus of the medical and mental health community regarding the appropriate treatment for gender dysphoria. Am. Med. Ass'n, Policy H-185.950, Removing Financial Barriers to Care for Transgender Patients (modified 2016), https://policysearch.ama-assn.org/policyfinder/detail/Removing%20Financial%20Barriers%20to%20Care%20for%20Transgender%20Patients%20H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml; Am. Psych. Ass'n *Task Force Report*, *supra*, at 32; AAP Technical Report, *supra*, at e307-08.

The recommended treatment for gender dysphoria includes assessment, counseling, and, as appropriate, social transition, hormone therapy, and surgical interventions to bring the body into alignment with one's gender identity.[4] Am.

[4] Some clinicians still offer versions of "reparative" or "conversion" therapy based on the idea that being transgender is a mental disorder. However, all leading medical professional organizations that have considered the issue have explicitly rejected such treatments. *See* Am. Med. Ass'n, Policy Number H-160.991, Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations (2018), https://policysearch.ama-assn.org/policyfinder/detail/Health%20Care%20Needs%20of%20Lesbian,%20Gay,%20Bisexual,%20Transgender%20and%20Queer%20Populations%20H-160.991?uri=%2FAMADoc%2FHOD.xml-0-805.xml; Am. Sch. Counselor Ass'n, The School Counselor and LGBTQ Youth (2016), https://www.schoolcounselor.org/Standards-Positions/Position-Statements/ASCA-Position-Statements/The-School-Counselor-and-LGBTQ-Youth; Hilary Daniel et al., *Lesbian, Gay, Bisexual, and Transgender Health Disparities: Executive*

Psych. Ass'n *Task Force Report*, *supra* note 10, at 32-39; William Byne et al., Am. Psychiatric Ass'n Workgroup on Treatment of Gender Dysphoria, *Assessment and Treatment of Gender Dysphoria and Gender Variant Patients: A Primer for Psychiatrists*, 175 Am. J. Psychiatry 1046 (2018); AAP Technical Report, *supra*, at e307-09. However, each patient requires an individualized treatment plan that accounts for the patient's specific needs. Am. Psych. Ass'n *Task Force Report*, *supra*, at 32. The task of deciding on an individualized treatment plan should be left to the patient and their medical professionals—not an outside organization such as an insurance provider.

For some adults and adolescents, hormone treatment which helps develop secondary sex characteristics that affirm an individual's gender identity may be medically necessary to treat their gender dysphoria. *See* Am. Med. Ass'n, Policy H-185.950, *supra*; Am. Psych. Ass'n *Guidelines*, *supra*, at 861, 862; Center of Excellence for Transgender Health, University of California, San Francisco, Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People 23 (Madeline B. Deutsch ed., 2d ed. June 17, 2016), https://transcare.ucsf.edu/sites/transcare.ucsf.edu/files/Transgender-PGACG-6-17-

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Summary of a Policy Position Paper from the American College of Physicians, 163 Annals Internal Med. 135, 136 (2015); AAP Technical Report, *supra*, at e307-08; *see* Am. Psychoanalytic Ass'n, *Position Statement on Attempts to Chan*, *supra*.

16.pdf; WPATH *Standards of Care*, *supra*, at 33-34, 54. The Endocrine Society, the oldest and largest global professional membership organization representing the field of endocrinology, considers these treatments to be the standard of care for gender dysphoria. Wylie C. Hembree *et al.*, *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. Clinical Endocrinology & Metabolism 3869, 3869-70 (2017) https://academic.oup.com/jcem/article/102/11/3869/4157558; *see also* Alessandra D. Fisher *et al.*, *Cross-Sex Hormone Treatment and Psychobiological Changes in Transsexual Persons: Two-Year Follow-Up Data*, 101 J. Clinical Endocrinology & Metabolism 4260 (2016). A transgender woman undergoing hormone therapy, for example, will have hormone levels within the same range as other women; and just as they do in any other woman, these hormones will affect most of her major body systems. Wylie C. Hembree *et al.*, *supra*, at 3885-88; *see also* Brill & Pepper, *supra*, at 217. Hormone therapy physically changes the patient's genitals and secondary sex characteristics such as breast growth, female-associated fat distribution, softening of the skin, and decreased muscle mass in women, and increased muscle mass, increased body and facial hair, male-pattern baldness (for some), and a deepening of the voice in men. Wylie C. Hembree *et al.*, *supra*, at 3886-89. Hormones have been clinically proven as an effective treatment for gender dysphoria with a low rate of complications. Jack L. Turban et al., *Pubertal Suppression for Transgender Youth*

and Risk of Suicidal Ideation, 145 Pediatrics (2020); *see* Henk Asscheman *et al.*, *A Long-Term Follow-Up Study of Mortality in Transsexuals Receiving Treatment with Cross-Sex Hormones*, 164 Eur. J. Endocrinology 635 (2011), https://eje.bioscientifica.com/view/journals/eje/164/4/635.xml; Paul Van Kesteren *et al.*, *Mortality and Morbidity in Transsexual Subjects Treated with Cross-Sex Hormones*, 47 Clinical Endocrinology 337 (1997).

For children experiencing the onset of puberty, treatment may include medication to prevent further progression of puberty ("pubert[y] blockers"). Wylie C. Hembree *et al.*, *supra*, at 3880-83. This fully reversible treatment allows children with gender dysphoria to delay the development of secondary sex characteristics that do not match their gender identity, giving them additional time to decide whether hormone treatment to feminize or masculinize the body is appropriate. *Id*. at 3880; Am. Psych. Ass'n *Guidelines*, *supra*, at 842; WPATH *Standards of Care*, *supra*, at 18-20.

Surgical interventions may also be an appropriate and medically necessary treatment for some patients. WPATH *Standards of Care*, *supra*, at 54-56. These procedures could include chest reconstruction surgery for transgender men, breast augmentation for transgender women, or genital surgeries, including removal of the testicles, the primary source of testosterone production, in women who are transgender. Wylie C. Hembree *et al.*, *supra*, at 3893-95; *see also* WPATH

Standards of Care, *supra* note 19, at 57-58. Decades of clinical evidence show these surgical procedures are effective in reducing gender dysphoria and improving mental health. Annelou L.C. de Vries *et al.*, *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 Pediatrics 696 (2014); William Byne *et al.*, *Report of the American Psychiatric Association Task Force on Treatment of Gender Identity Disorder*, 41 Arch. Sexual Behav. 759, 778-79 (2012); Mohammad Hassan Murad *et al.*, *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 Clinical Endocrinology 214 (2010); Luk Gijs & Anne Brewaeys, *Surgical Treatment of Gender Dysphoria in Adults and Adolescents: Recent Developments, Effectiveness, and Challenges*, 18 Ann. Rev. Sex Rsch. 178 (2007); Jan Eldh *et al.*, *Long-Term Follow Up After Sex Reassignment Surgery*, 31 Scand. J. Plastic Reconstructive Surgery & Hand Surgery 39 (1997). Empirical studies reflect the importance of the interplay among treatments, finding hormone therapy in conjunction with psychotherapy and, for some, surgery, to be necessary elements of treating severe levels of gender dysphoria. *See* Gianna E. Israel & Donald E. Tarver II, *Transgender Care: Recommended Guidelines, Practical Information & Personal Accounts* 56-73 (1997).

Ultimately—regardless of the particular treatments required for a specific individual and when such treatment begins—the goal is for individuals with gender

dysphoria to experience "identity integration," where "being transgender is no longer the most important signifier of one's identity" and the individual can refocus on his or her relationships, school, job, and other life activities. Walter Bockting & Eli Coleman, *Developmental Stages of the Transgender Coming-Out Process: Toward an Integrated Identity, in Principles of Transgender Medicine and Surgery* 185, 202-03 (Randi Ettner et al., eds., 2d ed. 2013).

II. The Consequences Of Living Without Gender Affirming Care Can Be Irreversibly Detrimental to Patient Health.

The treatments described above, when prescribed by a medical professional, are not elective treatments. For transgender patients struggling with gender dysphoria these treatments are urgent and medically necessary for the health of the patient. *See* WPATH *Standards of Care*, *supra*, at 8 (relying on the multiple sources to conclude that "hormone therapy and surgery have been found to be medically necessary to alleviate gender dysphoria in many people"). The biggest barrier to both safe hormonal therapy and to appropriate treatment for transgender patients is the lack of access to care. Daphna Stroumsa, *The State of Transgender Health Care: Policy, Law, and Medical Frameworks*, 104 Am. J. Pub. Health e31 (March 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3953767/. By delaying care because of lack of access or denial of coverage, transgender individuals face not just the potential worsening of their gender dysphoria, but an onset of other negative

health conditions that endanger the health of the patient. According to a 2015 study by the UCLA School of Law's Williams Institute, failing to receive surgical care where it was needed led to a 16.6% increase in prevalence of suicidal thoughts and 3.4% higher rate of actually attempting suicide in the preceding year. Jody L. Herman *et al.*, The Williams Institute, Suicide Thoughts and Attempts Among Transgender Adults Findings From the 2015 U.S. Transgender Study 16-17 (Sept. 2019). The study also showed that failure to receive hormones similarly increased the prevalence of suicidal thoughts by 15% and increased suicide attempts by 2.4%. *Id.* Overall, where a transgender individual "wanted, and subsequently received[] hormone therapy and/or surgical care[, they] had substantially lower prevalence of . . . suicide [sic] thoughts and attempts than those who wanted hormone therapy and surgical care but had not received them [in the past year]." *Id.*; *see also* Jack L. Turban *et al.*, *supra*, at 2, 8 (finding a significant inverse association between treatment with pubertal suppression during adolescence and lifetime suicidal ideation among transgender adults who sought out this treatment). Further, other recent studies have also shown "lower depressive symptoms in gender dysphoria individuals receiving hormonal treatment. . . . [and] report[ed] higher levels of self-esteem due to the hormonal treatment intervention." Rosalia Costa & Marco Colizzi, *The Effect of Cross-Sex Hormonal Treatment on Gender Dysphoria Individuals' Mental Health: A Systematic Review*, 12 Neuropsychiatric Disease & Treatment

1953, 1962 (2016). Studies also report that hormone therapy leads to lower rates of anxiety, higher quality of life, fewer problems with socialization, and fewer functional impairments. *Id.* at 1964-65.

Although group health plans can negotiate lower rates for care, the costs of these treatments without insurance overage are often unaffordable for the individual. While there may still be issues with affordability even with insurance, including issues of what the insurer deems "medically necessary," policies like the ones at issue, which create blanket bans *ensure* that medical treatment remains outside the reach of many who need it. The policies in place force parties to either pay out of pocket for medically necessary care, or else seek supplementary insurance coverage which itself may cost thousands of dollars per year. For many transgender patients, the result is the same: an inability to access medically necessary medical interventions. *See generally*, ACOG Committee Opinion on transgender and gender-diverse individuals, https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

CONCLUSION

For the foregoing reasons, *amici* respectfully urge this Court to grant summary judgment for the Plaintiffs.

Respectfully submitted, this the 11th day of April, 2022.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1) the undersigned counsel hereby certifies that the brief, in support of a motion, which is prepared using a proportionally spaced font, is less than 6,250 words (excluding cover, captions, indexes, tables of authorities, certificates of service, and this certificate of word count, counsel's signature block, and appendixes) as reported by word-processing software used to prepare this brief.

Respectfully submitted, this the 11th day of April, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that, on this date, the foregoing was filed electronically. Notice of this filing will be sent by operation of the Court's Electronic Filing System to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

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Exhibit F

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-00272-LCB-LPA

EXPERT REBUTTAL DISCLOSURE REPORT OF
GEORGE RICHARD BROWN, M.D., DFAPA

I, George R. Brown, declare as follows:

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated and would so testify if called as a witness. I reserve the right to supplement or amend this report based on any future information that is provided to me, including but not limited to information produced by Defendants in discovery or in response to Defendants' expert disclosures.

3. I previously submitted an expert report that was served on March 1, 2021 setting forth my opinions on: (1) the medical condition known as Gender Dysphoria; (2) the prevailing treatment protocols for a diagnosis of Gender Dysphoria, their efficacy, and the cost-effectiveness of this care; (3) whether there is a legitimate medical basis for the exclusions in the health plans offered by the North Carolina State Health Plan for Teachers

following the WPATH Standards of Care (SOC). This is likely because, in my understanding and experience, no such scientifically-reliable literature has been published in at least the last 15 years.

27. Defendants' experts also erroneously generalize about the appropriate course of treatment for Gender Dysphoria in adults or adolescents based on data about pre-pubertal children. This is inappropriate. The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition ("DSM-5") recognizes separate criteria for diagnosing Gender Dysphoria in children, on the one hand, and adults and adolescents on the other. The WPATH Standards of Care (SOC) have distinct standards of care for pre-pubertal children, adolescents and adults. As noted in my original report, the WPATH SOC, version 7 (Coleman, et al, 2011), are the nationally and internationally accepted standards of care for the evaluation and treatment of a diagnosis of Gender Dysphoria in adolescents and adults. These standards of care are also specifically followed by the largest healthcare systems in the United States (Department of Veterans Affairs, Kaiser-Permanente) as well as most major insurers of healthcare in the United States, including the corporate policy for Blue Cross and Blue Shield which specifically references these WPATH standards. *See* Blue Cross Blue Shield of North Carolina, Corporate Medical Policy, *Gender Affirmation Surgery and Hormone Therapy* (2021). They are also utilized as standards of care by many Departments of Corrections, the Federal Bureau of Prisons, the National Health Service of the UK, and many other countries as well. Coverage for transgender health care has been considered medically necessary for appropriately diagnosed individuals suffering from

B. Defendants' Experts Ignore the Fact that Treatment for Gender Dysphoria Has Long Been Accepted as Appropriate and Medically Necessary.

78. Defendants' experts claim that treatments for Gender Dysphoria are experimental and not medically necessary. These opinions are far out of step with mainstream medicine and the standard approaches of most healthcare systems in the United States. There is a wide availability of psychiatric, medical, and surgical treatments for transgender people suffering from Gender Dysphoria. Those treatments have been recognized as medically necessary care by the largest healthcare systems in the United States, and by being covered by the largest third-party insurance companies in the United States. This further underscores that Defendants experts are out of step with the relevant medical community and accepted standards of care for the treatment of Gender Dysphoria in adolescents and adults.

79. Although no medical, surgical, or psychiatric treatments are without risks or side effects, the treatments for adolescents and adults with diagnosed Gender Dysphoria have been found to be generally safe and effective, with favorable outcomes on a variety of outcome measures (Kuper, et al., 2019; Carmichael, et al., 2021; Bustos, et al., 2021; van der Miesen, et al., 2020; Simonsen, et al., 2015; Murad, et al., 2010; Almazan and Keuroghlian, 2021). Defendants' experts criticize my opinions and the opinions of other of Plaintiff's experts for supposedly ignoring relevant scientific literature, but notably, they fail to acknowledge these recent and highly relevant studies. These studies confirm what experts in the field have long known: the widely accepted standard-of-care treatments for

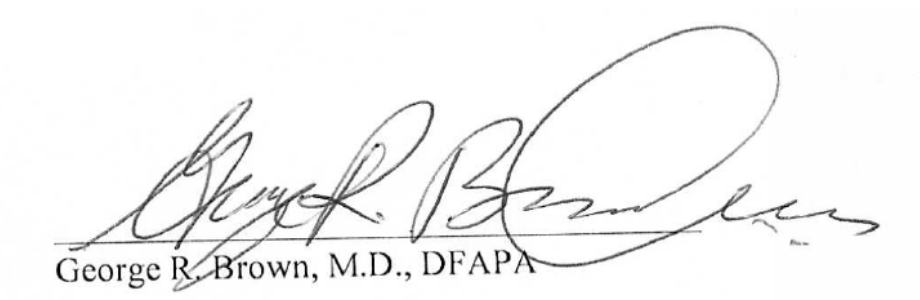
adolescents and adults diagnosed with Gender Dysphoria are medically necessary and associated with a favorable risk/benefit ratio for most patients who are deemed appropriate for these interventions.

80. Defendants' witnesses further situate themselves outside the mainstream of the medical field by rejecting well-accepted treatment protocols recognized by the major medical and mental health professional associations in the United States. As set forth in my original report, the World Professional Association of Transgender Health publishes Standards of Care for treating Gender Dysphoria. WPATH is an internationally recognized association comprising nearly 2,500 medical, surgical, mental health, and other professionals who specialize in the evaluation and treatment of transgender and gender non-conforming people. The WPATH Standards of Care, which are in their seventh revision, represent the evidence-based consensus of experts in the field and have been recognized as the authoritative treatment protocols by the major medical and mental health associations in the United States, including the American Psychiatric Association, the American Medical Association, the American Psychological Association, and the American Academy of Pediatrics.

81. The Veterans Health Administration ("VHA")—the largest integrated health care system in the United States—treats transgender veterans largely based on the guidelines set forth in the current version of the WPATH SOC, and references these standards in their national training programs. I have been directly involved with the

to transition to the male gender role. This is a misinterpretation of that statement, and is an example of Dr. Lappert engaging in the "confirmation bias" that he claims to be present in all of the clinicians' records and in my evaluations of the Plaintiffs. Had Dr. Lappert interviewed C.B., as I did, he would have learned that that comment meant that C.B. was tired of the lengthy process of "being trans" and wanted to get to the point where "trans" no longer identified him and he could just be identified as a "man" and not as a "transgender man." It should also be noted that no fewer than seven clinicians have diagnosed C.B. as having the diagnosis of Gender Dysphoria.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 10th day of June, 2021.



George R. Brown, M.D., DFAPA

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

MAXWELL KADEL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:19CV272
DALE FOLWELL, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER

LORETTA C. BIGGS, District Judge.

Plaintiffs are transgender individuals or the parents of transgender individuals who receive health insurance through the North Carolina State Health Plan for Teachers and State Employees ("NCSHP" or the "Plan"). (ECF No. 75 ¶¶ 1, 7–12.) They allege that the Plan's categorical exclusion of coverage for treatments "leading to or in connection with sex changes or modifications" discriminates against them on the basis of sex and transgender status in violation of the Equal Protection Clause and the Affordable Care Act ("ACA") and seek declaratory, injunctive, and monetary relief. (*Id.* ¶¶ 1, 139–53, 165–74.) Plaintiff Dana Caraway additionally alleges that NCSHP and her employer, the North Carolina Department of Public Safety ("DPS"), discriminated against her on the basis of sex by offering and administering the Plan in violation of Title VII of the Civil Rights Act of 1964. (*Id.* ¶¶ 175–188.) Before the Court are cross motions for summary judgment filed by DPS, NCSHP, and

Plaintiffs, (ECF Nos. 132; 136; 178); Plaintiffs' motions to exclude expert testimony, (ECF Nos. 202; 204; 206; 208; 212); and Plaintiffs' motions to seal, (ECF Nos. 182; 210).[1]

For the reasons stated herein, the Court finds that the Plan's exclusion discriminates based on sex and transgender status in violation of the Equal Protection Clause and discriminates because of sex in violation of Title VII. The Court will reserve a ruling on claims alleged under the ACA pending further Order from this Court.

I. BACKGROUND

A. Plaintiffs' experiences with the Plan

Plaintiff Connor Thonen-Fleck is a 19-year-old man. (ECF No. 179-2 ¶ 2.) He is also transgender. (*Id.* ¶ 3.) Thonen-Fleck was "designated 'female' at birth" but identifies and lives his life as a man. (*Id.*) In his words, he "demonstrated stereotypically masculine tendencies and characteristics from a young age," and by 15 years old, "had socially transitioned and was living in [his] authentic male gender identity in all aspects of [his] life." (*Id.* ¶¶ 5–6.) His male identity is now reflected in his legal name, gender marker, birth certificate, and driver's license. (*Id.* ¶ 8.)

Before Connor and his family understood what it meant to be transgender, Connor "was in serious and increasing distress" and suffered from depression and suicidal ideation.

[1] These include: a Motion for Summary Judgment filed by Defendant North Carolina Department of Public Safety, (ECF No. 132); a Motion for Partial Summary Judgment filed by Defendants Dale Folwell, Dee Jones, and NCSHP, (ECF No. 136); Plaintiffs' Motion for Summary Judgment, (ECF No. 178); Plaintiffs' Motion to Seal Exhibits to Plaintiffs' Motion for Summary Judgment, (ECF No. 182); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Peter Robie, (ECF No. 202); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul W. Hruz, (ECF No. 204); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul R. McHugh, (ECF No. 206); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert, (ECF No. 208); Plaintiff's Motion to Seal portions of Dr. Lappert's report, (ECF No. 210); and Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D., (ECF No. 212).

(*Id.* ¶ 5; ECF No. 179-3 ¶ 6.) His psychiatrist diagnosed him with gender dysphoria. (ECF No. 185-1 at 40–41; *see* ECF No. 179-2 ¶ 7.) Gender dysphoria is "a condition that is characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex." (ECF No. 219 at 10; *see* ECF No. 197 at 13.) Treatments may include therapy, medications, or surgery to align the patient's physiology with their identity and "allow[ ] the individual to transition from his or her birth assigned sex to the sex associated with his or her gender identity." (ECF No. 219 at 10.) In Connor's case, his physicians recommended counseling, hormone therapy beginning in January 2018, and ultimately chest reconstruction surgery in May 2019 "to bring [his] body into better alignment with [his] gender identity and lived experience and further reduce [his] symptoms of gender dysphoria." (ECF Nos. 179-2 ¶¶ 7, 9–10; 179-3 ¶ 15.) In his father's words, "it was clear that being a teenage boy without a typically male chest was very painful for [Connor]." (ECF No. 179-3 ¶ 13.)

Connor has health insurance through his father, who is a state employee at the University of North Carolina, Greensboro and a member of the North Carolina State Health Plan for Teachers and State Employees ("NCSHP" or the "Plan"). (*Id.* ¶¶ 2–4.) When Connor was prescribed testosterone treatments in 2018, NCSHP denied coverage due to a categorical exception for "[t]reatment or studies to or in connection with sex changes or modifications and related care." (*Id.* at 22.) Connor's chest surgery also was not covered. (*Id.* ¶ 14.) As a consequence, the family had to delay the surgery, and Connor worked after school to help raise money for his healthcare. (*Id.* ¶¶ 14–15; ECF No. 179-2 ¶ 14.) Eventually, the family saved enough to pay out of pocket. (ECF No. 179-3 ¶ 15.) Connor and his father testify that

the treatments were "life-changing" and "critical for [his] ongoing development and functioning as a young adult." (*Id.* ¶ 16; ECF No. 179-2 ¶ 16.) Connor will need ongoing access to hormone therapy and anticipates requiring additional surgery to continue treatment of his gender dysphoria. (ECF No. 179-2 ¶ 17.)

Connor's experience is typical of remaining Plaintiffs. Plaintiffs are all current or former North Carolina state employees or dependents of state employees who receive health insurance through NCSHP. (ECF Nos. 179-1 ¶¶ 2, 5; 179-4 ¶¶ 2, 8; 179-5 ¶ 19; 179-6 ¶¶ 2, 5; 179-7 ¶¶ 5–6; 179-9 ¶¶ 2, 16.) Plaintiffs or their dependents identify as transgender. (ECF Nos. 179-1 ¶ 2; 179-4 ¶ 2; 179-5 ¶ 4; 179-7 ¶ 2; 179-9 ¶ 3.) These Plaintiffs each formed their gender identities early in childhood, (*see, e.g.*, ECF No. 179-5 ¶ 6 ("Ever since I was a young child, I have known that I am [a] boy.")); *see generally* ECF Nos. 179-1 ¶ 6; 179-4 ¶ 4–5; 179-6 ¶¶ 7–8; 179-9 ¶ 9), and have suffered from anxiety and depression caused by suppression of their gender identities, discrimination and harassment from peers, and living with physical features not typical of the gender with which they identify, (ECF Nos. 179-1 ¶ 8; 179-4 ¶ 4; 179-5 ¶¶ 13, 24; 179-7 ¶ 7; 179-9 ¶ 11). Each has been diagnosed with gender dysphoria. (ECF Nos. 179-1 ¶ 6; 179-4 ¶¶ 4, 5, 9; 179-5 ¶ 14; 179-7 ¶ 8; 179-9 ¶ 19; 185-1 at 31, 34, 37, 40–41, 43, 60.) And each has been denied coverage for procedures prescribed to treat gender dysphoria, to include puberty delaying medication, hormone therapy, mastectomy, mammaplasty, vaginoplasty, and vocal therapy. (ECF Nos. 179-1 ¶¶ 7, 9–15; 179-4 ¶¶ 9–10; 179-5 ¶¶ 20–22; 179-7 ¶¶ 13–17; 179-9 ¶¶ 20–21, 23–26.)

B. The Exclusion

The basis for NCSHP's denial of coverage is an exclusion that dates back to the 1990s. (ECF No. 137-2 at 16:10-13.) The North Carolina General Assembly originally formed NCSHP to administer "one or more group health plans that are comprehensive in coverage" and tasked the State Treasurer, NCSHP Executive Administrator, and NCSHP Board of Trustees with certain "duties and responsibilities as fiduciaries for the Plan." N.C. Gen. Stat. § 135-48.2(a). The Plan is North Carolina's largest insurer with approximately 740,000 members. (ECF Nos. 137-1 at 35:9-12; 137-2 at 74:1-5.) Individual members pay a monthly premium with additional funding coming from the state. (ECF Nos. 137-2 at 102:22-24, 105:22-24; 137-3 at 1.) From January to August 2018, NCSHP had collected approximately $2.4 billion in revenue and had a cash balance of approximately $1.1 billion. (ECF No. 184 at 132, 142.)

The Plan only covers "medically necessary" services but does not cover all medically necessary services. (ECF No. 137-2 at 58:4-7.) "Medically necessary services or supplies" are defined by North Carolina statute as those services or supplies that are (1) "[p]rovided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease" and "not for experimental, investigational, or cosmetic purposes," (2) "[n]ecessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease, or its symptoms," (3) [w]ithin generally accepted standard of medical care in the community," and (4) "[n]ot solely for the convenience of the insured, the insured's family, or the provider." N.C. Gen. Stat. § 58-3-200(b).

Each year, NCSHP adopts and publishes PPO Plan Benefit Booklets that list the healthcare that is and is not covered by the Plan. (*See* ECF No. 184 at 56–104.) The Plan's third-party administrators, Blue Cross/Blue Shield of North Carolina ("Blue Cross") and CVS/Caremark ("CVS"), then implement the booklet using the national billing practices and medical coding system of the healthcare industry. (ECF Nos. 137-1 at 119:9-10; 197-14 ¶ 11.) From the 1990s to 2016, the Plan contained two exclusions relevant to Plaintiffs' causes of actions. The 2016 Plan did not cover:

- Psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation.
- Treatment or studies leading to or in connection with sex changes or modifications and related care.

(ECF No. 184 at 59–60.) According to Defendants, the first exception has never been implemented and is no longer part of the Plan. (*See* ECF Nos. 137 at 13 n.2; 137-4 ¶ 27.) Blue Cross and CVS do give effect to the second exclusion by identifying specific treatments that are not covered. (ECF No. 137-4 ¶¶ 20–21; *see, e.g.*, ECF No. 179-3 at 12–13.) According to Blue Cross, four procedures are not covered by the Plan "regardless of the diagnostic code," to include "Intersex Surgery, Male to Female," "Intersex Surgery, Female to Male," "Vaginoplasty for Intersex State," and "Clitoroplasty for Intersex State." (ECF No. 137-4 ¶ 20.) Two dozen other procedures are not covered when the procedural diagnostic code is for "Transsexualism" or "Personal history of sex reassignment." (*Id.* ¶ 21.) CVS likewise may deny coverage for medication, such as puberty blockers or hormone treatments, due to the exclusion. (*See* ECF No. 179-3 at 13 (denying coverage for testosterone where the associated diagnosis was "Transsexualism").)

The Plan did briefly cover "*Medically necessary* services for the treatment of gender dysphoria" in 2017. (ECF No. 184 at 63.) On May 18, 2016, the U.S. Department of Health and Human Services ("HHS") promulgated a final rule prohibiting "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375, 31471–72 (May 18, 2016). The NCSHP Board of Trustees acted to comply with the regulation and considered "remov[ing] the blanket exclusions that relate to treatment or studies leading to or in connection with sex changes or modifications and related care" and instead covering "medically necessary services for the treatment of gender dysphoria." (ECF No. 185-2 at 34.) At that time, the Board estimated that coverage would cost between $344,013 and $862,292 per year. (ECF No. 184 at 36.) Ultimately, the Board elected to remove the exclusion only for the 2017 year, and it went back into effect in 2018. (ECF No. 185-2 at 35; *see* ECF No. 184 at 66–67.) The total cost to NCSHP of removing the exclusion in 2017 was $404,609.26. (ECF No. 184 at 23.)

C. Scientific background

"The health care community's understanding of what it means to be transgender has advanced greatly over the past century." (ECF No. 219 at 2 (Brief of *Amici Curiae* the American Medical Association, *et al.*).) The health care community now understands that being transgender relates to a person's "internal sense" of gender and is not a psychiatric condition. (*Id.* at 7.) "Every person has a gender identity." (*Id.*) A "cisgender" person's internal gender aligns with their physiological, chromosomal, and birth-assigned sex. (*Id.* at 5.) But not all individuals who "depart from stereotypical male and female appearances and

roles" identify as transgender; rather, transgender individuals are those who "consistently, persistently, and insistently" identify as a gender "different from the sex they were assigned at birth." (*Id.* at 8–9.) Being transgender "implies no impairment in a person's judgment, stability, or general social or vocational capabilities." (*Id.* at 2.)

While being transgender is not itself a psychiatric condition, many transgender individuals experience severe anxiety and distress as a result of having physiology or an assigned sex that does not match their "deeply felt, inherent sense of their gender." (*Id.* at 5, 10 (internal quotations omitted).) Like Plaintiffs, many of these transgender individuals have been diagnosed with gender dysphoria. (*Id.* at 10.) Gender dysphoria is "characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex." (*Id.*) The Diagnostic and Statistical Manual of Mental Disorders, volume 5 ("DSM" or "DSM-5"), published by the American Psychiatric Association, provides diagnostic criteria for gender dysphoria in adults, to include "[a] marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration," plus "clinically significant distress or impairment in social, occupational, or other important areas of functioning." (*Id.* at 10–11 (quoting DSM-5).)

Gender dysphoria "can cause debilitating distress, depression, impairment of function, self-mutilation to alter one's genitals or secondary sex characteristics, other self-injurious behaviors, and suicide." (*Id.* at 11.) It is treated both through counseling and medical and surgical treatments to bring the patient's physiology in line with their gender identity. (*Id.* at 13.) The World Professional Association for Transgender Health ("WPATH") publishes Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming

People. (*Id.* at 12.) The current Standards of Care ("WPATH-7") recommended treatments "include[ ] assessment, counseling, and, as appropriate, social transition, hormone therapy, and surgical interventions." (*Id.* at 13.) These treatments are recommended on a case-by-case basis, and "each patient requires an individualized treatment plan that accounts for the patient's specific needs." (*Id.* at 14.)

Plaintiffs' experts testify that such medical and surgical treatment for gender dysphoria is "medically necessary treatment" for many individuals with gender dysphoria. (ECF No. 185-1 at 23, 238, 331, 333.) They testify that these are "safe and effective treatment[s] for gender dysphoria" that are governed by "well-established community standards." (*Id.* at 23, 192.) They report that such treatments are supported by "[d]ecades of methodologically sound and rigorous scientific research," and that "every relevant medical and behavioral health association agrees that gender-confirming care is a medically necessary treatment for individuals with gender dysphoria." (*Id.* at 238, 333.) Eight professional medical associations agree in their amicus brief with Plaintiffs' experts' assessment. (*See generally* ECF No. 219.)

Defendants' experts dispute this testimony. They testify that medical and surgical treatments have significant medical risks and consequences, and the research supporting such treatments is of "low quality." (ECF Nos. 215-1 at 49, 52, 53, 56; 215-2 at 10, 13; 215-3 at 7, 52–54; 215-4 at 17–19, 29–39.) They contest the efficacy of the DSM-5 and WPATH-7 and challenge the credibility and motivations of what they call the "Transgender Treatment Industry." (ECF Nos. 215-1 at 15, 36–40, 47; 215-2 at 6–9, 10–12; 215-3 at 8, 28–31, 36–39; 215-4 at 6–8, 12.) Some of Defendants' experts testify that gender dysphoria should be treated by counseling alone and medical or surgical interventions are not medically necessary, (*see, e.g.*,

ECF No. 215-3 at 16–17, 50–52), while one testifies that physicians should proceed cautiously in prescribing medication and surgery on a case-by-case basis, (*see* ECF No. 213-3 at 152:20-25)

D. Procedural history

Plaintiffs filed their suit on March 11, 2019, against Defendant Dale Folwell, in his official capacity as State Treasurer of North Carolina, Defendant Dee Jones, in her official capacity as Executive Administrator of NCSHP, and NCSHP (collectively, "Health Plan Defendants"), and three public universities: the University of North Carolina at Chapel Hill, North Carolina State University, and the University of North Carolina, Greensboro (collectively, "University Defendants"). (ECF No. 1.) Plaintiffs initially alleged violations of the Equal Protection Clause, Title IX of the Education Amendments of 1972, and the ACA. (*Id.* ¶¶ 124–157.)

University Defendants moved to dismiss Plaintiffs' claims against them on July 8, 2019, for lack of standing and failure to state a claim under Title IX. (ECF No. 30.) Health Plan Defendants likewise filed a motion to dismiss on the same day, arguing that Plaintiffs failed to state claims under the Equal Protection Clause or the ACA. (ECF No. 32.) On March 10, 2020, the Court denied both motions. (ECF No. 45.) Health Plan Defendants filed an interlocutory appeal of their denial on April 8, 2020. (ECF No. 50.) The Fourth Circuit affirmed this Court's Order on September 1, 2021. (ECF Nos. 113; 114.) Health Plan Defendants filed a petition for certiorari in the U.S. Supreme Court on November 8, 2021, (ECF No. 127), which was denied on January 18, 2022, (ECF No. 195).

In the interim, Plaintiffs filed a motion to amend their complaint on August 3, 2020. (ECF No. 62.) Plaintiffs' motion was granted on March 5, 2021. (ECF No. 74.) Plaintiff's First Amended Complaint (the "Complaint") added Dana Caraway as a Plaintiff, DPS as a Defendant, and a fourth cause of action arising under Title VII against NCSHP, DPS, and University Defendants. (ECF No. 75 ¶¶ 12, 18, 130–37.) University Defendants subsequently settled with Plaintiffs and have been dismissed from this suit. (ECF No. 112.)

DPS and Plan Defendants filed their motions for summary judgment on November 30, 2021. (ECF Nos. 132; 136.) Plaintiffs originally filed two summary judgment motions on the same day. (ECF Nos. 138; 152.) On December 10, 2021, the Court struck Plaintiffs' motions and allowed Plaintiffs to file a single dispositive motion with an accompanying memorandum not to exceed 9,000 words. (ECF No. 176.) Plaintiffs then filed their Motion for Summary Judgment on December 20, 2021. (ECF No. 178.) Plaintiffs simultaneously filed a Motion to Seal certain paragraphs of their expert's testimony that describe in detail Plaintiffs' medical history. (ECF No. 182.) Plaintiffs filed their motions to exclude Defendants' experts' testimony on February 2, 2022, along with a motion to seal portions of one expert's report which likewise details Plaintiffs' medical history. (ECF Nos. 202; 204; 206; 208; 210; 212.)

The American Medical Association ("AMA"), American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Psychiatric Association ("APA"), Endocrine Society, North American Society for Pediatric and Adolescent Gynecology, National Association of Nurse Practitioners in Women's Health, and Society of

OB/GYN Hospitalists, together filed an amicus brief with leave of the Court on April 11, 2022, in support of Plaintiffs' summary judgment motion. (ECF No. 219.)

Trial is set in this case for July 5, 2022. (ECF No. 115.) The parties have filed a Joint Motion to Specially Set Trial and Allow 8-10 Days for Proceedings. (ECF No. 225.)

II. MOTIONS TO EXCLUDE TESTIMONY

The Court will first address Plaintiffs' motions to exclude expert testimony. The admissibility of expert opinion is governed by Rule 702 of the Federal Rules of Evidence and the Supreme Court's landmark ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides that a witness "who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:"

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Thus, expert testimony is admissible only if: (1) the expert is qualified, (2) the testimony is relevant, and (3) the testimony is based on reliable scientific methodology.[2] *See Daubert*, 509 U.S. at 594–95. The Court must find these elements "at the outset, . . . by a preponderance of proof." *Id.* at 592; *id.* n.10.

[2] Although *Daubert* interpreted an earlier version of Rule 702, "the standard of review that was established for *Daubert* challenges is still appropriate" to assess the admissibility of expert testimony. *United States v. Parra*, 402 F.3d 752, 758 (7th Cir. 2005); *see In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prod. Liab. Litig.*, 424 F. Supp. 3d 781, 789 (N.D. Cal. 2020) ("[N]o obvious conflict arises between [Rule 702] as amended and *Daubert*, at least as relevant to the issues in this case."); *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 282 (4th Cir. 2021) ("Rule 702 was amended specifically to affirm the trial courts role as gatekeeper." (internal quotations omitted)).

An expert is *qualified* if he or she has "specialized knowledge that will assist the trier of fact in understanding the evidence or determining a fact in issue." *United States v. Young*, 916 F.3d 368, 379 (4th Cir. 2019). A witness' qualifications are "liberally judged by Rule 702," and "a person may qualify to render expert testimony in any one of the five ways listed" by the Rule: "knowledge, skill, experience, training, or education." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *see Cooper v. Lab'y Corp. of Am. Holdings*, 150 F.3d 376, 380 (4th Cir. 1998). However, the expert must be qualified to testify "on the issue for which the opinion is proffered." *Kopf*, 993 F.2d at 377. "[G]eneral knowledge," skill, experience, training, or education is insufficient to qualify an expert, and an expert qualified in one field may be unqualified to testify in others. *Cooper*, 150 F.3d at 380–81 (finding that a witness who had "a general knowledge of chemistry" and "experience with breath alcohol testing" was not an expert in "the field of urine alcohol testing"); *see Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 199 (4th Cir. 2013) (finding that a Ph.D.-holding neuropsychologist and neurotoxicologist was not a medical doctor and therefore was "not qualified to diagnose the cause of [plaintiff's] alleged symptoms"); *see also Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) ("The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas.") (collecting cases).

An expert who is qualified must provide testimony that is relevant. An expert's opinion is *relevant* if it "fit[s]" the facts of the case, meaning it has "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591–92. "This ensures that the expert 'helps the trier of fact to understand the evidence or to determine a fact in issue.'" *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (quoting *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th

Cir. 2017)). An outmoded or inapplicable standard that "does not even apply to" the facts at issue "categorically lacks 'a valid scientific connection to the pertinent inquiry'" and is "the touchstone of irrelevancy." *Id.* at 289 (quoting *Daubert*, 509 U.S. at 592). "Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.* at 281.

Finally, relevant testimony must also by reliable. An expert's opinion is *reliable* if it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* (emphasis omitted) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). While the subject of scientific testimony must not "be 'known' to a certainty," it must be "derived by the scientific method" and "supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. Reliability is a "flexible" inquiry that must focus "solely on principles and methodology, not on the conclusions that they generate." *Id.* at 594–95. In *Daubert*, the Court outlined a non-exhaustive list of factors to guide lower courts in assessing reliability, including: (1) whether the theory can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) its potential rate of error; (4) whether standards exist to control the technique's operation; and (5) the degree of acceptance of the methodology within the relevant scientific community. *Id.* at 593–94. These factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony," and courts have "broad latitude" in choosing which factors are "reasonable measures of reliability in a particular case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150, 153 (1999).

"One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted

independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*"); Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments); *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 470 (M.D.N.C. 2006); *see McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 1008 (4th Cir. 2020) (Agee, J., concurring in part and dissenting in part). "An 'expert' opinion is considered unreliable and inadmissible under *Daubert* where . . . the expert has developed the opinions expressly for purposes of testifying in the case . . . ." *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158, at *5 (4th Cir. 1998) (unpublished); *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1369 (11th Cir. 2014).

"Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge . . . exercises more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595. Rule 702 "imposes a special gatekeeping obligation on the trial judge to ensure that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Sardis*, 10 F.4th at 281 (internal quotations omitted). A court cannot "abandon the gatekeeping function" by deferring its responsibility to the jury. *Id.* at 282 (quoting *Kumho*, 526 U.S. at 159 (Scalia, J., concurring)). Ultimately, a district court's Rule 702 analysis "necessarily amount[s] to an exercise of broad discretion guided by the overarching criteria of relevance and reliability." *Belville v. Ford Motor Co.*, 919 F.3d 224, 233 (4th Cir. 2019).

Although Rule 702 "is not intended to serve as a replacement for the adversary system," *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 631 (4th Cir. 2018), this Court takes seriously its gatekeeping role to protect lay

jurors from "powerful and quite misleading" expert testimony, *Daubert*, 509 U.S. at 595. The Court will address each of Plaintiffs' motions to exclude expert testimony in turn.

A. Dr. Peter Robie (ECF No. 202)

Dr. Peter Robie is a primary care physician and Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine at Wake Forest School of Medicine. (ECF No. 215-5.) Robie is also a member of the NCSHP Board of Trustees and has provided medical knowledge during the Board's deliberations. (*Id.*) Defendants plan to call Robie only to testify (1) "to the medical knowledge he has shared with other Board members" and (2) that "physicians must know the chromosomal sex of patients" to provide competent medical care. (*Id.*) Robie "does not seek to provide testimony on the efficacy of gender dysphoria treatment or the lack thereof" and has not submitted an expert report. (ECF No. 215 at 15.)

Regarding the medical knowledge Robie shared with other Boards members, Defendants do not plan to elicit Robie's expert opinion; rather, he plans to testify as a fact witness to information he provided to the Board. Rule 702 is therefore inapplicable. The Court expresses no opinion on the admissibility or relevance of the proffered testimony.

Regarding Robie's testimony concerning chromosomal sex, Defendants do not explain why they seek to introduce this opinion. Elsewhere, Defendants have argued that "[h]ealthcare providers must know a patient's sex for *every* medical diagnosis" to rebut a hypothetical argument 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." (ECF No. 197 at 32.) However, in Section III.A.i., *infra*, this Court finds that heightened

scrutiny is appropriate in this case because the *Plan* discriminates based on sex on its face, not because Plaintiffs' medical providers considered their sexes. Thus, Robie's testimony is not relevant to any fact at issue. Regardless, Robie's failure to submit an expert report or provide any basis for his opinion other than a vague reference to his years of practice precludes this Court from finding that his expert opinion is based on a reliable methodology under Rule 702.

Accordingly, Plaintiffs' motion to exclude Robie as an expert witness will be granted. This Court expresses no opinion as to whether he may be called as a fact witness.

B. Dr. Paul Hruz (ECF No. 204)

Dr. Hruz is a board-certified specialist in pediatric endocrinology, Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes and Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine in St. Louis, Missouri. (ECF No. 215-3 ¶¶ 2–3.) He holds a Ph.D. and M.D. from the Medical College of Wisconsin. (*Id.* at ¶ 2.) He additionally served as chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012–2017 and Director of the Pediatric Endocrinology Fellowship Program from 2008–2016. (*Id.*) He has published 60 scholarly articles over two decades in the fields of metabolism, cardiology, HIV, and ethics. (*Id.* ¶ 4.) He was a founding member of Washington University's multidisciplinary Disorders of Sexual Development program and has participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development during his career. (*Id.* ¶ 6.)

Hruz offers a wide range of conclusions that fall into five main categories: mental healthcare, medical and surgical care, informed consent, criticism of medical associations, and

political criticisms. First, he offers several opinions on the mental health treatment of gender dysphoria, to include that "[m]ental health care professionals are unreliable human 'lie detectors' [whose diagnoses are] 'often no better than flipping a coin,'" (*id.* ¶ 28); that the DSM is scientifically unreliable; (*see id.* ¶ 13.B); that gender dysphoria is caused by a "social contagion," (*id.* ¶ 41); that "the vast majority of children who report gender dysphoria" will "desist," meaning that "if left untreated, [they will] grow out of the problem . . . and willingly accept their biological sex," (*id.* ¶¶ 8, 53); and that a "watchful waiting" approach whereby mental health providers "neither encourage nor discourage transgender identification" is the most effective form of treatment, (*id.* ¶¶ 52–53). Second, he will testify to the risks associated with hormone treatments and surgery to treat gender dysphoria, particularly in prepubescent children. (*Id.* ¶¶ 57, 58, 60.) Third, he will testify that healthcare providers often fail to obtain informed consent from patients by inaccurately describing the risks associated with hormone therapy or surgery. (*Id.* ¶ 36.) Fourth, he will criticize organizations that support gender affirming care, such as the AMA, WPATH, and the American Psychiatric Association, as unscientific and politically motivated. (*See e.g. id.* ¶ 34.A.) Fifth, he will testify that "Cancel Culture," "transgender and allied political activists," and the "Transgender Treatment Industry" are attempting to "silence open public debate on the risks and benefits of transgender medical procedures and political ideologies." (*Id.* ¶¶ 64–66.)

Plaintiffs have offered evidence that calls Hruz's motivations—and thereby, his reliability—into serious question. Hruz admits a connection to the Alliance Defending Freedom ("ADF"), a political organization with both "moral objections" and scientific objections to the treatments at issue. (ECF Nos. 205-2 at 241:10–242:15; 209-3 at 81:5-13.)

Early in his research of gender dysphoria, Hruz told a fellow doctor that he had "a significant problem with the entire issue" and "whole idea of transgender." (ECF No. 205-10 ¶ 11–13 (testifying that Hruz's concerns about the relevant treatments were not "based on science" but rather were "a matter of [his] faith").) Hruz does not recall making these statements. (ECF No. 205-2 at 249:19–251:6.) Hruz also met with parents of transgender children early in his research "to understand the unique difficulties experienced by this patient population." (ECF No. 215-3 ¶ 7.) One such parent testifies that the conversation had a "religious tone" and was not "based on science," and that Hruz "kept insisting that [her] child was not normal and would never be normal," that "the idea of doing surgeries on transgender people is—is wrong," and in response to her assertion that transgender children without supportive parents are at an increased risk of suicide, that "[s]ome children are born in this world to suffer and die." (ECF No. 205-11 at 27:17-24, 28:20-23, 29:21–30:1, 37:13-19.) Plaintiffs argue that this evidence shows Hruz's "expert" testimony did not grow naturally from his work as an endocrinologist; rather, he manufactured his opinions expressly for purposes of testifying against medical care against which he has moral and political objections.

Based on the preponderance of the evidence, this Court finds the following:

First, Hruz is not qualified to offer expert opinions on the diagnosis of gender dysphoria, the DSM, gender dysphoria's potential causes, the likelihood that a patient will "desist," or the efficacy of mental health treatments. Hruz is not a psychiatrist, psychologist, or mental healthcare professional. He has never diagnosed a patient with gender dysphoria, treated gender dysphoria, treated a transgender patient, conducted any original research about gender dysphoria diagnosis or its causes, or published any scientific, peer-reviewed literature

on gender dysphoria. (ECF Nos. 205-2 at 35:5–36:11, 42:14–49:23, 88:18–90:6; 205-4 at 24:11-14, 25:20-23, 61:17–64:7.) Merely reading literature in a scientific field does not qualify a witness—even an educated witness—as an expert. *See Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.").

Second, Hruz is qualified as an endocrinologist to testify to the risks associated with puberty blocking medication and hormone therapy. This testimony is broadly relevant to assessing whether the Plan's exclusion is substantially related to the state's interest in protecting employees and the public from ineffective medical treatments. It also appears sufficiently reliable, as it is based on Hruz's long career treating patients and conducting academic research on the effects of hormone treatments. However, Hruz's testimony that focuses on the risks associated with providing hormone therapy to prepubescent children—children who have not begun puberty—is not relevant. (*See, e.g.*, ECF No. 215-3 ¶ 54.) By his own admission, "no medical and surgical interventions are initiated until after the onset of puberty" under any model of treatment, (ECF No. 205-2 at 125:23–126:5), and Plaintiffs appear to concede that hormone treatment is not medically necessary to treat gender dysphoria in prepubescent children, (ECF No. 205 at 11–12). In this case, the youngest Plaintiff received puberty blocking medication when puberty began around age 12. (*See* ECF No. 179-5 ¶¶ 13–14.) Thus, a discussion of risks to prepubescent children is irrelevant to this case and would likely serve only to confuse the jury. Additionally, Hruz is not a surgeon and has no experience with surgery for gender dysphoria and, therefore, is not qualified to testify to the risks

associated with surgery or the standard of care used by surgeons for obtaining informed consent for surgery.

Third, Hruz provides no scientific basis to his conclusion that "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'" or that endocrinologists generally do not obtain informed consent from their gender dysphoric patients. Hruz is not a statistician and does not discuss in his report how he came to those conclusions, what data he relied upon, or what methodology he applied to that data. This testimony will therefore be excluded as unreliable.

Fourth, it does not appear that Hruz has any experience with the AMA, WPATH, or American Psychological Association upon which to base his criticisms. (*See* ECF No. 215-3 ¶ 34.) He is therefore not qualified to testify about the credibility of those organizations. Moreover, Hruz's criticism of the AMA appears largely based on its historical support of eugenics procedures not at issue in this case, and Hruz has not explained what scientific methodology if any he used to compare and contrast treatment of gender dysphoria with the eugenics movement. (*See id.* ¶ 34.A.) Hruz is not qualified to opine on the deficiencies of the DSM and the American Psychological because he is not a mental health professional. (*See id.* ¶ 34.C.) Given that other of Defendants' experts are intimately familiar with the "consensus building" method employed by WPATH, the AMA, and similar organizations, the Court finds that Hruz has not offered any reliable testimony on this subject that will help the trier of fact.

Finally, it does not appear that his repeated references in his report to a "Gender Transition Industry," "Cancel Culture," and political activists working to "silence open public

debate" has any basis, scientific or otherwise. (*See id.* ¶ 65.) He provides no evidence of such a conspiracy or any reliable methodology supporting his opinion as required by Rule 702. Rather, his conspiratorial intimations and outright accusations sound in political hyperbole and pose a clear risk of inflaming the jury and prejudicing Plaintiffs. It is the Federal Rules of Evidence, not some "Cancel Culture," that excludes this portion of Hruz's testimony. Since these claims are not based in any methodology and will not assist the trier of fact, this testimony is inadmissible.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and Hruz is limited in his testimony to a discussion of the risks associated with prescribing hormone treatments to adolescents and adults.

C. Dr. Paul R. McHugh (ECF No. 206)

Dr. Paul R. McHugh is a licensed psychiatrist and Distinguished Service Professor of Psychiatry at Johns Hopkins University School of Medicine with more than fifty years of experience. (ECF No. 215-2 at 1–2.) He holds an M.D. from Harvard Medical School and was qualified in both Psychiatry and Neurology by the American Board of Psychology and Neurology. (*Id.*) He served as director of the Department of Psychiatry and Behavioral Science at Johns Hopkins Medical School and psychiatrist-in-chief at Johns Hopkins Hospital for nearly 30 years and served as Chairman of the Medical Board of Johns Hopkins University Hospital from 1984–1989. (*Id.* at 2.) He has published several books and numerous peer reviewed articles in scientific journals. (*Id.* at 3.) He was elected to the Institute of Medicine of the National Academies of Science in 1992 and is a Distinguished Life Fellow of the American Psychiatric Association. (*Id.* at 4.)

McHugh's fifteen-page report offers cursory opinions on a wide range of topics. According to their brief, Defendants primarily seek to elicit from McHugh testimony that the DSM is unreliable and was not scientifically formed, and that no rigorous scientific research proves that medical or surgical treatments for gender dysphoria will improve the wellbeing of patients. (ECF No. 215 at 28–31.) His report also contains several "Summary Opinions" on the causes of gender dysphoria, rates of desistence, and acceptance of treatments within the medical community. (ECF No. 215-2 at 12–14.)

Based on the preponderance of the evidence, the Court finds that McHugh is qualified as an expert in the field of psychiatry by his more than fifty years of experience as a psychiatrist and academic. Further, his general description of the process by which the current edition of the DSM was created and opinion about the scientific limitations of such a process are broadly relevant to rebut Plaintiffs' expert testimony, as Plaintiffs' experts use and rely on the DSM's definition of gender dysphoria. This testimony is based in McHugh's personal knowledge and experience and is sufficiently reliable to be admissible.

However, Defendants have failed to show that McHugh's more specific criticisms of the DSM's approach to gender dysphoria are relevant or based on reliable science. McHugh's primary criticisms of the DSM come from his work on various "Psychiatric Misadventures," to include "lobotomies," "repressed memory therapy," and "multiple personality disorder"—issues that are not relevant to this case. (*See id.* at 5–6, 9–10.) To the extent he offers this testimony to show that treatment for gender dysphoria is "yet another Psychiatric Misadventure," (*id.* at 10–11), his argument-by-analogy does not appear to be based on any

reliable scientific methodology. Instead, he simply suggests that, because the DSM was wrong before, it might be wrong again. Such speculation is inadmissible under Rule 702.

Next, he testifies that "national research reviews in England, Sweden, and Finland as well [as] a Chochrane Review and studies by multiple researchers have concluded that the evidentiary base for these experimental treatments [for gender dysphoria] is weak and demonstrates few benefits or actually shows this procedures [sic] can cause more harm than good." (*Id.* at 10.) But his report does not cite to any such reviews or studies, (*id.*), and when questioned about them at deposition, he could not recall if the "national reviews" in England or Finland were peer-reviewed or published in scientific journals, and admitted that the Swedish "national review" was not a national review at all, but rather an academic scientific study by Swedish researchers, (ECF No. 207-3 at 300:19–301:20, 302:20–303:6). The Court therefore finds that McHugh's discussion of such studies is not based on reliable science.

Similarly, he testifies without any definition, explanation, or supportive methodology that "the exponential growth [of gender dysphoria] in patients was indeed predicted and is readily explained by a social contagion theory." (ECF No. 215-2 at 11 ("[S]ocial contagion *seems* more likely." (emphasis added)).) He supports this claim with a citation to his own article coauthored by Hruz and published in *The New Atlantis*, (*id.*), which he admits is neither a peer-reviewed nor a scientific publication, (ECF No. 207-3 at 264:1-19). He readily concedes that the number of gender dysphoric patients who have been influenced by a social contagion is "currently unknown" and that his opinion is "a hypothesis and not a statement of fact"; he fails to address whether his "social contagion" hypothesis has been tested or peer-reviewed, if there is a known error rate, or what standards exist to measure its reliability; and it is clear that

his theory has not been accepted by relevant scientific community. (ECF Nos. 207-3 at 299:14–300:5; 215-2 at 13.) Instead, he advocates that research be done on this theory. (*See* ECF No. 215-2 at 12 ("The Transgender Treatment Industry has failed to conduct competent research on the social contagion theory."), 13 ("Detailed psycho-social investigations of such patients [who were manipulated by a source of social contagion] may be necessary.").) Thus, the Court finds that McHugh's speculative opinions on "social contagion" hypotheses are inadmissible.

Finally, he testifies that his views on the DSM "is generally accepted by the relevant scientific community." (*Id.* at 8.) His support for this assertion is based on blog posts and an inaccurate claim that the National Institute of Mental Health ("NIMH") withdrew support from the DSM. (*Id.* at 7–8.) He acknowledged during deposition, however, that "[t]he National Institute of Mental Health has not changed its position on DSM-5" and still considers the DSM to be "the best information currently available for clinical diagnosis of mental disorders." (ECF No. 207-2 at 116:10–117:17, 119:3–122:11.) Further, McHugh gives no explanation or reasoning to support the "summary opinions" tacked on to the end of his report, giving the Court no meaningful way to assess their reliability. Thus, the Court finds that these opinions are likewise unreliable and inadmissible.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and McHugh is limited to testifying about the process by which the DSM was formed and his opinion about the limited scientific reliability of such a process generally.

D. Dr. Patrick W. Lappert (ECF No. 208)

Dr. Patrick W. Lappert is a retired plastic and reconstructive surgeon with experience in the United States Navy and Marine Corps, university teaching hospitals, and private practice. (ECF Nos. 215-4 at 1–3; 209-3 at 475:11-19.) During his 24 years of military service, he served in a number of roles, to include flight surgeon, Chairman of the Department of Plastic and Reconstructive Surgery at the Naval Hospital in Portsmouth, Virginia, and Specialty Leader for Plastic Reconstructive Surgery for the Surgeon General of the Navy. (ECF No. 215-4 at 2–3.) He also served during this period as Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery. (*Id.* at 2.) He has several publications in peer-reviewed medical journals and one medical textbook, the most recent of which was published in 2000. (*Id.* at 3.) He retired from the Navy in 2002 and entered private practice as a solo practitioner. (*Id.* at 3–4; ECF No. 209-3 at 475:11-19.) He was board certified in surgery from 1992–2002 and in plastic surgery from 1997–2018. (ECF Nos. 215-4 at 2; 209-3 at 23:10-18.) He retired from active surgical practice in August 2020. (ECF No. 209-3 at 24:22–25:11.) During his career, he treated thousands of patients, performed many of the surgeries at issue in this case to treat ailments other than gender dysphoria, and treated transgender patients during transition and de-transition. (ECF No. 215-4 at 4.)

Lappert primarily seeks to offer opinions that surgical treatments for gender dysphoria are not supported by rigorous scientific study and pose severe health risks. (*See id.* at 5–10, 17–20, 29–39.) He additionally offers opinions on the reliability of the DSM, WPATH, and professional medical organizations; the frequency of desistance or "de-transitioning"; requirements of informed consent; and acceptance of gender dysphoria treatments by the

relevant scientific community. (*Id.* at 15–17, 21–25, 40.) Finally, he offers specific opinions about the medical care received by Plaintiffs based on their medical records. (ECF No. 211-2 at 49–57.)

As with Hruz, Plaintiffs offer evidence that calls Lappert's bias and reliability into serious question. Like Hruz, Lappert has worked closely with ADF. Lappert attended an ADF-sponsored conference in which a speaker lamented the "poverty of [experts] who are willing to testify" against the treatments at issue in this case, and where attendees "were asked whether they would be willing to participate as expert witnesses." (ECF No. 209-2 at 90:13–91:13.) Prior to attending this conference, he had not been published on gender dysphoria or the risks of hormone blockers or served as an expert witness, although he had spoken publicly about gender dysphoria. (*Id.* at 84:3–85:4.) Since attending, he has "actively lobbied" for laws that would prohibit doctors from offering medical or surgical treatments for gender dysphoria to adolescents in Alabama, Arkansas, Texas, and Utah, and agreed in deposition that doctors offering these treatments should be "criminally prosecute[d]." (*Id.* at 52:4-18, 54:7–55:2, 57:8-15, 61:16–64:20.) And he has stated publicly that parents who "discuss[ ] gender identity issues with children" are "sexualizing them" and "grooming a generation." (*Id.* at 461:1–462:5). As with Dr. Hruz, Plaintiffs argue that Lappert's testimony did not grow naturally from his research, but was instead crafted at ADF's request for purposes of litigation.

Based on the preponderance of the evidence, the Court finds the following:

i. Qualifications

Lappert is qualified as an expert in plastic surgery. He is thus qualified to opine on the risks associated with surgery used to treat gender dysphoria, the role surgeons play in treating

gender dysphoria under the WPATH standards, the standard of care of informed consent among surgeons, the perspective of the relevant plastic surgeon community, and whether the surgeons obtained informed consent in Plaintiffs' specific cases. Plaintiffs argue that he is not qualified because he has not performed any of the procedures at issue in this case within the last three years as required of experts by the Code of Ethics of the American Society of Plastic Surgeons ("ASPS"). (ECF Nos. 209 at 8; 209-5 §§ 2.IV1, VII.F.) Although Lappert's failure to qualify as an expert under the ASPS requirements weighs against his qualification, the preponderance of evidence, including his extensive career and relatively recent retirement, supports that he is qualified to offer expert testimony in the field of plastic surgery.

Lappert is not qualified to render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments obtained by Plaintiffs. Lappert is not a psychiatrist, psychologist, or mental health professional, nor has he ever diagnosed a patient with gender dysphoria. He is not an endocrinologist, nor has he ever treated a patient with hormone therapies. By his own admission, he "do[es] not hold [himself] out as an expert in diagnosing mental health conditions outside, potentially, of body dysmorphic disorder" and does not have any "expertise in treating mental health conditions." (ECF No. 209-3 at 75:7-16.)

Lappert is also not qualified to opine on the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria. He is not a statistician or epidemiologist, and there is no evidence in his report or deposition

that he has any experience, specialized training, or knowledge about crafting a research study, analyzing data, or conducting a clinical trial. (*See generally id.* at 129:13–134:19.) His publications appear to include case reports and opinion essays, and he has not published any original research in two decades. (*Id.*) His brief academic career appears limited to teaching and overseeing clinic practitioners, not conducting research. (ECF No. 215-4 at 2–4.) Just as an epidemiologist or statistician would not be qualified to perform surgery, a surgeon with little to no research experience is not qualified to opine on the veracity of statistical studies.

Last, Lappert is qualified to testify to his personal, anecdotal experience treating patients who sought treatment to, in Lappert's words, "de-transition." He is not qualified, however, to offer expert opinions on the rates of desistance and "de-transitioning" among gender dysphoric patients generally for the reasons above.

ii. Relevance

Lappert's testimony concerning surgical risks, the role of the surgeon under WPATH, the plastic surgeon community, and anecdotal experience with "de-transitioning" are all relevant to assessing whether the Plan's exclusion is substantially related to the state's interest in protecting employees and the public from ineffective medical treatments. His testimony concerning informed consent, however, is irrelevant. First, his testimony that Plaintiff Thonen-Fleck was incapable of giving informed consent is based on his age, history with mental illness, and lack of medication. (ECF No. 211-2 at 53–54.) Even if true, Lappert does not dispute that Thonen-Fleck's father was able to (and did) give informed consent. (*See* ECF No. 179-3 ¶ 13 ("Based on medical advice, I understand this surgery to have been medically necessary.").) Lappert's broader discussion of informed consent merely sets up his conclusion

that surgeons are not adhering to that standard of care generally—a speculative conclusion that is not supported by any survey or data, scientific or otherwise. Thus, Lappert's discussion of informed consent is not admissible.

iii. Reliability

First, Lappert's testimony concerning the risks associated with certain surgeries appears to be based on his professional experience and training and sufficiently reliable to be admitted under Rule 702. Additionally, his anecdotal testimony concerning "de-transitioning" is admissible but is not a reliable basis for any broader opinion about the rates of desistance, the likelihood that gender dysphoric patients will later "de-transition," or the general efficacy of surgical treatment for gender dysphoria.

Second, his testimony concerning the role of the surgeon under the WPATH guidelines, and more specifically his criticism that surgeons are not able or required to verify a gender dysphoria diagnosis, appears to arise from his extensive experience as a plastic surgeon and is admissible. However, his broader criticism of WPATH-7 appears to be unscientific opinion and speculation. (ECF No. 209-3 at 184:3-6, 186:23–187:5, 188:15-18 (conceding that he has "not been involved with the development" of WPATH-7, does not "know what kind of scientific literature [review] the WPATH conducted as part of drafting" WPATH-7, and is "not an expert on how Version 7 of the WPATH was developed").) Likewise, in addition to not being qualified in endocrinology or psychiatry, he has not shown the reliability of his criticisms of the Endocrine Society's Guidelines for Treatment of Gender Dysphoria, (*id.* at 200:12-18 (agreeing that he is "not an expert in how the Endocrine Society developed" its guidelines)); the DSM-5, (*id.* at 193:14-18 (agreeing that he "do[es] not have

expert firsthand knowledge of how the DSM-5 was developed"); the AMA's position on these treatments, (*id.* at 47:13-18 (stating he does not have "personal knowledge" of "how the AMA came to issue [its] consensus statement")); or the American Academy of Pediatrics' position, (*id.* at 48:14-23 (admitting he has no "personal knowledge" of how the position was adopted)). And as with Dr. Hruz and Dr. McHugh, Lappert's analogy of treatments of gender dysphoria to eugenics efforts in the early and mid-twentieth century lack any reference to what scientific methodology he used to compare and contrast the treatments.

Third, Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has "never been generally accepted by the relevant scientific community." (*See* ECF No. 215-4 at 22.) Lappert agrees that "every major expert medical association disagrees with [him]" and have "all taken [the] position that this treatment is in fact medically necessary," (ECF No. 209-2 at 40:15-22), and virtually every major health insurer agrees, (*id.* at 384:21–385:3, 427:4–428:7, 430:12–431:6, 434:17–434:20; *see* ECF Nos. 209-10 at 2; 209-11 at 1–4; 209-12 at 3–8; 209-13 at 2–3)). There is no evidence that he has conducted any surveys that would support his repeated conclusory claims concerning the "relevant scientific communities (biology, genetics, neonatolgy [sic], medicine, psychology, etc.)." (ECF No. 215-4 at 40.) Thus, Defendants have failed to meet their burden to show that this testimony is based on reliable science.

Finally, Lappert makes repeated references in his report to a "Transgender Treatment Industry ('TTI')." (*See id.* at 12.) He opines that "[m]embers of the TTI have a vested interest in believing that science has already justified their existence," asks "[w]ill one day the medical profession look at support for transitioning youth in the same manner the eugenics movement

is now regarded?", and hypothesizes that healthcare providers "want the patient to suffer depression and anxiety [because] *such untreated suffering motivates vulnerable patients* to undergo the often painful and damaging experimental 'transitioning' process." (*Id.* at 12, 15.) In his deposition, however, he made clear that he does not "know where [the term TTI] came from" does not "know who originated it," and doesn't "know even if it was me that originated it, actually." (ECF No. 209-3 at 19:19–20:2.) He is not aware of any peer-reviewed scientific article that has used that term. (*Id.* at 20:17-21.) Thus, the Court finds that references to a Transgender or Gender Treatment Industry and related conspiratorial accusations are nothing more than rank speculation designed to distract or inflame the jury and has no business in expert testimony.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and Lappert is limited to testifying to (1) the risks associated with the surgeries at issue in this case; (2) his anecdotal experience treating patients seeking to "de-transition"; and (3) the WPATH recommended role of the surgeon in treating gender dysphoria as compared to the role of the surgeon in other surgical contexts.

E. Stephen B. Levine, M.D. (ECF No. 212)

Dr. Stephen B. Levine is a licensed physician and Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. (ECF No. 215-1 ¶ 1.) He holds an M.D. from Case Western and has received numerous grants for scientific research and program development. (*Id.*) He maintains an active private clinical practice and specializes in treatment of "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." (*Id.* ¶¶ 1–2.) He is the recipient of the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research and is a Distinguished Life Fellow of the American Psychiatric Association. (*Id.* ¶ 2.) He serves as Co-Director of the Gender Diversity Clinic, which he founded at Case Western in 1974. (*Id.* ¶ 3.) He has treated dozens of transgender patients through the clinic and supervised other therapists. (*Id.*) He was an early member of the organization now called WPATH and served as the Chairman of the WPATH Standards of Care Committee that developed WPATH-5. (*Id.*)

Levine's testimony primarily falls into three categories: the risks of medical and surgical treatment to children, the function of WPATH, and the quality of research supporting medical and surgical care for gender dysphoria. First, he testifies that "active affirmation of transgender identity in young children . . . raises ethical and public health concerns." (*Id.* ¶ 8(e).) He testifies that healthcare providers should "delay any transitions [until] after the onset of puberty," that "*encouraging social transition in children remains controversial*," that a majority of prepubescent children diagnosed with gender dysphoria will desist, and that mental health professionals should employ psychotherapy and a "watchful waiting approach" in treating children with gender dysphoria. (*Id.* ¶¶ 29, 38, 54, 62.) Second, he "provide[s] some context concerning" WPATH, which he calls a "private, activist, non-science, organization." (*Id.* ¶¶ 45–53.) Finally, he testifies that the scientific research demonstrating the benefits of medical and surgical treatments of gender dysphoria are of "low quality." (*Id.* ¶ 68(g).)

Notably, Levine does not testify that medical and surgical care for gender dysphoria is categorically inappropriate. (*See, e.g.*, *id.* ¶ 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.") Despite his view that only "low quality" evidence supports the efficacy of these treatments, he does not advocate for "denying endocrine treatment or surgical treatment" to all transgender people, a position he calls "draconian," (ECF No. 213-3 at 73:4-7, 84:21–85:11, ("I'm not advocating denying endocrine treatment or surgical treatment."), 152:1-6, 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").) He concedes that he does not know how often medical or surgical care helps alleviate symptoms of gender dysphoria and does not offer an opinion as to the portion of these procedures that are necessary and unnecessary. (*Id.* at 67:24–68:3 ("It is not our [clinic's] knowledge base to know who's going to do better and who's going to do worse and who is not going to have any difference at all with hormones or with surgery.").) He testifies that this lack of high-quality evidence should encourage physicians treating gender dysphoria to be "cautious" and that transgender patients "have a right to be more fully informed" about the risks and rewards of such care, but ultimately agrees that "doctor[s] need to decide" when medical and surgical care is necessary on "a case-by-case basis." (*Id.* at 152:20-25; ECF No. 215-1 ¶ 126 ("Science not politics needs to drive trans care.").) In his own practice, Levine adheres to the WPATH Standards of Care and personally provides letters of authorization for medical and surgical treatments for his gender dysphoric patients after advising them on the risks associated with those treatments. (ECF No. 213-3 at 55:13-17, 56:2-5, 112:16-21, 176:8-16, 225:24–226:17.) Levine testifies anecdotally that "[i]n [his] experience," mental health providers "too often encourage or permit decision based on a great deal of patient and professional blind optimism" and fail to adequately inform patients

of the inadequacies in the research supporting treatments for gender dysphoria. (ECF No. 215-1 ¶ 105.) He does not offer any quantifiable metrics to identify how many doctors provide informed consent and proceed with caution, and how many do not.

Based on the preponderance of the evidence, the Court finds that Levine is qualified as both a mental health provider and researcher. He is qualified to offer expert testimony on the treatment of gender dysphoria and the efficacy and findings of research studies evaluating gender dysphoria treatments. His personal work treating transgender patients, extensive experience conducting scientific research, review of the relevant literature, and thorough discussion of relevant scientific studies in his report qualify him as an expert witness. The Court additionally finds the following:

First, Levine's testimony concerning the risks of medical and surgical treatment for adolescents is relevant to assessing whether the Plan's exclusion is substantially related to Defendants' governmental interest in protecting employees and the public from ineffective medical treatments. However, Levine's criticism of medical or surgical treatment of gender dysphoria in prepubescent children is not relevant, as Plaintiffs have conceded that such treatments are not medically necessary until the onset of puberty. *See* Section II.B, *supra*. Likewise, Levine's opinions on mental health approaches to social transition are irrelevant as well, as Defendants maintain that the Plan's exclusion of coverage for mental health treatments of gender dysphoria has never been given effect and is no longer part of the Plan. (*See* ECF Nos. 137 n.2; 137-4 ¶ 27.)

Second, Levine is qualified by his personal experience with WPATH to provide background and critique the WPATH Standards of Care. This testimony is relevant to rebut

Plaintiffs' experts who appear to use and rely in part on the WPATH-7 and is reliably based on Levine's expert knowledge and personal experience with the organization.

Third, Levine's analysis of the relevant scientific research supporting gender affirming medical care is relevant to assessing whether the Plan's exclusion is substantially related to Defendants' governmental interest in protecting employees and the public from ineffective medical treatments. Further, his opinion that the available scientific research is of "low quality" appears reliably based on his review of the relevant literature, experience conducting scientific research, and a "widely accepted hierarchy of reliability" that distinguishes between case studies on the "low" end and randomized double-blind clinical trials on the "high" end. (*See* ECF No. 215-1 ¶ 68.) His criticism of the methodology of some of these studies similarly appears reliable.[3] (*Id.* ¶¶ 74–79.)

However, Levine's testimony regarding desistance rates does not appear to be based on reliable methodology. During deposition, Levine was unable to recall many of the studies that purportedly support his conclusion. (ECF No. 213-3 at 191:20-192:14.) His anecdotal testimony concerning adults and adolescents who regret their transitions appears to be based on a misreading of an article that reviewed entries on the website Reddit. (*See* ECF No. 215-1 ¶¶ 35, 56, 98.) He admitted during deposition that the article referred to 16,000 entries—not 60,000, as he repeatedly stated in his report—and that he had no knowledge of the content

[3] Contrary to Plaintiffs' characterization, Levine does not testify that medical or surgical treatment of gender dysphoria *increases* a patient's chance of negative mental health outcomes, but rather that, in his view, no reliable studies show that such treatments *reduce* the likelihood of such outcomes. (ECF No. 215-1 ¶¶ 74–79.)

of those entries or whether any of the authors actually de-transitioned or regret their transitions. (*Id.* at 196:3-7, 201:12-25)

Fourth, as discussed, it does not appear that he offers any categorical opinion as to the medical necessity of medical and surgical treatments of gender dysphoria, nor does he testify that healthcare providers are prescribing such treatment without due caution and informed consent beyond his anecdotal "experience." To the extent that Defendants seek to introduce testimony from Levine to that effect, he has not provided the Court with any data or methodology from which such claims could be made. Levine has conducted no research to identify which physicians are proceeding as he does and which do not, rendering any broader opinion about the practice of such healthcare providers pure speculation.

Finally, for the same reasons identified regarding Dr. Lappert, *supra*, Levine's reference to a "Transgender Treatment Industry" does not appear to be based on any science whatsoever and is not admissible.

In sum, Plaintiffs' motion will be granted in part and denied in part, and Levine's testimony will be limited to (1) identifying risks associated with prescribing medication and surgery to adolescents, (2) discussing WPATH, and (3) criticizing the quality of the research on treatments for gender dysphoria.

III. MOTIONS FOR SUMMARY JUDGMENT

Plaintiffs argue that they are entitled to summary judgment on their three claims arising under the Equal Protection Clause, Title VII, and the ACA. (ECF No. 179.) DPS argues that it is entitled to summary judgment on Plaintiff Caraway's Title VII claim. (ECF No. 133.)

Plan Defendants argue that NCSHP is entitled to summary judgment on Plaintiff's Title VII and ACA claims. (ECF No. 136.) The Court will address each claim in turn.

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 citations and 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) (citing *Jacobs*, 780 F.3d at 568). A court "cannot weigh the evidence or make credibility determinations," *Jacobs*, 780 F.3d at 569 (citations omitted), 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, *Witt v. W. Va. State Police, Troop 2*, 633 F.3d 272, 276 (4th Cir. 2011) (quoting *Scott v. Harris*, 550 U.S. 372, 378 (2007)).

Where the nonmovant will bear the burden of proof at trial, the party seeking summary judgment bears the initial burden of "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party carries this burden, then the burden shifts to the nonmoving party to point out "specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In so doing, "the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence." *Dash*

v. Mayweather, 731 F.3d 303, 311 (4th Cir. 2013). Instead, the nonmoving party must support its assertions by "citing to particular parts of . . . the record" or "showing that the materials cited do not establish the absence . . . of a genuine dispute." Fed. R. Civ. P. 56(c)(1); *see also Celotex*, 477 U.S. at 324. Expert testimony must be admissible to create a genuine issue of material fact. *See Cavallo v. Star Enter.*, 100 F.3d 1150, 1159 (4th Cir. 1996).

A. Equal Protection Clause

The Fourteenth Amendment to the U.S. Constitution prohibits states from denying "to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. The Equal Protection Clause is "essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985). When considering an equal protection claim, a court must determine (1) "what level of scrutiny applies" and (2) "whether the law or policy at issue survives such scrutiny." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir.), *as amended* (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021).

i. The Plan facially discriminates based on sex and transgender status

"In determining what level of scrutiny applies to a plaintiff's equal protection claim, we look to the basis of the distinction between the classes of persons." *Id.* (citing *United States v. Carolene Products Co.*, 304 U.S. 144, 152 n.4 (1938)). Generally, a state policy "is presumed to be valid and will be sustained if the classification drawn by the [policy] is rationally related to a legitimate state interest." *Cleburne*, 473 U.S. at 440. This general rule "gives way," however, when the policy discriminates based on membership in certain suspect classes. *Id.* In the Fourth Circuit, laws that discriminate based on sex or transgender status receive intermediate

scrutiny. *Grimm*, 972 F.3d at 608, 610. Such policies are unconstitutional "unless [they are] substantially related to a sufficiently important governmental interest." *Id.* at 608 (quoting *Celburne*, 473 U.S. at 441).

To show that a policy discriminates based on sex or transgender status, a plaintiff must show discriminatory intent and disproportionate impact. *See Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 265 (1977). "No inquiry into legislative purpose is necessary," however, when the suspect classification "appears on the face" of the policy. *Shaw v. Reno*, 509 U.S. 630, 642 (1993). A policy that facially discriminates based on membership in a suspect class is "immediately suspect because, '[a]bsent searching judicial inquiry . . . , there is simply no way of determining what classifications are "benign" or "remedial" and what classifications are in fact motivated by illegitimate"' governmental objectives. *Id.* at 642–43 (quoting *Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989) (plurality opinion)); *see also Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 273 (1979) ("Classifications based upon gender, not unlike those based upon race, have traditionally been the touchstone for pervasive and often subtle discrimination.").

A facial inquiry is what it sounds like: a review of the language of the policy to see whether it is facially neutral or "deal[s] in explicitly racial [or gendered] terms." *Washington v. Seattle Sch. Dist. No. 1*, 458 U.S. 457, 485 (1982) (citing *Hunter v. Erickson*, 393 U.S. 385 (1969)). A policy that uses racial or gendered terms "falls into an inherently suspect category" even if it creates classifications that are not "obviously pernicious." *Id.* at 485, 487. The "crucial difference" between facially discriminatory and facially neutral laws is that the former "plainly rests on distinctions based on" a suspect classification. *Id.* at 485 (internal quotations omitted).

In *Grimm*, the Fourth Circuit held that a school policy limiting students to use of the restroom and locker room facility that corresponded to their "biological genders" discriminated on its face based on sex. *Grimm*, 972 F.3d at 608–10. First, it reasoned that the policy "necessarily rests on a sex classification" and "cannot be stated without referencing sex." *Id.* at 608. Second, the court found that the policy "subjected [plaintiff] to sex discrimination because he was viewed as failing to conform to the sex stereotype propagated by the Policy." *Id.* at 608. Thus, the Fourth Circuit applied intermediate scrutiny. *Id.* at 609.

Additionally, the court held that the bathroom policy facially discriminated against plaintiff based on his status as a transgender boy. *Id.* at 613. The court identified transgender individuals as a quasi-suspect class consisting of those "who consistently, persistently, and insistently express a gender that, on a binary, we would think of as opposite to their assigned sex." *Id.* at 594, 613 (internal quotations omitted). The court then held that the policy—which provided "alternative appropriate private facilit[ies]" for students "with gender identity issues"— facially discriminated against plaintiff based on his membership in this class. *Id.* at 609, 613.

Here, the Plan excludes "[t]reatment or studies leading to or in connection with *sex* changes or modifications and related care." (ECF No. 184 at 67 (emphasis added).) This exception does not identify any diagnoses or treatments. Instead, the broad language of the Plan distinguishes between medically necessary[4] treatments that align with the member's

[4] Defendants dispute that the treatments excluded by the Plan are medically necessary in fact. However, the Plan already limits coverage to treatments that are medically necessary. (ECF No. 137-2 at 58:4-7.) Thus, for purposes of this facial inquiry alone, the exclusion only applies to treatments that are otherwise considered medically necessary.

biological sex and medically necessary treatments—often the *same* medically necessary treatments—that do not align with his sex.

These exclusions facially discriminate based on sex and transgender status. First, like in *Grimm*, this exclusion "necessarily rests on a sex classification" because it cannot be stated or effectuated "without referencing sex." *See Grimm*, 972 F.3d at 608; *c.f. Hunter*, 393 U.S. at 391. As reasoned by the U.S. Supreme Court, "try writing out instructions" for which treatments are excluded "without using the words man, woman, or sex (or some synonym). It can't be done." *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1746 (2020). It is impossible to determine whether a particular treatment is connected to "sex changes or modifications and related care"—and thus, whether the exclusion applies—without comparing the member's biological sex before the treatment to how it might be impacted by the treatment.

Second, the Plan overtly discriminates against members for "failing to conform to the sex stereotype propagated by the [Plan]." *See Grimm*, 972 F.3d at 608. The Plan expressly limits members to coverage for treatments that align their physiology with their biological sex and prohibits coverage for treatments that "change or modify" physiology to conflict with assigned sex. For example, puberty suppressing medication may be covered if medically necessary. (*See, e.g.*, ECF Nos. 201-1 at 4–22). But a transgender boy will not receive coverage for such medication—even if medically necessary—because, in the language of the Plan, it would "change or modify" his physiology in a way that does not match his female biological sex. (*See id.*) This is textbook sex discrimination. *Grimm*, 972 F.3d at 608; *see generally Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989) (plurality opinion) (holding that employers who "insist[ed] that [individuals] matched the stereotype associated with their group" committed

sex discrimination under Title VII); *Bostock*, 140 S. Ct. at 1741 ("[A]n employer who fires a woman, Hannah, because she is insufficiently feminine and also fires a man, Bob, for being insufficiently masculine may treat men and women as groups more or less equally. But in *both* cases the employer fires an individual in part because of sex.").

Third, the Plan also transparently discriminates against its transgender members. As mentioned, the quasi-suspect class identified by the Fourth Circuit is defined as those "who consistently, persistently, and insistently express a gender that, on a binary, we would think of as opposite to their assigned sex." *Grimm*, 972 F.3d at 594. Transgender men are men; transgender women are women. *Id.* at 610 ("[Plaintiff] did not question his gender identity at all; he knew he was a boy."). This holding by the Fourth Circuit is likewise supported by the undisputed evidence in this case. (*See, e.g.*, ECF Nos. 179-2 ¶¶ 2–3 ("I am a 19-year-old man. I am also transgender."); 179-5 ¶¶ 2, 4 ("I am a boy. . . . I am transgender, which means that I was designated 'female' at birth, even though I am and identify as male."); 137-2 at 85:10–87:22 (stating that NCSHP members may align their sex identification marker in NCSHP's records with their gender identity without proof of their physical anatomy, DNA, or chromosomal make up); *see also* ECF No. 219 at 6 ("A transgender man is a man. A transgender woman is a woman.").) Under the Plan, however, transgender members are classified as seeking to "change or modify" their gender or sex while cisgender members are not. So, a cisgender man who receives medically necessary testosterone is covered, while a transgender man who receives medically necessary testosterone is not. Like in *Grimm*, the Plan "privileges sex-assigned-at-birth over [Plaintiffs'] medically confirmed, persistent and consistent gender identity." *Grimm*, 972 F.3d at 610. Thus, it will receive intermediate scrutiny.

Defendants raise four arguments against finding that the Plan discriminates based on sex or transgender status.

First, Defendants argue that the Plan does not discriminate based on sex or transgender status but based on diagnosis. (ECF No. 197 at 28.) Specifically, they characterize the Plan as covering medically necessary treatments for some ailments but not for others, such as gender dysphoria. (*Id.*) Some Plan administrators do consider the exclusions to be "blanket exclusions for the treatment of gender dysphoria." (*See, e.g.*, ECF No. 185-2 at 34.) However, whether a policy is facially discriminatory is determined with reference to the language of the policy, not the underlying intent of its adopters or administrators. *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991) ("[T]he absence of a malevolent motive does not convert a facially discriminatory policy into a neutral policy with a discriminatory effect."). Thus, Defendants' evidence does not create a genuine issue of material fact as to whether the Plan discriminates *on its face.* [5]

Further, even if the Court credited Defendant's characterization of the Plan as applying only to diagnoses of gender dysphoria, it would still receive intermediate scrutiny. Discrimination against individuals suffering from gender dysphoria is also discrimination based on sex and transgender status. As with the Plan's exclusions, one cannot explain gender dysphoria "without referencing sex" or a synonym. *See Grimm*, 972 F.3d at 608. A hypothetical from the Supreme Court is directly on point:

[5] Moreover, undisputed evidence shows the exclusions do not simply attach to treatments related to a diagnosis of gender dysphoria in practice. As discussed, preauthorization for some surgeries is denied due to the exclusion "regardless of the diagnostic code," and preauthorization for others is denied if the procedural code accompanying the treatment is "transsexualism" or "personal history of sex reassignment." (ECF No. 197-14 ¶¶ 20–21.)

> Suppose an employer asked homosexual or transgender applicants to tick a box on its application form. The employer then had someone else redact any information that could be used to discern sex. The resulting applications would disclose which individuals are homosexual or transgender without revealing whether they also happen to be men or women. Doesn't that possibility indicate that the employer's discrimination against homosexual or transgender persons cannot be sex discrimination?
>
> No, it doesn't. . . . There is no way for an applicant to decide whether to check the homosexual or transgender box without considering sex. To see why, imagine an applicant doesn't know what the words homosexual or transgender mean. Then try writing out instructions for who should check the box without using the words man, woman, or sex (or some synonym). It can't be done.

Bostock, 140 S. Ct. at 1746. The same is true here. Even if Plan administrators see only a box checked "gender dysphoria," the diagnostician cannot know whether to check that box without considering sex.[6] Defendants' first argument is unpersuasive.

Second, Defendants argue that Plaintiffs are not similarly situated to members who receive similar treatments for different diagnoses. (ECF No. 197 at 29.) Members who receive hormone therapy, testosterone, or a mastectomy for gender dysphoria, they argue, are not similarly situated to members who seek those same treatments for prostate, testicular, or breast cancer. (*Id.*) This argument, however, is a *justification* for Defendants' facial sex and transgender discrimination, not an argument that the exclusions are facially neutral. *See Tuan Anh Nguyen v. I.N.S.*, 533 U.S. 53, 62–64, 73 (2001) (conducting "similarly situated" analysis of a facially discriminatory law in its application of intermediate scrutiny rather than to determine what level of scrutiny applied). It is sufficient at this stage that those affected and unaffected

[6] Defendants argue that "[h]ealthcare providers must know a patient's sex for *every* medical diagnosis," (ECF No. 197 at 32), but this argument misstates the issue. Gender dysphoria cannot be explained at all without reference to sex, while most other diagnoses—even those that are specific to members of only one sex—can be explained neutrally.

by the exclusion are all members of the Plan who seek similar or identical treatments. The factor used by the Plan to distinguish between covered and uncovered treatments is that the later "change or modify" the patient's assigned sex. Other factors not evidenced on the face of the Plan that may distinguish the two groups are not proper for consideration at this stage in the Court's analysis. *See Klinger v. Dep't of Corr.*, 31 F.3d 727, 731 (8th Cir. 1994) ("The similarly situated inquiry focuses on whether the plaintiffs are similarly situated to another group *for purposes of the challenged government action*. . . . [It] depends on what government action the plaintiffs are challenging." (emphasis added)).

Third, Defendants argue that the Plan does in fact cover many over-the-counter pharmaceuticals regardless of transgender status because neither the Plan nor its administrators "*ever know* the reason" for such purchases. (ECF No. 197 at 26.) But a policy that makes coverage turn on sex or transgender status receives heightened scrutiny even if administrators do not actually know members' sex or transgender status in practice. *C.f. Bostock*, 140 S. Ct. at 1746 ("By intentionally setting out a rule that makes hiring turn on [sex], the employer violates the law, whatever he might know or not know about individual applicants."). A facially discriminatory policy likewise receives heightened scrutiny even if it is not applied in all cases. *See, e.g.*, *Fisher v. Univ. of Tex. at Austin*, 579 U.S. 365, 384 (2016) (applying heightened scrutiny to a race-conscious admissions policy even though "race consciousness played a role in only a small portion of admissions decisions").

Fourth, Defendants analogize this case to *Geduldig v. Aiello*, 417 U.S. 484 (1974). In *Geduldig*, the Supreme Court held that a state health program that denied coverage for pregnancy did not discriminate based on sex. *Id.* at 494. The Court reasoned that the program

did "not exclude anyone from benefit eligibility because of gender but merely remove[d] one physical condition—pregnancy—from the list of compensable disabilities." *Id.* at 496 n.20. "Normal pregnancy is an objectively identifiable physical condition with unique characteristics," and while "only women can become pregnant," the group of members who are not pregnant "includes members of both sexes." *Id.* But the same cannot be said here. The Plan does not merely exclude one "objectively identifiable physical condition with unique characteristics" from coverage; rather, it excludes *treatments* that lead or are connected to *sex* changes or modifications. Pregnancy can be explained without reference to sex, gender, or transgender status.[7] The same cannot be said of the exclusion at issue here.

In sum, there is no genuine issue of material fact about the language of the Plan: it facially discriminates based on sex and transgender status. The Court will accordingly apply intermediate scrutiny.

ii. Defendants have not established a genuine issue of material fact as to whether the Plan is substantially related to an important governmental interest

Policies that discriminate based on sex or transgender status are unconstitutional "unless [they are] substantially related to a sufficiently important governmental interest." *Grimm*, 972 F.3d at 608 (quoting *Celburne*, 473 U.S. at 441). To survive intermediate scrutiny,

[7] *Pregnancy*, Dorland's Illustrated Medical Dictionary (33d ed. 2020) ("[T]he condition of having a developing embryo or fetus in the body, after union of an oocyte and spermatozoon."); *Pregnant*, American Heritage Medical Dictionary (2d ed. rev. 2007) ("Carrying developing offspring within the body); *see Pregnant*, Merriam-Webster, https://www.merriam-webster.com/dictionary/pregnant (last updated May 25, 2022) ("containing a developing embryo, fetus, or unborn offspring within the body"). *But see Pregnancy*, Stedman's Medical Dictionary (28th ed. 2006) ("The state of a female after conception and until the termination of the gestation.").

the state bears the burden to "provide an 'exceedingly persuasive justification' for its classification." *Id.* (quoting *United States v. Virginia*, 518 U.S. 515, 534 (1996)).

Defendants raise two justifications for the relevant exclusions. First, they argue that the exclusions limit health care costs. (ECF No. 197 at 40.) Until 2018, North Carolina provided free health insurance to its public employees. (ECF No. 137-2 at 106:2-4.) When the North Carolina General Assembly limited increases in its contribution to the Plan in 2016 to 4% per year, however, NCSHP was unable to keep up with the rapid 7% annual increase in healthcare costs. (*Id.* at 102:22-24.) At Defendant Folwell's direction, NCSHP cut benefits and charged employees premiums for the first time. (*Id.* at 102:19-21, 106:2-4.) Now, "a whole lot of employees have to work one week out of a month just to cover their Health Plan for their family." (*Id.* at 105:22-24.)

While such a justification may be sufficient under the rational basis test, *see Geduldig*, 417 U.S. at 496, a state may not "protect the public fisc by drawing an invidious distinction between classes of its citizens" under heightened scrutiny, *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 263 (1974). That is especially true here, as the estimated $300,000–$900,000 saved by the exclusion per year pales in comparison to NCSHP's billion-dollar cash balance and saves each of the Plan's 740,000 members about one dollar each. Such a paltry limit on health care costs is not an important governmental interest.

Second, Defendants argue that the relevant treatments excluded by the Plan are not effective. (ECF No. 197 at 11–17.) Viewed in the abstract, the Court finds that withholding Plan funds from ineffective medical treatments serves an important governmental interest. The state has an obvious interest in protecting its employees and their families from ineffective

medical treatments and a derivative interest in reducing the prevalence of such treatments generally by cutting them off from access to the Plan's considerable resources. (*See* ECF No. 137-1 at 35:7-12 (stating that the Plan is the largest purchaser of healthcare and pharmaceuticals in North Carolina)). Protecting public health is an important governmental interest. *Eline v. Town of Ocean City*, 7 F.4th 214, 222 n.8 (4th Cir. 2021), *cert. denied*, 142 S. Ct. 1117 (2022).

Thus, the remaining issue is whether the exclusions are substantially related to Defendant's interest in protecting its employees and the public from ineffective medical treatments.[8] Defendants attempt to establish this substantial relationship via their experts' testimony. However, as found in Part II, *supra*, much of this testimony is inadmissible. Inadmissible testimony cannot establish a genuine issue of material fact for purposes of summary judgment. *See Md. Highways Contractors Ass'n v. Maryland*, 933 F.2d 1246, 1251 (4th Cir. 1991).

Defendants' admissible expert testimony, even when taken in the light most favorable to Defendants, does not support that the Plan's exclusion substantially excludes treatments that are ineffective. First, while Dr. Hruz and Dr. Lappert testify that the medicines and surgeries used to treat gender dysphoria can have serious health risks and consequences, it is

[8] Plaintiffs argue "[b]inding circuit precedent recognizes that . . . medical treatments for gender dysphoria 'are safe, effective, and often medically necessary.'" (ECF No. 201 at 3 (quoting *Kadel v. N.C. State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422, 428 (4th Cir.), *as amended* (Dec. 2, 2021), *cert. denied sub nom. N.C. Health Plan for Tchrs. & State Emps. v. Kadel*, 142 S. Ct. 861 (2022)).) However, the relevant quote comes from the Fourth Circuit's background discussion of gender dysphoria. *See Kadel*, 12 F.4th at 428. This Court does not read the Fourth Circuit's ruling in *Kadel*—which concerned a jurisdictional issue—to resolve this consequential issue as a matter of fact or law. Thus, the effectiveness of these treatments remains an issue of fact that must be resolved in the first instance.

also undisputed that gender dysphoria is a serious diagnosis that, if left untreated, can lead to self-mutilation and suicide. NCSHP covers many of these same treatments for other serious illnesses notwithstanding their risks and side effects. Without evidence that the treatments are ineffective to treat gender dysphoria, Defendants cannot meet their burden to show that the risks substantially outweigh the benefits so as to justify their sex- and transgender-based policy.

Second, Defendants point to Dr. Levine's testimony to argue that these treatments are categorically ineffective. But that is not Levine's testimony. He testifies that the available research is not sufficiently reliable to prove that treatments are effective, but repeatedly and emphatically testifies that this lack of high-level research is *not* reason to justify withholding treatment from all gender dysphoric patients. Rather, he testifies that *doctors and patients*, when fully aware of the risks and elusive benefits of available treatments, should decide if medicine or surgery is necessary *as he does in his own practice*. This is Plaintiffs' request: that they and their doctors, not their sex or transgender status, determine when their treatments are appropriate. Levine does not and cannot reliably testify as to how often doctors prescribe unnecessary treatments or fail to obtain informed consent. Thus, Levine's testimony also does not create a genuine issue of material fact as to whether the Plan's exclusion substantially excludes ineffective treatments.

Finally, anecdotal recounting of individual patient experiences and wholesale criticism of WPATH, the DSM, and various professional associations, even when taken as true, is insufficient to meet Defendants' burden of showing that the Plan's discriminatory exclusion is substantially related to an important governmental interest. At most, this evidence

challenges the credibility of some—but not all—of Plaintiffs' evidence showing that medical and surgical treatments for gender dysphoria are effective.

Moreover, Defendants have a clear, sex- and transgender-neutral alternative to the exclusion. In 2017, the Plan covered "medically necessary services for the treatment of gender dysphoria," and NCSHP's third-party administrators, Blue Cross and CVS, appear able to distinguish between medically necessary and unnecessary treatments. (*See, e.g.*, 185-2 at 89–99 (distinguishing in the Blue Cross Corporate Medical Policy between medically necessary and unnecessary treatments for gender dysphoria). To the extent that Defendants can anecdotally establish that *some* treatments for gender dysphoria are ineffective, they have not offered any admissible evidence to show that the Plan's categorical exclusion better protects members from ineffective treatments than the more narrow exclusion of medically *unnecessary* treatments for gender dysphoria. Thus, Defendants cannot meet their burden under intermediate scrutiny. *See Caban v. Mohammed*, 441 U.S. 380, 392 (1979) (invalidating an adoption law where "the State's interest . . . can be protected by means that do not draw such an inflexible gender-based distinction."); *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 650 (1974) (invalidating a maternity policy where a more "narrow method of protecting the school board's interest in teacher fitness" was available); *see also Cleburne*, 473 U.S. at 476 (Marshall, J., concurring in the judgment in part and dissenting in part) ("When statutes rest on impermissibly overbroad generalizations, our cases [applying intermediate scrutiny] have invalidated the presumption on its face.") (collecting cases).

Thus, Plaintiffs are entitled to summary judgment on their Equal Protection Claim.

B. Title VII

The Court next addresses Plaintiff Caraway's Title VII claims against DPS and NCSHP.

It is a violation of Title VII for an employer to "discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's . . . sex." 42 U.S.C. § 2000e-2(a)(1). "Health insurance and other fringe benefits are 'compensation, terms, conditions, or privileges of employment'" under Title VII.[9] *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 682 (1983).

DPS, NCSHP, and Plaintiffs each move for summary judgement on Plaintiff Caraway's Title VII claims. (ECF Nos. 132; 136; 178.) NCSHP argues it is not Caraway's employer. (ECF No. 137 at 25–33.) DPS argues that Caraway lacks standing and cannot show that DPS caused her injury. (ECF No. 133 at 21–22.) Caraway argues that no genuine issue of material fact exists as to her Title VII claim and she is entitled to judgment as a matter of law as to liability, "reserving issues of damages . . . for trial." (ECF No. 179 at 4, 32–37.) The Court will address these arguments in turn.

i. Plaintiff Caraway

Caraway is a transgender woman and corrections officer for DPS. (ECF No. 179-9 ¶¶ 5, 8.) She is required to maintain health insurance by DPS given the nature of her job and is a member of NCSHP. (*Id.* ¶ 16.) She was diagnosed with gender dysphoria and began hormone replacement therapy in mid-2018, and underwent "intersex surgery" and a

[9] Whether a benefit is "compensation" under Title VII is a question of federal law, not state law. Defendants' contention that the Plan does not constitute compensation under state law is therefore inapposite.

"mammaplasty" on August 5, 2020. (*Id.* ¶¶ 19–20; *id.* at 13.) Due to the exclusion, NCSHP has only occasionally covered her hormone therapy and did not cover her surgery. (*Id.* ¶¶ 21, 24, 28; *see id.* at 13.) She consequently delayed surgery approximately nine months until she could pay the $27,000 bill out of pocket. (*Id.* ¶¶ 23–25.) Caraway is still employed with DPS. (*Id.* ¶ 6.) Although the treatment she has received "has helped" relieve symptoms from her gender dysphoria "up to a point," she anticipates requiring continued hormone treatments and additional surgery. (*Id.* ¶¶ 29–33.)

ii. NCSHP is not Caraway's employer

NCSHP argues that it is not liable to Caraway under Title VII because it is not her employer. (ECF No. 137 at 25–28.) It is undisputed that Caraway is employed by DPS. (*See* ECF No. 179-9 ¶ 5.) Caraway argues that NCSHP is also her employer—and therefore liable under Title VII—because (1) it is DPS's agent and (2) DPS and NCSHP jointly employ her. (ECF No. 188 at 15–18.)

1. NCSHP is not DPS's agent

Title VII defines "employer" as either "a person engaged in an industry affecting commerce" that employs fifteen or more employees and "any agent of such a person." 42 U.S.C. § 2000e(b). An "employer," in turn, is prohibited from discriminating "against any individual with respect to [her] compensation, terms, conditions, or privileges of employment" because of her sex. § 2000e-2(a)(1). "Title VII's purpose [is to] eliminat[e] discrimination in employment based on race, color, religion, sex, or national origin." *Butler v. Drive Auto. Indus. of Am., Inc.*, 793 F.3d 404, 409 (4th Cir. 2015) (internal quotations omitted). "Title VII should

be liberally construed in light of its remedial purpose . . . [and] such liberal construction is also to be given to the definition of 'employer.'" *Id.* (internal quotations omitted).

Title VII "does not define the term 'agent.'" *Lissau v. S. Food Serv., Inc.*, 159 F.3d 177, 180 (4th Cir. 1998). In *Lissau*, the Fourth Circuit held that "individual supervisors are not liable under Title VII." *Id.* at 181. Rejecting an argument that an individual supervisor may be held liable as the "agent" of the employer, the court "interpret[ted] the inclusion of agent in Title VII's definition of employer simply to establish a limit on an employer's liability for its employees' actions." *Id.* at 180; *see also Birkbeck v. Marvel Lighting Corp.*, 30 F.3d 507, 510 (4th Cir. 1994) (reading an identical provision in the Age Discrimination in Employment Act to be "an unremarkable expression of respondeat superior—that discriminatory personnel actions taken by an employer's agent may create liability for the employer").

The Fourth Circuit has not addressed the present situation where a plaintiff alleges that an entity, rather than an individual supervisor, is liable under Title VII by virtue of being an agent. (*See* ECF No. 74 at 22–24.) Other circuits have held "that Title VII plaintiffs may maintain a suit directly against an entity acting as the agent of an employer, but only under certain circumstances." *Alam v. Miller Brewing Co.*, 709 F.3d 662, 668–69 (7th Cir. 2013) (citations omitted). These circuits recognize agency liability where the agent "exercise[s] control over an important aspect of [the plaintiff's] employment," *Carparts Distrib. Ctr., Inc. v. Auto. Wholesaler's Ass'n of New England, Inc.*, 37 F.3d 12, 17 (1st Cir. 1994); where the agent "significantly affects access of any individual to employment opportunities," *Spirt v. Teachers Ins. & Annuity Ass'n*, 691 F.2d 1054, 1063 (2d Cir. 1982), *vacated and remanded on other grounds*, 463 U.S. 1223 (1983); or where "an employer delegates sufficient control of some traditional

rights over employees to a third party," *Nealey v. Univ. Health Servs., Inc.*, 114 F. Supp. 2d 1358, 1367 (S.D. Ga. 2000) (quoting *Lyes v. City of Riviera Beach*, 166 F.3d 1332, 1341 (11th Cir. 1999)).

Here, even if the Court were to assume that entities may be held liable as agents under Title VII in the Fourth Circuit, Caraway has failed to show that NCSHP operates as DPS's agent.[10] At common law, "[a]n agent is one who consents to act on behalf on another and subject to the other's control." *Swallows v. Barnes & Noble Book Stores, Inc.*, 128 F.3d 990, 996 (6th Cir. 1997) (citing Restatement (Second) of Agency § 1 (1958)); *see Meritor Sav. Bank, FSB v. Vinson*, 477 U.S. 57, 72 (1986) (interpreting Title VII's definition of "employer" and use of the term of "agent" against a common law backdrop). Plaintiffs have submitted no evidence that NCSHP is subject to DPS's control. On the contrary, it appears undisputed that "state law delegates control over employee health coverage to NCSHP." (ECF No. 188 at 18 (citing N.C. Gen. Stat. § 135-48.2(a)).) Although DPS provides the Plan to its employees and assists in its implementation, *see* Section III.B.iii, *infra*, DPS has no legal control over NCSHP or the Plan, *see generally* §§ 135-48.1–48.62, and Carraway has failed to produce any evidence to show that DPS has control over NCSHP in fact.

2. NCSHP is not a joint employer

An individual may have more than one employer within the meaning of Title VII. *Butler*, 793 F.3d at 408. The "principal guidepost" to observe in determining an employee's

[10] In its March 5, 2021, Order, this Court concluded that *Lissau* nor *Birkbeck* control this case, as those cases concern individual supervisors sued in their individual capacities. (ECF No. 74 at 22–24.) Consequently, the Court held that Caraway's Title VII claims against NCSHP were not futile and allowed Plaintiffs to amend their Complaint. (*Id.* at 24.) The Court does not disturb that reasoned conclusion here. Rather, the Court finds that Plaintiffs have not submitted sufficient evidence at the summary judgment stage to create a genuine issue of material fact as to whether NCSHP is DPS's agent.

employers is "'the common-law element of control,' drawn from the law of agency." *Id.* at 409 (quoting *Clackamas Gastroenterology Assocs., P.C. v. Wells*, 538 U.S. 440, 448 (2003)). In *Butler*, the Fourth Circuit adopted a nine-factor test to determine whether a Title VII plaintiff "is jointly employed by two or more entities." *Id.* at 414. These factors are:

(1) authority to hire and fire the individual;

(2) day-to-day supervision of the individual, including employee discipline;

(3) whether the putative employer furnishes the equipment used and the place of work;

(4) possession of and responsibility over the individual's employment records, including payroll, insurance, and taxes;

(5) the length of time during which the individual has worked for the putative employer;

(6) whether the putative employer provides the individual with formal or informal training;

(7) whether the individual's duties are akin to a regular employee's duties;

(8) whether the individual is assigned solely to the putative employer; and

(9) whether the individual and putative employer intended to enter into an employment relationship.

Id. "[N]one of these factors are dispositive and . . . courts can modify the factors to the specific industry context." *Id.* Generally, however, the first three of these factors will be "most important," and the ninth factor will be "of minimal consequence." *Id.* at 414, 414 n.12.

Here, there is no evidence that NCSHP has authority to hire, fire, supervise, or discipline Plaintiff Caraway (factors one and two). (ECF Nos. 137-12 at 101:6–102:11, 104:1-15, 105:20-25; 137-13 at 34:4-18, 39:16-18.) NCSHP does not provide her with any equipment or workplace (factor three), (ECF Nos. 137-12 at 102:9-10, 111:4-19; 137-13 at 45:9-16), or

training (factor six), (ECF Nos. 137-12 at 99:10-20; 137-13 at 37:12-16, 48:8-13). Caraway has never been assigned to perform work for NCSHP (factors five and eight), (ECF No. 137-12 at 93:7-16), and as a prison guard, her duties are not akin to duties of NCSHP's employees, which include managing implementation of the Plan (factor seven), (*see, e.g.*, ECF No. 137-2 at 69:23–70:8). There is no evidence NCSHP or Caraway intended to enter into an employment relationship (factor nine). (*See* ECF No. 137-12 at 93:7-16 ("The only employer I worked for in the last 27 years . . . was [DPS].").) Finally, while it is possible that NCSHP possessed some of Caraway's insurance records (factor four), she has failed to identify evidence in the record to support this inference.

Plaintiffs argue that NCSHP is an employer because it exercises "'control' over the health coverage relevant to this case." (ECF No. 188 at 18.) The guidepost identified in *Clackamas* and *Butler*, however, is not control over one aspect of employment, but rather "practical control of the employee." *Butler*, 793 F.3d at 414; *see Clackamas*, 538 U.S. at 448 ("[T]he relevant factors defining the master-servant relationship focus on the master's control *over the servant*." (emphasis added)). A joint employer need not have total control over all aspects of the employment; however, Plaintiffs have cited no legal authority to support that an entity's control over an individual's employment-based health insurance renders it the individual's employer where all nine factors identified in *Butler* weigh against finding joint employment.

Even taking all evidence in the light most favorable to Plaintiffs, they have failed to create a genuine issue of material fact as to whether NCSHP is Plaintiff Caraway's employer.

Accordingly, NCSHP will be granted summary judgment on Caraway's Title VII claim, and Caraway's motion for summary judgment will be denied as to this claim.

iii. DPS is liable under Title VII for providing the Plan to Caraway

DPS argues that it is entitled to summary judgment because (1) Caraway does not have standing to sue DPS and (2) Caraway cannot show that DPS caused her injuries under Title VII. (ECF No. 133.)

1. Caraway has standing to sue DPS

DPS first argues that Caraway's injuries are not fairly traceable to its conduct as required for standing because, pursuant to state law, DPS has no power to establish or implement the Plan. (ECF No. 133 at 8–22.)

Parties invoking federal jurisdiction bear the burden of establishing that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). Traceability requires a causal connection between the defendant's conduct and the plaintiff's injury, such that "there is a genuine nexus" between the two. *See Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 161 (4th Cir. 2000). "[T]he 'fairly traceable standard is not equivalent to a requirement of tort causation.'" *Hutton v. Nat'l Bd. of Exam'rs in Optometry, Inc.*, 892 F.3d 613, 623 (4th Cir. 2018) (quoting *Friends*, 204 F.3d at 161). At the summary judgment stage, "the plaintiff can no longer rest on . . . 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts,' which for purposes of the summary judgment motion will be taken to be true." *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

On March 10, 2020, this Court found that Plaintiffs had standing at the motion to dismiss stage to sue University Defendants notwithstanding standing arguments similar to those raised by DPS here. (ECF No. 45 at 7–10.) Although University Defendants could not dictate the Plan's terms, benefits, or exclusions under North Carolina law, this Court held that Plaintiffs' allegations that University Defendants hired Plaintiffs, offered the Plan to them, and participate in its availability provided a sufficient nexus between the alleged injuries and University Defendants to establish standing. (*Id.* at 8.) This traceability was "further bolstered" by allegations that University Defendants funded the Plan in part and played an active role in collecting erroneous payments and settling claims regarding health benefits. (*Id.* at 8–9.)

Here, Plaintiffs have submitted evidence that DPS is similarly involved in providing and administering the Plan. First, it appears undisputed that DPS "provides health care coverage to its employees through the NCSHP." (ECF Nos. 75 ¶ 18; 96 ¶ 18; 184 at 205:20-22; *see also* ECF No. 133 at 14 (arguing that DPS was "*require[d]* . . . to offer the [Plan] to [its] current and former employees." (citing § 135-48.42(a)).) Defendants agree that DPS "play[s] a role in getting eligible employees enrolled in the Plan" by providing employees with electronic registration forms and making available a Health Benefit Representative to help the employee enroll. (ECF No. 184 at 178:9–179:18 (NCSHP dep.), 220:7–221:16 (DPS dep.).) DPS then reviews an applicant's eligibility to confirm that she is either a new hire or has become a full-time employee. (*Id.* at 179:1-5.) A DPS employee can make changes to her health insurance benefits by filing a qualifying life event, which DPS must review and approve. (*Id.* at 211:15–212:22.) DPS additionally contributes $521.96 per month per employee to help

cover the cost of the Plan. (*Id.* at 54, 205:25–206:3, 207:6-10.) Plaintiff Caraway was made eligible for the Plan by virtue of her employment with DPS. (*Id.* at 177:10-19.) And Plaintiff was required by DPS to have health insurance and received coverage under the Plan as part of her compensation. (ECF Nos. 179-9 ¶ 16; 187-1 at 5–6.)

DPS argues that it "did not make the decision to exclude gender-confirming healthcare coverage" from the Plan nor has "any authority to choose a healthcare coverage option for its employees other than what was offered through the Plan." (ECF No. 133 at 17–18.) It describes the contacts with the Plan outlined above as "ministerial duties," the majority of which "are strictly dictated by statute." (*Id.* at 18.) As Plaintiffs correctly contend, however, there is no "ministerial" exception to the standing doctrine. (ECF No. 187 at 12 (citing *Nelson v. Warner*, 12 F.4th 376, 385 (4th Cir. 2021)).) In *Nelson*, the Fourth Circuit held that candidates who were placed second on election ballots based on party affiliation pursuant to West Virginia law suffered an injury that was fairly traceable to the conduct of state election officials who prepared the ballots in accordance with the statute. *Nelson*, 12 F.4th at 385; *see also Strickland v. Alexander*, 772 F.3d 876, 886 (11th Cir. 2014) ("[T]he fact that '[defendant's] duties are ministerial in nature' [does not] somehow render [plaintiff's] injury not fairly traceable to [defendant]."). Similarly here, DPS administers the Plan by providing it to its employees as part of their compensation, enrolling employees in the Plan, confirming their eligibility, approving qualifying life events, and partially funding the Plan. Thus, Plaintiff's injuries are fairly traceable to DPS's conduct, notwithstanding its contention that its role in administering the Plan is merely ministerial.

Additionally, the Court finds that Caraway has submitted sufficient evidence to demonstrate injury and redressability at the summary judgment stage. As this Court previously found with regard to Plaintiffs' Title IX claims, a favorable ruling on Caraway's Title VII claim could redress Caraway's injury through monetary or declaratory relief. (*See* ECF No. 45 at 9–10.) Thus, Caraway has sufficiently established standing to sue DPS.

2. Caraway was denied coverage because of her sex

To prevail under Title VII, a plaintiff must typically show that "the defendant's conduct did in fact cause the plaintiff's injury," *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013), meaning plaintiff's injury "would not have happened 'but for' the purported cause," *Bostock*, 140 S. Ct. at 1739. *But see id.* at 1740 (noting that "liability can sometimes follow even if sex *wasn't* a but-for cause of the employer's challenged decision" under the "motivating factor test"). The but-for test directs courts "to change one thing at a time and see if the outcome changes." *Id.* at 1739. But-for causation "can be a sweeping standard" because "[o]ften, events have multiple but-for causes." *Id.* "[A] defendant cannot avoid liability just by citing some *other* factor that contributed to its challenged employment decision." *Id.*

Discrimination against a transgender employee violates Title VII. *Id.* at 1741. The Supreme Court reasoned that an employer who "fires a transgender employee who was identified as a male at birth but now identifies as a female" but "retains an otherwise identical employee who was identified as female at birth . . . intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth" in violation of Title VII. *Id.* Like with discrimination based on sexual orientation, "the

individual employee's sex plays an unmistakable and impermissible role in the discharge decision." *Id.* at 1741–42.

Here, a straightforward application of the but-for test supports that Caraway's birth-assigned sex was a but-for cause of her injury. Caraway received hormone treatments and surgery that aligned her physiology more closely with that of a stereotypical woman. Because Caraway was identified as a male at birth, the Plan and its administrators considered these treatments to be "leading to or in connection with sex changes or modifications and related care." (ECF No. 179-9 at 13.) If she was not assigned the sex of male of birth, then the treatments would not "change" or "modify" her sex, and they would not fall within the exclusion. Defendants have not submitted any admissible evidence to refute that these treatments were "medically necessary," and it appears both NCSHP and Blue Cross agree that they would have been covered in absence of the exclusion. (ECF Nos. 137-2 at 58:4-23, 72:4-6 (Jones dep.); 185-2 at 89–99; *see also* ECF No. 179-9 at 13 (citing only the exclusion as the reason Caraway's surgery was not covered).) Since the Plan covers some hormone treatments, (*see* ECF No. 197-9), and may cover breast augmentation, vaginal repair, or vaginal construction surgery that is not to treat "transsexualism" or "personal history of sex reassignment," (ECF No. 137-4 ¶ 21), it appears that Caraway would be able to receive the same or similar surgery if she had been identified as female at birth.

DPS does not dispute this straightforward application of the but-for test. Instead, it argues (similar to its standing argument above) that it did not "establish [or] implement" the Plan, and therefore its actions are not a but-for cause of Caraway's injury. (ECF No. 133 at 11.) But as discussed above, it is undisputed that DPS "provided" Plaintiff Caraway with

health insurance under the Plan as part of her compensation and performed various tasks to help implement the Plan. The fact that DPS did not create the Plan or decide what it covered is not dispositive. Put simply, if DPS had not provided Caraway with discriminatory health insurance, she would not have been injured. DPS's conduct is therefore a but-for cause of her injury.

DPS counters: but we had no choice! State law required DPS to provide Plaintiff with insurance under the Plan and forbade it from providing other or supplemental health insurance. But compliance with state law is no defense to a federal violation. U.S. Const. art. VI cl. 2; *Arizona v. United States*, 567 U.S. 387, 399 (2012) ("[S]tate laws are pre-empted . . . where compliance with both federal and state regulations is a physical impossibility.") (internal quotations omitted); *see, e.g.*, *Green v. Sch. Bd. of New Kent Cty.*, 391 U.S. 430, 432–33, 435 (1968) (prohibiting school boards from complying with state laws that mandated racial segregation in public schools in conflict with the Fourteenth Amendment). Moreover, the statutes creating the Plan expressly contemplated such a conflict and instructed DPS to eschew state law for federal law. *See* N.C. Gen. Stat. §§ 135-48.4 ("If any provision of this Article is in conflict with applicable federal law, federal law shall control to the extent of the conflict."), 135-48.42(a) ("*Except as otherwise required by applicable federal law*, new employees must be given the opportunity to enroll. . . ." (emphasis added)).

Thus, Caraway will be granted summary judgment on her Title VII claim against DPS, and DPS's motion for summary judgment will be denied as to this claim. The remaining issue of damages will be reserved for trial.

C. ACA

Lastly, NCSHP moves for summary judgment on Plaintiffs' claims arising under the ACA. (ECF No. 136.) Plaintiffs move for partial summary judgment on this claim, reserving the issue of damages for trial. (ECF Nos. 178; 179 at 4.)

The ACA provides that "an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 [or] title IX of the Education Amendments of 1972, . . . be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). The ACA explicitly incorporates Title VI and Title IX, and "[t]he Fourth Circuit looks to Title VII . . . to guide the 'evaluation of claims under Title IX.'" *Hammons v. Univ. of Md. Med. Sys. Corp.*, 551 F. Supp. 3d 567, 590 (D. Md. 2021), *reconsideration denied*, No. CV DKC 20-2088, 2021 WL 4951921 (D. Md. Oct. 25, 2021) (quoting *Grimm*, 972 F.3d at 616). The test announced in *Bostock* is therefore the appropriate test to determine whether a policy discriminates in violation of the ACA. *See id.* Thus, for the reasons identified in Section III.B.ii.2, *supra*, there is no genuine issue of material fact disputing that the Plan discriminated against Caraway on the basis of her sex.

NCSHP argues instead that it is not liable under the ACA because it is not a "health program or activity." (ECF No. 137 at 33–37.) The term is not defined in the statute. The U.S. Department of Health and Human Services ("HHS")—the federal agency tasked with promulgating regulations to implement this prohibition, *see* 42 U.S.C. § 18116(c)—initially interpreted "health program or activity" to include entities "principally engaged in providing or administering . . . health insurance coverage," among others. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31467 (May 18, 2016). In June 2020, however,

HHS revised its rules. Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160, 37244–45 (June 19, 2020) (codified at 45 C.F.R. § 92.3(b), (c)). Its current interpretation expressly excludes "entit[ies] principally or otherwise engaged in the business of providing health insurance" from the definition of "health program or activity." 45 C.F.R. § 92.3(c).

Various litigants have challenged HHS's changed interpretation of the statute as arbitrary and capricious, and the question remains pending in multiple federal courts. *See, e.g., Boston All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Hum. Servs.*, 557 F. Supp. 3d 224, 237–39 (D. Mass. 2021). These courts have stayed proceedings as "HHS's efforts to reconsider the 2020 Rule are underway," the Department "intends to issue a Notice of Proposed Rulemaking in early 2022," and its actions "provide every indication that it is preparing to initiate a wholesale revision of the 2020 Rule." *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. CV 20-1630 (JEB), 2021 WL 4033072, at *3 (D.D.C. Sept. 3, 2021).

It appearing to the Court that the agency interpretation at issue may change or be enjoined before trial is set to commence in this case on July 5, 2022; that resolution of this issue in this case could have nation-wide implications; that Plaintiffs will receive the declaratory and injunctive relief they seek by virtue of this Order and will therefore not be prejudiced by a delay in resolving this issue; and that discovery has closed and motion practice has ended, meaning NCSHP will not be prejudiced by a delay in resolving this issue; the Court, therefore, will reserve judgment on this portion of Defendant's motion pending further Order from this Court.

D. Permanent injunction

Plaintiffs seek a permanent injunction. (ECF No. 75 ¶ B.) "[A] plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156 (2010). Plaintiffs must demonstrate: (1) irreparable injury; (2) inadequacy of available remedies at law, such as monetary damages; (3) an injunction is warranted after "considering the balance of hardships between the plaintiff and defendant"; and (4) "that the public interest would not be disserved by a permanent injunction." *Id.* at 156–57. Permanent injunctions are particularly appropriate in discrimination cases to prevent continued discrimination. *See Albemarle Paper Co. v. Moody*, 422 U.S. 405, 417 (1975) (noting that the "primary objective" of Title VII "was a prophylactic one" to "remove barriers that have operated in the past").

Here, Plaintiffs have shown that they will require continued medical care to treat their gender dysphoria and that, barring judicial or legislative intervention, NCSHP intends to maintain the exclusion. (ECF No. 185-2 at 83 (Folwell) (vowing to maintain the exclusion "[u]ntil the court system, a legislative body or voters tell us that we 'have to,' 'when to,' and 'how to' spend taxpayers' money on sex change operations").) The exclusion has and will continue to force Plaintiffs and others delay or forgo medically necessary treatments, since most do not have funds available to pay for treatments out of pocket and then be reimbursed through monetary damages. These significant hardships faced by Plaintiffs outweigh the minimal hardship on Defendants, particularly given that Defendants and their third-party administrators were able to identify and cover medically necessary care in 2017. Finally, an injunction is likely to cost the public substantially less than awarding damages after-the-fact,

since NCSHP can negotiate lower prices than individual members can negotiate while paying out of pocket.

Prohibitory injunctions that "aim to maintain the status quo and prevent irreparable harm" are favored over mandatory injunctions that "alter the status quo." *League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 235–36 (4th Cir. 2014) (discussing preliminary injunctions). The status quo is "the last uncontested status between the parties which preceded the controversy." *Id.* at 236 (quoting *Pashby v. Delia*, 709 F.3d 307, 320 (4th Cir. 2013)). A plaintiff who seeks to enjoin enforcement of a new policy and "require a party who has recently disturbed the status quo to reverse its actions" seeks a prohibitory injunction, not a mandatory one. *Id.*; *see also Disability Rts. S.C. v. McMaster*, 564 F. Supp. 3d 413, § IV.A (D.S.C. 2021) (finding that the status quo in was "the position of the parties prior to the enactment of" the challenged policy), *vacated in part on other grounds*, 24 F.4th 893 (4th Cir. 2022).

Here, the last uncontested status between the parties existed during 2017, when Defendants covered medically necessary services for the treatment of gender dysphoria. Thus, Plaintiffs' request to enjoin enforcement of the exclusion and reimpose the uncontested 2017 rule seeks a prohibitory injunction. This Court finds that reimposing the 2017 rule is the appropriate remedy.

Accordingly, the Court will permanently enjoin NCSHP from enforcing the Plan's exclusion and order NCSHP to reinstate coverage for "medically necessary services of treatment for gender dysphoria."

IV. MOTIONS TO SEAL

Finally, Plaintiffs seek to seal portions of expert reports that describe in detail Plaintiffs' experiences with gender dysphoria and transition, to include portions of Dr. George Richard Brown's report, filed in support of their motion for summary judgment, (ECF No. 182), and portions of Dr. Lappert's report, filed in support of their *Daubert* motion to exclude his testimony, (ECF No. 210).

A motion to seal "presents the seeming tension between several legitimate interests." *Va. Dep't of State Police v. Washington Post*, 386 F.3d 567, 574 (4th Cir. 2004). On one hand, the public has a right, derived from both common law and the First Amendment, "of public access to documents or materials filed in a district court." *Id.* at 575. On the other hand, individuals have an interest in keeping sensitive medical information private. *Watson v. Lowcountry Red Cross*, 974 F.2d 482, 487 (4th Cir. 1992); *Boone v. Bd. of Governors of Univ. of N.C.*, 395 F. Supp. 3d 657, 665 (M.D.N.C. 2019), *aff'd*, 858 F. App'x 622 (4th Cir. 2021). Congress and the State of North Carolina have recognized the significance of an individual's interest in keeping medical information private, *see* 42 U.S.C. § 1320d-6(a); N.C. Gen. Stat. § 58-2-105(a), and the Fourth Circuit has held that such information "should receive scrupulously confidential treatment" when it concerns subject matter that faces public stigma, *Watson*, 974 F.2d at 487.

A. Dr. Brown's report (ECF No. 182)

When the subject of the motion to seal is documents attached to a summary judgment motion in a civil case, "the more rigorous First Amendment standard" governs the court's analysis. *Washington Post*, 386 F.3d at 576 (quoting *Rushford v. New Yorker Mag., Inc.*, 846 F.2d 249, 253 (4th Cir. 1988)). Under this standard, "a district court may restrict access 'only on

the basis of a compelling governmental interest, and only if the denial is narrowly tailored to serve that interest.'" *Id.* at 575 (quoting *Stone v. Univ. of Md. Med. Sys. Corp.*, 855 F.2d 178, 180 (4th Cir. 1988)). "Public access serves to promote the trustworthiness of the judicial process, to curb judicial abuses, and to provide the public with a more complete understanding of the judicial system, including a better perception of fairness." *Doe v. Pub. Citizen*, 749 F.3d 246, 266 (4th Cir. 2014). "Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like a fiat and requires rigorous justification." *Id.* Thus, before granting a motion to seal, a court must "(1) provide public notice of the sealing request and a reasonable opportunity for the public to voice objections to the motion; (2) consider less drastic alternatives to closure; and (3) . . . state its reasons—with specific findings—supporting closure and its rejections of less drastic alternatives." *Id.* at 272.

Here, Plaintiffs' motion to seal has been publicly docketed since its date of filing on December 20, 2021. (ECF No. 182.) Thus, the public has had ample notice and opportunity to oppose the motion. Plaintiffs seek to seal medical information of the most intimate and sensitive nature concerning their struggles with, and treatment of, gender dysphoria, often during adolescence. (*Id.*) Gender dysphoria and transition remains highly stigmatized, lending greater weight to Plaintiffs' argument that there is a compelling interest to keep this information private. *Watson*, 974 F.2d at 487. The Court is also concerned that denying Plaintiffs' motion could have a chilling effect on future litigants who want to challenge unlawful discrimination but do not want their personal and private medical history put on display. Defendants, who have full access to an unredacted copy of Brown's report, will not be prejudiced by granting Plaintiffs' motion, and no member of the public has requested

access. Further, the only piece of evidence relied upon by this Court in this Order which Plaintiffs seek to seal is Brown's testimony that each Plaintiff has been diagnosed with gender dysphoria—a fact that is repeated in Plaintiffs' unredacted declarations, discussed in this Order, and not disputed by Defendants. Thus, the Court finds Plaintiffs' privacy interest outweighs the public's limited interest in learning the private medical details of Plaintiffs' experiences with gender dysphoria. Finally, the Court finds that there are no alternatives to closure, and Plaintiffs' request to seal only small portions of Browns' testimony is narrowly tailored to the compelling interest discussed herein.

Plaintiffs' motion will be granted.

B. Dr. Lappert's report (ECF No. 210)

When the motions sought to be sealed are in connection with an evidentiary motion rather than a motion seeking dispositive relief, "the right of access at issue arises under the common law." *Lord Corp. v. S & B Tech. Prods., Inc.*, No. 5:09-CV-205-D, 2012 WL 895947, at *1 (E.D.N.C. Mar. 15, 2012); *see generally Washington Post*, 386 F.3d at 576–77 (holding that the First Amendment attached to dispositive motions in civil cases). "The common law presumes a right of the public to inspect and copy all judicial records and documents." *Washington Post*, 386 F.3d at 575 (internal quotations omitted) (citing *Nixon v. Warner Comm., Inc.*, 435 U.S. 589, 597 (1978)). However, "[t]he distinction between the rights of access afforded by the common law and the First Amendment is 'significant.'" *Id.* (quoting *In re Baltimore Sun Co.*, 886 F.2d 60, 64 (4th Cir. 1989)). The common law "does not afford as much substantive protection to the interests of the press and the public" or "as much access . . . as does the First Amendment." *Id.* Thus, the presumption of access "can be rebutted if countervailing interests heavily

outweigh the public interest in access." *Id.* "[T]he party seeking to overcome the presumption bears the burden of showing some significant interest that outweighs the presumption." *Id.* (quoting *Rushford*, 846 F.2d at 253).

Here, the information contained in Lappert's report is marked "CONFIDENTIAL" and is similar to the sensitive medical information discussed by Brown. Lappert does not state any expert opinions in this section that are admissible, *see* Section II.D.ii, *supra*, further reducing the public's right of access. And, as above, no member of the public has requested access, and Defendants have access to an unredacted copy of their own expert's report. Thus, the Court finds that, under the more deferential common law standard, Plaintiffs' interest in privacy heavily outweighs the public's interest in access.

Thus, Plaintiffs motions to seal will be granted.

CONCLUSION

Issues surrounding transgender healthcare evoke strong emotional and political opinions. *See Grimm*, 972 F.3d at 594 ("[M]any of us carry heavy baggage into any discussion of gender and sex."). But politics and emotion are not admissible as evidence in a court of law. Plaintiffs' doctors, their experts, every major medical association, and Defendants' own third-party administrators all agree that, in certain cases, gender affirming medical and surgical care can be medically necessary to treat gender dysphoria. Defendants attempt to create scientific controversy in this uniform agreement through experts who mix their scientific analysis with hypothetical speculation and political hyperbole. Only science that is relevant, reliable, and offered by a qualified expert is admissible, however, and the admissible portions of Defendants' expert's testimony, even when taken in the light most favorable to Defendants,

do not justify the exclusion at issue. Defendants' belief that gender affirming care is ineffective and unnecessary is simply not supported by the record. Consequently, their categorical sex- and transgender-based exclusion of gender affirming treatments from coverage unlawfully discriminates against Plaintiffs in violation of the U.S. Constitution and Title VII.

ORDER

IT IS THEREFORE ORDERED that DPS's Motion for Summary Judgment, (ECF No. 132), is **DENIED.**

IT IS FURTHER ORDERED that Plan Defendants' Partial Summary Judgment, (ECF No. 136), is **GRANTED** in part and **JUDGMENT IS RESERVED** in part. It is **GRANTED** as to Plaintiff Caraway's claim arising under Title VII against NCSHP. **JUDGMENT IS RESERVED** regarding Plaintiffs' claims arising under the ACA pending further Order from this Court.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Summary Judgment, (ECF No. 178), is **GRANTED** in part, **DENIED** in part, and **JUDGMENT IS RESERVED** in part. It is **GRANTED** with respect to Plaintiffs' claims arising under the Equal Protection Clause and Plaintiff Caraway's claim arising under Title VII against DPS. It is **DENIED** as to Caraway's Title VII claim against NCSHP. **JUDGMENT IS RESERVED** regarding Plaintiffs' claims arising under the ACA pending further Order from this Court. Defendants are **PERMANENTLY ENJOINED** from enforcing the Plan's exclusion and are **ORDERED** to reinstate coverage for "medically necessary services for the treatment of gender dysphoria." The issue of damages is reserved for trial.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Seal Exhibits to Plaintiffs' Motion for Summary Judgment, (ECF No. 182), is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Peter Robie, (ECF No. 202), is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul W. Hruz, (ECF No. 204), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul R. McHugh, (ECF No. 206), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert, (ECF No. 208), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiff's Motion to Seal portions of Dr. Lappert's report, (ECF No. 210), is **GRANTED.**

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D., (ECF No. 212), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

This, the 10th day of June 2022.

/s/ Loretta C. Biggs
United States District Judge

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

MAXWELL KADEL, *et al.*,

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*,

Defendants.

No. 1:19-cv-272-LCB

NOTICE OF INTERLOCUTORY APPEAL

Notice is hereby given that Defendants Dale Folwell, *in his official capacity as State Treasurer of North Carolina*, and Dee Jones, *in her official capacity as Executive Administrator of the North Carolina State Health Plan for Teachers and State Employees*, hereby appeal to the United States Court of Appeals for the Fourth Circuit.

This appeal pursuant to Title 28, United States Code, Section 1292(a)(1) is taken from the Memorandum Opinion and Order, (Doc. No. 234), entered against these two defendants June 10, 2022. *See* Fed. R. App. P. 4(a)(1)(A).[1]

Respectfully submitted this the 1st day of July, 2022.

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[1] Defendant North Carolina State Health Plan for Teachers and State Employees was not a party to the Plaintiffs' claim for injunctive relief. (Amended Complaint, Count 1, Doc. No. 75, 34-37). The Court has "reserved judgment" on the sole remaining claim involving this defendant—regarding the applicability of Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116—and placed the matter on its December 2022 trial calendar.

CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of July, 2022, the foregoing Notice of Interlocutory Appeal was filed electronically with the Clerk of Court using the CM/ECF electronic filing system, which will send notification of such filing to all registered users.

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, *v.* NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES, *Defendant*.	No. 1:19-cv-272-LCB

MOTION TO CORRECT
MEMORANDUM OPINION AND ORDER

Pursuant to Federal Rule of Civil Procedure 60(a), Defendant North Carolina State Health Plan for Teachers and State Employees ("State Health Plan") respectfully moves this Court to correct the portions of its Memorandum Opinion and Order[1] inadvertently suggesting that Defendant State Health Plan (as opposed to Dale Folwell (*in his official capacity as State Treasurer of North Carolina)* and Dee Jones (*in her official capacity as Executive Administrator of the State Health Plan))* is

[1] Doc. No. 234, entered June 10, 2022.

subject to the injunction, issued pursuant to Title 42, United State Code, Section 1983, *et seq*., against the state official co-defendants.

For the reasons set forth in the accompanying memorandum, this Court should promptly enter an Order correcting its Memorandum Opinion and Order as follows: On page 67, "NCSHP" in lines 18-19 should be replaced with "state official Defendants" or similarly limiting language. And on page 72, "Defendants" in line 18 should be replaced with "state official Defendants" or similarly limiting language.

A proposed Order is attached.

Respectfully submitted this the 7th day of July, 2022.

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CERTIFICATE OF WORD COUNT

Pursuant to L.R. 7.3(d)(1), the undersigned certifies that this Memorandum complies with the Court's word limit as calculated using the word count feature of the word processing software. Specifically, this Brief contains less than 175 words. This count includes the body of the brief and headings, but does not include the caption, signature lines, this certificate, or the certificate of service.

This the 7th day of July, 2022.

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

MAXWELL KADEL, *et al.*, *Plaintiffs*, *v.* NORTH CAROLINA STATE HEALTH PLAN FOR TEACHERS AND STATE EMPLOYEES, *Defendant*.	No. 1:19-cv-272-LCB

STATE HEALTH PLAN DEFENDANT'S MEMORANDUM IN SUPPORT OF MOTION TO CORRECT MEMORANDUM OPINION AND ORDER

Pursuant to Federal Rule of Civil Procedure 60(a), Defendant North Carolina State Health Plan for Teachers and State Employees ("State Health Plan") has respectfully moved this Court to correct portions of its Memorandum Opinion and Order. (Doc. No. 234, entered June 10, 2022). Specifically, Defendant State Health Plan has requested corrections to the clerical errors in the Memorandum Opinion and Order suggesting that it (as opposed to Dale Folwell (*in his official capacity as State Treasurer of North Carolina)* and Dee Jones (*in her official capacity as Executive Administrator of the State Health Plan*)) is subject to the

injunction, issued pursuant to Title 42, United States Code, Section 1983, *et seq*., against the state official co-defendants.

Defendant State Health Plan, an agency of the State of North Carolina, is not subject to suit under Section 1 of the Fourteenth Amendment to the United States Constitution, as enforceable pursuant to 42 U.S.C. § 1983. A State "is not a person within the meaning of § 1983." *Will v. Mich. Dep't of State Police*, 491 U.S. 58, 64 (1989). Moreover, under the Eleventh Amendment, "[a]bsent waiver, neither a State nor agencies acting under its control may be subject to suit in federal court." *Puerto Rico Aqueduct & Sewer Auth. v. Metcalf & Eddy, Inc.*, 506 U.S. 139, 144 (1993) (quoting *Welch v. Texas Dept. of Highways and Public Transportation,* 483 U.S. 468, 480 (1987) (plurality opinion)) (internal punctuation omitted). *See also Doyle v. Hogan*, 1 F.4th 249, 254 (4th Cir. 2021) ("In general, States may not be haled into federal court without their consent[,]" though "suits may, at least sometimes, be brought in federal court to enjoin a state officer from enforcing an unconstitutional act"). Given North Carolina's constitutional and 11th Amendment sovereign immunity—and the Supreme Court's decisions in

Ex parte Young and its progeny—this Court can only issue injunctive relief issue against the appropriate state officials.

For these reasons, presumably, Defendant State Health Plan is not a party to Plaintiffs' Count 1 claim for injunctive relief pursuant to 42 U.S.C. § 1983, *et seq*. (Doc. No. 75, p.34-37). Rather, Plaintiffs only sued Dale Folwell and Dee Jones (*in their official capacities)* for injunctive relief in Count 1 of their Amended Complaint. *Id.* As this Court has previously acknowledged, in Count 1, "Plaintiffs bring an Equal Protection claim against Defendants Folwell and Jones in their official capacities." (Doc. No. 45 p.20)

Given North Carolina's sovereign immunity, this Court can only issue injunctive relief under the claim in Count 1 against the state officials named pursuant to *Ex Parte Young*. Suits under *Ex Parte Young* "are deemed to be against officials and not the States or their agencies, which retain their immunity against all suits in federal court." *Puerto Rico Aqueduct*, 506 U.S. at 146.

Because (1) the Plaintiffs have not sought injunctive relief against the State Health Plan pursuant to Count 1 of their Complaint, (2) the Court has no authority to issue an injunction against the State Health

Plan under Count 1, and (3) the Court has deferred judgment on the only remaining claim against the State Health Plan, the Court should clarify its current Order.

Wherefore, this Court should promptly enter an Order correcting its Memorandum Opinion and Order as follows: On page 67, "NCSHP" in lines 18-19 should be replaced with "state official Defendants." And on page 72, "Defendants" in line 18 should be replaced with "state official Defendants."

Respectfully submitted this the 7th day of July, 2022.

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This the 7th day of July, 2022.

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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-00272-LCB-LPA

NOTICE OF NON-OPPOSITION TO STATE HEALTH PLAN'S MOTION TO CORRECT

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that Plaintiffs 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 do not oppose the relief sought in the State Health Plan's Motion to Correct. ECF No. 247.

Dated: July 15, 2022

Respectfully submitted,

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* Appearing by special appearance pursuant to L.R. 83.1(d).

CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

Dated: July 15, 2022

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

MAXWELL KADEL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:19CV272
DALE FOLWELL, *et al.*,	)	
	)	
Defendants.	)	
	)	

NOTICE OF INTENT TO CORRECT AND CLARIFY MEMORANDUM OPINION AND ORDER

LORETTA C. BIGGS, District Judge.

On July 7, 2022, Defendant North Carolina State Health Plan for Teachers and State Employees ("NCSHP") filed the present unopposed[1] Motion pursuant to Rule 60(a) of the Federal Rules of Civil Procedure, (ECF No. 247), to Correct this Court's Memorandum Opinion and Order, entered on June 10, 2022, (ECF No. 234). Prior to NCSHP's filing of this motion, Defendants Dale Folwell, *in his official capacity as State Treasurer of North Carolina*, and Dee Jones, *in her official capacity as Executive Administrator of the NCSHP*, filed a Notice of Interlocutory Appeal in the above captioned matter on July 1, 2022. (ECF No. 245.) That appeal was docketed in the United States Court of Appeals for the Fourth Circuit on July 8, 2022, on the same day that the present motion was submitted to this Court. (ECF No. 249.) NCSHP subsequently filed its own Notice of Interlocutory Appeal on July 11, which was

[1] (*See* ECF No. 254.)

docketed on July 12. (ECF Nos. 250; 252.) The Fourth Circuit consolidated these appeals on July 12, 2022. (ECF No. 253.)

Pursuant to Rule 62.1(a) of the Federal Rules of Civil Procedure, this Court files this **Notice** to inform the parties and the Fourth Circuit that it would grant NCSHP's motion, (ECF No. 247), if the court of appeals remands for that purpose, *see* Fed. R. Civ. P. 62.1(a)(3).

Rule 60(a) allows a court to "correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record." Fed. R. Civ. P. 60(a). The Rule "is not confined just to fixing typographical and other clerical errors," but also allows a court to correct or clarify an "inconsistency between the text of an order or judgment and the district court's intent when it entered the order or judgment." *Sartin v. McNair L. Firm PA*, 756 F.3d 259, 265–66 (4th Cir. 2014). Once an appeal has been docketed in the appellate court and while it is pending, however, "such a mistake may be corrected only with the appellate court's leave." Fed. R. Civ. P. 60(a). In such cases, the district court may (1) defer considering the motion, (2) deny the motion, or (3) state either "that it would grant the motion if the court of appeals remands for that purpose" or "that the motion raises a substantial issue." Fed. R. Civ. P. 62.1(a).

This Court, in its Order entered on June 10, 2022, granted in part Plaintiffs' Motion for Summary Judgment and entered a permanent injunction against "Defendants." (ECF No. 234 at 72.) The accompanying Memorandum Opinion mistakenly stated that "the Court will permanently enjoin NCSHP from enforcing the Plan's exclusion and order NCSHP to reinstate coverage. . . ." (*Id.* at 67.) As NCSHP correctly notes, the proper Defendants to Plaintiffs' request for a permanent injunction are Defendants Dale Folwell, in his official

capacity as State Treasurer of North Carolina, and Dee Jones, in her official capacity as Executive Administrator of the State Health Plan. (ECF No. 247 at 1–2; *see* ECF No. 75 at 34.) This Court's original intent was to enjoin Defendants Folwell and Jones in their official capacities, not Defendant NCSHP, as reflected in an earlier Order which was affirmed by the Fourth Circuit. *See Kadel v. Folwell*, 446 F. Supp. 3d 1, 17 (M.D.N.C. 2020) ("Plaintiffs bring an Equal Protection claim against Defendants Folwell and Jones in their official capacities."), *aff'd sub nom. Kadel v. N.C. State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422 (4th Cir.), *as amended* (Dec. 2, 2021), *cert. denied*, 142 S. Ct. 861 (2022).

Accordingly, if the Fourth Circuit remanded the above captioned matter for the purpose of allowing this Court to address NCSHP's motion, this Court would grant the motion and (1) correct its Memorandum Opinion on page 67 to state that "the Court will permanently enjoin Defendants Folwell and Jones, *in their official capacities*, ~~NCSHP~~ from enforcing the Plan's exclusion and order ~~NCSHP~~ them to reinstate coverage," and (2) clarify its Order on page 72 to state that "Defendants Folwell and Jones, *in their official capacities*, are **PERMANENTLY ENJOINED** from enforcing the Plan's exclusion. . . ." (*See* ECF No. 234 at 67, 72.) These changes do not otherwise alter the substance of the Court's Opinion and Order.

Pursuant to Rule 62.1(b), this Court instructs Defendant NCSHP to "promptly notify the circuit clerk" of this Notice. Fed. R. Civ. P. 62.1(b); *see* Fed. R. App. P. 12.1(a).

This, the 18th day of July 2022.

/s/ Loretta C. Biggs
United States District Judge

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

MAXWELL KADEL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:19CV272
DALE FOLWELL, *et al.*,	)	
	)	
Defendants.	)	
	)	

ORDER

LORETTA C. BIGGS, District Judge.

The above-captioned matter is before this Court on limited remand from the Fourth Circuit Court of Appeals, *see Kadel v. Folwell*, No. 22-1721 (4th Cir. August 2, 2022); (ECF No. 258), for the purpose of resolving the unopposed Motion to Correct Memorandum Opinion and Order, filed by Defendant North Carolina State Health Plan for Teachers and State Employees ("NCSHP"), (ECF Nos. 247; 254).

For the reasons stated in this Court's Notice of Intent to Correct and Clarify Memorandum Opinion and Order, entered on July 18, 2022, (ECF No. 255), Defendant NCSHP's unopposed Motion Memorandum Opinion and Order, (ECF no. 247), is hereby **GRANTED**. A corrected version of this Court's Memorandum Opinion and Order, originally entered on June 10, 2022, (ECF No. 234), will be filed simultaneously with this Order. The filing of this Order and the corrected Memorandum Opinion and Order

completes this Court's proceedings related to the Fourth Circuit Court of Appeal's limited remand.

This, the 10th day of August 2022.

/s/ Loretta C. Biggs
United States District Judge

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

MAXWELL KADEL, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	1:19CV272
DALE FOLWELL, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION AND ORDER
(CORRECTED VERSION)

LORETTA C. BIGGS, District Judge.

Plaintiffs are transgender individuals or the parents of transgender individuals who receive health insurance through the North Carolina State Health Plan for Teachers and State Employees ("NCSHP" or the "Plan"). (ECF No. 75 ¶¶ 1, 7–12.) They allege that the Plan's categorical exclusion of coverage for treatments "leading to or in connection with sex changes or modifications" discriminates against them on the basis of sex and transgender status in violation of the Equal Protection Clause and the Affordable Care Act ("ACA") and seek declaratory, injunctive, and monetary relief. (*Id.* ¶¶ 1, 139–53, 165–74.) Plaintiff Dana Caraway additionally alleges that NCSHP and her employer, the North Carolina Department of Public Safety ("DPS"), discriminated against her on the basis of sex by offering and administering the Plan in violation of Title VII of the Civil Rights Act of 1964. (*Id.* ¶¶ 175–188.) Before the Court are cross motions for summary judgment filed by DPS, NCSHP, and

Plaintiffs, (ECF Nos. 132; 136; 178); Plaintiffs' motions to exclude expert testimony, (ECF Nos. 202; 204; 206; 208; 212); and Plaintiffs' motions to seal, (ECF Nos. 182; 210).[1]

For the reasons stated herein, the Court finds that the Plan's exclusion discriminates based on sex and transgender status in violation of the Equal Protection Clause and discriminates because of sex in violation of Title VII. The Court will reserve a ruling on claims alleged under the ACA pending further Order from this Court.

I. BACKGROUND

A. Plaintiffs' experiences with the Plan

Plaintiff Connor Thonen-Fleck is a 19-year-old man. (ECF No. 179-2 ¶ 2.) He is also transgender. (*Id.* ¶ 3.) Thonen-Fleck was "designated 'female' at birth" but identifies and lives his life as a man. (*Id.*) In his words, he "demonstrated stereotypically masculine tendencies and characteristics from a young age," and by 15 years old, "had socially transitioned and was living in [his] authentic male gender identity in all aspects of [his] life." (*Id.* ¶¶ 5–6.) His male identity is now reflected in his legal name, gender marker, birth certificate, and driver's license. (*Id.* ¶ 8.)

Before Connor and his family understood what it meant to be transgender, Connor "was in serious and increasing distress" and suffered from depression and suicidal ideation.

[1] These include: a Motion for Summary Judgment filed by Defendant North Carolina Department of Public Safety, (ECF No. 132); a Motion for Partial Summary Judgment filed by Defendants Dale Folwell, Dee Jones, and NCSHP, (ECF No. 136); Plaintiffs' Motion for Summary Judgment, (ECF No. 178); Plaintiffs' Motion to Seal Exhibits to Plaintiffs' Motion for Summary Judgment, (ECF No. 182); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Peter Robie, (ECF No. 202); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul W. Hruz, (ECF No. 204); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul R. McHugh, (ECF No. 206); Plaintiffs' Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert, (ECF No. 208); Plaintiff's Motion to Seal portions of Dr. Lappert's report, (ECF No. 210); and Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D., (ECF No. 212).

(*Id.* ¶ 5; ECF No. 179-3 ¶ 6.) His psychiatrist diagnosed him with gender dysphoria. (ECF No. 185-1 at 40–41; *see* ECF No. 179-2 ¶ 7.) Gender dysphoria is "a condition that is characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex." (ECF No. 219 at 10; *see* ECF No. 197 at 13.) Treatments may include therapy, medications, or surgery to align the patient's physiology with their identity and "allow[ ] the individual to transition from his or her birth assigned sex to the sex associated with his or her gender identity." (ECF No. 219 at 10.) In Connor's case, his physicians recommended counseling, hormone therapy beginning in January 2018, and ultimately chest reconstruction surgery in May 2019 "to bring [his] body into better alignment with [his] gender identity and lived experience and further reduce [his] symptoms of gender dysphoria." (ECF Nos. 179-2 ¶¶ 7, 9–10; 179-3 ¶ 15.) In his father's words, "it was clear that being a teenage boy without a typically male chest was very painful for [Connor]." (ECF No. 179-3 ¶ 13.)

Connor has health insurance through his father, who is a state employee at the University of North Carolina, Greensboro and a member of the North Carolina State Health Plan for Teachers and State Employees ("NCSHP" or the "Plan"). (*Id.* ¶¶ 2–4.) When Connor was prescribed testosterone treatments in 2018, NCSHP denied coverage due to a categorical exception for "[t]reatment or studies to or in connection with sex changes or modifications and related care." (*Id.* at 22.) Connor's chest surgery also was not covered. (*Id.* ¶ 14.) As a consequence, the family had to delay the surgery, and Connor worked after school to help raise money for his healthcare. (*Id.* ¶¶ 14–15; ECF No. 179-2 ¶ 14.) Eventually, the family saved enough to pay out of pocket. (ECF No. 179-3 ¶ 15.) Connor and his father testify that

the treatments were "life-changing" and "critical for [his] ongoing development and functioning as a young adult." (*Id.* ¶ 16; ECF No. 179-2 ¶ 16.) Connor will need ongoing access to hormone therapy and anticipates requiring additional surgery to continue treatment of his gender dysphoria. (ECF No. 179-2 ¶ 17.)

Connor's experience is typical of remaining Plaintiffs. Plaintiffs are all current or former North Carolina state employees or dependents of state employees who receive health insurance through NCSHP. (ECF Nos. 179-1 ¶¶ 2, 5; 179-4 ¶¶ 2, 8; 179-5 ¶ 19; 179-6 ¶¶ 2, 5; 179-7 ¶¶ 5–6; 179-9 ¶¶ 2, 16.) Plaintiffs or their dependents identify as transgender. (ECF Nos. 179-1 ¶ 2; 179-4 ¶ 2; 179-5 ¶ 4; 179-7 ¶ 2; 179-9 ¶ 3.) These Plaintiffs each formed their gender identities early in childhood, (*see, e.g.*, ECF No. 179-5 ¶ 6 ("Ever since I was a young child, I have known that I am [a] boy.")); *see generally* ECF Nos. 179-1 ¶ 6; 179-4 ¶ 4–5; 179-6 ¶¶ 7–8; 179-9 ¶ 9), and have suffered from anxiety and depression caused by suppression of their gender identities, discrimination and harassment from peers, and living with physical features not typical of the gender with which they identify, (ECF Nos. 179-1 ¶ 8; 179-4 ¶ 4; 179-5 ¶¶ 13, 24; 179-7 ¶ 7; 179-9 ¶ 11). Each has been diagnosed with gender dysphoria. (ECF Nos. 179-1 ¶ 6; 179-4 ¶¶ 4, 5, 9; 179-5 ¶ 14; 179-7 ¶ 8; 179-9 ¶ 19; 185-1 at 31, 34, 37, 40–41, 43, 60.) And each has been denied coverage for procedures prescribed to treat gender dysphoria, to include puberty delaying medication, hormone therapy, mastectomy, mammaplasty, vaginoplasty, and vocal therapy. (ECF Nos. 179-1 ¶¶ 7, 9–15; 179-4 ¶¶ 9–10; 179-5 ¶¶ 20–22; 179-7 ¶¶ 13–17; 179-9 ¶¶ 20–21, 23–26.)

B. The Exclusion

The basis for NCSHP's denial of coverage is an exclusion that dates back to the 1990s. (ECF No. 137-2 at 16:10-13.) The North Carolina General Assembly originally formed NCSHP to administer "one or more group health plans that are comprehensive in coverage" and tasked the State Treasurer, NCSHP Executive Administrator, and NCSHP Board of Trustees with certain "duties and responsibilities as fiduciaries for the Plan." N.C. Gen. Stat. § 135-48.2(a). The Plan is North Carolina's largest insurer with approximately 740,000 members. (ECF Nos. 137-1 at 35:9-12; 137-2 at 74:1-5.) Individual members pay a monthly premium with additional funding coming from the state. (ECF Nos. 137-2 at 102:22-24, 105:22-24; 137-3 at 1.) From January to August 2018, NCSHP had collected approximately $2.4 billion in revenue and had a cash balance of approximately $1.1 billion. (ECF No. 184 at 132, 142.)

The Plan only covers "medically necessary" services but does not cover all medically necessary services. (ECF No. 137-2 at 58:4-7.) "Medically necessary services or supplies" are defined by North Carolina statute as those services or supplies that are (1) "[p]rovided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease" and "not for experimental, investigational, or cosmetic purposes," (2) "[n]ecessary for and appropriate to the diagnosis, treatment, cure, or relief of a health condition, illness, injury, disease, or its symptoms," (3) [w]ithin generally accepted standard of medical care in the community," and (4) "[n]ot solely for the convenience of the insured, the insured's family, or the provider." N.C. Gen. Stat. § 58-3-200(b).

Each year, NCSHP adopts and publishes PPO Plan Benefit Booklets that list the healthcare that is and is not covered by the Plan. (*See* ECF No. 184 at 56–104.) The Plan's third-party administrators, Blue Cross/Blue Shield of North Carolina ("Blue Cross") and CVS/Caremark ("CVS"), then implement the booklet using the national billing practices and medical coding system of the healthcare industry. (ECF Nos. 137-1 at 119:9-10; 197-14 ¶ 11.) From the 1990s to 2016, the Plan contained two exclusions relevant to Plaintiffs' causes of actions. The 2016 Plan did not cover:

- Psychological assessment and psychotherapy treatment in conjunction with proposed gender transformation.
- Treatment or studies leading to or in connection with sex changes or modifications and related care.

(ECF No. 184 at 59–60.) According to Defendants, the first exception has never been implemented and is no longer part of the Plan. (*See* ECF Nos. 137 at 13 n.2; 137-4 ¶ 27.) Blue Cross and CVS do give effect to the second exclusion by identifying specific treatments that are not covered. (ECF No. 137-4 ¶¶ 20–21; *see, e.g.*, ECF No. 179-3 at 12–13.) According to Blue Cross, four procedures are not covered by the Plan "regardless of the diagnostic code," to include "Intersex Surgery, Male to Female," "Intersex Surgery, Female to Male," "Vaginoplasty for Intersex State," and "Clitoroplasty for Intersex State." (ECF No. 137-4 ¶ 20.) Two dozen other procedures are not covered when the procedural diagnostic code is for "Transsexualism" or "Personal history of sex reassignment." (*Id.* ¶ 21.) CVS likewise may deny coverage for medication, such as puberty blockers or hormone treatments, due to the exclusion. (*See* ECF No. 179-3 at 13 (denying coverage for testosterone where the associated diagnosis was "Transsexualism").)

The Plan did briefly cover "*Medically necessary* services for the treatment of gender dysphoria" in 2017. (ECF No. 184 at 63.) On May 18, 2016, the U.S. Department of Health and Human Services ("HHS") promulgated a final rule prohibiting "categorical coverage exclusion[s] or limitation[s] for all health services related to gender transition." Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375, 31471–72 (May 18, 2016). The NCSHP Board of Trustees acted to comply with the regulation and considered "remov[ing] the blanket exclusions that relate to treatment or studies leading to or in connection with sex changes or modifications and related care" and instead covering "medically necessary services for the treatment of gender dysphoria." (ECF No. 185-2 at 34.) At that time, the Board estimated that coverage would cost between $344,013 and $862,292 per year. (ECF No. 184 at 36.) Ultimately, the Board elected to remove the exclusion only for the 2017 year, and it went back into effect in 2018. (ECF No. 185-2 at 35; *see* ECF No. 184 at 66–67.) The total cost to NCSHP of removing the exclusion in 2017 was $404,609.26. (ECF No. 184 at 23.)

C. Scientific background

"The health care community's understanding of what it means to be transgender has advanced greatly over the past century." (ECF No. 219 at 2 (Brief of *Amici Curiae* the American Medical Association, *et al.*).) The health care community now understands that being transgender relates to a person's "internal sense" of gender and is not a psychiatric condition. (*Id.* at 7.) "Every person has a gender identity." (*Id.*) A "cisgender" person's internal gender aligns with their physiological, chromosomal, and birth-assigned sex. (*Id.* at 5.) But not all individuals who "depart from stereotypical male and female appearances and

roles" identify as transgender; rather, transgender individuals are those who "consistently, persistently, and insistently" identify as a gender "different from the sex they were assigned at birth." (*Id.* at 8–9.) Being transgender "implies no impairment in a person's judgment, stability, or general social or vocational capabilities." (*Id.* at 2.)

While being transgender is not itself a psychiatric condition, many transgender individuals experience severe anxiety and distress as a result of having physiology or an assigned sex that does not match their "deeply felt, inherent sense of their gender." (*Id.* at 5, 10 (internal quotations omitted).) Like Plaintiffs, many of these transgender individuals have been diagnosed with gender dysphoria. (*Id.* at 10.) Gender dysphoria is "characterized by clinically significant distress and anxiety resulting from the incongruence between an individual's gender identity and birth-assigned sex." (*Id.*) The Diagnostic and Statistical Manual of Mental Disorders, volume 5 ("DSM" or "DSM-5"), published by the American Psychiatric Association, provides diagnostic criteria for gender dysphoria in adults, to include "[a] marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration," plus "clinically significant distress or impairment in social, occupational, or other important areas of functioning." (*Id.* at 10–11 (quoting DSM-5).)

Gender dysphoria "can cause debilitating distress, depression, impairment of function, self-mutilation to alter one's genitals or secondary sex characteristics, other self-injurious behaviors, and suicide." (*Id.* at 11.) It is treated both through counseling and medical and surgical treatments to bring the patient's physiology in line with their gender identity. (*Id.* at 13.) The World Professional Association for Transgender Health ("WPATH") publishes Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming

People. (*Id.* at 12.) The current Standards of Care ("WPATH-7") recommended treatments "include[ ] assessment, counseling, and, as appropriate, social transition, hormone therapy, and surgical interventions." (*Id.* at 13.) These treatments are recommended on a case-by-case basis, and "each patient requires an individualized treatment plan that accounts for the patient's specific needs." (*Id.* at 14.)

Plaintiffs' experts testify that such medical and surgical treatment for gender dysphoria is "medically necessary treatment" for many individuals with gender dysphoria. (ECF No. 185-1 at 23, 238, 331, 333.) They testify that these are "safe and effective treatment[s] for gender dysphoria" that are governed by "well-established community standards." (*Id.* at 23, 192.) They report that such treatments are supported by "[d]ecades of methodologically sound and rigorous scientific research," and that "every relevant medical and behavioral health association agrees that gender-confirming care is a medically necessary treatment for individuals with gender dysphoria." (*Id.* at 238, 333.) Eight professional medical associations agree in their amicus brief with Plaintiffs' experts' assessment. (*See generally* ECF No. 219.)

Defendants' experts dispute this testimony. They testify that medical and surgical treatments have significant medical risks and consequences, and the research supporting such treatments is of "low quality." (ECF Nos. 215-1 at 49, 52, 53, 56; 215-2 at 10, 13; 215-3 at 7, 52–54; 215-4 at 17–19, 29–39.) They contest the efficacy of the DSM-5 and WPATH-7 and challenge the credibility and motivations of what they call the "Transgender Treatment Industry." (ECF Nos. 215-1 at 15, 36–40, 47; 215-2 at 6–9, 10–12; 215-3 at 8, 28–31, 36–39; 215-4 at 6–8, 12.) Some of Defendants' experts testify that gender dysphoria should be treated by counseling alone and medical or surgical interventions are not medically necessary, (*see, e.g.*,

ECF No. 215-3 at 16–17, 50–52), while one testifies that physicians should proceed cautiously in prescribing medication and surgery on a case-by-case basis, (*see* ECF No. 213-3 at 152:20-25)

D. Procedural history

Plaintiffs filed their suit on March 11, 2019, against Defendant Dale Folwell, in his official capacity as State Treasurer of North Carolina, Defendant Dee Jones, in her official capacity as Executive Administrator of NCSHP, and NCSHP (collectively, "Health Plan Defendants"), and three public universities: the University of North Carolina at Chapel Hill, North Carolina State University, and the University of North Carolina, Greensboro (collectively, "University Defendants"). (ECF No. 1.) Plaintiffs initially alleged violations of the Equal Protection Clause, Title IX of the Education Amendments of 1972, and the ACA. (*Id.* ¶¶ 124–157.)

University Defendants moved to dismiss Plaintiffs' claims against them on July 8, 2019, for lack of standing and failure to state a claim under Title IX. (ECF No. 30.) Health Plan Defendants likewise filed a motion to dismiss on the same day, arguing that Plaintiffs failed to state claims under the Equal Protection Clause or the ACA. (ECF No. 32.) On March 10, 2020, the Court denied both motions. (ECF No. 45.) Health Plan Defendants filed an interlocutory appeal of their denial on April 8, 2020. (ECF No. 50.) The Fourth Circuit affirmed this Court's Order on September 1, 2021. (ECF Nos. 113; 114.) Health Plan Defendants filed a petition for certiorari in the U.S. Supreme Court on November 8, 2021, (ECF No. 127), which was denied on January 18, 2022, (ECF No. 195).

In the interim, Plaintiffs filed a motion to amend their complaint on August 3, 2020. (ECF No. 62.) Plaintiffs' motion was granted on March 5, 2021. (ECF No. 74.) Plaintiff's First Amended Complaint (the "Complaint") added Dana Caraway as a Plaintiff, DPS as a Defendant, and a fourth cause of action arising under Title VII against NCSHP, DPS, and University Defendants. (ECF No. 75 ¶¶ 12, 18, 130–37.) University Defendants subsequently settled with Plaintiffs and have been dismissed from this suit. (ECF No. 112.)

DPS and Plan Defendants filed their motions for summary judgment on November 30, 2021. (ECF Nos. 132; 136.) Plaintiffs originally filed two summary judgment motions on the same day. (ECF Nos. 138; 152.) On December 10, 2021, the Court struck Plaintiffs' motions and allowed Plaintiffs to file a single dispositive motion with an accompanying memorandum not to exceed 9,000 words. (ECF No. 176.) Plaintiffs then filed their Motion for Summary Judgment on December 20, 2021. (ECF No. 178.) Plaintiffs simultaneously filed a Motion to Seal certain paragraphs of their expert's testimony that describe in detail Plaintiffs' medical history. (ECF No. 182.) Plaintiffs filed their motions to exclude Defendants' experts' testimony on February 2, 2022, along with a motion to seal portions of one expert's report which likewise details Plaintiffs' medical history. (ECF Nos. 202; 204; 206; 208; 210; 212.)

The American Medical Association ("AMA"), American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Psychiatric Association ("APA"), Endocrine Society, North American Society for Pediatric and Adolescent Gynecology, National Association of Nurse Practitioners in Women's Health, and Society of

OB/GYN Hospitalists, together filed an amicus brief with leave of the Court on April 11, 2022, in support of Plaintiffs' summary judgment motion. (ECF No. 219.)

Trial is set in this case for July 5, 2022. (ECF No. 115.) The parties have filed a Joint Motion to Specially Set Trial and Allow 8-10 Days for Proceedings. (ECF No. 225.)

II. MOTIONS TO EXCLUDE TESTIMONY

The Court will first address Plaintiffs' motions to exclude expert testimony. The admissibility of expert opinion is governed by Rule 702 of the Federal Rules of Evidence and the Supreme Court's landmark ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Rule 702 provides that a witness "who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:"

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Thus, expert testimony is admissible only if: (1) the expert is qualified, (2) the testimony is relevant, and (3) the testimony is based on reliable scientific methodology.[2] *See Daubert*, 509 U.S. at 594–95. The Court must find these elements "at the outset, . . . by a preponderance of proof." *Id.* at 592; *id.* n.10.

[2] Although *Daubert* interpreted an earlier version of Rule 702, "the standard of review that was established for *Daubert* challenges is still appropriate" to assess the admissibility of expert testimony. *United States v. Parra*, 402 F.3d 752, 758 (7th Cir. 2005); *see In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prod. Liab. Litig.*, 424 F. Supp. 3d 781, 789 (N.D. Cal. 2020) ("[N]o obvious conflict arises between [Rule 702] as amended and *Daubert*, at least as relevant to the issues in this case."); *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 282 (4th Cir. 2021) ("Rule 702 was amended specifically to affirm the trial courts role as gatekeeper." (internal quotations omitted)).

An expert is *qualified* if he or she has "specialized knowledge that will assist the trier of fact in understanding the evidence or determining a fact in issue." *United States v. Young*, 916 F.3d 368, 379 (4th Cir. 2019). A witness' qualifications are "liberally judged by Rule 702," and "a person may qualify to render expert testimony in any one of the five ways listed" by the Rule: "knowledge, skill, experience, training, or education." *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993); *see Cooper v. Lab'y Corp. of Am. Holdings*, 150 F.3d 376, 380 (4th Cir. 1998). However, the expert must be qualified to testify "on the issue for which the opinion is proffered." *Kopf*, 993 F.2d at 377. "[G]eneral knowledge," skill, experience, training, or education is insufficient to qualify an expert, and an expert qualified in one field may be unqualified to testify in others. *Cooper*, 150 F.3d at 380–81 (finding that a witness who had "a general knowledge of chemistry" and "experience with breath alcohol testing" was not an expert in "the field of urine alcohol testing"); *see Zellers v. NexTech Ne., LLC*, 533 F. App'x 192, 199 (4th Cir. 2013) (finding that a Ph.D.-holding neuropsychologist and neurotoxicologist was not a medical doctor and therefore was "not qualified to diagnose the cause of [plaintiff's] alleged symptoms"); *see also Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 391 (D. Md. 2001) ("The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas.") (collecting cases).

An expert who is qualified must provide testimony that is relevant. An expert's opinion is *relevant* if it "fit[s]" the facts of the case, meaning it has "a valid scientific connection to the pertinent inquiry." *Daubert*, 509 U.S. at 591–92. "This ensures that the expert 'helps the trier of fact to understand the evidence or to determine a fact in issue.'" *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021) (quoting *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th

Cir. 2017)). An outmoded or inapplicable standard that "does not even apply to" the facts at issue "categorically lacks 'a valid scientific connection to the pertinent inquiry'" and is "the touchstone of irrelevancy." *Id.* at 289 (quoting *Daubert*, 509 U.S. at 592). "Simply put, if an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.* at 281.

Finally, relevant testimony must also by reliable. An expert's opinion is *reliable* if it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* (emphasis omitted) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). While the subject of scientific testimony must not "be 'known' to a certainty," it must be "derived by the scientific method" and "supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert*, 509 U.S. at 590. Reliability is a "flexible" inquiry that must focus "solely on principles and methodology, not on the conclusions that they generate." *Id.* at 594–95. In *Daubert*, the Court outlined a non-exhaustive list of factors to guide lower courts in assessing reliability, including: (1) whether the theory can be (and has been) tested; (2) whether it has been subjected to peer review and publication; (3) its potential rate of error; (4) whether standards exist to control the technique's operation; and (5) the degree of acceptance of the methodology within the relevant scientific community. *Id.* at 593–94. These factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony," and courts have "broad latitude" in choosing which factors are "reasonable measures of reliability in a particular case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150, 153 (1999).

"One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted

independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*"); Fed. R. Evid. 702, Advisory Comm. Notes (2000 Amendments); *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 470 (M.D.N.C. 2006); *see McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 1008 (4th Cir. 2020) (Agee, J., concurring in part and dissenting in part). "An 'expert' opinion is considered unreliable and inadmissible under *Daubert* where . . . the expert has developed the opinions expressly for purposes of testifying in the case . . . ." *Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158, at *5 (4th Cir. 1998) (unpublished); *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1369 (11th Cir. 2014).

"Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge . . . exercises more control over experts than over lay witnesses." *Daubert*, 509 U.S. at 595. Rule 702 "imposes a special gatekeeping obligation on the trial judge to ensure that an expert's testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Sardis*, 10 F.4th at 281 (internal quotations omitted). A court cannot "abandon the gatekeeping function" by deferring its responsibility to the jury. *Id.* at 282 (quoting *Kumho*, 526 U.S. at 159 (Scalia, J., concurring)). Ultimately, a district court's Rule 702 analysis "necessarily amount[s] to an exercise of broad discretion guided by the overarching criteria of relevance and reliability." *Belville v. Ford Motor Co.*, 919 F.3d 224, 233 (4th Cir. 2019).

Although Rule 702 "is not intended to serve as a replacement for the adversary system," *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 631 (4th Cir. 2018), this Court takes seriously its gatekeeping role to protect lay

jurors from "powerful and quite misleading" expert testimony, *Daubert*, 509 U.S. at 595. The Court will address each of Plaintiffs' motions to exclude expert testimony in turn.

A. Dr. Peter Robie (ECF No. 202)

Dr. Peter Robie is a primary care physician and Assistant Professor and Clinical Associate Professor at the Department of Internal Medicine at Wake Forest School of Medicine. (ECF No. 215-5.) Robie is also a member of the NCSHP Board of Trustees and has provided medical knowledge during the Board's deliberations. (*Id.*) Defendants plan to call Robie only to testify (1) "to the medical knowledge he has shared with other Board members" and (2) that "physicians must know the chromosomal sex of patients" to provide competent medical care. (*Id.*) Robie "does not seek to provide testimony on the efficacy of gender dysphoria treatment or the lack thereof" and has not submitted an expert report. (ECF No. 215 at 15.)

Regarding the medical knowledge Robie shared with other Boards members, Defendants do not plan to elicit Robie's expert opinion; rather, he plans to testify as a fact witness to information he provided to the Board. Rule 702 is therefore inapplicable. The Court expresses no opinion on the admissibility or relevance of the proffered testimony.

Regarding Robie's testimony concerning chromosomal sex, Defendants do not explain why they seek to introduce this opinion. Elsewhere, Defendants have argued that "[h]ealthcare providers must know a patient's sex for *every* medical diagnosis" to rebut a hypothetical argument 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." (ECF No. 197 at 32.) However, in Section III.A.i., *infra*, this Court finds that heightened

scrutiny is appropriate in this case because the *Plan* discriminates based on sex on its face, not because Plaintiffs' medical providers considered their sexes. Thus, Robie's testimony is not relevant to any fact at issue. Regardless, Robie's failure to submit an expert report or provide any basis for his opinion other than a vague reference to his years of practice precludes this Court from finding that his expert opinion is based on a reliable methodology under Rule 702.

Accordingly, Plaintiffs' motion to exclude Robie as an expert witness will be granted. This Court expresses no opinion as to whether he may be called as a fact witness.

B. Dr. Paul Hruz (ECF No. 204)

Dr. Hruz is a board-certified specialist in pediatric endocrinology, Associate Professor of Pediatrics in the Division of Pediatric Endocrinology and Diabetes and Associate Professor of Cellular Biology and Physiology in the Division of Biology and Biological Sciences at Washington University School of Medicine in St. Louis, Missouri. (ECF No. 215-3 ¶¶ 2–3.) He holds a Ph.D. and M.D. from the Medical College of Wisconsin. (*Id.* at ¶ 2.) He additionally served as chief of the Division of Pediatric Endocrinology and Diabetes at Washington University from 2012–2017 and Director of the Pediatric Endocrinology Fellowship Program from 2008–2016. (*Id.*) He has published 60 scholarly articles over two decades in the fields of metabolism, cardiology, HIV, and ethics. (*Id.* ¶ 4.) He was a founding member of Washington University's multidisciplinary Disorders of Sexual Development program and has participated in the care of hundreds of infants and children, including adolescents, with disorders of sexual development during his career. (*Id.* ¶ 6.)

Hruz offers a wide range of conclusions that fall into five main categories: mental healthcare, medical and surgical care, informed consent, criticism of medical associations, and

political criticisms. First, he offers several opinions on the mental health treatment of gender dysphoria, to include that "[m]ental health care professionals are unreliable human 'lie detectors' [whose diagnoses are] 'often no better than flipping a coin,'" (*id.* ¶ 28); that the DSM is scientifically unreliable; (*see id.* ¶ 13.B); that gender dysphoria is caused by a "social contagion," (*id.* ¶ 41); that "the vast majority of children who report gender dysphoria" will "desist," meaning that "if left untreated, [they will] grow out of the problem . . . and willingly accept their biological sex," (*id.* ¶¶ 8, 53); and that a "watchful waiting" approach whereby mental health providers "neither encourage nor discourage transgender identification" is the most effective form of treatment, (*id.* ¶¶ 52–53). Second, he will testify to the risks associated with hormone treatments and surgery to treat gender dysphoria, particularly in prepubescent children. (*Id.* ¶¶ 57, 58, 60.) Third, he will testify that healthcare providers often fail to obtain informed consent from patients by inaccurately describing the risks associated with hormone therapy or surgery. (*Id.* ¶ 36.) Fourth, he will criticize organizations that support gender affirming care, such as the AMA, WPATH, and the American Psychiatric Association, as unscientific and politically motivated. (*See e.g. id.* ¶ 34.A.) Fifth, he will testify that "Cancel Culture," "transgender and allied political activists," and the "Transgender Treatment Industry" are attempting to "silence open public debate on the risks and benefits of transgender medical procedures and political ideologies." (*Id.* ¶¶ 64–66.)

Plaintiffs have offered evidence that calls Hruz's motivations—and thereby, his reliability—into serious question. Hruz admits a connection to the Alliance Defending Freedom ("ADF"), a political organization with both "moral objections" and scientific objections to the treatments at issue. (ECF Nos. 205-2 at 241:10–242:15; 209-3 at 81:5-13.)

Early in his research of gender dysphoria, Hruz told a fellow doctor that he had "a significant problem with the entire issue" and "whole idea of transgender." (ECF No. 205-10 ¶ 11–13 (testifying that Hruz's concerns about the relevant treatments were not "based on science" but rather were "a matter of [his] faith").) Hruz does not recall making these statements. (ECF No. 205-2 at 249:19–251:6.) Hruz also met with parents of transgender children early in his research "to understand the unique difficulties experienced by this patient population." (ECF No. 215-3 ¶ 7.) One such parent testifies that the conversation had a "religious tone" and was not "based on science," and that Hruz "kept insisting that [her] child was not normal and would never be normal," that "the idea of doing surgeries on transgender people is—is wrong," and in response to her assertion that transgender children without supportive parents are at an increased risk of suicide, that "[s]ome children are born in this world to suffer and die." (ECF No. 205-11 at 27:17-24, 28:20-23, 29:21–30:1, 37:13-19.) Plaintiffs argue that this evidence shows Hruz's "expert" testimony did not grow naturally from his work as an endocrinologist; rather, he manufactured his opinions expressly for purposes of testifying against medical care against which he has moral and political objections.

Based on the preponderance of the evidence, this Court finds the following:

First, Hruz is not qualified to offer expert opinions on the diagnosis of gender dysphoria, the DSM, gender dysphoria's potential causes, the likelihood that a patient will "desist," or the efficacy of mental health treatments. Hruz is not a psychiatrist, psychologist, or mental healthcare professional. He has never diagnosed a patient with gender dysphoria, treated gender dysphoria, treated a transgender patient, conducted any original research about gender dysphoria diagnosis or its causes, or published any scientific, peer-reviewed literature

on gender dysphoria. (ECF Nos. 205-2 at 35:5–36:11, 42:14–49:23, 88:18–90:6; 205-4 at 24:11-14, 25:20-23, 61:17–64:7.) Merely reading literature in a scientific field does not qualify a witness—even an educated witness—as an expert. *See Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002) ("A scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty.").

Second, Hruz is qualified as an endocrinologist to testify to the risks associated with puberty blocking medication and hormone therapy. This testimony is broadly relevant to assessing whether the Plan's exclusion is substantially related to the state's interest in protecting employees and the public from ineffective medical treatments. It also appears sufficiently reliable, as it is based on Hruz's long career treating patients and conducting academic research on the effects of hormone treatments. However, Hruz's testimony that focuses on the risks associated with providing hormone therapy to prepubescent children—children who have not begun puberty—is not relevant. (*See, e.g.*, ECF No. 215-3 ¶ 54.) By his own admission, "no medical and surgical interventions are initiated until after the onset of puberty" under any model of treatment, (ECF No. 205-2 at 125:23–126:5), and Plaintiffs appear to concede that hormone treatment is not medically necessary to treat gender dysphoria in prepubescent children, (ECF No. 205 at 11–12). In this case, the youngest Plaintiff received puberty blocking medication when puberty began around age 12. (*See* ECF No. 179-5 ¶¶ 13–14.) Thus, a discussion of risks to prepubescent children is irrelevant to this case and would likely serve only to confuse the jury. Additionally, Hruz is not a surgeon and has no experience with surgery for gender dysphoria and, therefore, is not qualified to testify to the risks

associated with surgery or the standard of care used by surgeons for obtaining informed consent for surgery.

Third, Hruz provides no scientific basis to his conclusion that "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'" or that endocrinologists generally do not obtain informed consent from their gender dysphoric patients. Hruz is not a statistician and does not discuss in his report how he came to those conclusions, what data he relied upon, or what methodology he applied to that data. This testimony will therefore be excluded as unreliable.

Fourth, it does not appear that Hruz has any experience with the AMA, WPATH, or American Psychological Association upon which to base his criticisms. (*See* ECF No. 215-3 ¶ 34.) He is therefore not qualified to testify about the credibility of those organizations. Moreover, Hruz's criticism of the AMA appears largely based on its historical support of eugenics procedures not at issue in this case, and Hruz has not explained what scientific methodology if any he used to compare and contrast treatment of gender dysphoria with the eugenics movement. (*See id.* ¶ 34.A.) Hruz is not qualified to opine on the deficiencies of the DSM and the American Psychological because he is not a mental health professional. (*See id.* ¶ 34.C.) Given that other of Defendants' experts are intimately familiar with the "consensus building" method employed by WPATH, the AMA, and similar organizations, the Court finds that Hruz has not offered any reliable testimony on this subject that will help the trier of fact.

Finally, it does not appear that his repeated references in his report to a "Gender Transition Industry," "Cancel Culture," and political activists working to "silence open public

debate" has any basis, scientific or otherwise. (*See id.* ¶ 65.) He provides no evidence of such a conspiracy or any reliable methodology supporting his opinion as required by Rule 702. Rather, his conspiratorial intimations and outright accusations sound in political hyperbole and pose a clear risk of inflaming the jury and prejudicing Plaintiffs. It is the Federal Rules of Evidence, not some "Cancel Culture," that excludes this portion of Hruz's testimony. Since these claims are not based in any methodology and will not assist the trier of fact, this testimony is inadmissible.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and Hruz is limited in his testimony to a discussion of the risks associated with prescribing hormone treatments to adolescents and adults.

C. Dr. Paul R. McHugh (ECF No. 206)

Dr. Paul R. McHugh is a licensed psychiatrist and Distinguished Service Professor of Psychiatry at Johns Hopkins University School of Medicine with more than fifty years of experience. (ECF No. 215-2 at 1–2.) He holds an M.D. from Harvard Medical School and was qualified in both Psychiatry and Neurology by the American Board of Psychology and Neurology. (*Id.*) He served as director of the Department of Psychiatry and Behavioral Science at Johns Hopkins Medical School and psychiatrist-in-chief at Johns Hopkins Hospital for nearly 30 years and served as Chairman of the Medical Board of Johns Hopkins University Hospital from 1984–1989. (*Id.* at 2.) He has published several books and numerous peer reviewed articles in scientific journals. (*Id.* at 3.) He was elected to the Institute of Medicine of the National Academies of Science in 1992 and is a Distinguished Life Fellow of the American Psychiatric Association. (*Id.* at 4.)

McHugh's fifteen-page report offers cursory opinions on a wide range of topics. According to their brief, Defendants primarily seek to elicit from McHugh testimony that the DSM is unreliable and was not scientifically formed, and that no rigorous scientific research proves that medical or surgical treatments for gender dysphoria will improve the wellbeing of patients. (ECF No. 215 at 28–31.) His report also contains several "Summary Opinions" on the causes of gender dysphoria, rates of desistence, and acceptance of treatments within the medical community. (ECF No. 215-2 at 12–14.)

Based on the preponderance of the evidence, the Court finds that McHugh is qualified as an expert in the field of psychiatry by his more than fifty years of experience as a psychiatrist and academic. Further, his general description of the process by which the current edition of the DSM was created and opinion about the scientific limitations of such a process are broadly relevant to rebut Plaintiffs' expert testimony, as Plaintiffs' experts use and rely on the DSM's definition of gender dysphoria. This testimony is based in McHugh's personal knowledge and experience and is sufficiently reliable to be admissible.

However, Defendants have failed to show that McHugh's more specific criticisms of the DSM's approach to gender dysphoria are relevant or based on reliable science. McHugh's primary criticisms of the DSM come from his work on various "Psychiatric Misadventures," to include "lobotomies," "repressed memory therapy," and "multiple personality disorder"—issues that are not relevant to this case. (*See id.* at 5–6, 9–10.) To the extent he offers this testimony to show that treatment for gender dysphoria is "yet another Psychiatric Misadventure," (*id.* at 10–11), his argument-by-analogy does not appear to be based on any

reliable scientific methodology. Instead, he simply suggests that, because the DSM was wrong before, it might be wrong again. Such speculation is inadmissible under Rule 702.

Next, he testifies that "national research reviews in England, Sweden, and Finland as well [as] a Chochrane Review and studies by multiple researchers have concluded that the evidentiary base for these experimental treatments [for gender dysphoria] is weak and demonstrates few benefits or actually shows this procedures [sic] can cause more harm than good." (*Id.* at 10.) But his report does not cite to any such reviews or studies, (*id.*), and when questioned about them at deposition, he could not recall if the "national reviews" in England or Finland were peer-reviewed or published in scientific journals, and admitted that the Swedish "national review" was not a national review at all, but rather an academic scientific study by Swedish researchers, (ECF No. 207-3 at 300:19–301:20, 302:20–303:6). The Court therefore finds that McHugh's discussion of such studies is not based on reliable science.

Similarly, he testifies without any definition, explanation, or supportive methodology that "the exponential growth [of gender dysphoria] in patients was indeed predicted and is readily explained by a social contagion theory." (ECF No. 215-2 at 11 ("[S]ocial contagion *seems* more likely." (emphasis added)).) He supports this claim with a citation to his own article coauthored by Hruz and published in *The New Atlantis*, (*id.*), which he admits is neither a peer-reviewed nor a scientific publication, (ECF No. 207-3 at 264:1-19). He readily concedes that the number of gender dysphoric patients who have been influenced by a social contagion is "currently unknown" and that his opinion is "a hypothesis and not a statement of fact"; he fails to address whether his "social contagion" hypothesis has been tested or peer-reviewed, if there is a known error rate, or what standards exist to measure its reliability; and it is clear that

his theory has not been accepted by relevant scientific community. (ECF Nos. 207-3 at 299:14–300:5; 215-2 at 13.) Instead, he advocates that research be done on this theory. (*See* ECF No. 215-2 at 12 ("The Transgender Treatment Industry has failed to conduct competent research on the social contagion theory."), 13 ("Detailed psycho-social investigations of such patients [who were manipulated by a source of social contagion] may be necessary.").) Thus, the Court finds that McHugh's speculative opinions on "social contagion" hypotheses are inadmissible.

Finally, he testifies that his views on the DSM "is generally accepted by the relevant scientific community." (*Id.* at 8.) His support for this assertion is based on blog posts and an inaccurate claim that the National Institute of Mental Health ("NIMH") withdrew support from the DSM. (*Id.* at 7–8.) He acknowledged during deposition, however, that "[t]he National Institute of Mental Health has not changed its position on DSM-5" and still considers the DSM to be "the best information currently available for clinical diagnosis of mental disorders." (ECF No. 207-2 at 116:10–117:17, 119:3–122:11.) Further, McHugh gives no explanation or reasoning to support the "summary opinions" tacked on to the end of his report, giving the Court no meaningful way to assess their reliability. Thus, the Court finds that these opinions are likewise unreliable and inadmissible.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and McHugh is limited to testifying about the process by which the DSM was formed and his opinion about the limited scientific reliability of such a process generally.

D. Dr. Patrick W. Lappert (ECF No. 208)

Dr. Patrick W. Lappert is a retired plastic and reconstructive surgeon with experience in the United States Navy and Marine Corps, university teaching hospitals, and private practice. (ECF Nos. 215-4 at 1–3; 209-3 at 475:11-19.) During his 24 years of military service, he served in a number of roles, to include flight surgeon, Chairman of the Department of Plastic and Reconstructive Surgery at the Naval Hospital in Portsmouth, Virginia, and Specialty Leader for Plastic Reconstructive Surgery for the Surgeon General of the Navy. (ECF No. 215-4 at 2–3.) He also served during this period as Teaching Faculty at Eastern Virginia Medical School, Division of Plastic Surgery. (*Id.* at 2.) He has several publications in peer-reviewed medical journals and one medical textbook, the most recent of which was published in 2000. (*Id.* at 3.) He retired from the Navy in 2002 and entered private practice as a solo practitioner. (*Id.* at 3–4; ECF No. 209-3 at 475:11-19.) He was board certified in surgery from 1992–2002 and in plastic surgery from 1997–2018. (ECF Nos. 215-4 at 2; 209-3 at 23:10-18.) He retired from active surgical practice in August 2020. (ECF No. 209-3 at 24:22–25:11.) During his career, he treated thousands of patients, performed many of the surgeries at issue in this case to treat ailments other than gender dysphoria, and treated transgender patients during transition and de-transition. (ECF No. 215-4 at 4.)

Lappert primarily seeks to offer opinions that surgical treatments for gender dysphoria are not supported by rigorous scientific study and pose severe health risks. (*See id.* at 5–10, 17–20, 29–39.) He additionally offers opinions on the reliability of the DSM, WPATH, and professional medical organizations; the frequency of desistance or "de-transitioning"; requirements of informed consent; and acceptance of gender dysphoria treatments by the

relevant scientific community. (*Id.* at 15–17, 21–25, 40.) Finally, he offers specific opinions about the medical care received by Plaintiffs based on their medical records. (ECF No. 211-2 at 49–57.)

As with Hruz, Plaintiffs offer evidence that calls Lappert's bias and reliability into serious question. Like Hruz, Lappert has worked closely with ADF. Lappert attended an ADF-sponsored conference in which a speaker lamented the "poverty of [experts] who are willing to testify" against the treatments at issue in this case, and where attendees "were asked whether they would be willing to participate as expert witnesses." (ECF No. 209-2 at 90:13–91:13.) Prior to attending this conference, he had not been published on gender dysphoria or the risks of hormone blockers or served as an expert witness, although he had spoken publicly about gender dysphoria. (*Id.* at 84:3–85:4.) Since attending, he has "actively lobbied" for laws that would prohibit doctors from offering medical or surgical treatments for gender dysphoria to adolescents in Alabama, Arkansas, Texas, and Utah, and agreed in deposition that doctors offering these treatments should be "criminally prosecute[d]." (*Id.* at 52:4-18, 54:7–55:2, 57:8-15, 61:16–64:20.) And he has stated publicly that parents who "discuss[ ] gender identity issues with children" are "sexualizing them" and "grooming a generation." (*Id.* at 461:1–462:5). As with Dr. Hruz, Plaintiffs argue that Lappert's testimony did not grow naturally from his research, but was instead crafted at ADF's request for purposes of litigation.

Based on the preponderance of the evidence, the Court finds the following:

i. Qualifications

Lappert is qualified as an expert in plastic surgery. He is thus qualified to opine on the risks associated with surgery used to treat gender dysphoria, the role surgeons play in treating

gender dysphoria under the WPATH standards, the standard of care of informed consent among surgeons, the perspective of the relevant plastic surgeon community, and whether the surgeons obtained informed consent in Plaintiffs' specific cases. Plaintiffs argue that he is not qualified because he has not performed any of the procedures at issue in this case within the last three years as required of experts by the Code of Ethics of the American Society of Plastic Surgeons ("ASPS"). (ECF Nos. 209 at 8; 209-5 §§ 2.IV1, VII.F.) Although Lappert's failure to qualify as an expert under the ASPS requirements weighs against his qualification, the preponderance of evidence, including his extensive career and relatively recent retirement, supports that he is qualified to offer expert testimony in the field of plastic surgery.

Lappert is not qualified to render opinions about the diagnosis of gender dysphoria, its possible causes, the efficacy of the DSM, the efficacy of puberty blocking medication or hormone treatments, the appropriate standard of informed consent for mental health professionals or endocrinologists, or any opinion on the non-surgical treatments obtained by Plaintiffs. Lappert is not a psychiatrist, psychologist, or mental health professional, nor has he ever diagnosed a patient with gender dysphoria. He is not an endocrinologist, nor has he ever treated a patient with hormone therapies. By his own admission, he "do[es] not hold [himself] out as an expert in diagnosing mental health conditions outside, potentially, of body dysmorphic disorder" and does not have any "expertise in treating mental health conditions." (ECF No. 209-3 at 75:7-16.)

Lappert is also not qualified to opine on the efficacy of randomized clinical trials, cohort studies, or other longitudinal, epidemiological, or statistical studies of gender dysphoria. He is not a statistician or epidemiologist, and there is no evidence in his report or deposition

that he has any experience, specialized training, or knowledge about crafting a research study, analyzing data, or conducting a clinical trial. (*See generally id.* at 129:13–134:19.) His publications appear to include case reports and opinion essays, and he has not published any original research in two decades. (*Id.*) His brief academic career appears limited to teaching and overseeing clinic practitioners, not conducting research. (ECF No. 215-4 at 2–4.) Just as an epidemiologist or statistician would not be qualified to perform surgery, a surgeon with little to no research experience is not qualified to opine on the veracity of statistical studies.

Last, Lappert is qualified to testify to his personal, anecdotal experience treating patients who sought treatment to, in Lappert's words, "de-transition." He is not qualified, however, to offer expert opinions on the rates of desistance and "de-transitioning" among gender dysphoric patients generally for the reasons above.

ii. Relevance

Lappert's testimony concerning surgical risks, the role of the surgeon under WPATH, the plastic surgeon community, and anecdotal experience with "de-transitioning" are all relevant to assessing whether the Plan's exclusion is substantially related to the state's interest in protecting employees and the public from ineffective medical treatments. His testimony concerning informed consent, however, is irrelevant. First, his testimony that Plaintiff Thonen-Fleck was incapable of giving informed consent is based on his age, history with mental illness, and lack of medication. (ECF No. 211-2 at 53–54.) Even if true, Lappert does not dispute that Thonen-Fleck's father was able to (and did) give informed consent. (*See* ECF No. 179-3 ¶ 13 ("Based on medical advice, I understand this surgery to have been medically necessary.").) Lappert's broader discussion of informed consent merely sets up his conclusion

that surgeons are not adhering to that standard of care generally—a speculative conclusion that is not supported by any survey or data, scientific or otherwise. Thus, Lappert's discussion of informed consent is not admissible.

iii. Reliability

First, Lappert's testimony concerning the risks associated with certain surgeries appears to be based on his professional experience and training and sufficiently reliable to be admitted under Rule 702. Additionally, his anecdotal testimony concerning "de-transitioning" is admissible but is not a reliable basis for any broader opinion about the rates of desistance, the likelihood that gender dysphoric patients will later "de-transition," or the general efficacy of surgical treatment for gender dysphoria.

Second, his testimony concerning the role of the surgeon under the WPATH guidelines, and more specifically his criticism that surgeons are not able or required to verify a gender dysphoria diagnosis, appears to arise from his extensive experience as a plastic surgeon and is admissible. However, his broader criticism of WPATH-7 appears to be unscientific opinion and speculation. (ECF No. 209-3 at 184:3-6, 186:23–187:5, 188:15-18 (conceding that he has "not been involved with the development" of WPATH-7, does not "know what kind of scientific literature [review] the WPATH conducted as part of drafting" WPATH-7, and is "not an expert on how Version 7 of the WPATH was developed").) Likewise, in addition to not being qualified in endocrinology or psychiatry, he has not shown the reliability of his criticisms of the Endocrine Society's Guidelines for Treatment of Gender Dysphoria, (*id.* at 200:12-18 (agreeing that he is "not an expert in how the Endocrine Society developed" its guidelines)); the DSM-5, (*id.* at 193:14-18 (agreeing that he "do[es] not have

expert firsthand knowledge of how the DSM-5 was developed"); the AMA's position on these treatments, (*id.* at 47:13-18 (stating he does not have "personal knowledge" of "how the AMA came to issue [its] consensus statement")); or the American Academy of Pediatrics' position, (*id.* at 48:14-23 (admitting he has no "personal knowledge" of how the position was adopted)). And as with Dr. Hruz and Dr. McHugh, Lappert's analogy of treatments of gender dysphoria to eugenics efforts in the early and mid-twentieth century lack any reference to what scientific methodology he used to compare and contrast the treatments.

Third, Lappert has provided the Court with no data or methodology used to draw his conclusion that surgical treatment for gender dysphoria has "never been generally accepted by the relevant scientific community." (*See* ECF No. 215-4 at 22.) Lappert agrees that "every major expert medical association disagrees with [him]" and have "all taken [the] position that this treatment is in fact medically necessary," (ECF No. 209-2 at 40:15-22), and virtually every major health insurer agrees, (*id.* at 384:21–385:3, 427:4–428:7, 430:12–431:6, 434:17–434:20; *see* ECF Nos. 209-10 at 2; 209-11 at 1–4; 209-12 at 3–8; 209-13 at 2–3)). There is no evidence that he has conducted any surveys that would support his repeated conclusory claims concerning the "relevant scientific communities (biology, genetics, neonatolgy [sic], medicine, psychology, etc.)." (ECF No. 215-4 at 40.) Thus, Defendants have failed to meet their burden to show that this testimony is based on reliable science.

Finally, Lappert makes repeated references in his report to a "Transgender Treatment Industry ('TTI')." (*See id.* at 12.) He opines that "[m]embers of the TTI have a vested interest in believing that science has already justified their existence," asks "[w]ill one day the medical profession look at support for transitioning youth in the same manner the eugenics movement

is now regarded?", and hypothesizes that healthcare providers "want the patient to suffer depression and anxiety [because] *such untreated suffering motivates vulnerable patients* to undergo the often painful and damaging experimental 'transitioning' process." (*Id.* at 12, 15.) In his deposition, however, he made clear that he does not "know where [the term TTI] came from" does not "know who originated it," and doesn't "know even if it was me that originated it, actually." (ECF No. 209-3 at 19:19–20:2.) He is not aware of any peer-reviewed scientific article that has used that term. (*Id.* at 20:17-21.) Thus, the Court finds that references to a Transgender or Gender Treatment Industry and related conspiratorial accusations are nothing more than rank speculation designed to distract or inflame the jury and has no business in expert testimony.

Accordingly, Plaintiffs' motion will be granted in part and denied in part, and Lappert is limited to testifying to (1) the risks associated with the surgeries at issue in this case; (2) his anecdotal experience treating patients seeking to "de-transition"; and (3) the WPATH recommended role of the surgeon in treating gender dysphoria as compared to the role of the surgeon in other surgical contexts.

E. Stephen B. Levine, M.D. (ECF No. 212)

Dr. Stephen B. Levine is a licensed physician and Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine. (ECF No. 215-1 ¶ 1.) He holds an M.D. from Case Western and has received numerous grants for scientific research and program development. (*Id.*) He maintains an active private clinical practice and specializes in treatment of "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." (*Id.* ¶¶ 1–2.) He is the recipient of the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research and is a Distinguished Life Fellow of the American Psychiatric Association. (*Id.* ¶ 2.) He serves as Co-Director of the Gender Diversity Clinic, which he founded at Case Western in 1974. (*Id.* ¶ 3.) He has treated dozens of transgender patients through the clinic and supervised other therapists. (*Id.*) He was an early member of the organization now called WPATH and served as the Chairman of the WPATH Standards of Care Committee that developed WPATH-5. (*Id.*)

Levine's testimony primarily falls into three categories: the risks of medical and surgical treatment to children, the function of WPATH, and the quality of research supporting medical and surgical care for gender dysphoria. First, he testifies that "active affirmation of transgender identity in young children . . . raises ethical and public health concerns." (*Id.* ¶ 8(e).) He testifies that healthcare providers should "delay any transitions [until] after the onset of puberty," that "*encouraging social transition in children remains controversial*," that a majority of prepubescent children diagnosed with gender dysphoria will desist, and that mental health professionals should employ psychotherapy and a "watchful waiting approach" in treating children with gender dysphoria. (*Id.* ¶¶ 29, 38, 54, 62.) Second, he "provide[s] some context concerning" WPATH, which he calls a "private, activist, non-science, organization." (*Id.* ¶¶ 45–53.) Finally, he testifies that the scientific research demonstrating the benefits of medical and surgical treatments of gender dysphoria are of "low quality." (*Id.* ¶ 68(g).)

Notably, Levine does not testify that medical and surgical care for gender dysphoria is categorically inappropriate. (*See, e.g.*, *id.* ¶ 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.") Despite his view that only "low quality" evidence supports the efficacy of these treatments, he does not advocate for "denying endocrine treatment or surgical treatment" to all transgender people, a position he calls "draconian," (ECF No. 213-3 at 73:4-7, 84:21–85:11, ("I'm not advocating denying endocrine treatment or surgical treatment."), 152:1-6, 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that.").) He concedes that he does not know how often medical or surgical care helps alleviate symptoms of gender dysphoria and does not offer an opinion as to the portion of these procedures that are necessary and unnecessary. (*Id.* at 67:24–68:3 ("It is not our [clinic's] knowledge base to know who's going to do better and who's going to do worse and who is not going to have any difference at all with hormones or with surgery.").) He testifies that this lack of high-quality evidence should encourage physicians treating gender dysphoria to be "cautious" and that transgender patients "have a right to be more fully informed" about the risks and rewards of such care, but ultimately agrees that "doctor[s] need to decide" when medical and surgical care is necessary on "a case-by-case basis." (*Id.* at 152:20-25; ECF No. 215-1 ¶ 126 ("Science not politics needs to drive trans care.").) In his own practice, Levine adheres to the WPATH Standards of Care and personally provides letters of authorization for medical and surgical treatments for his gender dysphoric patients after advising them on the risks associated with those treatments. (ECF No. 213-3 at 55:13-17, 56:2-5, 112:16-21, 176:8-16, 225:24–226:17.) Levine testifies anecdotally that "[i]n [his] experience," mental health providers "too often encourage or permit decision based on a great deal of patient and professional blind optimism" and fail to adequately inform patients

of the inadequacies in the research supporting treatments for gender dysphoria. (ECF No. 215-1 ¶ 105.) He does not offer any quantifiable metrics to identify how many doctors provide informed consent and proceed with caution, and how many do not.

Based on the preponderance of the evidence, the Court finds that Levine is qualified as both a mental health provider and researcher. He is qualified to offer expert testimony on the treatment of gender dysphoria and the efficacy and findings of research studies evaluating gender dysphoria treatments. His personal work treating transgender patients, extensive experience conducting scientific research, review of the relevant literature, and thorough discussion of relevant scientific studies in his report qualify him as an expert witness. The Court additionally finds the following:

First, Levine's testimony concerning the risks of medical and surgical treatment for adolescents is relevant to assessing whether the Plan's exclusion is substantially related to Defendants' governmental interest in protecting employees and the public from ineffective medical treatments. However, Levine's criticism of medical or surgical treatment of gender dysphoria in prepubescent children is not relevant, as Plaintiffs have conceded that such treatments are not medically necessary until the onset of puberty. *See* Section II.B, *supra*. Likewise, Levine's opinions on mental health approaches to social transition are irrelevant as well, as Defendants maintain that the Plan's exclusion of coverage for mental health treatments of gender dysphoria has never been given effect and is no longer part of the Plan. (*See* ECF Nos. 137 n.2; 137-4 ¶ 27.)

Second, Levine is qualified by his personal experience with WPATH to provide background and critique the WPATH Standards of Care. This testimony is relevant to rebut

Plaintiffs' experts who appear to use and rely in part on the WPATH-7 and is reliably based on Levine's expert knowledge and personal experience with the organization.

Third, Levine's analysis of the relevant scientific research supporting gender affirming medical care is relevant to assessing whether the Plan's exclusion is substantially related to Defendants' governmental interest in protecting employees and the public from ineffective medical treatments. Further, his opinion that the available scientific research is of "low quality" appears reliably based on his review of the relevant literature, experience conducting scientific research, and a "widely accepted hierarchy of reliability" that distinguishes between case studies on the "low" end and randomized double-blind clinical trials on the "high" end. (*See* ECF No. 215-1 ¶ 68.) His criticism of the methodology of some of these studies similarly appears reliable.[3] (*Id.* ¶¶ 74–79.)

However, Levine's testimony regarding desistance rates does not appear to be based on reliable methodology. During deposition, Levine was unable to recall many of the studies that purportedly support his conclusion. (ECF No. 213-3 at 191:20-192:14.) His anecdotal testimony concerning adults and adolescents who regret their transitions appears to be based on a misreading of an article that reviewed entries on the website Reddit. (*See* ECF No. 215-1 ¶¶ 35, 56, 98.) He admitted during deposition that the article referred to 16,000 entries—not 60,000, as he repeatedly stated in his report—and that he had no knowledge of the content

[3] Contrary to Plaintiffs' characterization, Levine does not testify that medical or surgical treatment of gender dysphoria *increases* a patient's chance of negative mental health outcomes, but rather that, in his view, no reliable studies show that such treatments *reduce* the likelihood of such outcomes. (ECF No. 215-1 ¶¶ 74–79.)

of those entries or whether any of the authors actually de-transitioned or regret their transitions. (*Id.* at 196:3-7, 201:12-25)

Fourth, as discussed, it does not appear that he offers any categorical opinion as to the medical necessity of medical and surgical treatments of gender dysphoria, nor does he testify that healthcare providers are prescribing such treatment without due caution and informed consent beyond his anecdotal "experience." To the extent that Defendants seek to introduce testimony from Levine to that effect, he has not provided the Court with any data or methodology from which such claims could be made. Levine has conducted no research to identify which physicians are proceeding as he does and which do not, rendering any broader opinion about the practice of such healthcare providers pure speculation.

Finally, for the same reasons identified regarding Dr. Lappert, *supra*, Levine's reference to a "Transgender Treatment Industry" does not appear to be based on any science whatsoever and is not admissible.

In sum, Plaintiffs' motion will be granted in part and denied in part, and Levine's testimony will be limited to (1) identifying risks associated with prescribing medication and surgery to adolescents, (2) discussing WPATH, and (3) criticizing the quality of the research on treatments for gender dysphoria.

III. MOTIONS FOR SUMMARY JUDGMENT

Plaintiffs argue that they are entitled to summary judgment on their three claims arising under the Equal Protection Clause, Title VII, and the ACA. (ECF No. 179.) DPS argues that it is entitled to summary judgment on Plaintiff Caraway's Title VII claim. (ECF No. 133.)

Plan Defendants argue that NCSHP is entitled to summary judgment on Plaintiff's Title VII and ACA claims. (ECF No. 136.) The Court will address each claim in turn.

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 citations and 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) (citing *Jacobs*, 780 F.3d at 568). A court "cannot weigh the evidence or make credibility determinations," *Jacobs*, 780 F.3d at 569 (citations omitted), 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, *Witt v. W. Va. State Police, Troop 2*, 633 F.3d 272, 276 (4th Cir. 2011) (quoting *Scott v. Harris*, 550 U.S. 372, 378 (2007)).

Where the nonmovant will bear the burden of proof at trial, the party seeking summary judgment bears the initial burden of "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case." *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). If the moving party carries this burden, then the burden shifts to the nonmoving party to point out "specific facts showing that there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In so doing, "the nonmoving party must rely on more than conclusory allegations, mere speculation, the building of one inference upon another, or the mere existence of a scintilla of evidence." *Dash*

v. Mayweather, 731 F.3d 303, 311 (4th Cir. 2013). Instead, the nonmoving party must support its assertions by "citing to particular parts of . . . the record" or "showing that the materials cited do not establish the absence . . . of a genuine dispute." Fed. R. Civ. P. 56(c)(1); *see also Celotex*, 477 U.S. at 324. Expert testimony must be admissible to create a genuine issue of material fact. *See Cavallo v. Star Enter.*, 100 F.3d 1150, 1159 (4th Cir. 1996).

A. Equal Protection Clause

The Fourteenth Amendment to the U.S. Constitution prohibits states from denying "to any person within its jurisdiction the equal protection of the laws." U.S. Const. amend. XIV, § 1. The Equal Protection Clause is "essentially a direction that all persons similarly situated should be treated alike." *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 439 (1985). When considering an equal protection claim, a court must determine (1) "what level of scrutiny applies" and (2) "whether the law or policy at issue survives such scrutiny." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 607 (4th Cir.), *as amended* (Aug. 28, 2020), *cert. denied*, 141 S. Ct. 2878 (2021).

i. The Plan facially discriminates based on sex and transgender status

"In determining what level of scrutiny applies to a plaintiff's equal protection claim, we look to the basis of the distinction between the classes of persons." *Id.* (citing *United States v. Carolene Products Co.*, 304 U.S. 144, 152 n.4 (1938)). Generally, a state policy "is presumed to be valid and will be sustained if the classification drawn by the [policy] is rationally related to a legitimate state interest." *Cleburne*, 473 U.S. at 440. This general rule "gives way," however, when the policy discriminates based on membership in certain suspect classes. *Id.* In the Fourth Circuit, laws that discriminate based on sex or transgender status receive intermediate

scrutiny. *Grimm*, 972 F.3d at 608, 610. Such policies are unconstitutional "unless [they are] substantially related to a sufficiently important governmental interest." *Id.* at 608 (quoting *Celburne*, 473 U.S. at 441).

To show that a policy discriminates based on sex or transgender status, a plaintiff must show discriminatory intent and disproportionate impact. *See Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 265 (1977). "No inquiry into legislative purpose is necessary," however, when the suspect classification "appears on the face" of the policy. *Shaw v. Reno*, 509 U.S. 630, 642 (1993). A policy that facially discriminates based on membership in a suspect class is "immediately suspect because, '[a]bsent searching judicial inquiry . . . , there is simply no way of determining what classifications are "benign" or "remedial" and what classifications are in fact motivated by illegitimate"' governmental objectives. *Id.* at 642–43 (quoting *Richmond v. J.A. Croson Co.*, 488 U.S. 469, 493 (1989) (plurality opinion)); *see also Pers. Adm'r of Mass. v. Feeney*, 442 U.S. 256, 273 (1979) ("Classifications based upon gender, not unlike those based upon race, have traditionally been the touchstone for pervasive and often subtle discrimination.").

A facial inquiry is what it sounds like: a review of the language of the policy to see whether it is facially neutral or "deal[s] in explicitly racial [or gendered] terms." *Washington v. Seattle Sch. Dist. No. 1*, 458 U.S. 457, 485 (1982) (citing *Hunter v. Erickson*, 393 U.S. 385 (1969)). A policy that uses racial or gendered terms "falls into an inherently suspect category" even if it creates classifications that are not "obviously pernicious." *Id.* at 485, 487. The "crucial difference" between facially discriminatory and facially neutral laws is that the former "plainly rests on distinctions based on" a suspect classification. *Id.* at 485 (internal quotations omitted).

In *Grimm*, the Fourth Circuit held that a school policy limiting students to use of the restroom and locker room facility that corresponded to their "biological genders" discriminated on its face based on sex. *Grimm*, 972 F.3d at 608–10. First, it reasoned that the policy "necessarily rests on a sex classification" and "cannot be stated without referencing sex." *Id.* at 608. Second, the court found that the policy "subjected [plaintiff] to sex discrimination because he was viewed as failing to conform to the sex stereotype propagated by the Policy." *Id.* at 608. Thus, the Fourth Circuit applied intermediate scrutiny. *Id.* at 609.

Additionally, the court held that the bathroom policy facially discriminated against plaintiff based on his status as a transgender boy. *Id.* at 613. The court identified transgender individuals as a quasi-suspect class consisting of those "who consistently, persistently, and insistently express a gender that, on a binary, we would think of as opposite to their assigned sex." *Id.* at 594, 613 (internal quotations omitted). The court then held that the policy—which provided "alternative appropriate private facilit[ies]" for students "with gender identity issues"— facially discriminated against plaintiff based on his membership in this class. *Id.* at 609, 613.

Here, the Plan excludes "[t]reatment or studies leading to or in connection with *sex* changes or modifications and related care." (ECF No. 184 at 67 (emphasis added).) This exception does not identify any diagnoses or treatments. Instead, the broad language of the Plan distinguishes between medically necessary[4] treatments that align with the member's

[4] Defendants dispute that the treatments excluded by the Plan are medically necessary in fact. However, the Plan already limits coverage to treatments that are medically necessary. (ECF No. 137-2 at 58:4-7.) Thus, for purposes of this facial inquiry alone, the exclusion only applies to treatments that are otherwise considered medically necessary.

biological sex and medically necessary treatments—often the *same* medically necessary treatments—that do not align with his sex.

These exclusions facially discriminate based on sex and transgender status. First, like in *Grimm*, this exclusion "necessarily rests on a sex classification" because it cannot be stated or effectuated "without referencing sex." *See Grimm*, 972 F.3d at 608; *c.f. Hunter*, 393 U.S. at 391. As reasoned by the U.S. Supreme Court, "try writing out instructions" for which treatments are excluded "without using the words man, woman, or sex (or some synonym). It can't be done." *Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1746 (2020). It is impossible to determine whether a particular treatment is connected to "sex changes or modifications and related care"—and thus, whether the exclusion applies—without comparing the member's biological sex before the treatment to how it might be impacted by the treatment.

Second, the Plan overtly discriminates against members for "failing to conform to the sex stereotype propagated by the [Plan]." *See Grimm*, 972 F.3d at 608. The Plan expressly limits members to coverage for treatments that align their physiology with their biological sex and prohibits coverage for treatments that "change or modify" physiology to conflict with assigned sex. For example, puberty suppressing medication may be covered if medically necessary. (*See, e.g.*, ECF Nos. 201-1 at 4–22). But a transgender boy will not receive coverage for such medication—even if medically necessary—because, in the language of the Plan, it would "change or modify" his physiology in a way that does not match his female biological sex. (*See id.*) This is textbook sex discrimination. *Grimm*, 972 F.3d at 608; *see generally Price Waterhouse v. Hopkins*, 490 U.S. 228, 251 (1989) (plurality opinion) (holding that employers who "insist[ed] that [individuals] matched the stereotype associated with their group" committed

sex discrimination under Title VII); *Bostock*, 140 S. Ct. at 1741 ("[A]n employer who fires a woman, Hannah, because she is insufficiently feminine and also fires a man, Bob, for being insufficiently masculine may treat men and women as groups more or less equally. But in *both* cases the employer fires an individual in part because of sex.").

Third, the Plan also transparently discriminates against its transgender members. As mentioned, the quasi-suspect class identified by the Fourth Circuit is defined as those "who consistently, persistently, and insistently express a gender that, on a binary, we would think of as opposite to their assigned sex." *Grimm*, 972 F.3d at 594. Transgender men are men; transgender women are women. *Id.* at 610 ("[Plaintiff] did not question his gender identity at all; he knew he was a boy."). This holding by the Fourth Circuit is likewise supported by the undisputed evidence in this case. (*See, e.g.*, ECF Nos. 179-2 ¶¶ 2–3 ("I am a 19-year-old man. I am also transgender."); 179-5 ¶¶ 2, 4 ("I am a boy. . . . I am transgender, which means that I was designated 'female' at birth, even though I am and identify as male."); 137-2 at 85:10–87:22 (stating that NCSHP members may align their sex identification marker in NCSHP's records with their gender identity without proof of their physical anatomy, DNA, or chromosomal make up); *see also* ECF No. 219 at 6 ("A transgender man is a man. A transgender woman is a woman.").) Under the Plan, however, transgender members are classified as seeking to "change or modify" their gender or sex while cisgender members are not. So, a cisgender man who receives medically necessary testosterone is covered, while a transgender man who receives medically necessary testosterone is not. Like in *Grimm*, the Plan "privileges sex-assigned-at-birth over [Plaintiffs'] medically confirmed, persistent and consistent gender identity." *Grimm*, 972 F.3d at 610. Thus, it will receive intermediate scrutiny.

Defendants raise four arguments against finding that the Plan discriminates based on sex or transgender status.

First, Defendants argue that the Plan does not discriminate based on sex or transgender status but based on diagnosis. (ECF No. 197 at 28.) Specifically, they characterize the Plan as covering medically necessary treatments for some ailments but not for others, such as gender dysphoria. (*Id.*) Some Plan administrators do consider the exclusions to be "blanket exclusions for the treatment of gender dysphoria." (*See, e.g.*, ECF No. 185-2 at 34.) However, whether a policy is facially discriminatory is determined with reference to the language of the policy, not the underlying intent of its adopters or administrators. *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am., UAW v. Johnson Controls, Inc.*, 499 U.S. 187, 199 (1991) ("[T]he absence of a malevolent motive does not convert a facially discriminatory policy into a neutral policy with a discriminatory effect."). Thus, Defendants' evidence does not create a genuine issue of material fact as to whether the Plan discriminates *on its face.* [5]

Further, even if the Court credited Defendant's characterization of the Plan as applying only to diagnoses of gender dysphoria, it would still receive intermediate scrutiny. Discrimination against individuals suffering from gender dysphoria is also discrimination based on sex and transgender status. As with the Plan's exclusions, one cannot explain gender dysphoria "without referencing sex" or a synonym. *See Grimm*, 972 F.3d at 608. A hypothetical from the Supreme Court is directly on point:

[5] Moreover, undisputed evidence shows the exclusions do not simply attach to treatments related to a diagnosis of gender dysphoria in practice. As discussed, preauthorization for some surgeries is denied due to the exclusion "regardless of the diagnostic code," and preauthorization for others is denied if the procedural code accompanying the treatment is "transsexualism" or "personal history of sex reassignment." (ECF No. 197-14 ¶¶ 20–21.)

> Suppose an employer asked homosexual or transgender applicants to tick a box on its application form. The employer then had someone else redact any information that could be used to discern sex. The resulting applications would disclose which individuals are homosexual or transgender without revealing whether they also happen to be men or women. Doesn't that possibility indicate that the employer's discrimination against homosexual or transgender persons cannot be sex discrimination?
>
> No, it doesn't. . . . There is no way for an applicant to decide whether to check the homosexual or transgender box without considering sex. To see why, imagine an applicant doesn't know what the words homosexual or transgender mean. Then try writing out instructions for who should check the box without using the words man, woman, or sex (or some synonym). It can't be done.

Bostock, 140 S. Ct. at 1746. The same is true here. Even if Plan administrators see only a box checked "gender dysphoria," the diagnostician cannot know whether to check that box without considering sex.[6] Defendants' first argument is unpersuasive.

Second, Defendants argue that Plaintiffs are not similarly situated to members who receive similar treatments for different diagnoses. (ECF No. 197 at 29.) Members who receive hormone therapy, testosterone, or a mastectomy for gender dysphoria, they argue, are not similarly situated to members who seek those same treatments for prostate, testicular, or breast cancer. (*Id.*) This argument, however, is a *justification* for Defendants' facial sex and transgender discrimination, not an argument that the exclusions are facially neutral. *See Tuan Anh Nguyen v. I.N.S.*, 533 U.S. 53, 62–64, 73 (2001) (conducting "similarly situated" analysis of a facially discriminatory law in its application of intermediate scrutiny rather than to determine what level of scrutiny applied). It is sufficient at this stage that those affected and unaffected

[6] Defendants argue that "[h]ealthcare providers must know a patient's sex for *every* medical diagnosis," (ECF No. 197 at 32), but this argument misstates the issue. Gender dysphoria cannot be explained at all without reference to sex, while most other diagnoses—even those that are specific to members of only one sex—can be explained neutrally.

by the exclusion are all members of the Plan who seek similar or identical treatments. The factor used by the Plan to distinguish between covered and uncovered treatments is that the later "change or modify" the patient's assigned sex. Other factors not evidenced on the face of the Plan that may distinguish the two groups are not proper for consideration at this stage in the Court's analysis. *See Klinger v. Dep't of Corr.*, 31 F.3d 727, 731 (8th Cir. 1994) ("The similarly situated inquiry focuses on whether the plaintiffs are similarly situated to another group *for purposes of the challenged government action*. . . . [It] depends on what government action the plaintiffs are challenging." (emphasis added)).

Third, Defendants argue that the Plan does in fact cover many over-the-counter pharmaceuticals regardless of transgender status because neither the Plan nor its administrators "*ever know* the reason" for such purchases. (ECF No. 197 at 26.) But a policy that makes coverage turn on sex or transgender status receives heightened scrutiny even if administrators do not actually know members' sex or transgender status in practice. *C.f. Bostock*, 140 S. Ct. at 1746 ("By intentionally setting out a rule that makes hiring turn on [sex], the employer violates the law, whatever he might know or not know about individual applicants."). A facially discriminatory policy likewise receives heightened scrutiny even if it is not applied in all cases. *See, e.g.*, *Fisher v. Univ. of Tex. at Austin*, 579 U.S. 365, 384 (2016) (applying heightened scrutiny to a race-conscious admissions policy even though "race consciousness played a role in only a small portion of admissions decisions").

Fourth, Defendants analogize this case to *Geduldig v. Aiello*, 417 U.S. 484 (1974). In *Geduldig*, the Supreme Court held that a state health program that denied coverage for pregnancy did not discriminate based on sex. *Id.* at 494. The Court reasoned that the program

did "not exclude anyone from benefit eligibility because of gender but merely remove[d] one physical condition—pregnancy—from the list of compensable disabilities." *Id.* at 496 n.20. "Normal pregnancy is an objectively identifiable physical condition with unique characteristics," and while "only women can become pregnant," the group of members who are not pregnant "includes members of both sexes." *Id.* But the same cannot be said here. The Plan does not merely exclude one "objectively identifiable physical condition with unique characteristics" from coverage; rather, it excludes *treatments* that lead or are connected to *sex* changes or modifications. Pregnancy can be explained without reference to sex, gender, or transgender status.[7] The same cannot be said of the exclusion at issue here.

In sum, there is no genuine issue of material fact about the language of the Plan: it facially discriminates based on sex and transgender status. The Court will accordingly apply intermediate scrutiny.

ii. Defendants have not established a genuine issue of material fact as to whether the Plan is substantially related to an important governmental interest

Policies that discriminate based on sex or transgender status are unconstitutional "unless [they are] substantially related to a sufficiently important governmental interest." *Grimm*, 972 F.3d at 608 (quoting *Celburne*, 473 U.S. at 441). To survive intermediate scrutiny,

[7] *Pregnancy*, Dorland's Illustrated Medical Dictionary (33d ed. 2020) ("[T]he condition of having a developing embryo or fetus in the body, after union of an oocyte and spermatozoon."); *Pregnant*, American Heritage Medical Dictionary (2d ed. rev. 2007) ("Carrying developing offspring within the body); *see Pregnant*, Merriam-Webster, https://www.merriam-webster.com/dictionary/pregnant (last updated May 25, 2022) ("containing a developing embryo, fetus, or unborn offspring within the body"). *But see Pregnancy*, Stedman's Medical Dictionary (28th ed. 2006) ("The state of a female after conception and until the termination of the gestation.").

the state bears the burden to "provide an 'exceedingly persuasive justification' for its classification." *Id.* (quoting *United States v. Virginia*, 518 U.S. 515, 534 (1996)).

Defendants raise two justifications for the relevant exclusions. First, they argue that the exclusions limit health care costs. (ECF No. 197 at 40.) Until 2018, North Carolina provided free health insurance to its public employees. (ECF No. 137-2 at 106:2-4.) When the North Carolina General Assembly limited increases in its contribution to the Plan in 2016 to 4% per year, however, NCSHP was unable to keep up with the rapid 7% annual increase in healthcare costs. (*Id.* at 102:22-24.) At Defendant Folwell's direction, NCSHP cut benefits and charged employees premiums for the first time. (*Id.* at 102:19-21, 106:2-4.) Now, "a whole lot of employees have to work one week out of a month just to cover their Health Plan for their family." (*Id.* at 105:22-24.)

While such a justification may be sufficient under the rational basis test, *see Geduldig*, 417 U.S. at 496, a state may not "protect the public fisc by drawing an invidious distinction between classes of its citizens" under heightened scrutiny, *Mem'l Hosp. v. Maricopa Cnty.*, 415 U.S. 250, 263 (1974). That is especially true here, as the estimated $300,000–$900,000 saved by the exclusion per year pales in comparison to NCSHP's billion-dollar cash balance and saves each of the Plan's 740,000 members about one dollar each. Such a paltry limit on health care costs is not an important governmental interest.

Second, Defendants argue that the relevant treatments excluded by the Plan are not effective. (ECF No. 197 at 11–17.) Viewed in the abstract, the Court finds that withholding Plan funds from ineffective medical treatments serves an important governmental interest. The state has an obvious interest in protecting its employees and their families from ineffective

medical treatments and a derivative interest in reducing the prevalence of such treatments generally by cutting them off from access to the Plan's considerable resources. (*See* ECF No. 137-1 at 35:7-12 (stating that the Plan is the largest purchaser of healthcare and pharmaceuticals in North Carolina)). Protecting public health is an important governmental interest. *Eline v. Town of Ocean City*, 7 F.4th 214, 222 n.8 (4th Cir. 2021), *cert. denied*, 142 S. Ct. 1117 (2022).

Thus, the remaining issue is whether the exclusions are substantially related to Defendant's interest in protecting its employees and the public from ineffective medical treatments.[8] Defendants attempt to establish this substantial relationship via their experts' testimony. However, as found in Part II, *supra*, much of this testimony is inadmissible. Inadmissible testimony cannot establish a genuine issue of material fact for purposes of summary judgment. *See Md. Highways Contractors Ass'n v. Maryland*, 933 F.2d 1246, 1251 (4th Cir. 1991).

Defendants' admissible expert testimony, even when taken in the light most favorable to Defendants, does not support that the Plan's exclusion substantially excludes treatments that are ineffective. First, while Dr. Hruz and Dr. Lappert testify that the medicines and surgeries used to treat gender dysphoria can have serious health risks and consequences, it is

[8] Plaintiffs argue "[b]inding circuit precedent recognizes that . . . medical treatments for gender dysphoria 'are safe, effective, and often medically necessary.'" (ECF No. 201 at 3 (quoting *Kadel v. N.C. State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422, 428 (4th Cir.), *as amended* (Dec. 2, 2021), *cert. denied sub nom. N.C. Health Plan for Tchrs. & State Emps. v. Kadel*, 142 S. Ct. 861 (2022)).) However, the relevant quote comes from the Fourth Circuit's background discussion of gender dysphoria. *See Kadel*, 12 F.4th at 428. This Court does not read the Fourth Circuit's ruling in *Kadel*—which concerned a jurisdictional issue—to resolve this consequential issue as a matter of fact or law. Thus, the effectiveness of these treatments remains an issue of fact that must be resolved in the first instance.

also undisputed that gender dysphoria is a serious diagnosis that, if left untreated, can lead to self-mutilation and suicide. NCSHP covers many of these same treatments for other serious illnesses notwithstanding their risks and side effects. Without evidence that the treatments are ineffective to treat gender dysphoria, Defendants cannot meet their burden to show that the risks substantially outweigh the benefits so as to justify their sex- and transgender-based policy.

Second, Defendants point to Dr. Levine's testimony to argue that these treatments are categorically ineffective. But that is not Levine's testimony. He testifies that the available research is not sufficiently reliable to prove that treatments are effective, but repeatedly and emphatically testifies that this lack of high-level research is *not* reason to justify withholding treatment from all gender dysphoric patients. Rather, he testifies that *doctors and patients*, when fully aware of the risks and elusive benefits of available treatments, should decide if medicine or surgery is necessary *as he does in his own practice*. This is Plaintiffs' request: that they and their doctors, not their sex or transgender status, determine when their treatments are appropriate. Levine does not and cannot reliably testify as to how often doctors prescribe unnecessary treatments or fail to obtain informed consent. Thus, Levine's testimony also does not create a genuine issue of material fact as to whether the Plan's exclusion substantially excludes ineffective treatments.

Finally, anecdotal recounting of individual patient experiences and wholesale criticism of WPATH, the DSM, and various professional associations, even when taken as true, is insufficient to meet Defendants' burden of showing that the Plan's discriminatory exclusion is substantially related to an important governmental interest. At most, this evidence

challenges the credibility of some—but not all—of Plaintiffs' evidence showing that medical and surgical treatments for gender dysphoria are effective.

Moreover, Defendants have a clear, sex- and transgender-neutral alternative to the exclusion. In 2017, the Plan covered "medically necessary services for the treatment of gender dysphoria," and NCSHP's third-party administrators, Blue Cross and CVS, appear able to distinguish between medically necessary and unnecessary treatments. (*See, e.g.*, 185-2 at 89–99 (distinguishing in the Blue Cross Corporate Medical Policy between medically necessary and unnecessary treatments for gender dysphoria). To the extent that Defendants can anecdotally establish that *some* treatments for gender dysphoria are ineffective, they have not offered any admissible evidence to show that the Plan's categorical exclusion better protects members from ineffective treatments than the more narrow exclusion of medically *unnecessary* treatments for gender dysphoria. Thus, Defendants cannot meet their burden under intermediate scrutiny. *See Caban v. Mohammed*, 441 U.S. 380, 392 (1979) (invalidating an adoption law where "the State's interest . . . can be protected by means that do not draw such an inflexible gender-based distinction."); *Cleveland Bd. of Educ. v. LaFleur*, 414 U.S. 632, 650 (1974) (invalidating a maternity policy where a more "narrow method of protecting the school board's interest in teacher fitness" was available); *see also Cleburne*, 473 U.S. at 476 (Marshall, J., concurring in the judgment in part and dissenting in part) ("When statutes rest on impermissibly overbroad generalizations, our cases [applying intermediate scrutiny] have invalidated the presumption on its face.") (collecting cases).

Thus, Plaintiffs are entitled to summary judgment on their Equal Protection Claim.

B. Title VII

The Court next addresses Plaintiff Caraway's Title VII claims against DPS and NCSHP.

It is a violation of Title VII for an employer to "discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment, because of such individual's . . . sex." 42 U.S.C. § 2000e-2(a)(1). "Health insurance and other fringe benefits are 'compensation, terms, conditions, or privileges of employment'" under Title VII.[9] *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 682 (1983).

DPS, NCSHP, and Plaintiffs each move for summary judgement on Plaintiff Caraway's Title VII claims. (ECF Nos. 132; 136; 178.) NCSHP argues it is not Caraway's employer. (ECF No. 137 at 25–33.) DPS argues that Caraway lacks standing and cannot show that DPS caused her injury. (ECF No. 133 at 21–22.) Caraway argues that no genuine issue of material fact exists as to her Title VII claim and she is entitled to judgment as a matter of law as to liability, "reserving issues of damages . . . for trial." (ECF No. 179 at 4, 32–37.) The Court will address these arguments in turn.

i. Plaintiff Caraway

Caraway is a transgender woman and corrections officer for DPS. (ECF No. 179-9 ¶¶ 5, 8.) She is required to maintain health insurance by DPS given the nature of her job and is a member of NCSHP. (*Id.* ¶ 16.) She was diagnosed with gender dysphoria and began hormone replacement therapy in mid-2018, and underwent "intersex surgery" and a

[9] Whether a benefit is "compensation" under Title VII is a question of federal law, not state law. Defendants' contention that the Plan does not constitute compensation under state law is therefore inapposite.

"mammaplasty" on August 5, 2020. (*Id.* ¶¶ 19–20; *id.* at 13.) Due to the exclusion, NCSHP has only occasionally covered her hormone therapy and did not cover her surgery. (*Id.* ¶¶ 21, 24, 28; *see id.* at 13.) She consequently delayed surgery approximately nine months until she could pay the $27,000 bill out of pocket. (*Id.* ¶¶ 23–25.) Caraway is still employed with DPS. (*Id.* ¶ 6.) Although the treatment she has received "has helped" relieve symptoms from her gender dysphoria "up to a point," she anticipates requiring continued hormone treatments and additional surgery. (*Id.* ¶¶ 29–33.)

ii. NCSHP is not Caraway's employer

NCSHP argues that it is not liable to Caraway under Title VII because it is not her employer. (ECF No. 137 at 25–28.) It is undisputed that Caraway is employed by DPS. (*See* ECF No. 179-9 ¶ 5.) Caraway argues that NCSHP is also her employer—and therefore liable under Title VII—because (1) it is DPS's agent and (2) DPS and NCSHP jointly employ her. (ECF No. 188 at 15–18.)

1. NCSHP is not DPS's agent

Title VII defines "employer" as either "a person engaged in an industry affecting commerce" that employs fifteen or more employees and "any agent of such a person." 42 U.S.C. § 2000e(b). An "employer," in turn, is prohibited from discriminating "against any individual with respect to [her] compensation, terms, conditions, or privileges of employment" because of her sex. § 2000e-2(a)(1). "Title VII's purpose [is to] eliminat[e] discrimination in employment based on race, color, religion, sex, or national origin." *Butler v. Drive Auto. Indus. of Am., Inc.*, 793 F.3d 404, 409 (4th Cir. 2015) (internal quotations omitted). "Title VII should

be liberally construed in light of its remedial purpose . . . [and] such liberal construction is also to be given to the definition of 'employer.'" *Id.* (internal quotations omitted).

Title VII "does not define the term 'agent.'" *Lissau v. S. Food Serv., Inc.*, 159 F.3d 177, 180 (4th Cir. 1998). In *Lissau*, the Fourth Circuit held that "individual supervisors are not liable under Title VII." *Id.* at 181. Rejecting an argument that an individual supervisor may be held liable as the "agent" of the employer, the court "interpret[ted] the inclusion of agent in Title VII's definition of employer simply to establish a limit on an employer's liability for its employees' actions." *Id.* at 180; *see also Birkbeck v. Marvel Lighting Corp.*, 30 F.3d 507, 510 (4th Cir. 1994) (reading an identical provision in the Age Discrimination in Employment Act to be "an unremarkable expression of respondeat superior—that discriminatory personnel actions taken by an employer's agent may create liability for the employer").

The Fourth Circuit has not addressed the present situation where a plaintiff alleges that an entity, rather than an individual supervisor, is liable under Title VII by virtue of being an agent. (*See* ECF No. 74 at 22–24.) Other circuits have held "that Title VII plaintiffs may maintain a suit directly against an entity acting as the agent of an employer, but only under certain circumstances." *Alam v. Miller Brewing Co.*, 709 F.3d 662, 668–69 (7th Cir. 2013) (citations omitted). These circuits recognize agency liability where the agent "exercise[s] control over an important aspect of [the plaintiff's] employment," *Carparts Distrib. Ctr., Inc. v. Auto. Wholesaler's Ass'n of New England, Inc.*, 37 F.3d 12, 17 (1st Cir. 1994); where the agent "significantly affects access of any individual to employment opportunities," *Spirt v. Teachers Ins. & Annuity Ass'n*, 691 F.2d 1054, 1063 (2d Cir. 1982), *vacated and remanded on other grounds*, 463 U.S. 1223 (1983); or where "an employer delegates sufficient control of some traditional

rights over employees to a third party," *Nealey v. Univ. Health Servs., Inc.*, 114 F. Supp. 2d 1358, 1367 (S.D. Ga. 2000) (quoting *Lyes v. City of Riviera Beach*, 166 F.3d 1332, 1341 (11th Cir. 1999)).

Here, even if the Court were to assume that entities may be held liable as agents under Title VII in the Fourth Circuit, Caraway has failed to show that NCSHP operates as DPS's agent.[10] At common law, "[a]n agent is one who consents to act on behalf on another and subject to the other's control." *Swallows v. Barnes & Noble Book Stores, Inc.*, 128 F.3d 990, 996 (6th Cir. 1997) (citing Restatement (Second) of Agency § 1 (1958)); *see Meritor Sav. Bank, FSB v. Vinson*, 477 U.S. 57, 72 (1986) (interpreting Title VII's definition of "employer" and use of the term of "agent" against a common law backdrop). Plaintiffs have submitted no evidence that NCSHP is subject to DPS's control. On the contrary, it appears undisputed that "state law delegates control over employee health coverage to NCSHP." (ECF No. 188 at 18 (citing N.C. Gen. Stat. § 135-48.2(a)).) Although DPS provides the Plan to its employees and assists in its implementation, *see* Section III.B.iii, *infra*, DPS has no legal control over NCSHP or the Plan, *see generally* §§ 135-48.1–48.62, and Carraway has failed to produce any evidence to show that DPS has control over NCSHP in fact.

2. NCSHP is not a joint employer

An individual may have more than one employer within the meaning of Title VII. *Butler*, 793 F.3d at 408. The "principal guidepost" to observe in determining an employee's

[10] In its March 5, 2021, Order, this Court concluded that *Lissau* nor *Birkbeck* control this case, as those cases concern individual supervisors sued in their individual capacities. (ECF No. 74 at 22–24.) Consequently, the Court held that Caraway's Title VII claims against NCSHP were not futile and allowed Plaintiffs to amend their Complaint. (*Id.* at 24.) The Court does not disturb that reasoned conclusion here. Rather, the Court finds that Plaintiffs have not submitted sufficient evidence at the summary judgment stage to create a genuine issue of material fact as to whether NCSHP is DPS's agent.

employers is "'the common-law element of control,' drawn from the law of agency." *Id.* at 409 (quoting *Clackamas Gastroenterology Assocs., P.C. v. Wells*, 538 U.S. 440, 448 (2003)). In *Butler*, the Fourth Circuit adopted a nine-factor test to determine whether a Title VII plaintiff "is jointly employed by two or more entities." *Id.* at 414. These factors are:

(1) authority to hire and fire the individual;

(2) day-to-day supervision of the individual, including employee discipline;

(3) whether the putative employer furnishes the equipment used and the place of work;

(4) possession of and responsibility over the individual's employment records, including payroll, insurance, and taxes;

(5) the length of time during which the individual has worked for the putative employer;

(6) whether the putative employer provides the individual with formal or informal training;

(7) whether the individual's duties are akin to a regular employee's duties;

(8) whether the individual is assigned solely to the putative employer; and

(9) whether the individual and putative employer intended to enter into an employment relationship.

Id. "[N]one of these factors are dispositive and . . . courts can modify the factors to the specific industry context." *Id.* Generally, however, the first three of these factors will be "most important," and the ninth factor will be "of minimal consequence." *Id.* at 414, 414 n.12.

Here, there is no evidence that NCSHP has authority to hire, fire, supervise, or discipline Plaintiff Caraway (factors one and two). (ECF Nos. 137-12 at 101:6–102:11, 104:1-15, 105:20-25; 137-13 at 34:4-18, 39:16-18.) NCSHP does not provide her with any equipment or workplace (factor three), (ECF Nos. 137-12 at 102:9-10, 111:4-19; 137-13 at 45:9-16), or

training (factor six), (ECF Nos. 137-12 at 99:10-20; 137-13 at 37:12-16, 48:8-13). Caraway has never been assigned to perform work for NCSHP (factors five and eight), (ECF No. 137-12 at 93:7-16), and as a prison guard, her duties are not akin to duties of NCSHP's employees, which include managing implementation of the Plan (factor seven), (*see, e.g.*, ECF No. 137-2 at 69:23–70:8). There is no evidence NCSHP or Caraway intended to enter into an employment relationship (factor nine). (*See* ECF No. 137-12 at 93:7-16 ("The only employer I worked for in the last 27 years . . . was [DPS].").) Finally, while it is possible that NCSHP possessed some of Caraway's insurance records (factor four), she has failed to identify evidence in the record to support this inference.

Plaintiffs argue that NCSHP is an employer because it exercises "'control' over the health coverage relevant to this case." (ECF No. 188 at 18.) The guidepost identified in *Clackamas* and *Butler*, however, is not control over one aspect of employment, but rather "practical control of the employee." *Butler*, 793 F.3d at 414; *see Clackamas*, 538 U.S. at 448 ("[T]he relevant factors defining the master-servant relationship focus on the master's control *over the servant*." (emphasis added)). A joint employer need not have total control over all aspects of the employment; however, Plaintiffs have cited no legal authority to support that an entity's control over an individual's employment-based health insurance renders it the individual's employer where all nine factors identified in *Butler* weigh against finding joint employment.

Even taking all evidence in the light most favorable to Plaintiffs, they have failed to create a genuine issue of material fact as to whether NCSHP is Plaintiff Caraway's employer.

Accordingly, NCSHP will be granted summary judgment on Caraway's Title VII claim, and Caraway's motion for summary judgment will be denied as to this claim.

iii. DPS is liable under Title VII for providing the Plan to Caraway

DPS argues that it is entitled to summary judgment because (1) Caraway does not have standing to sue DPS and (2) Caraway cannot show that DPS caused her injuries under Title VII. (ECF No. 133.)

1. Caraway has standing to sue DPS

DPS first argues that Caraway's injuries are not fairly traceable to its conduct as required for standing because, pursuant to state law, DPS has no power to establish or implement the Plan. (ECF No. 133 at 8–22.)

Parties invoking federal jurisdiction bear the burden of establishing that they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)). Traceability requires a causal connection between the defendant's conduct and the plaintiff's injury, such that "there is a genuine nexus" between the two. *See Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 161 (4th Cir. 2000). "[T]he 'fairly traceable standard is not equivalent to a requirement of tort causation.'" *Hutton v. Nat'l Bd. of Exam'rs in Optometry, Inc.*, 892 F.3d 613, 623 (4th Cir. 2018) (quoting *Friends*, 204 F.3d at 161). At the summary judgment stage, "the plaintiff can no longer rest on . . . 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts,' which for purposes of the summary judgment motion will be taken to be true." *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

On March 10, 2020, this Court found that Plaintiffs had standing at the motion to dismiss stage to sue University Defendants notwithstanding standing arguments similar to those raised by DPS here. (ECF No. 45 at 7–10.) Although University Defendants could not dictate the Plan's terms, benefits, or exclusions under North Carolina law, this Court held that Plaintiffs' allegations that University Defendants hired Plaintiffs, offered the Plan to them, and participate in its availability provided a sufficient nexus between the alleged injuries and University Defendants to establish standing. (*Id.* at 8.) This traceability was "further bolstered" by allegations that University Defendants funded the Plan in part and played an active role in collecting erroneous payments and settling claims regarding health benefits. (*Id.* at 8–9.)

Here, Plaintiffs have submitted evidence that DPS is similarly involved in providing and administering the Plan. First, it appears undisputed that DPS "provides health care coverage to its employees through the NCSHP." (ECF Nos. 75 ¶ 18; 96 ¶ 18; 184 at 205:20-22; *see also* ECF No. 133 at 14 (arguing that DPS was "*require[d]* . . . to offer the [Plan] to [its] current and former employees." (citing § 135-48.42(a)).) Defendants agree that DPS "play[s] a role in getting eligible employees enrolled in the Plan" by providing employees with electronic registration forms and making available a Health Benefit Representative to help the employee enroll. (ECF No. 184 at 178:9–179:18 (NCSHP dep.), 220:7–221:16 (DPS dep.).) DPS then reviews an applicant's eligibility to confirm that she is either a new hire or has become a full-time employee. (*Id.* at 179:1-5.) A DPS employee can make changes to her health insurance benefits by filing a qualifying life event, which DPS must review and approve. (*Id.* at 211:15–212:22.) DPS additionally contributes $521.96 per month per employee to help

cover the cost of the Plan. (*Id.* at 54, 205:25–206:3, 207:6-10.) Plaintiff Caraway was made eligible for the Plan by virtue of her employment with DPS. (*Id.* at 177:10-19.) And Plaintiff was required by DPS to have health insurance and received coverage under the Plan as part of her compensation. (ECF Nos. 179-9 ¶ 16; 187-1 at 5–6.)

DPS argues that it "did not make the decision to exclude gender-confirming healthcare coverage" from the Plan nor has "any authority to choose a healthcare coverage option for its employees other than what was offered through the Plan." (ECF No. 133 at 17–18.) It describes the contacts with the Plan outlined above as "ministerial duties," the majority of which "are strictly dictated by statute." (*Id.* at 18.) As Plaintiffs correctly contend, however, there is no "ministerial" exception to the standing doctrine. (ECF No. 187 at 12 (citing *Nelson v. Warner*, 12 F.4th 376, 385 (4th Cir. 2021)).) In *Nelson*, the Fourth Circuit held that candidates who were placed second on election ballots based on party affiliation pursuant to West Virginia law suffered an injury that was fairly traceable to the conduct of state election officials who prepared the ballots in accordance with the statute. *Nelson*, 12 F.4th at 385; *see also Strickland v. Alexander*, 772 F.3d 876, 886 (11th Cir. 2014) ("[T]he fact that '[defendant's] duties are ministerial in nature' [does not] somehow render [plaintiff's] injury not fairly traceable to [defendant]."). Similarly here, DPS administers the Plan by providing it to its employees as part of their compensation, enrolling employees in the Plan, confirming their eligibility, approving qualifying life events, and partially funding the Plan. Thus, Plaintiff's injuries are fairly traceable to DPS's conduct, notwithstanding its contention that its role in administering the Plan is merely ministerial.

Additionally, the Court finds that Caraway has submitted sufficient evidence to demonstrate injury and redressability at the summary judgment stage. As this Court previously found with regard to Plaintiffs' Title IX claims, a favorable ruling on Caraway's Title VII claim could redress Caraway's injury through monetary or declaratory relief. (*See* ECF No. 45 at 9–10.) Thus, Caraway has sufficiently established standing to sue DPS.

2. Caraway was denied coverage because of her sex

To prevail under Title VII, a plaintiff must typically show that "the defendant's conduct did in fact cause the plaintiff's injury," *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013), meaning plaintiff's injury "would not have happened 'but for' the purported cause," *Bostock*, 140 S. Ct. at 1739. *But see id.* at 1740 (noting that "liability can sometimes follow even if sex *wasn't* a but-for cause of the employer's challenged decision" under the "motivating factor test"). The but-for test directs courts "to change one thing at a time and see if the outcome changes." *Id.* at 1739. But-for causation "can be a sweeping standard" because "[o]ften, events have multiple but-for causes." *Id.* "[A] defendant cannot avoid liability just by citing some *other* factor that contributed to its challenged employment decision." *Id.*

Discrimination against a transgender employee violates Title VII. *Id.* at 1741. The Supreme Court reasoned that an employer who "fires a transgender employee who was identified as a male at birth but now identifies as a female" but "retains an otherwise identical employee who was identified as female at birth . . . intentionally penalizes a person identified as male at birth for traits or actions that it tolerates in an employee identified as female at birth" in violation of Title VII. *Id.* Like with discrimination based on sexual orientation, "the

individual employee's sex plays an unmistakable and impermissible role in the discharge decision." *Id.* at 1741–42.

Here, a straightforward application of the but-for test supports that Caraway's birth-assigned sex was a but-for cause of her injury. Caraway received hormone treatments and surgery that aligned her physiology more closely with that of a stereotypical woman. Because Caraway was identified as a male at birth, the Plan and its administrators considered these treatments to be "leading to or in connection with sex changes or modifications and related care." (ECF No. 179-9 at 13.) If she was not assigned the sex of male of birth, then the treatments would not "change" or "modify" her sex, and they would not fall within the exclusion. Defendants have not submitted any admissible evidence to refute that these treatments were "medically necessary," and it appears both NCSHP and Blue Cross agree that they would have been covered in absence of the exclusion. (ECF Nos. 137-2 at 58:4-23, 72:4-6 (Jones dep.); 185-2 at 89–99; *see also* ECF No. 179-9 at 13 (citing only the exclusion as the reason Caraway's surgery was not covered).) Since the Plan covers some hormone treatments, (*see* ECF No. 197-9), and may cover breast augmentation, vaginal repair, or vaginal construction surgery that is not to treat "transsexualism" or "personal history of sex reassignment," (ECF No. 137-4 ¶ 21), it appears that Caraway would be able to receive the same or similar surgery if she had been identified as female at birth.

DPS does not dispute this straightforward application of the but-for test. Instead, it argues (similar to its standing argument above) that it did not "establish [or] implement" the Plan, and therefore its actions are not a but-for cause of Caraway's injury. (ECF No. 133 at 11.) But as discussed above, it is undisputed that DPS "provided" Plaintiff Caraway with

health insurance under the Plan as part of her compensation and performed various tasks to help implement the Plan. The fact that DPS did not create the Plan or decide what it covered is not dispositive. Put simply, if DPS had not provided Caraway with discriminatory health insurance, she would not have been injured. DPS's conduct is therefore a but-for cause of her injury.

DPS counters: but we had no choice! State law required DPS to provide Plaintiff with insurance under the Plan and forbade it from providing other or supplemental health insurance. But compliance with state law is no defense to a federal violation. U.S. Const. art. VI cl. 2; *Arizona v. United States*, 567 U.S. 387, 399 (2012) ("[S]tate laws are pre-empted . . . where compliance with both federal and state regulations is a physical impossibility.") (internal quotations omitted); *see, e.g.*, *Green v. Sch. Bd. of New Kent Cty.*, 391 U.S. 430, 432–33, 435 (1968) (prohibiting school boards from complying with state laws that mandated racial segregation in public schools in conflict with the Fourteenth Amendment). Moreover, the statutes creating the Plan expressly contemplated such a conflict and instructed DPS to eschew state law for federal law. *See* N.C. Gen. Stat. §§ 135-48.4 ("If any provision of this Article is in conflict with applicable federal law, federal law shall control to the extent of the conflict."), 135-48.42(a) ("*Except as otherwise required by applicable federal law*, new employees must be given the opportunity to enroll. . . ." (emphasis added)).

Thus, Caraway will be granted summary judgment on her Title VII claim against DPS, and DPS's motion for summary judgment will be denied as to this claim. The remaining issue of damages will be reserved for trial.

C. ACA

Lastly, NCSHP moves for summary judgment on Plaintiffs' claims arising under the ACA. (ECF No. 136.) Plaintiffs move for partial summary judgment on this claim, reserving the issue of damages for trial. (ECF Nos. 178; 179 at 4.)

The ACA provides that "an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 [or] title IX of the Education Amendments of 1972, . . . be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). The ACA explicitly incorporates Title VI and Title IX, and "[t]he Fourth Circuit looks to Title VII . . . to guide the 'evaluation of claims under Title IX.'" *Hammons v. Univ. of Md. Med. Sys. Corp.*, 551 F. Supp. 3d 567, 590 (D. Md. 2021), *reconsideration denied*, No. CV DKC 20-2088, 2021 WL 4951921 (D. Md. Oct. 25, 2021) (quoting *Grimm*, 972 F.3d at 616). The test announced in *Bostock* is therefore the appropriate test to determine whether a policy discriminates in violation of the ACA. *See id.* Thus, for the reasons identified in Section III.B.ii.2, *supra*, there is no genuine issue of material fact disputing that the Plan discriminated against Caraway on the basis of her sex.

NCSHP argues instead that it is not liable under the ACA because it is not a "health program or activity." (ECF No. 137 at 33–37.) The term is not defined in the statute. The U.S. Department of Health and Human Services ("HHS")—the federal agency tasked with promulgating regulations to implement this prohibition, *see* 42 U.S.C. § 18116(c)—initially interpreted "health program or activity" to include entities "principally engaged in providing or administering . . . health insurance coverage," among others. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31376, 31467 (May 18, 2016). In June 2020, however,

HHS revised its rules. Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority, 85 Fed. Reg. 37160, 37244–45 (June 19, 2020) (codified at 45 C.F.R. § 92.3(b), (c)). Its current interpretation expressly excludes "entit[ies] principally or otherwise engaged in the business of providing health insurance" from the definition of "health program or activity." 45 C.F.R. § 92.3(c).

Various litigants have challenged HHS's changed interpretation of the statute as arbitrary and capricious, and the question remains pending in multiple federal courts. *See, e.g., Boston All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Hum. Servs.*, 557 F. Supp. 3d 224, 237–39 (D. Mass. 2021). These courts have stayed proceedings as "HHS's efforts to reconsider the 2020 Rule are underway," the Department "intends to issue a Notice of Proposed Rulemaking in early 2022," and its actions "provide every indication that it is preparing to initiate a wholesale revision of the 2020 Rule." *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. CV 20-1630 (JEB), 2021 WL 4033072, at *3 (D.D.C. Sept. 3, 2021).

It appearing to the Court that the agency interpretation at issue may change or be enjoined before trial is set to commence in this case on July 5, 2022; that resolution of this issue in this case could have nation-wide implications; that Plaintiffs will receive the declaratory and injunctive relief they seek by virtue of this Order and will therefore not be prejudiced by a delay in resolving this issue; and that discovery has closed and motion practice has ended, meaning NCSHP will not be prejudiced by a delay in resolving this issue; the Court, therefore, will reserve judgment on this portion of Defendant's motion pending further Order from this Court.

D. Permanent injunction

Plaintiffs seek a permanent injunction. (ECF No. 75 ¶ B.) "[A] plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156 (2010). Plaintiffs must demonstrate: (1) irreparable injury; (2) inadequacy of available remedies at law, such as monetary damages; (3) an injunction is warranted after "considering the balance of hardships between the plaintiff and defendant"; and (4) "that the public interest would not be disserved by a permanent injunction." *Id.* at 156–57. Permanent injunctions are particularly appropriate in discrimination cases to prevent continued discrimination. *See Albemarle Paper Co. v. Moody*, 422 U.S. 405, 417 (1975) (noting that the "primary objective" of Title VII "was a prophylactic one" to "remove barriers that have operated in the past").

Here, Plaintiffs have shown that they will require continued medical care to treat their gender dysphoria and that, barring judicial or legislative intervention, NCSHP intends to maintain the exclusion. (ECF No. 185-2 at 83 (Folwell) (vowing to maintain the exclusion "[u]ntil the court system, a legislative body or voters tell us that we 'have to,' 'when to,' and 'how to' spend taxpayers' money on sex change operations").) The exclusion has and will continue to force Plaintiffs and others delay or forgo medically necessary treatments, since most do not have funds available to pay for treatments out of pocket and then be reimbursed through monetary damages. These significant hardships faced by Plaintiffs outweigh the minimal hardship on Defendants, particularly given that Defendants and their third-party administrators were able to identify and cover medically necessary care in 2017. Finally, an injunction is likely to cost the public substantially less than awarding damages after-the-fact,

since NCSHP can negotiate lower prices than individual members can negotiate while paying out of pocket.

Prohibitory injunctions that "aim to maintain the status quo and prevent irreparable harm" are favored over mandatory injunctions that "alter the status quo." *League of Women Voters of N.C. v. North Carolina*, 769 F.3d 224, 235–36 (4th Cir. 2014) (discussing preliminary injunctions). The status quo is "the last uncontested status between the parties which preceded the controversy." *Id.* at 236 (quoting *Pashby v. Delia*, 709 F.3d 307, 320 (4th Cir. 2013)). A plaintiff who seeks to enjoin enforcement of a new policy and "require a party who has recently disturbed the status quo to reverse its actions" seeks a prohibitory injunction, not a mandatory one. *Id.*; *see also Disability Rts. S.C. v. McMaster*, 564 F. Supp. 3d 413, § IV.A (D.S.C. 2021) (finding that the status quo in was "the position of the parties prior to the enactment of" the challenged policy), *vacated in part on other grounds*, 24 F.4th 893 (4th Cir. 2022).

Here, the last uncontested status between the parties existed during 2017, when Defendants covered medically necessary services for the treatment of gender dysphoria. Thus, Plaintiffs' request to enjoin enforcement of the exclusion and reimpose the uncontested 2017 rule seeks a prohibitory injunction. This Court finds that reimposing the 2017 rule is the appropriate remedy.

Accordingly, the Court will permanently enjoin Defendants Folwell and Jones, *in their official capacities*, from enforcing the Plan's exclusion and order them to reinstate coverage for "medically necessary services for the treatment of gender dysphoria."

IV. MOTIONS TO SEAL

Finally, Plaintiffs seek to seal portions of expert reports that describe in detail Plaintiffs' experiences with gender dysphoria and transition, to include portions of Dr. George Richard Brown's report, filed in support of their motion for summary judgment, (ECF No. 182), and portions of Dr. Lappert's report, filed in support of their *Daubert* motion to exclude his testimony, (ECF No. 210).

A motion to seal "presents the seeming tension between several legitimate interests." *Va. Dep't of State Police v. Washington Post*, 386 F.3d 567, 574 (4th Cir. 2004). On one hand, the public has a right, derived from both common law and the First Amendment, "of public access to documents or materials filed in a district court." *Id.* at 575. On the other hand, individuals have an interest in keeping sensitive medical information private. *Watson v. Lowcountry Red Cross*, 974 F.2d 482, 487 (4th Cir. 1992); *Boone v. Bd. of Governors of Univ. of N.C.*, 395 F. Supp. 3d 657, 665 (M.D.N.C. 2019), *aff'd*, 858 F. App'x 622 (4th Cir. 2021). Congress and the State of North Carolina have recognized the significance of an individual's interest in keeping medical information private, *see* 42 U.S.C. § 1320d-6(a); N.C. Gen. Stat. § 58-2-105(a), and the Fourth Circuit has held that such information "should receive scrupulously confidential treatment" when it concerns subject matter that faces public stigma, *Watson*, 974 F.2d at 487.

A. Dr. Brown's report (ECF No. 182)

When the subject of the motion to seal is documents attached to a summary judgment motion in a civil case, "the more rigorous First Amendment standard" governs the court's analysis. *Washington Post*, 386 F.3d at 576 (quoting *Rushford v. New Yorker Mag., Inc.*, 846 F.2d 249, 253 (4th Cir. 1988)). Under this standard, "a district court may restrict access 'only on

the basis of a compelling governmental interest, and only if the denial is narrowly tailored to serve that interest.'" *Id.* at 575 (quoting *Stone v. Univ. of Md. Med. Sys. Corp.*, 855 F.2d 178, 180 (4th Cir. 1988)). "Public access serves to promote the trustworthiness of the judicial process, to curb judicial abuses, and to provide the public with a more complete understanding of the judicial system, including a better perception of fairness." *Doe v. Pub. Citizen*, 749 F.3d 246, 266 (4th Cir. 2014). "Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like a fiat and requires rigorous justification." *Id.* Thus, before granting a motion to seal, a court must "(1) provide public notice of the sealing request and a reasonable opportunity for the public to voice objections to the motion; (2) consider less drastic alternatives to closure; and (3) . . . state its reasons—with specific findings—supporting closure and its rejections of less drastic alternatives." *Id.* at 272.

Here, Plaintiffs' motion to seal has been publicly docketed since its date of filing on December 20, 2021. (ECF No. 182.) Thus, the public has had ample notice and opportunity to oppose the motion. Plaintiffs seek to seal medical information of the most intimate and sensitive nature concerning their struggles with, and treatment of, gender dysphoria, often during adolescence. (*Id.*) Gender dysphoria and transition remains highly stigmatized, lending greater weight to Plaintiffs' argument that there is a compelling interest to keep this information private. *Watson*, 974 F.2d at 487. The Court is also concerned that denying Plaintiffs' motion could have a chilling effect on future litigants who want to challenge unlawful discrimination but do not want their personal and private medical history put on display. Defendants, who have full access to an unredacted copy of Brown's report, will not be prejudiced by granting Plaintiffs' motion, and no member of the public has requested

access. Further, the only piece of evidence relied upon by this Court in this Order which Plaintiffs seek to seal is Brown's testimony that each Plaintiff has been diagnosed with gender dysphoria—a fact that is repeated in Plaintiffs' unredacted declarations, discussed in this Order, and not disputed by Defendants. Thus, the Court finds Plaintiffs' privacy interest outweighs the public's limited interest in learning the private medical details of Plaintiffs' experiences with gender dysphoria. Finally, the Court finds that there are no alternatives to closure, and Plaintiffs' request to seal only small portions of Browns' testimony is narrowly tailored to the compelling interest discussed herein.

Plaintiffs' motion will be granted.

B. Dr. Lappert's report (ECF No. 210)

When the motions sought to be sealed are in connection with an evidentiary motion rather than a motion seeking dispositive relief, "the right of access at issue arises under the common law." *Lord Corp. v. S & B Tech. Prods., Inc.*, No. 5:09-CV-205-D, 2012 WL 895947, at *1 (E.D.N.C. Mar. 15, 2012); *see generally Washington Post*, 386 F.3d at 576–77 (holding that the First Amendment attached to dispositive motions in civil cases). "The common law presumes a right of the public to inspect and copy all judicial records and documents." *Washington Post*, 386 F.3d at 575 (internal quotations omitted) (citing *Nixon v. Warner Comm., Inc.*, 435 U.S. 589, 597 (1978)). However, "[t]he distinction between the rights of access afforded by the common law and the First Amendment is 'significant.'" *Id.* (quoting *In re Baltimore Sun Co.*, 886 F.2d 60, 64 (4th Cir. 1989)). The common law "does not afford as much substantive protection to the interests of the press and the public" or "as much access . . . as does the First Amendment." *Id.* Thus, the presumption of access "can be rebutted if countervailing interests heavily

outweigh the public interest in access." *Id.* "[T]he party seeking to overcome the presumption bears the burden of showing some significant interest that outweighs the presumption." *Id.* (quoting *Rushford*, 846 F.2d at 253).

Here, the information contained in Lappert's report is marked "CONFIDENTIAL" and is similar to the sensitive medical information discussed by Brown. Lappert does not state any expert opinions in this section that are admissible, *see* Section II.D.ii, *supra*, further reducing the public's right of access. And, as above, no member of the public has requested access, and Defendants have access to an unredacted copy of their own expert's report. Thus, the Court finds that, under the more deferential common law standard, Plaintiffs' interest in privacy heavily outweighs the public's interest in access.

Thus, Plaintiffs motions to seal will be granted.

CONCLUSION

Issues surrounding transgender healthcare evoke strong emotional and political opinions. *See Grimm*, 972 F.3d at 594 ("[M]any of us carry heavy baggage into any discussion of gender and sex."). But politics and emotion are not admissible as evidence in a court of law. Plaintiffs' doctors, their experts, every major medical association, and Defendants' own third-party administrators all agree that, in certain cases, gender affirming medical and surgical care can be medically necessary to treat gender dysphoria. Defendants attempt to create scientific controversy in this uniform agreement through experts who mix their scientific analysis with hypothetical speculation and political hyperbole. Only science that is relevant, reliable, and offered by a qualified expert is admissible, however, and the admissible portions of Defendants' expert's testimony, even when taken in the light most favorable to Defendants,

do not justify the exclusion at issue. Defendants' belief that gender affirming care is ineffective and unnecessary is simply not supported by the record. Consequently, their categorical sex- and transgender-based exclusion of gender affirming treatments from coverage unlawfully discriminates against Plaintiffs in violation of the U.S. Constitution and Title VII.

For the reasons stated herein, the Court enters the following:

ORDER

IT IS THEREFORE ORDERED that DPS's Motion for Summary Judgment, (ECF No. 132), is **DENIED.**

IT IS FURTHER ORDERED that Plan Defendants' Partial Summary Judgment, (ECF No. 136), is **GRANTED** in part and **JUDGMENT IS RESERVED** in part. It is **GRANTED** as to Plaintiff Caraway's claim arising under Title VII against NCSHP. **JUDGMENT IS RESERVED** regarding Plaintiffs' claims arising under the ACA pending further Order from this Court.

IT IS FURTHER ORDERED that Plaintiffs' Motion for Summary Judgment, (ECF No. 178), is **GRANTED** in part, **DENIED** in part, and **JUDGMENT IS RESERVED** in part. It is **GRANTED** with respect to Plaintiffs' claims arising under the Equal Protection Clause and Plaintiff Caraway's claim arising under Title VII against DPS. Defendants Folwell and Jones*, in their official capacities*, are **PERMANENTLY ENJOINED** from enforcing the Plan's exclusion and are **ORDERED** to reinstate coverage for "medically necessary services for the treatment of gender dysphoria." The motion is **DENIED** as to Caraway's Title VII claim against NCSHP. **JUDGMENT IS RESERVED** regarding Plaintiffs' claims arising

under the ACA pending further Order from this Court. The issue of damages is reserved for trial.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Seal Exhibits to Plaintiffs' Motion for Summary Judgment, (ECF No. 182), is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Peter Robie, (ECF No. 202), is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul W. Hruz, (ECF No. 204), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Paul R. McHugh, (ECF No. 206), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Dr. Patrick W. Lappert, (ECF No. 208), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

IT IS FURTHER ORDERED that Plaintiff's Motion to Seal portions of Dr. Lappert's report, (ECF No. 210), is **GRANTED.**

IT IS FURTHER ORDERED that Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D., (ECF No. 212), is **GRANTED** in part and **DENIED** in part in accordance with this Memorandum Opinion and Order.

This, the 10th day of August 2022.

/s/ Loretta C. Biggs
United States District Judge