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

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. PATRICK W. LAPPERT

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Plaintiffs respectfully submit this memorandum of law in support of their motion to exclude the expert testimony of Dr. Patrick W. Lappert.

INTRODUCTION[1]

Dr. Lappert holds himself out as being board-certified in both plastic surgery and general surgery. He is neither: his certification in plastic surgery lapsed in 2018, and he has not been board-certified in surgery since ***2002***. Moreover, in his entire career, Dr. Lappert has never performed a single surgical procedure to treat gender dysphoria—which is not surprising, since he considers those procedures to be "intentional mutilation" and "child abuse." Dr. Lappert has no reliable basis to opine about gender-affirming surgery, and his purported expert opinions about those procedures should be excluded.

And Dr. Lappert's opinions outside of surgery are even more ripe for exclusion. Straying far afield from his surgical experience, Dr. Lappert gives a smorgasbord of opinions that he is not qualified to provide, and for which he has no basis. For example, he criticizes how organizations like the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society have developed guidelines for diagnosis and treatment of gender dysphoria, despite admitting that he does not know the first thing about how those guidelines were created. He speculates about whether puberty-blocking treatment is appropriate for adolescents, even though he is not an endocrinologist and he admits "that's not [his] area of expertise." He criticizes the process by which patients are

[1] Unless otherwise noted, all emphasis is added, and all citations, alterations, and ellipsis are omitted. Exhibits referenced herein are attached to the concurrently-filed Declaration of Dmitriy Tishyevich.

diagnosed with gender dysphoria, despite admitting that he has "very limited psychiatric / psychological knowledge," is not "a licensed mental healthcare provider of any kind," and is not qualified to make this diagnosis himself. And he also offers rank speculation about patients with gender dysphoria who "detransition" or experience "regret," even though he concedes he has no reliable data to quantify these phenomena. These and other of Dr. Lappert's many non-surgery opinions are both unreliable and irrelevant, and they should all be excluded accordingly.

Dr. Lappert's deposition also made clear that he is certainly not a dispassionate expert who will offer neutral "specialized knowledge" to "help the trier of fact to understand the evidence," as Rule 702 contemplates. Far from it. In addition to calling gender-affirming surgery "intentional mutilation," Dr. Lappert says that parents who talk to their children about gender identity issues are "sexualizing them" and "grooming" them for abuse. He accuses doctors who provide gender-affirming treatment of being part of a "Transgender Treatment Industry" cabal—a term that he concedes is certainly not "commonly used" in his professional field, and is instead "idiosyncratic" to his report. He has given inflammatory presentations on gender-affirming surgery, opining that performing these surgeries is a "moral violation" for physicians and that "changing a person's sex is a lie." He tours the country, urging state legislatures to outlaw gender-affirming treatment for minors. And he also thinks that states should "criminally prosecute doctors" that provide this critically-needed treatment—even though ***every*** reputable

medical organization in the country, including his own professional society, has said that such treatment is medically necessary and appropriate.

Even if Dr. Lappert's opinions were reliable under Rule 702 (and they are not), and even if they had any minimal probative value (and they do not), that value would be far outweighed by unfair prejudice and confusion of the issues under Rule 403. For these reasons, and as explained below, all of Dr. Lappert's opinions should be excluded.

LEGAL STANDARD

Federal Rule of Evidence 702 places "a special gatekeeping obligation" on the trial court to ensure that an expert's testimony is "relevant to the task at hand" and "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993); *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281 (4th Cir. 2021). As the Fourth Circuit recently reaffirmed, "the importance of the gatekeeping function cannot be overstated." *Sardis*, 10 F.4th at 283.

"The proponent of the testimony must establish its admissibility by a preponderance of proof." *Mod. Auto. Network, LLC v. E. All. Ins. Co.*, 416 F. Supp. 3d 529, 537 (M.D.N.C. 2019). The first step is to determine if the expert is qualified to give the proffered opinion, which requires examining the expert's professional qualifications and "full range of experience and training." *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012). If the expert is not qualified, the testimony should be excluded. *See SMD Software, Inc. v. EMove, Inc.*, 945 F. Supp. 2d 628, 639 (E.D.N.C. 2013).

Even if the expert is qualified, the court must consider the relevancy of the expert's testimony as "a precondition to admissibility." *Sardis*, 10 F.4th at 282. To be relevant, the testimony must have "a valid scientific connection to the pertinent inquiry." *Id.* at 281. "If an opinion is not relevant to a fact at issue, *Daubert* requires that it be excluded." *Id.*

The opinion must also be based on a reliable foundation, with the inquiry focusing on the expert's "principles and methodology" to assess whether it is "based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Id.* at 281-82. In evaluating reliability, courts consider, among other things, whether: (1) the theory "can be and has been tested"; (2) has been "subjected to peer review and publication"; (3) "the known or potential rate of error"; and (4) "whether the technique is generally accepted in the scientific community." *Id.* at 281.

When an expert relies upon experience and training rather than a specific methodology, the application of the *Daubert* factors is more limited. *See Freeman v. Case Corp.*, 118 F.3d 1011, 1016 n.6 (4th Cir. 1997). In those cases, courts consider: "1) how the expert's experience leads to the conclusion reached; 2) why that experience is a sufficient basis for the opinion; and 3) how that experience is reliably applied to the facts of the case." *SAS Inst., Inc. v. World Programming Ltd.*, 125 F. Supp. 3d 579, 589 (E.D.N.C. 2015).

Finally, the Fourth Circuit has cautioned that although the trial court has "broad latitude" to determine reliability, it must still engage in the gatekeeping process and not simply "delegate the issue to the jury." *Sardis*, 10 F.4th at 281. Even rigorous cross-

examination is not a substitute for the court's gatekeeping role. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017).

ARGUMENT

I. Dr. Lappert Is Not Qualified to Offer Any of His Purported Opinions.

An expert witness must have "knowledge, skill, experience, training, or education" that would assist the trier of fact. *Kopf v. Skyrm*, 993 F.2d 374, 377 (4th Cir. 1993). "[Q]ualifications alone do not suffice," however. *Clark v. Takata Corp.*, 192 F.3d 750, 759 n.5 (7th Cir. 1999); *Patel ex rel. Patel v. Menard, Inc.*, 2011 WL 4738339, at *1 (S.D. Ind. Oct. 6, 2011). Even "a supremely qualified expert cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method and are reliable and relevant." *Clark*, 192 F.3d at 759 n.5.

Moreover, "an expert's qualifications must be within the same technical area as the subject matter of the expert's testimony; in other words, a person with expertise may only testify as to matters within that person's expertise." *Martinez v. Sakurai Graphic Sys. Corp.*, 2007 WL 2570362, at *2 (N.D. Ill. Aug. 30, 2007); *Lebron v. Sec. of Fla. Dept. of Children and Families*, 772 F.3d 1352, 1369 (11th Cir. 2014).

Importantly, this qualification inquiry is subject-specific, because "[g]eneralized knowledge of a particular subject will not necessarily enable an expert to testify as to a specific subset of the general field of the expert's knowledge." *Martinez*, 2007 WL 2570362, at *2. "For example, no medical doctor is automatically an expert in every medical issue merely because he or she has graduated from medical school or has achieved

certification in a medical specialty." *O'Conner v. Commonwealth Edison Co.*, 807 F. Supp. 1376, 1390 (C.D. Ill. 1992), *aff'd*, 13 F.3d 1090 (7th Cir. 1994). Dr. Lappert fails these requirements, for reasons below.

A. Dr. Lappert Has Never Performed Gender-Affirming Surgery and Is Not Qualified to Opine on Such Procedures.

Dr. Lappert's report represents that he is "Board Certified in Surgery and Plastic Surgery." (Ex. 1 at 1.) This is not true. As he admitted, his "plastic surgery board certificate expired at the end of 2018." (Ex. 2 at 23.) His "board certification in surgery" expired "in 2002"; thus, he has not "been board-certified in surgery" for "over nineteen years." (*Id.* at 31-32.)

These are not trivial fibs, because physicians are not allowed to hold themselves out as board-certified unless they actually have a ***current*** board certificate. The American Board of Plastic Surgeons unequivocally prohibits such misrepresentations, stating that "when a physician misrepresents certification status," as Dr. Lappert did here, "ABPS may notify local credentialing bodies, licensing bodies, law enforcement agencies, and others." (*Id.* at 30; Ex. 3 at 3.) And the American Board of Surgery takes a similarly dim view of such misrepresentations, as Dr. Lappert also acknowledged. (Ex. 2 at 32 (agreeing it does not "surprise [him] that the [ABS] does not allow doctors to represent that they are board-certified in surgery unless they have a current board certificate.").)

Setting aside these misrepresentations about his credentials, Dr. Lappert is also not qualified to give expert opinions about gender-affirming surgery for a more basic reason: he has never even performed a single such procedure. He admitted that he has "never

performed facial feminization surgery" or "facial masculinization surgery" for any transgender patient. (*Id.* at 167.) The same is true for "transfeminine top surgery" and "chest reconstruction surgery." (*Id.* at 167.) He has also never "performed a vaginoplasty" nor "metoidioplasty." (*Id.* at 167-68.) In short, Dr. Lappert has "***never*** performed ***any kind*** of gender-affirming surgery in transgender patients." (*Id.* at 168; *id.* at 151 ("I have never treated a patient with gender dysphoria surgically.").) He was also emphatic that he would never perform such surgeries, because he personally does not "see them as beneficial" and thinks that they are "incorrect treatments." (*Id.* at 150.)

Dr. Lappert has not published any research on gender-affirming surgery either. He agreed that he has "not published any original research in peer-reviewed literature within the ***last 23 years***" at all—and of the six total articles that he did publish a quarter-century ago, not one was on gender-affirming surgeries for patients with gender dysphoria. (*Id.* at 129; *see id.* at 130-134.)

As a substitute for first-hand experience, Dr. Lappert cites a handful of studies in his report about supposed complications from gender-affirming surgery. But reading studies does not make one an expert. That is just the sort of "generalized knowledge of a particular subject" that courts have rejected as a qualification under Rule 702. *Martinez*, 2007 WL 2570362, at *2. As with the disqualified expert in *Lebron* who "reached his opinion . . . by relying on studies," reading literature is not enough. 772 F.3d at 1369.

It is also telling that the Code of Ethics of the American Society of Plastic Surgeons ("ASPS") prohibits members from giving this kind of unfounded testimony.[2] Section IV of that Code of Ethics says that "to help limit false, deceptive and/or misleading testimony, Members serving as expert witnesses ***must***: 1. Have ***recent and substantive experience*** (as defined in the Glossary of the Code) in the area in which they testify[.]" (Ex. 4 at 6.) The Glossary, in turn, defines "recent and substantive experience" to mean (among other requirements) that the member "has performed the specific procedure in question within three (3) years of the date of being retained as an expert witness." (*Id.* at 8.)

Dr. Lappert fails these requirements. Far from having actually performed any of the gender-affirming procedures that he criticizes in his report (*see* Ex. 1 at 29-39)—***ever***, let alone within the last three years—Dr. Lappert was emphatic that he would never perform such surgeries because he does not "see them as beneficial." (Ex. 2 at 150.) To be sure, the ASPS Code of Ethics is not a substitute for the Court's Rule 702 inquiry. But the fact that the ASPS prohibits members from providing these kinds of ill-informed expert opinions precisely to "help limit false, deceptive, and/or misleading [expert] testimony" from being offered in court (Ex. 4 at 6) should give the Court serious pause, to say the least, about allowing Dr. Lappert's testimony.

[2] Dr. Lappert resigned from ASPS around the time his board certification lapsed (Ex. 2 at 100-101), but he was a member from 1997 to 2017, and he agreed that ASPS is a "reputable organization" to which "93 or so percent of all plastic surgeons" in the country belong. (*Id.* at 102-103.)

B. Dr. Lappert Has No Basis to Offer Opinions on Topics Outside of Plastic Surgery.

Dr. Lappert also offers a grab-bag of opinions on topics far outside his field of plastic surgery—including endocrinology (*e.g.*, opining whether puberty-blocking agents and cross-sex hormones like testosterone are appropriate treatments for gender dysphoria), psychiatry (*e.g.*, criticizing how patients are diagnosed with gender dysphoria), and more.

Dr. Lappert has no qualifications or any other basis to give any of these opinions, and they all should be excluded. For example, he has no basis to opine about purported risks of puberty-blocking treatments, given that he agreed that he is "not an endocrinologist" and has "no specialized training or expertise in endocrinology." (Ex. 2 at 153, 204.) He also has "never prescribed any puberty-blocking drugs of any kind"; and indeed, he admitted: "I ***do not*** consider myself an expert in that area" and "that's not my area of expertise." (*Id.* at 201, 203.)

The same is true for Dr. Lappert's opinions on cross-sex hormone treatments—given that he admits that he has "never prescribed cross-sex hormones for treatment of gender dysphoria," and that he has "no firsthand experience with advising [his] patients about potential risks and benefits" of such treatment. (*Id.* at 214.) Here, again, Dr. Lappert conceded that he does not "hold [himself] out as an expert in endocrinology," and that he does not plan to offer "any expert opinions in endocrinology in this case because that's outside [his] scope of expertise." (*Id.* at 204.) All of his purported opinions related to endocrinology should be excluded accordingly.

Dr. Lappert also has no qualifications—or any other basis—to opine about diagnosis or treatment of mental conditions. He admits that he has "very limited psychiatric/psychological knowledge"; he is "not a psychiatrist" or "a licensed mental healthcare provider of any kind"; and in his "professional day-to-day practice," he "do[es] not diagnose mental health conditions of any kind." (*Id.* at 68, 153-54.)[3] Thus, as Dr. Lappert conceded, "for any patient that presents to [him] with a mental health condition," he would "send them to someone who is . . . trained in how to diagnose mental health conditions."). (*Id.* at 157.) And after all of these admissions, he also conceded that he "do[es] not hold [himself] out as an expert in ***diagnosing*** mental health conditions outside, potentially, of body dysmorphic disorder," and that he also does "not have special[ized] training or expertise in ***treating*** mental health conditions." (*Id.* at 75.)

In short, while Dr. Lappert does not even have the relevant expertise to opine about gender-affirming surgery, he certainly does not have the expertise to "waltz into the courtroom" and mislead a factfinder with purported expert testimony about endocrinology, psychiatry, or anything else. *See Clark*, 192 F.3d at 759 n.5. So at the very least, all of his opinions outside of plastic surgery should be excluded.

[3] Dr. Lappert said he feels qualified to identify a potential diagnosis of body dysmorphia, and to then "offer referral for psychiatric/psychological support and evaluation" to those patients. (Ex. 2 at 72.) Body dysmorphic disorder is a distinct condition from gender dysphoria, however, that "is primarily characterized by an excessive preoccupation with a perceived defect or flaw in appearance that others cannot see or would judge as slight in appearance." (Ex. 17 at 1; Ex. 2 at 71 ("They see a defect that you don't see.").)

II. Dr. Lappert's Opinions on Topics Outside of Gender-Affirming Surgery Do Not "Fit" the Disputed Issues, Are Unreliable, Or Both.

An expert's 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. & Prod. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018).

Even if the testimony is reliable, the court must still "satisfy itself that the proffered testimony is relevant to the issue at hand, for that is a precondition to admissibility." *Sardis*, 10 F.4th at 282. "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).

This case turns on whether Defendants' exclusion of coverage for gender-confirming health care treatments violates Plaintiffs' rights under the equal protection clause, Title VII, and Section 1557 of the Affordable Care Act. Many of Dr. Lappert's opinions are both unreliable and irrelevant to this inquiry, as described below.

A. Far from Being Generally Accepted, Dr. Lappert's Opinions Have Been Rejected by the Scientific Community.

General acceptance is a reliability factor, *Nease*, 848 F.3d at 229, and the fact that a particular theory "has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594. Dr. Lappert asserts that gender-affirming surgical and hormonal treatments "have not been accepted by the relevant

scientific communities" (Ex. 1 at 40), but this is not true. In fact, it is Dr. Lappert's opinions that are on the scientific fringe, to say the least.

Another court found as much just last year in addressing a challenge to Arkansas' state-law ban on gender-affirming treatment for minors, where Dr. Lappert had offered virtually identical opinions to support that ban. *Brandt v. Rutledge*, 4:21-cv-450 (E.D. Ark.); Ex. 2 at 33-34; Ex. 5 (Lappert *Brandt* Declaration). In *Brandt*, Dr. Lappert asserted that "'[g]ender affirming' treatments are experimental," which he agreed was "basically the same opinion that [he] offered in this case." (Ex. 2 at 35.) Drs. Hruz and Levine had also submitted similar declarations in *Brandt* in support of the ban. (*See id.* at 33-34.)

The *Brandt* court preliminarily enjoined the ban on August 2, 2021 (Ex. 6), squarely rejecting these opinions. That court recognized that "the consensus recommendation of medical organizations is that the ***only*** effective treatment for . . . gender dysphoria is to provide gender-affirming care," citing briefs from organizations like the American Medical Association, American Academy of Pediatrics, and many more. (*Id.* at 6 n.3; Br. of Am. Med. Ass'n, et al. (ECF No. 131 (expressing same views in this case).) *Brandt* also found that "gender-affirming treatment is supported by medical evidence that has been subject to rigorous study," and that "***every*** major expert medical association recognizes that gender-affirming care for transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people." (Ex. 6 at 7-8.)

As Dr. Lappert admitted, *Brandt*'s findings were "contrary to the opinions that [he] offered." (Ex. 2 at 39.) And as he also agreed, "every major expert medical association

disagrees with [him] because they've all taken [the] position that this treatment is in fact medically necessary." (*Id.* at 40; *see also id.* (agreeing the same is true regarding Drs. Hruz and Levine).) In fact, Dr. Lappert admits that there are at least "18 different professional medical organizations" that "take[] the view that's contrary to the opinions that [he] and Dr. Hruz and Dr. Levine are offering" here, testifying that "there's a consensus of consensus on this, exactly." (*Id.* at 42.)

That consensus also includes Dr. Lappert's own former association, the ASPS. While he says that gender-affirming surgery is experimental, the ASPS said the exact opposite in a February 2021 statement—stating that it "***firmly believes*** that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be," and promising to "continue its efforts to advocate across state legislatures for full access to medically necessary transition care." (Ex. 8 at 3.) So as Dr. Lappert admitted, the ASPS also "does not agree with [his] opinions that gender-affirming surgery is experimental." (Ex. 2 at 112-13.)

And it is not just professional medical associations either. ***Every major insurer*** in the country also says that gender-affirming surgical and hormonal treatments are medically necessary, as Dr. Lappert also admitted. (Ex. 2 at 334-38 & Ex. 9 at 2 (BCBS North Carolina policy, stating that "[s]ervices for gender affirming surgery and hormone therapy may be considered medically necessary when the criteria below are met"); Ex. 2 at 427-28 & Ex. 10 at 1 (similar for Aetna); Ex. 2 at 430-33 & Ex. 11 (similar for Cigna); Ex. 2 at 434-39 & Ex. 12 (similar for UnitedHealthCare).)

In short, this overwhelming consensus confirms that far from being generally accepted, Dr. Lappert's opinions are fringe and unreliable.

B. Dr. Lappert's Critiques of WPATH, Endocrine Society Guidelines, DSM-V, and Other Organizations' Positions Are Unreliable.

Aware that his views are contrary to those of every major medical society and professional organization, Dr. Lappert tries to dismiss every single one of them as partisan—part of the same supposed "Transgender Treatment Industry" that he crusades against. For example, he contends that the "WPATH, APA, AAP," and "AMA" all supposedly rely on a "non-scientific" methodology, and that the guidelines and position statements issued by every one of those organizations are "political" and are "not the product of a reliable scientific method." (Ex. 1 at 10-11.)

These opinions are—again—not generally accepted, to put it mildly. Just recently, the Fourth Circuit confirmed that the WPATH guidelines in particular "represent the consensus approach of the medical and mental health community" and "have been recognized by various courts, including [the Fourth Circuit], as the authoritative standards of care." *Grimm v. Gloucester Cty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020). "There are ***no*** other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups," in fact. *Id.* at 595-596.

Dr. Lappert's deposition further confirmed that his critiques are baseless *ipse dixit* because he admitted that he has no idea how any of these standards of care were actually developed, and on what scientific basis. Take WPATH SOC Version 7 ("WPATH7"), for example. Dr. Lappert admits that he has "not been involved with the development" of

WPATH7; he does not "know what kind of scientific literature [review] the WPATH conducted as part of drafting" WPATH7; he does not know what kind of "peer review" or "outside experts" or "public comments" the WPATH may have relied on in developing WPATH7, or how many "different drafts" the WPATH7 went through, or "what may have gone on during [WPATH] meetings or conferences" to discuss the development of WPATH7. (Ex. 2 at 184-87.) And after these admissions, Dr. Lappert unsurprisingly conceded that he is "***not an expert*** in how Version 7 of the WPATH was developed." (*Id.* at 188.) The same is true for WPATH SOC Version 8. (*Id.* at 189 (agreeing he does not "hold [himself] out as an expert on how Version 8" is being developed).)

The same is also true with respect to Dr. Lappert's critiques of other standards of care and position statements:

- Endocrine Society Guidelines for Treatment of Gender Dysphoria: Dr. Lappert does not know when these guidelines "were initially published" or "last revised"; he was "not involved with the[ir] development"; he does not know "what kind of scientific literature review" went into that development; thus, he agrees he is "***not an expert*** in how the Endocrine Society developed the original 2009 guidelines" or "the 2017 updates" (Ex. 2 at 195-200);

- DSM-5: Dr. Lappert has "not been involved with the development of DSM-5"; does not know "what kind of scientific literature review was done" during that development; does not know what went on during "different meetings or conferences" to "discuss that development"; thus, he "do[es] ***not*** have expert firsthand knowledge of how the DSM-5 was developed" (*id.* at 190-93);

- AMA Position Statement on Gender-Affirming Treatment: Dr. Lappert "do[es] not know how the AMA came to issue this consensus statement" and has "no personal knowledge what scientific literature they reviewed"; thus, he has "***no idea*** . . . how the AMA came to reach this consensus statement" (*id.* at 47-48);

- American Academy of Pediatrics Position Statement on Gender-Affirming Treatment: has no "personal knowledge" of how the AAP adopted this statement (*id.* at 48).

In the end, Dr. Lappert agreed more broadly that he does "not have firsthand knowledge of how ***any*** of those organizations came to reach these positions," and that he "do[es] not know what scientific literature they relied on." (*Id.* at 49-50.) He should not be allowed to mislead a factfinder with these unfounded *ipse dixit* critiques. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

C. Dr. Lappert's Opinions About the Need for Randomized Clinical Trials Are Unreliable.

A key component of Dr. Lappert's opinions is that surgical and hormone gender-affirming treatments are supposedly experimental because they are unsupported by results from randomized clinical trials ("RCTs"). (*See, e.g.*, Ex. 1 at 5 (arguing that "properly conducted [RCTs] and long-term treatment outcome studies" are necessary to make "experimental procedures actual, proven treatments"). But his deposition confirmed that these critiques are baseless because he agreed that: (1) it is common for surgeons to perform procedures unsupported by RCT results; and (2) in any event, it is not possible to conduct RCTs for hormonal or surgical gender-affirming treatments.

First, RCTs in surgery are exceedingly rare. The ASPS's Plastics and Reconstructive Surgery Journal—which Dr. Lappert agreed is the "premier peer-reviewed source for current information on reconstructive and cosmetic surgery" (Ex. 2 at 296)—confirms as much. As a 2019 study found, in 2018, "only ***2.1 percent*** of all publications" in the ASPS Journal "were level 1 [*i.e.*, RCT] evidence"; "in 2008 and 2013, those

percentages were ***0.3*** and ***1.7 percent*** respectively," as he also agreed. (*Id.* at 299, 302; Ex. 7 (Sugrue study)). Given this paucity of RCTs, Dr. Lappert unsurprisingly conceded that surgeons in the real world do not actually wait for RCT results before deciding that a particular procedure is non-experimental. (Ex. 2 at 294-95 (agreeing it is "not uncommon for plastic surgeons to perform procedures that are not supported by results from an RCT").) In fact, he ***himself*** does not even "think it's necessary for a surgical procedure to be supported by results from a[n] . . . RCT before it can be considered effective." (*Id.* at 285.) Rule 702 demands that experts apply "the same level of intellectual rigor [in the courtroom] that characterizes the practice of an expert in the relevant field." *Cooper*, 259 F.3d at 200. Here, though, Dr. Lappert tries to impose an impossible RCT-based standard that he concedes surgeons in the real world—including himself—do not actually apply.

Second, it is not possible to perform RCTs for gender-affirming surgery or hormonal treatment. Dr. Lappert conceded this too: he agreed "it is not possible to perform RCTs for some surgical procedures because you can't blind the patient or the investigator to what the procedure is" (meaning, it is impossible to do the surgery without the patient and the investigator knowing that it was done)—including for "phalloplasty," "metoidioplasty," and more generally for all types of what is "colloquially known as bottom surgery." (Ex. 2 at 315-16.) He also agreed the same is true for "puberty-blocking hormones," since they cause "observable physical effects"; thus, "it's not possible to do an RCT for puberty-blocking hormones" either. (*Id.* at 316-18.) And he also conceded that the same is true for

cross-sex hormones, because those also cause "physical effects" and thus "it's not possible to design a double-blind RCT" for those treatments. (*Id.* at 318-19.)

Given all this, Dr. Lappert should not be permitted to offer his misleading opinion that gender-affirming surgery and hormone treatments are experimental in the absence of RCT support.

D. Dr. Lappert's Speculation About "Detransitioners," "Regret" and "Social Contagion" Is Unreliable.

Dr. Lappert also opines that some patients will "drop out of transitioning or reverse the process" (so-called "detransitioners"); others will experience "regret" after surgery; and yet others supposedly develop gender dysphoria as a result of "social contagion" like "peer group, social media, [and] YouTube role modeling." (Ex. 1 at 21-22, 40.)

None of this passes *Daubert* muster. To start, none of these opinions are even remotely connected to Dr. Lappert's experience as a plastic surgeon, given that he studiously avoids performing gender-affirming surgical procedures due to his personal beliefs, and has "never treated a single patient for gender dysphoria." (Ex. 2 at 150-51; *SAS Inst., Inc.*, 125 F. Supp. 3d at 589 (when an expert relies on experience, he must show how his "experience leads to the conclusion reached" and "why that experience is a sufficient basis for the opinion").)

Next, Dr. Lappert's own report makes clear that these are all speculative hypotheses at best. For instance, he admits that the extent of "social contagion" is unknown, writing: "a currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by . . . social contagion and social pressure processes." (Ex. 1 at 40

(underlining in original).) He also wrote the same thing about "desistance" and "regret," stating that these phenomena have "to my knowledge ***not been quantified or well-studied***." (*Id.* at 21 (emphasis in original).)

Dr. Lappert's deposition confirmed that these opinions are pure guesswork. He conceded that he is "not aware of any peer-reviewed studies that quantifies the number of people" affected by social contagion, and that "we don't know the numbers." (Ex. 2 at 367-38; *id.* at 373 ("At present, we're ***hypothesizing*** about the actual cause.").) The same was true for his "regret" opinions. (*Id.* at 329 (agreeing "there's no data available on the percentage of people" treated for "gender dysphoria who experience regret.").

But "the courtroom is not the place for scientific guesswork, even of the inspired sort." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996); *accord, e.g.*, *Small v. WellDyne, Inc.*, 927 F.3d 169, 176-77 (4th Cir. 2019) (expert testimony "must not be based on belief or speculation"). Dr. Lappert's speculation about regret, de-transitioning, and social contagion should be excluded accordingly.

E. Dr. Lappert's Opinions About Risks Communicated to Plaintiffs Are Unreliable.

Dr. Lappert also purports to opine about what risks were or were not communicated to individual Plaintiffs before they started gender dysphoria treatment. (*See, e.g.*, Ex. 1 at 50 (for C.B., asserting there is no evidence that "the parents were counseled concerning" risks of "off-label use of puberty blocker"); *id.* (opining there was a "failure to obtain proper informed consent" for Plaintiff "CT-F").)

There is no basis for these opinions either. Dr. Lappert "did not meet with any of the plaintiffs" and has "never spoken" with any of them about what risks their doctors discussed. (Ex. 2 at 417-18.) He was "not present in any meetings that any of these plaintiffs may have had with their mental health professionals," or their "endocrinologists," or their "surgeons"; thus, outside of reviewing medical records, he has no idea "what was said or not said during those meetings." (*Id.* at 418-19.) With no reliable basis to say what was or was not communicated during these meetings, Dr. Lappert should not be permitted to create confusion with this speculation. *See, e.g.*, *Small*, 927 F.3d at 176-77.

III. Dr. Lappert's Opinions Are Based on His Personal Beliefs Rather than Science.

Reliability is a flexible inquiry, under which "courts must ensure that an expert's opinion is based on scientific, technical, or other specialized knowledge and not on belief or speculation." *Sardis*, 10 F.4th at 281. There is ample evidence that Dr. Lappert's opinions are so tainted by his strong personal views against gender-affirming care as to make those opinions unreliable. To be clear, Plaintiffs do not seek to impugn whatever moral or religious views Dr. Lappert may hold. But because those views plainly inform the opinions that he offers here—indeed, they seem to be the main driver of those opinions—they are something the Court should consider in assessing their reliability.

Dr. Lappert readily admits that he has "strong personal opinions on whether doctors should be providing gender-affirming treatment to minors." (Ex. 2 at 79.) That's putting it mildly. He has urged state legislatures in Utah, Arkansas, Alabama, and Texas (at least) to pass laws that would ban doctors from being able to provide this medical care for

adolescents. (*Id.* at 57, 61-62; *id.* at 54-55 (agreeing he has "actively lobbied to get these kinds of bans passed").) For example, he spoke in favor of the ban before the Alabama legislature and "publish[ed] an op-ed" that urged the legislature to protect what he called "gender-confused children." (Ex. 2 at 77, 64, 76 & Ex. 14.) He likewise threw his support behind a similar proposed ban in Utah—arguing to the legislature that "you can't change a person's sex," and that "all that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex." (Ex. 13 at 5).

Dr. Lappert was unapologetic about these opinions at his deposition. He testified that he "absolutely" stands by them, and that he "absolutely" considers "gender reassignment surgery to be an intentional mutilation." (Ex. 2 at 60.) What's more, he also wants doctors who perform these gender-affirming surgeries to be "criminally prosecute[d]"—agreeing that he thinks "that's a good idea." (*Id.* at 52.)

And even though Dr. Lappert was understandably more careful in how he phrased his expert report—avoiding inflammatory language that he uses outside of litigation, like calling gender-affirming care "intentional mutilation"—sometimes the mask slips. For instance, his report accuses every single doctor and organization who oppose his views of being part of some made-up "Transgender Treatment Industry." That is obviously not "a commonly used term in the field of treatment and diagnosis of gender dysphoria," as he admitted; instead, it is "idiosyncratic" to his report. (*Id.* at 21-22.)

Dr. Lappert has also worked closely with the Alliance Defending Freedom ("ADF"), an organization he agreed has "moral objections" to gender-affirming healthcare. (*Id.* at

83, 82.) Among other things, he attended an ADF conference that discussed the "poverty of [experts] who are willing to testify" about these anti-gender-affirming treatments. (*Id.* at 90-91.) Attendees at that conference "were asked whether they would be willing as participate as expert witnesses"; not coincidentally, Dr. Lappert became an expert witness for the first time after attending that conference. (*Id.* at 91.)

Dr. Lappert's report also unapologetically misgenders individual Plaintiffs—"referring to [them] in a way that doesn't align with their gender"—because in Dr. Lappert's view, he is "obliged to honor objective biological realities" (*id.* at 447), which is to say that he does not believe that a person's birth-assigned sex can ever be changed. (*See also id.* at 448 ("I think it's essential that we stick to the biological reality that . . . biological sex is ***immutable***.").)

And then there are Dr. Lappert's many public interviews and presentations where he crusades against gender-affirming care. These include, for example, his views that the religious conception of "the human person" "defines the 'end' of medical and surgical care." (Ex. 2 at 459.) They also include his opinions that "changing a person's sex is a lie and also a moral violation for a physician," and that gender-affirming surgery is "diabolical in every sense of the word." (*Id.* at 464 & Ex. 16 at 1, 7; Ex. 2 at 465 (agreeing that he "hold[s] those views"). And finally, these also include his inflammatory views that parents who "discuss[] gender identity issues with children" are "sexualizing them" (Ex. 2 at 462), and that these conversations are "grooming a generation" for abuse. (*Id.* at 461 & Ex. 15 (Dr. Lappert's presentation titled "Transgender Surgery & Christian Anthropology") at 23;

see also Ex. 16 at 1, 2 (another interview with Dr. Lappert titled "Plastic surgeon: sex-change operation 'utterly unacceptable' and a form of 'child abuse'"; reporting that "regarding children, Lappert said, sexualizing them at a young age with these ideas is grooming them for later abuse.").)

These are obviously not neutral, well-reasoned scientific opinions by a dispassionate expert. It is moral opprobrium masquerading as science, and it should be excluded as such.

CONCLUSION

For the foregoing reasons, the Court should exclude Dr. Lappert's opinions in full.

Dated: February 2, 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 6,250 words as indicated by Microsoft Word, the program used to prepare this document.

Dated: February 2, 2022

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CERTIFICATE OF SERVICE

I hereby 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: February 2, 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, in his official capacity as State Treasurer of North Carolina, *et al.,* *Defendants*.	Case No. 1:19-cv-00272-LCB-LPA

DECLARATION OF DMITRIY TISHYEVICH

Pursuant to 28 U.S.C.§ 1746, I, Dmitriy Tishyevich, do hereby declare as follows:

1. I am over 18 years of age.

2. I am a partner at the law firm McDermott Will & Emery LLP, and I serve as counsel of record for the Plaintiffs in the above-captioned matter.

3. I have personal knowledge of the facts 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' Motion to Exclude Expert Testimony of Dr. Patrick Lappert.

5. Attached as **Exhibit 1** is a true and correct copy of Dr. Lappert's May 1, 2021 expert report submitted by Defendants in this matter. (Pages 47 to 55 of this report reference confidential medical information for individual Plaintiffs, are subject to the

concurrently-filed Plaintiffs' Motion to Seal, and have been redacted from this exhibit accordingly.)

6. Attached as **Exhibit 2** is a true and correct copy of the transcript of the September 30, 2021 deposition of Dr. Lappert in this matter.

7. Attached as **Exhibit 3** is a true and correct copy of a printout of the webpage "Guidelines for Stating Certification Status," published by the American Society of Plastic Surgeons, entered as Exhibit 2 at Dr. Lappert's deposition.

8. Attached as **Exhibit 4** is a true and correct copy of the Code of Ethics of the American Society of Plastic Surgeons, updated September 25, 2017, entered as Exhibit 10 at Dr. Lappert's deposition.

9. Attached as **Exhibit 5** is a true and correct copy of the Declaration of Dr. Patrick W. Lappert, filed on July 9, 2021 in *Brandt, et al. v. Rutledge, et al.*, E.D. Ark. (Case No. 4:12-cv-450-JM), entered as Exhibit 3 at Dr. Lappert's deposition.

10. Attached as **Exhibit 6** is a true and correct copy of the August 2, 2021 Supplemental Order from *Brandt, et al. v. Rutledge, et al.*, E.D. Ark. (Case No. 4:12-cv-450-JM), entered as Exhibit 4 at Dr. Lappert's deposition.

11. Attached as **Exhibit 7** is a true and correct copy of "Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years?," by Conor M. Sugrue, FRCS, et al., published in Plastic Reconstructive Surgery—Global Open in September 2019, entered as Exhibit 17 at Dr. Lappert's deposition.

12. Attached as **Exhibit 8** is a true and correct copy of a printout of the webpage "State Focus on Gender Affirmation Intensifies," published by the American Society of Plastic Surgeons on February 25, 2021, entered as Exhibit 7 at Dr. Lappert's deposition.

13. Attached as **Exhibit 9** is a true and correct copy of the Blue Cross Blue Shield of North Carolina Corporate Medical Policy, Gender Affirmation Surgery and Hormone Therapy, updated March 2021, entered as Exhibit 23 at Dr. Lappert's deposition.

14. Attached as **Exhibit 10** is a true and correct copy of a printout of the webpage "Gender Affirming Surgery—Medical Clinical Policy Bulletins," published by Aetna, updated January 2021, entered as Exhibit 30 at Dr. Lappert's deposition.

15. Attached as **Exhibit 11** is a true and correct copy of the Cigna Medical Coverage Policy, Treatment of Gender Dysphoria, updated May 2021, entered as Exhibit 31 at Dr. Lappert's deposition.

16. Attached as **Exhibit 12** is a true and correct copy of the United HealthCare Commercial Medical Policy, Gender Dysphoria Treatment, updated April 2021, entered as Exhibit 32 at Dr. Lappert's deposition.

17. Attached as **Exhibit 13** is a true and correct copy of a document titled "Transgender 'Transition' Procedures Performed on Minors, Answers to Questions and Information for Joint Interim Committee, Submitted by [Utah House of Representatives member] Rep. Rex. P. Shipp," dated June 10, 2021, entered as Exhibit 5 at Dr. Lappert's deposition.

18. Attached as **Exhibit 14** is a true and correct copy of a printout of a webpage titled "Alabama bill that would criminalize treatment for transgender minors headed to full Alabama Senate," published on www.rocketcitynow.com, dated February 14, 2021, entered as Exhibit 6 at Dr. Lappert's deposition.

19. Attached as **Exhibit 15** is a true and correct copy of a presentation by Dr. Lappert titled "Transgender Surgery & Christian Anthropology," entered as Exhibit 33 at Dr. Lappert's deposition.

20. Attached as **Exhibit 16** is a true and correct copy of a printout of a webpage titled "Plastic surgeon: Sex-change operation 'utterly unacceptable' and a form of 'child abuse,'" published on www.lifesitenews.com, entered as Exhibit 34 at Dr. Lappert's deposition.

21. Attached as **Exhibit 17** is a true and correct copy of an abstract from C.M. Elliott & S. Wilhelm, "Body Dysmorphic Disorder," in the Encyclopedia of Mental Health (2d ed., 2016), *available at* https://doi.org/10.1016/B978-0-12-397045-9.00081-1.

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

Dated this 2nd of February 2022.

/s/ Dmitriy Tishyevich
Dmitriy Tishyevich

EXHIBIT 1

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. Plastic 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 the *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: <u>"Masculinizing" Female to "Male" - Complications:</u>

"Transgender Procedures Metoidioplasty: Following hormonally induced clitoromegally, the clitoris is released so that it hangs dependently, mimicking a small phallus, the urethra is lengthened by the use of mucosal, and/ or cutaneous flaps and/or grafts so that the urinary stream emerges from the tip of the counterfeit phallus. Reported complications with varying degrees of frequency:

1. Urethral strictures producing varying degrees of urinary obstruction and retention. a. Requires re-operation to open or dilate the scar strictures, additional grafts, urinary diversion through the use of a bladder catheter through the lower abdominal skin (suprapubic catheter)

2. Urethral- cutaneous fistulae (urine leaking from holes in the neo-urethra caused by wound healing problems and obstruction as in 1. above) a. Requires re-operative procedures as in 1. a. above.

3. Recurrent lower urinary tract infections caused by 1, and 2 above.

4. Chronic cysto-cutaneous fistula (urine leaking from the bladder through the skin of the lower abdomen) caused by the need for suprapubic catheter to divert the urinary stream to protect the neo-urethra construct if chronic distal urinary obstruction results from original or subsequent re-operation.

5. **Life-long reproductive sterilization**, since metoidioplasty is often accompanied by previous or subsequent hysterectomy and oophorectomy.

Phalloplasty: The construction of a counterfeit "neo-phallus". Typically accomplished by the transplantation of a vascularized, sensate flap of skin and associated soft tissue from the non-dominant forearm (Sensate Radial Forearm Flap). Blood vessels and sensory nerves in the flap are connected to blood vessels and nerve in the area of the native genital structures. A highly technical procedure requiring microscopic assistance. ***Many published studies do NOT report complication rates***. *Overall,* ***the reported complication rate is above 50% for the most favored operation to construct counterfeit phallus*** *(1).* The most frequent complications involve stricture or leakage of urine, and occurs in approximately 40% of all patients (2, 3, 4), requiring surgical correction. Infectious complication rate of 9%, with associated complete flap loss in 2% of patients have been reported in a patient series by Leriche et al., as is cited in a comprehensive review of phalloplasty complications (5). One single center review of a 20 year experience shows that blockage of blood flow to the pseudo-phallus, requiring reoperation occurs 11% of

the time (6). This same review showed complete loss of the construct occurred in 3% of patients, and 17% of patients showed significant wound healing issues requiring re-operation and long term wound care. In a comprehensive review of the most common phalloplasty surgeries, published in Clinics of Plastic Surgery in 2018, the authors state, *"**Phalloplasty is known for its high rate of complication**"*. Their systematic review of the literature showed complete flap loss approaching 2%, partial loss of the flap in 5-7% of cases, opening of wounds (dehisence) in 11% of patients, and a high rate of blood clot formation in the patient's legs with risk of pulmonary embolization due to the long operative time, patient positioning for surgery, and the prolonged bed rest required (5). Similar complication rates have been reported in a review of 269 phalloplasties performed at a single center in Germany over a 22 year period. A review of patients whose phalloplasties included the use of prosthetic implants ***showed implant associated complication rate of 44%, including infection, extrusion, surgical replacement, and the need for surgical removal*** *(8).* There is also a high complication rate associated with the defect caused by harvesting the forearm tissue that is used in the construction of the counterfeit phallus. Kuran et al. in a 2019 article reviewing 940 radial forearm flap surgeries (730 of which were in transgender patients) showed an overall complication rate of 8%. **Infection in 16%, chronic pain in 10%,** loss of strength and sensation in the limb in 5%, contracture with loss of mobility requiring occupational therapy in 6.5%, and failure of the covering skin graft in 4.5%. (9) In addition to the cosmetic result, and the ability to urinate while standing, ***it would be expected that the transgender scientific literature would rigorously investigate the effects of these surgeries on erotic sensibility but they have not.*** *Human sexuality and gender identity discordance is at the heart of the justification for these very elaborate surgeries which carry high*

complication rates, however, ***a review of outcomes in this area shows the low quality of outcomes data, and thus the experimental nature of these operations.*** *In a 2019 literature review by Morrison et al. (10) the authors found that of 341 articles that had been published in peer reviewed journals, only 26 were found suitable for analysis.*

The authors summarize by saying, " Little data are available on genital sensibility outcomes after phalloplasty, and there are no standardized approaches for assessment of either sensibility or erogenous perception." They then conclude by confessing, " it is difficult to draw evidence-based conclusions." This is a remarkable finding given that the human genital apparatus has two basic functions, namely reproduction and erotic sensibility. We know that reproduction is irreversibly destroyed by these operations, and now we see that erotic sensibility is degraded if not destroyed as well. Having thus excluded the entirety of genital function, all that remains is a cosmetic result, which is not a scientifically quantifiable product. In summary, masculinizing female to "male" surgeries are highly complex procedures with a very high complication rate. The scientific literature in this area of medicine is largely of low quality, and evidences the experimental nature of these operations. The most scientifically rigorous long-term studies (11,) show that the stated goals of the surgeries, including decreased anxiety, decreased psychiatric hospitalization, decreased substance abuse, decreased self harm, and decreased suicide are not met. The long term cohort study from Sweden shows that persons who have completed all transition steps from female to "male", when compared with a population matched cohort, have a substance abuse rate that is 3.5 times higher, a psychiatric hospitalization rate that is 3.5 times higher, a rate of incarceration for violent crime that is 9.9 times higher, and a suicide rate that is 40 times higher than the control group. When the authors graphed these

findings over time, they show that any improvement in these markers begins to disappear within 6 to 8 years following completion of surgery. This largely explains the suggestion of improvement seen in the low quality data that is tainted by short follow-up, and self-selection bias. The best population based, cohort matched, longitudinal studies appear to show that all that is achieved by these surgeries is a cosmetic result, and reproductive sterilization.

COMPLICATIONS:

1. Complete loss of the microvascular flap. Typically caused by technical failure of the venous connection, may also result from clot formation in the blood vessels, or pressure of swelling that compresses the blood supply. a. Requires major re-operation to remove the dead flap, and placement or retention of urinary diversion with the use of a suprapubic bladder catheter.

2. Partial loss of the microvascular flap. Caused by transient or persistent insufficiency of blood flow, with similar etiologies as in 1 above. a. Requires re-operation to debride (remove) dead tissue, and chronic wound care involving daily dressing changes, wound care visits. b. Requires placement or retention of urinary diversion with suprapubic catheter to prevent urinary contamination of the chronic wound.

3. Urethro-cutaneous fistulae (urine leakage from the counterfeit phallus). Caused by wound healing problems within the construct that may result from inadequate blood flow, pressure, or distal urinary obstruction. a. Requires placement or long term retention of the suprapubic catheter, and surgical procedures to repair the wound openings.

4. Urethral strictures with associated urinary obstruction of varying degrees. a. Repeated urethral dilation and/ or catheterization, or re-operation to relieve chronic strictures, and will likely require urinary diversion as above.

5. Lower Urinary Tract Infections: resulting from any or the above complications of surgery. 6. Extrusion of erectile and or testicular prostheses. Cause by presence of bacteria on the implanted devices. Bacteria may have been introduced at time of surgical placement, or may result from above complications of partial flap loss or lower urinary tract infections that result from above complications.

7. Partial or complete loss of erotic sensibility. Native clitoris is typically placed at the base of the counterfeit phallus as part of the construct. Some degree of incidental surgical injury to sensory nerves is expected. Sensation from the shaft of the counterfeit phallus, provided by the surgical connection of the forearm nerve to the groin nerves, is considered successful if it provides any tactile sensation. It is not expected to produces the erotic provocation that the sensory apparatus of the native vagina produces.

8. Upper extremity complications. Common problems with the donor site can include: partial or complete loss of the skin grafts used to cover the exposed muscles and tendons that results from harvesting the forearm flap. Uncommon, but nonetheless possible, ischemic hand injury (inadequate blood flow to hand). a. Chronic wound care to achieve healing, and to protect exposed tendons. b. Scarring and tendon injuries from exposure may result in loss of range of motion. This is typically temporary, but may become permanent, depending on the age of the patient, and will require occupational therapy (OT). c. Chronic pain from harvest of the flap, or complications of healing as above.

9. Lifelong Reproductive Sterilization. These surgeries are typically preceded by or followed by hysterectomy and oophorectomy. An essential human function is being destroyed in order to produce a cosmetic result.'

Vaginoplasty - Complications :

Feminizing surgeries, performed on male persons, include the creation of external and internal structures that mimic the appearance and function of female genitalia. The most commonly performed surgery, called "inversion vaginoplasty" uses tissues from the patient's native genital structures to create neo-vaginal labia majora and minora, and a skin sleeve that is inverted into the pelvis to create a receptive passage capable of receptive copulation. In the process of this operation, the patient is castrated, the penis is opened, the erectile tissues removed, a portion of the glans is preserved while trying to preserve the erotic innervation so that it can be used to create a neo-clitoris, the skin of the penis is surgically closed and inverted into the pelvis, while preserving its native blood supply. The scrotal skin is used to construct the labia, and the urethra is shortened to an opening at the base of the neo-clitoris. Other vaginoplasty operations may involve the use of vascularized flaps from the thighs or abdomen to create the receptive neo-vaginal structure. Portions of the lower intestinal tract may be used to create the receptive sleeve of the neo-vagina. These operations are often used when prior surgeries have failed for a variety of reasons that will be presented below, or they may be a first choice if the patient has a poverty of genital tissue. Such poverty is a common result of prior use of puberty blockade and cross-sex hormones if the patient has been the subject of treatments that began in early adolescence.

As documented in the NOTES section of this declaration, The scientific literature offered in support of the efficacy, safety, and cost-effectiveness of these procedures is of low quality, and comprised almost entirely of case-series reports that lack controls, are of short duration, suffer from various biases including self-selection and confirmation bias. These problems are attested to by citations offered by Dr. Schechter in his expert testimony for the plaintiff. Dr. Schechter, in support of the efficacy of vaginoplasty surgery, cites a 2014 paper (20) which is typical. It reports outcomes on a consecutive case series of 254 male to "female" surgical patients. The data presented in support of the efficacy of surgery was in the form of a ***questionnaire*** that asked questions about satisfaction with the result (subjective data). The average follow up interval was 5 years, with the longest follow up in a single patient at 7 years (short follow-up), and ***only 46% of patients completed the questionnaire*** (self-selection bias). In another of Dr. Schechter's cited articles, the authors present a prospective study **of only 39 patients (a very small sample)**, who are given ***questionnaires*** about their quality of life (subjective data), and the final evaluation of outcomes is ***only 6 months post operation*** (very short follow up given that research shows deep regret often begins on average ***10 years after surgery***. Based upon such ***low quality data***, the authors conclude by claiming that their study result, "endorses sex reassignment surgery as a valuable option for these patients."

In his expert testimony, Dr. Schechter, having defined gender dysphoria, then goes on to justify surgical treatment based upon "medical necessity". He states, "Gender dysphoria can lead to debilitating anxiety and depression, as well as serious incidents of self-harm, including self-mutilation, suicide attempts, and suicide. Yet with only a single exception, ***no measure was made of the effects of surgery*** on what is claimed to constitute the "medical necessity" for these

procedures. The long term research — the Branstrom study cited in detail in the Notes Section of this declaration showed NO benefits for transgender surgery and NO reduction in succeed and an ***increase*** in serious suicide attempts requiring hospitalization in patients ***receiving*** the surgery. ***These recent, long-term, published, peer reviewed, credible research findings are quite contrary to the claims of Dr Schechter and Dr Brown — as are the National Science Reviews in this area from England-NICE, Sweden, and Finland (see Notes section in this declaration).***

Scientific rigor would demand an examination of such outcomes as: rates of substance abuse, psychiatric hospitalization, self-harm, or suicide, and how they were changed by surgery. The only paper in Dr. Schechter's list of citations that asks these crucial questions concerning efficacy is a very comprehensive, long term, longitudinal population cohort study (11) ***which actually shows the opposite*** of what Dr. Schechter claims for these patient outcomes. When followed beyond 8 years post operatively, this paper shows patients receiving Dr Schechter's treatments have ***the same alarmingly high rates of hospitalization, substance abuse, self-harm, and completed suicide as persons who have had no medical or surgical intervention***. The fact that the citation is included by Dr. Schechter, but never discussed in his opinion regarding efficacy is troubling. In summary, on the issue of the safety and efficacy of these surgeries, the scientific support is very weak, ***while the scientific evidence rejecting the hypothesis of efficacy is quite strong.***

BREAST SURGERY - COMPLICATIONS:

Mastectomy/ Chest Masculinization, Breast Augmentation/ Chest Feminization

The surgical removal of the breasts, and the re-contouring of the chest through liposuction is a common procedure for women who seek to present as men. These operations are

performed in both men and women, for a variety of reasons, are very safe, and typically performed in the outpatient setting. It is important to understand that the only way of distinguishing cosmetic breast surgery from "medically indicated" surgery is based upon the diagnosis of underlying pathology. For example, breast reduction may be cosmetic, or it may be medically indicated. In both cases, the patient presents with a complaint that her breast are too big. The distinction between cosmetic breast reduction, and medically indicated breast reduction, is based upon the presenting symptoms of orthopedic problems caused by the weight of the breasts, but even then, the weight of the removed tissue is factored into the objective verification that the surgery was "medically necessary".

The same issues are at stake in breast enhancement for men seeking to present as women. Cross-sex hormones will have caused varying degrees of gynecomastia (breast enlargement in men). Surgical enhancement procedures are exactly the same in both men and women. Medically necessary surgery in women is based upon the diagnosis of an objective medical condition, such as Poland's syndrome (congenital absence of a breast), surgical absence of the breast following cancer care. In men, the objective diagnosis of gynecomastia might warrant surgery based upon medical necessity, but it would be a removal of tissue. A rare diagnosis of breast cancer in a man might warrant chest wall reconstruction after cancer care. On the other hand, cosmetic surgery of the breast is entirely about the subjective feelings of the patient, and that is all that we have in the case of the self-identified transgender patient.

In the case of transgender chest surgery, the diagnosis is based on the patient's subjective report of dysphoria, but the medical necessity is based on the expectation that surgery will relieve the patient of the risk of, among other things, major depression, self-harm behaviors, and

suicide. None of the papers cited by Dr. Schechter (20, 21, 22, 23, 24, 25)address themselves to the question of medical necessity for either masculinizing surgery, or feminizing surgery. They only address technical issues, management of complications, and subjective outcomes that employ precisely the same language that is used to assess cosmetic surgery of the breast. In summary, the medical necessity of transgender chest surgery is not supported by scientific evidence, and appears to be firmly in the category of cosmetic surgery.

19. **SUMMARY OF OPINIONS:**

— There are no currently no competently conducted, long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are helped by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the number or percentage of patients receiving gender affirming medical interventions who are injured or harmed by such procedures.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting the reliability and validity of assessing gender identity by relying solely upon the expressed desires of a patient.

— There are no long-term, peer-reviewed published, reliable and valid, research studies documenting any valid and reliable biological, medical, surgical, radiological, psychological, or other objective assessment of gender identity or gender dysphoria.

— A currently unknown percentage and number of patients reporting gender dysphoria suffer from mental illness(es) that complicate and may distort their judgments and perceptions of gender identity.

— A currently unknown percentage and number of patients reporting gender dysphoria are being manipulated by a — peer group, social media, YouTube role modeling, and/or parental — social contagion and social pressure processes.

— Patients suffering from gender dysphoria or related issues have a right to be protected from experimental, potentially harmful treatments lacking reliable and valid, peer reviewed, published, long-term scientific evidence of safety and effectiveness.

— It would be a serious violation of licensing rules, ethical rules, and professional standards of care for a health care professional to provide gender transition or related procedures to any patient without first properly obtaining informed consent including informing the patient and/or guardian(s) of the lack of valid and reliable on the long-term risks and benefits of "affirmation" treatments.

— A large percentage of children (over 80% in some studies) who questioned their gender identity will, if left alone, develop an acceptance of their natal (biological) sex.

— Medical treatments may differ significantly by sex according to chromosomal assessment but not gender identity. Misinforming physicians of a patient's biological sex can have deleterious effects on treatment for medical conditions.

— NOT GENERALLY ACCEPTED: Affirmation medical treatments — hormones and surgery — for gender dysphoria and "transitioning" have not been accepted by the relevant scientific communities (biology, genetics, neonatolgy, medicine, psychology, etc).

— NO KNOWN NOR PUBLISHED ERROR RATES: Gender transition "Affirmation" medical assessments and treatments — hormones and surgery — for gender dysphoria and

"transitioning" have no known, peer reviewed and published error rates — the treatments and assessment methods lack demonstrated, reliable and valid error rates.

— ASSOCIATION GUIDELINES AND ENDORSEMENTS ARE NOT SCIENCE : Political activists, political activist physicians, and politically active medical organizations that operate by voting methodologies (e.g, WPATH, the American Medical Association, the American Academy of Pediatrics, the American Endocrine Society) are not the relevant scientific community, they are politically active professional organizations. These organizations operate via consensus-seeking methodology (voting) and political ideologies (e.g., Critical Theory) rather than evidence-based scientific methodologies.

— ETHICAL RESTRICTIONS ON EXPERTS - WILL THERE BE A PROPER INVESTIGATION OF MISINFORMATION? : Experts in legal cases have an ethical obligation to honestly, fairly, and accurately disclose and discuss the international controversies regarding the safety, effectiveness, reliability, and credibility of the Gender Transition Industry. It is astonishing that in their expert declarations, Drs Schechter and Brown ***failed*** to disclose and discuss the controversies, complex issues, debates, and contrary national science review recommendations in this field. Dr Brown even swore in his declaration that… "***Nor is there any uncertainty or dispute in the medical field regarding the medical necessity of this care.***" It is difficult to imagine a more inaccurate summary of the state of the embattled, experimental Transgender Treatment Industry. Will such mis-information be properly investigated by the relevant authorities?

20. DR LAPPERT's RESEARCH NOTES: To assist in my testimony in this case. I include my notes, references and citations documenting the depth and breadth of the serious

controversies in this field. Over the past few years, the glaring defects in the research foundations of the Transgender Treatment Industry have been exposed for all the world to see.

> **Controversy** - 2015 Dutch Study by *Vrouenraets et al, Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,* Journal of Adolescent Health 57 (2015) 367e373. *...no consensus exists whether to use these early medical interventions*.....Results: Seven themes give rise to different, and even *opposing, views on treatment*: (1) *the lack of an explanatory model for GD*; (2) *the unknown nature of GD (normal variation?, social construct?, or mental illness?)*; (3) the role of physiological puberty in developing gender identity; (4) *the role of comorbidity [with severe mental illnesses]* ; (5) unknown possible *physical or psychological effects of (refraining from) early medical interventions*; (6) *child competence and decision making authority [to give truly informed consent to be sterilized for experimental procedures?]*; and (7) *the role of social context ...how GD is perceived.* Strikingly, the guidelines are debated both for being too liberal and for being too limiting. Conclusions: As long as *debate* remains on these seven themes and *only limited long-term data are available, there will be* ***no consensus on treatment.*** Therefore, more systematic interdisciplinary and (worldwide) multi-center research is required. It is striking that Drs. Brown and Schechter somehow both failed to properly report this ongoing international debate within their claimed filed of expertise.

> **2011 - Dhejne** et al. **(2011)**, Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden, PLOS ONE 6(2) e16885 ("Long Term"); See also, R. K. Simonsen et al. (2016), Long-Term Follow-Up of Individuals Undergoing Sex Reassignment Surgery: Psychiatric Morbidity & Mortality, Nordic J. of Psychiatry 70(4). Swedish follow-up study of patients who underwent sex-reassignment surgery over a 30-year periodfound a ***suicide rate in the post-Sex Reassignment Surgery (SRS) population 19.1 times greater*** — after affirmation treatment — than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions.

> **2021-2020 Carmichael** P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. medRxiv 2020.12.01.20241653 ... Self-harm did NOT improve and "no changes in psychological function," meaning no improvement. (Also, "YSR [Youth Self Report] data at 36 months (n = 6) were not analyzed."... no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found... children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16. The findings, from a study of 44 children treated by the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust in London, have emerged as the trust prepares to appeal against a High Court ruling that led NHS England to pause referrals of under 16s for puberty blockers.

> **See, 2020 Bränström and Panchankis long term surgical results NO benefit (data**

suggests and suggests an increased risk of serious suicide attempts) ...See also See, Kalin, N.H., Reassessing Mental Health Treatment Utilization Reduction in Transgender Individuals After Gender-Affirming Surgeries: A Comment by the Editor on the Process by the Editor-in-Chief The American Journal of Psychiatry, Am J Psychiatry 2020; 177:7 64; doi: 10.1176/appi.ajp.2020.20060803; See also, Anckarsäter, H., (MD, Ph.D.) and Gillberg, C., (M.D., Ph.D.) Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117 .

DEMOGRAPHICS... no biological explanation... The radical change in patient demographics from early onset in boys to teen girls with rapid onset— has been termed late-, adolescent-, or rapid-onset gender dysphoria — has now been seen in every gender clinic in the western world, and there has been a huge surge in the number of cases. "National College Health Assessment: ACHA-NCHA s://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Publications_and_Reports.aspx?hkey=d5fb767c-d15d-4efc-8c41-3546d92032c5 See, Kaltiala-Heino, Riittakerttu, Hannah Bergman, Marja Työläjärvi, and Louise Frisen. "Gender Dysphoria in Adolescence: Current Perspectives." Adolescent Health, Medicine and Therapeutics Volume9 (March 2018): 31–41. https://doi.org/10.2147/AHMT.S135432 See, Vries, Annelou L.C. de. "Challenges in Timing Puberty Suppression for Gender-Nonconforming Adolescents." Pediatrics 146, no. 4 (October 2020): e2020010611. https://doi.org/10.1542/peds.2020-010611. See, Zucker, Kenneth J. "Adolescents with Gender Dysphoria: Reflections on Some Contemporary Clinical and Research Issues." Archives of Sexual Behavior 48, no. 7 (October 2019): 1983–92. https://doi.org/10.1007/s10508-019-01518-8.
and reportedly Australia.

2020 See National Review for Great Britain (NICE), Deborah Cohen and Hannah Barnes, Evidence for puberty blockers use very low, says NICE at https://www.bbc.com/news/health-56601386 ["The evidence for using puberty blocking drugs to treat young people struggling with their gender identity is "very low", an official review has found. The National Institute of Health and Care Excellence (NICE) said existing studies of the drugs were small and "subject to bias and confounding".;

See, Asscheman H, Giltay EJ, Megens JA, et al. A long-term follow-up study of mortality in transsexuals receiving treatment with cross-sex hormones. *Eur J Endocrinol.* 2011;164:635-642. *"There is no evidence that transition reduces suicide when we look past 10 years, and there is some suggestion that suicide rates may actually increase after the transition honeymoon phase is over,"* says Malone, stressing the importance of providing proper evaluation and appropriate psychological treatment for any suicidal tendencies. (Supports the Branson conclusions after recantation and correction).

Sweden = Review of Gender dysphoria in children and adolescents: an inventory of the literature, SBU Policy Support no 307, 2019 www.sbu.se/en • registrator@sbu.se Contact SBU: Jan Adolfsson, Medical Advisor, Project Manager, jan.adolfsson@sbu.se,

English Proofreading: Project group and Jan Adolfsson, SBU [" No relevant randomized controlled (treatment outcome) trials in children and adolescents were found."] ; See, also e.g., FINLAND Issues Strict Guidelines for Treating Gender Dysphoria at https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/. In 2020, Finland reportedly became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that there is a lack of quality evidence to support the use of hormonal interventions in adolescents with gender dysphoria.... they also issued the guideline ordering "No surgical interventions are allowed for children under the age of 18".). As the ***methodological quality of the studies was already poor*** based on the type of study, thus no actual quality assessment or determination of the degree of evidence was performed."] ;

See, Cochrane Review (See, Haupt, C., Henke, M. et. al., Cochrane Database of Systematic Reviews Review - Intervention, Antiandrogen or estradiol treatment or both during hormone therapy in transitioning transgender women, 28 November 2020.)

See, Griffin, L., Clyde, K., Byng, R., Bewley, S., Sex, gender and gender identity: a re-evaluation of the evidence. BJPsych Bulletin (2020) doi:10.1192/bjb.2020.73, Cambridge University Press, 21 July 2020, the authors noted ***the hazardous error of mandating "affirmation treatments"*** — thus requiring the negligent practice of Confirmation Bias — rather than properly and carefully exploring alternative hypotheses — the standard, required ethical, medical standard of practice. ... As Griffin discussed, "Attempts to properly explore, formulate and treat coexisting mental illness in gender dysphoric populations, including that relating to childhood trauma, might be considered tantamount to 'conversion therapy'. Although mental illness is overrepresented in the trans population it is important to note that gender non-conformity itself is not a mental illness or disorder. ***As there is evidence that many psychiatric disorders persist despite positive affirmation and medical transition, it is puzzling why transition would come to be seen as a key goal rather than other outcomes, such as improved quality of life and reduced morbidity***. When the phenomena related to identity disorders and the evidence base are uncertain, it might be wiser for the profession to admit the uncertainties. Taking a supportive, exploratory (psychotherapy) approach with gender-questioning patients should not be considered conversion therapy."... In addition, Griffin et al wrote: "Transgender support groups have emphasized the risk of suicide. After controlling for coexisting mental health problems, studies show an increased risk of suicidal behaviour and self-harm in the transgender population, although ***underlying causality has not been convincingly demonstrated.***

See, Dyer, C., Puberty blockers do not alleviate negative thoughts in children with gender dysphoria, finds study BMJ 2021; 372 doi: https://doi.org/10.1136/bmj.n356 (Published 08 February 2021) Cite this as: BMJ 2021;372:n356 [Puberty blockers used to treat children aged 12 to 15 who have severe and persistent gender dysphoria had no significant effect on their psychological function, thoughts of self-harm, or body image, a study has found. However, as expected, the children experienced reduced growth in height and bone strength by the time they finished their treatment at age 16]

See, e.g., Wold, A. (M.D., Ph.D.) Gender-Corrective Surgery Promoting Mental Health in Persons With Gender Dysphoria Not Supported by Data Presented in Article, Am J Psychiatry 2020; 177:768; doi: 10.1176/appi.ajp.2020.19111170. [among the individuals examined in the Branstrom study, the risk of being hospitalized for a suicide attempt was 2.4 times HIGHER if they had undergone gender-corrective surgery than if they had not.... the data presented in the Branstrom article do not support the conclusion that surgery is beneficial to mental health in individuals with gender dysphoria."]
"Therefore, ... the data in the article ... ***OVERTURNS the authors' stated conclusions, suggesting that sex reassignment surgery is in fact associated with INCREASED mental health treatment*** See, Ring, A. (PhD) and Malone, W. , Confounding Effects on Mental Health Observations After Sex Reassignment Surgery, Am J Psychiatry 2020; 177:768–769; doi: 10.1176/appi.ajp.2020.19111169.

See, See, Van Mol, A., , Laidlaw, M. K., Grossman, M., McHugh, P. , Gender-Affirmation Surgery Conclusion Lacks Evidence, Am J Psychiatry 177:8, August 2020 ajp.psychiatryonline.org 765. "The study confirms the strong association between psychiatric morbidity and the experience of incongruity between gender identity and biological sex. However, the study does NOT demonstrate that either hormonal treatment or surgery has ANY effect on this morbidity. It seems that the main message of this article is that the incidence of mental health problems and suicide attempts is especially HIGH in the year AFTER the completion of gender-affirming surgery [It is telling that the authors some how ignored this most essential finding] ..." See, Curtis, D. (M.D., Ph.D.), Study of Transgender Patients: Conclusions Are Not Supported by Findings, Am J Psychiatry 2020; 177:766; doi: 10.1176/appi.ajp.2020.19111131.

See, Malone, W. and Roman, S. , Calling Into Question Whether Gender-Affirming Surgery Relieves Psychological Distress, Am J Psychiatry 2020; 177:766–767; doi: 10.1176/appi.ajp.2020.19111149. "Bränström and Pachankis study on mental health treatment and suicide attempts ... is misleading because the study design is flawed." "The authors first found what was already known ... the rate of psychiatric morbidity is much higher in persons with gender dysphoria compared with the general population (both before AND after "transitioning"). The authors then explored if the risk for mental health treatment changes as a function of years since starting HORMONAL treatment. They find NO effect (odds ratio = 1.0), but they do find a trend toward INCREASED risk of suicide attempts as a function of years since starting [gender affirmation] HORMONAL treatment. They somehow failed to publish this essential finding.
See, Landén, M. (M.D., Ph.D.) The Effect of Gender-Affirming Treatment on Psychiatric Morbidity Is Still Undecided, Am J Psychiatry 2020; 177:767–768; doi: 10.1176/appi.ajp.2020.19111165. this conclusion is not supported by the data presented in the article.

See, Bränström, R. and Pachankis, J. , Toward Rigorous Methodologies for Strengthening Causal Inference in the Association Between Gender-Affirming Care and Transgender Individuals' Mental Health: Response to Letters, Am J Psychiatry 2020; 177:769–772; doi: 10.1176/appi.ajp.2020.20050599.

2020 - Sweden, following a national review of transgender science, published a new guideline that is NOT consistent with WPATH protocols nor the opinions of Drs Schechter and Brown in this case. [https://genderreport.ca/finland-strict-guidelines-

for-treating-gender-dysphoria/ The SWEDISH NATIONAL GUIDELINES appear quite contrary to the opinions of Drs Brown and Schechter and WPATH.

2020 - Finland following a review of transgender science, became the first country in the world to issue new guidelines for this group of patients when it concluded similarly to the UK High Court that *there is **a lack of quality evidence** to support the use of hormonal interventions in adolescents with gender dysphoria*. This new Finnish guidance *prioritizes psychological therapy over treatment with hormones or surgery* and suggests different care plans for early-onset vs late-onset childhood gender dysphoria. The 2020 Finland guidelines state "***Only limited research has been conducted on transgender identity and other gender identity conflicts,** and comparative studies are very rare*."] The Finland National Guidelines appear quite contrary to the opinions of Drs Brown and Schechter and WPATH.

See, https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ Finland Clinical Guidelines and Conclusions Three reports were created by COHERE in Finland. The report "Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendation" clarifies the roles of different healthcare providers in a situation where a minor is uncertain about their gender identity. They also produced general recommendations for the treatment of transgender people, which applies to adults. And interestingly, a third and separate set of recommendations for the treatment of gender dysphoria related to non-binary people and people with gender identities other than opposite-sex gender identities. The summaries are available for download here:
Summary-transgender_enDownload
Summary_minors_enDownload
Summary_non-binary_enDownload

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21. Expert Report Limitations: My opinions and hypotheses in this matter are — as in all expert witness reports — subject to the limitations of documentary and related evidence, the impossibility of absolute predictions, as well as the limitations of social, biological, and medical science. All opinions have been offered to a reasonable degree of medical certainty. I have not met with, nor personally interviewed, anyone in this case. As always, I have no expert opinions regarding the veracity of witnesses in this case. I have not yet reviewed all of the evidence in this case and my opinions are subject to change at any time as new information becomes available to me. Only the trier of fact can determine the credibility of witnesses and how scientific research may or may not be related to the specific facts of any particular case. In

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

CONFIDENTIAL INFORMATION SECTION BELOW

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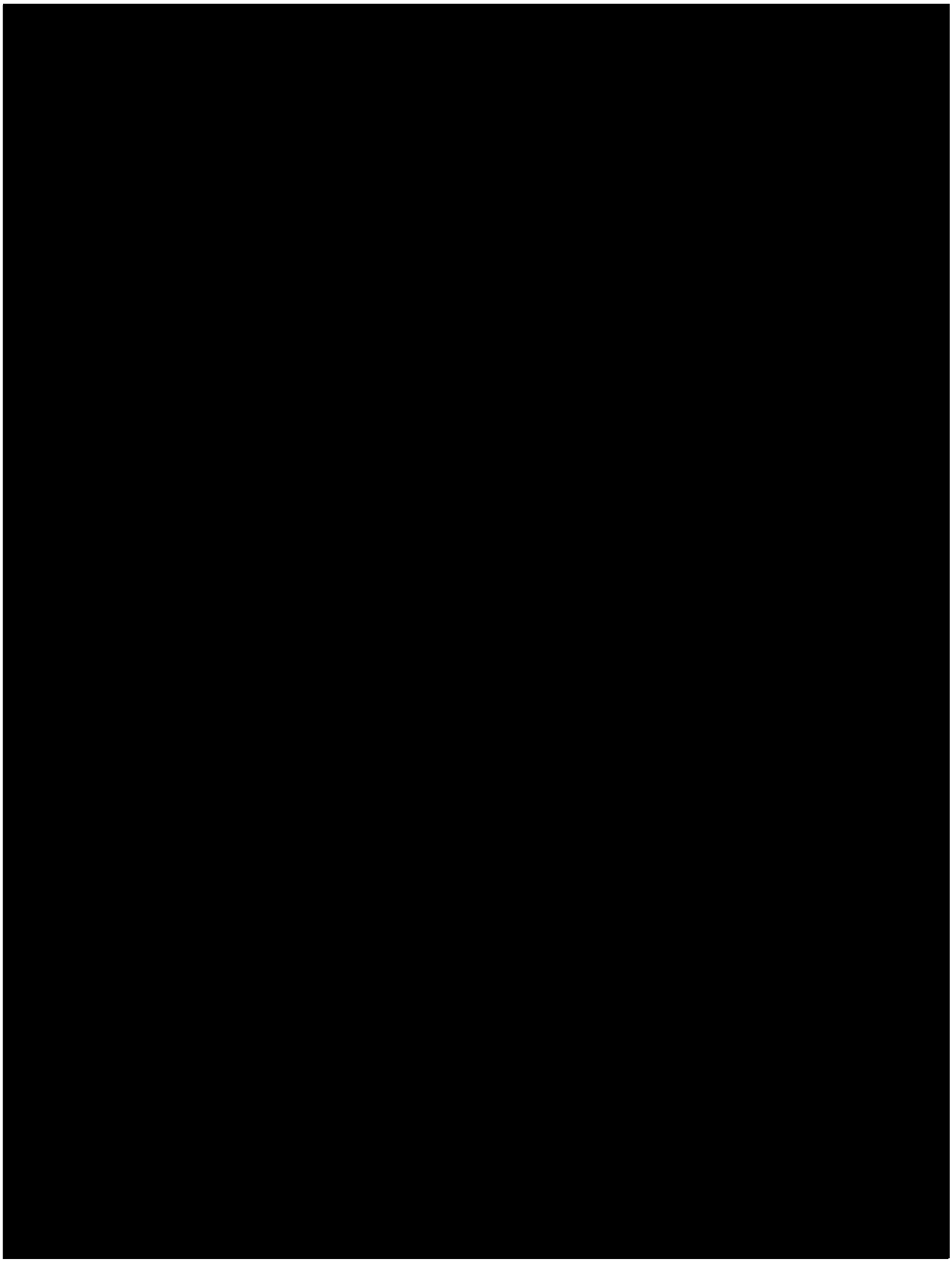

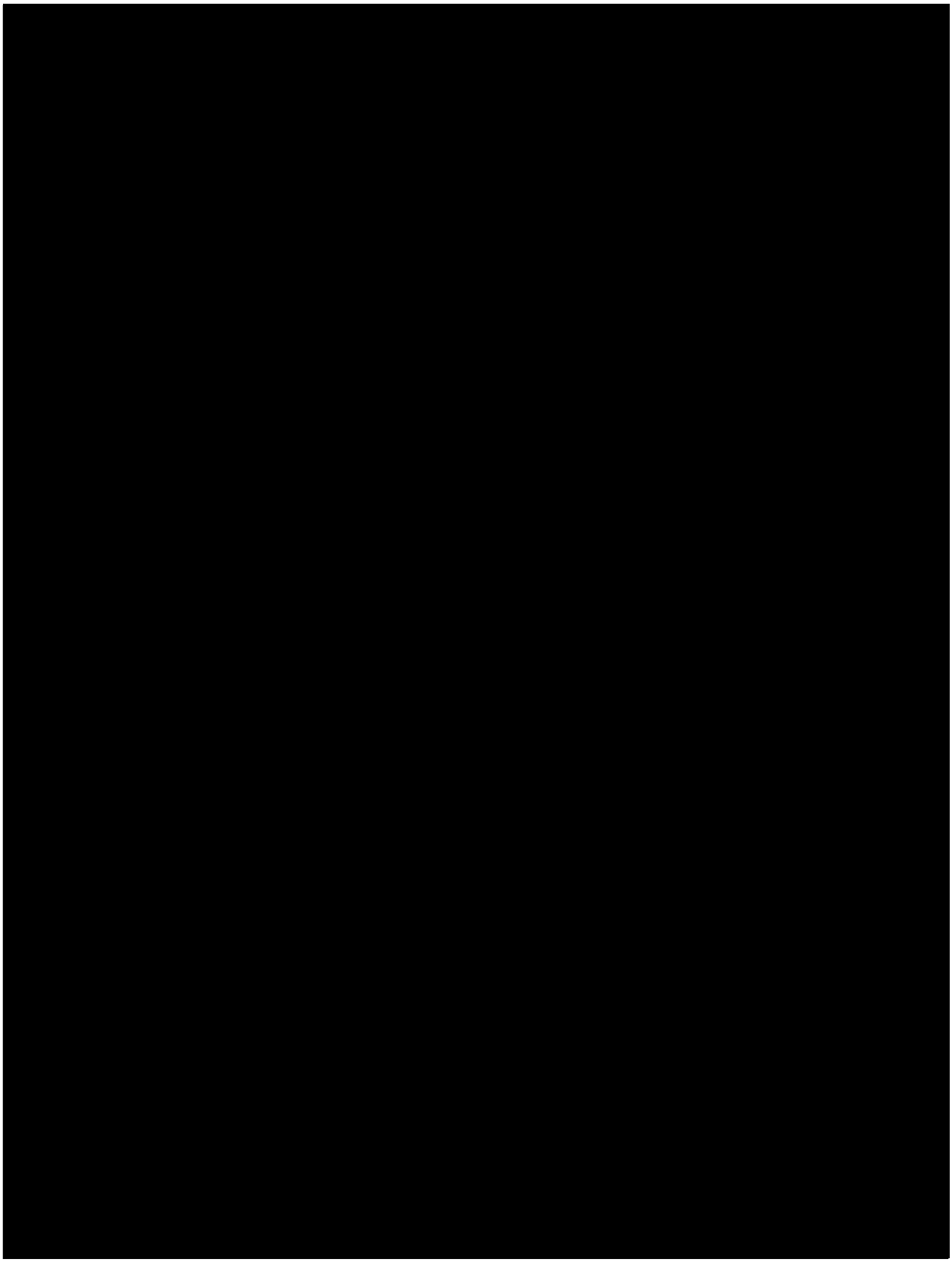

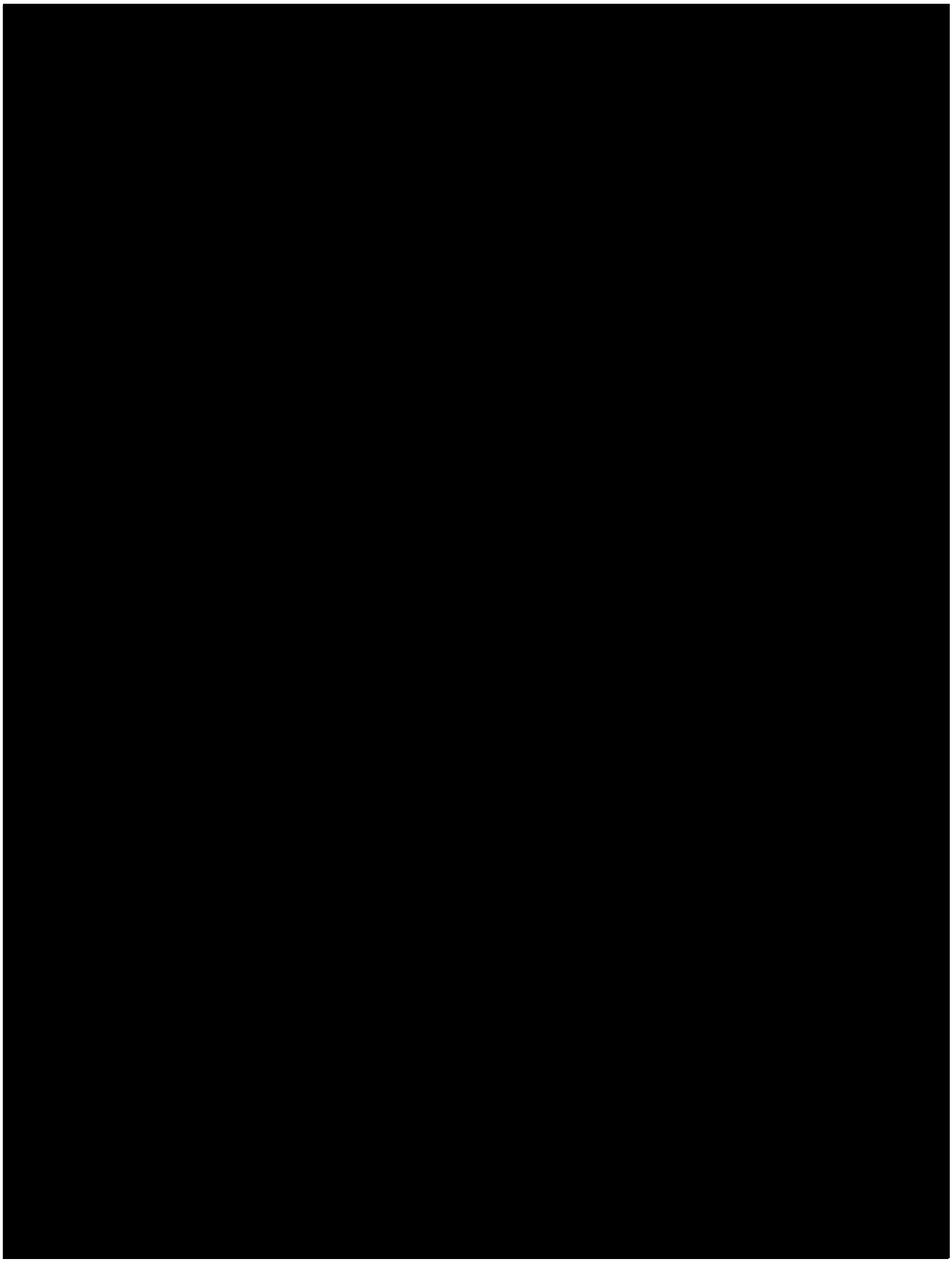

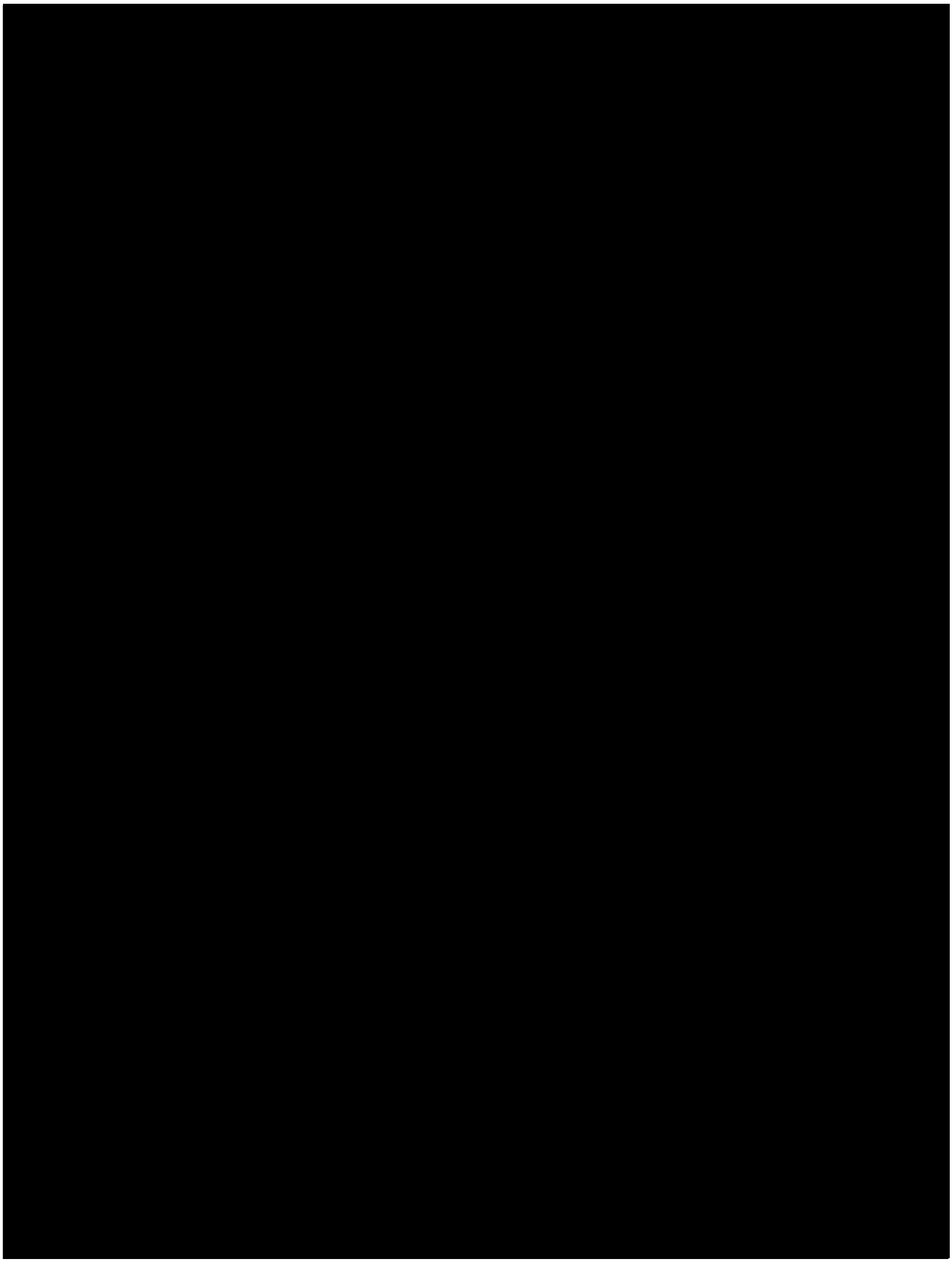

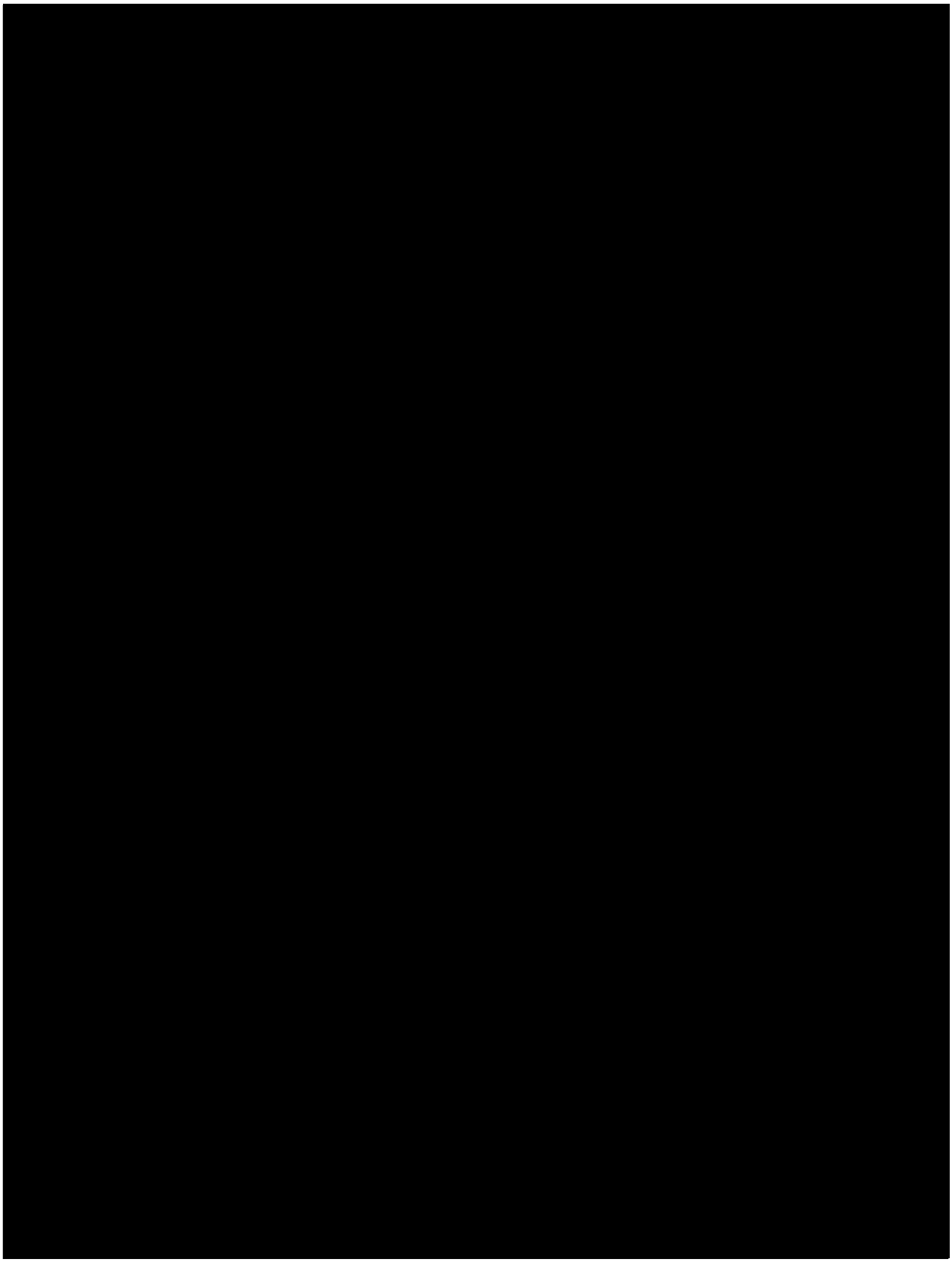

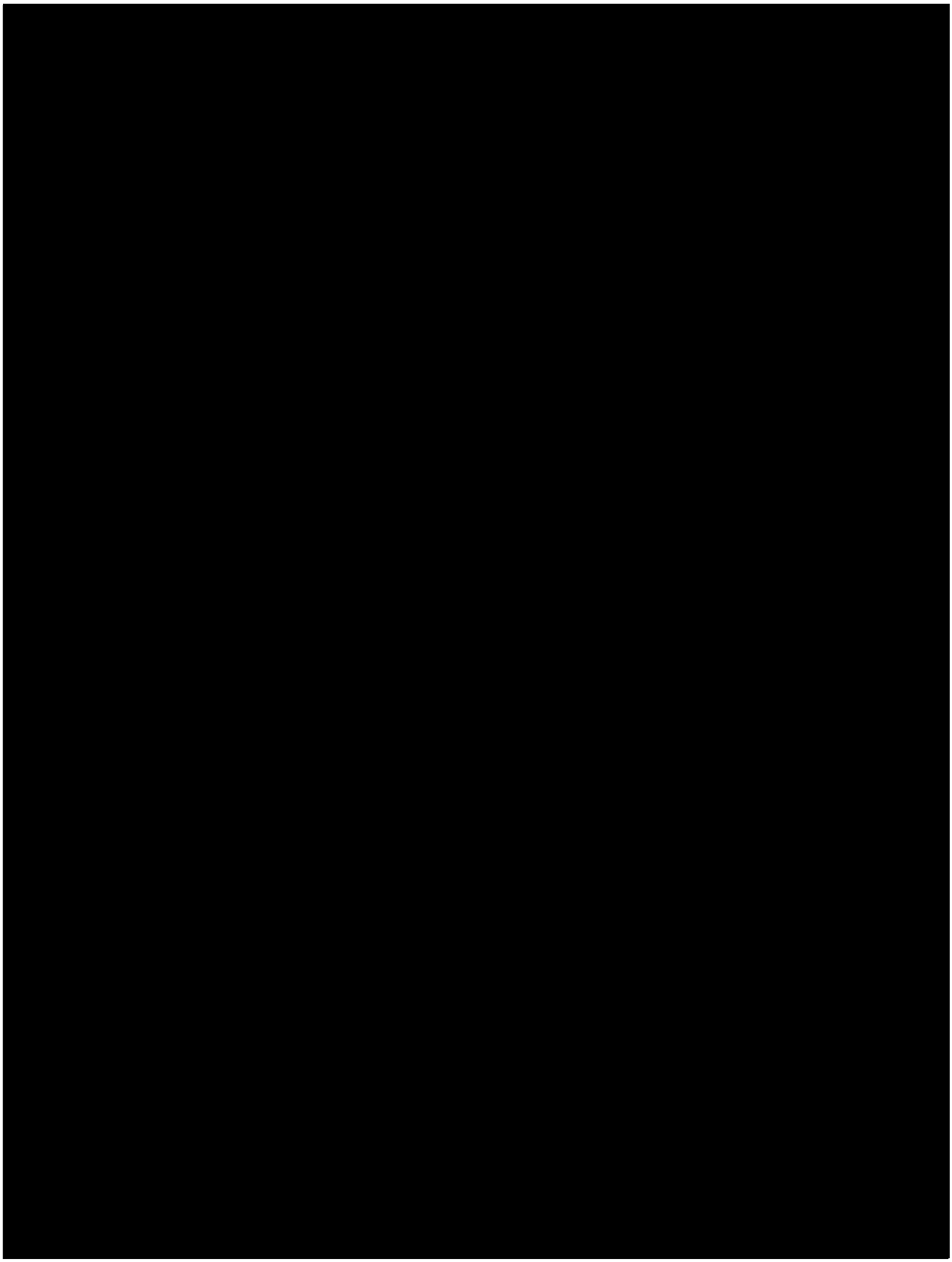

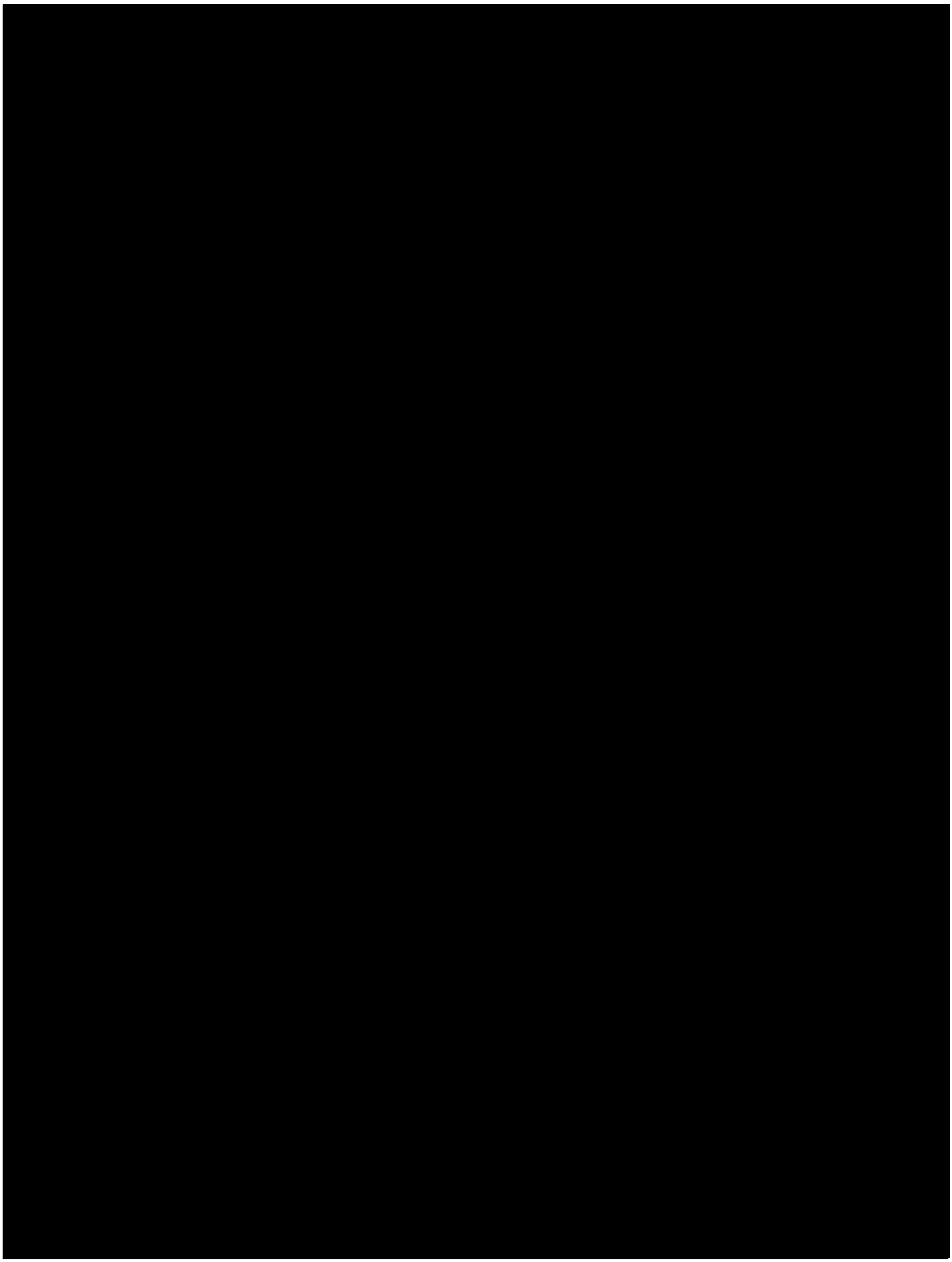

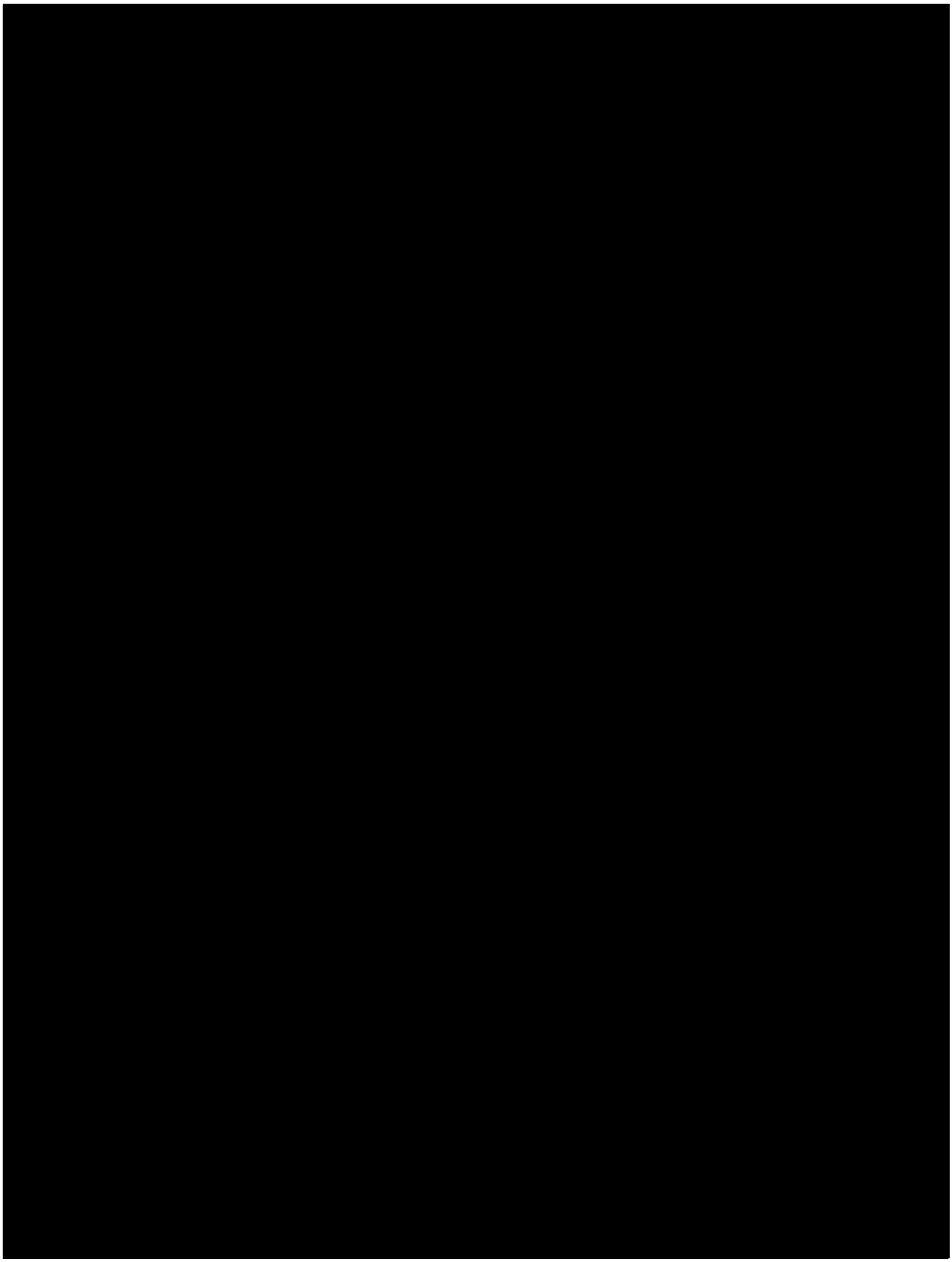

Pursuant to 28 U.S.C § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: _____

Signed: _____ **May 1, 2021**

Patrick W. Lappert, MD

EXHIBIT 2

Deposition of:

Patrick Lappert, M.D.

September 30, 2021

In the Matter of:

Kadel, et al vs. Folwell

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

CIVIL ACTION NO.: 1:19-cv-272-LCB-LPA

MAXWELL KADEL, et al.
Plaintiffs

v.

DALE FOLWELL, et al.
Defendants

REMOTE VIDEOTAPED VIDEOCONFERENCE
DEPOSITION TESTIMONY OF:
PATRICK LAPPERT, M.D.
September 30, 2021

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Andrew Baker, Videographer

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I, Lane C. Butler, a Court Reporter and Notary Public, State of Alabama at Large, acting as Notary, certify that on this date, pursuant to the Federal Rules of Civil Procedure, there came before me via remote videoconference from Decatur, Alabama, commencing at approximately 8:30 a.m. Central, on the 30th day of September, 2021, PATRICK LAPPER, M.D., witness in the above cause, for oral examination, whereupon the following proceedings were had:

THE VIDEOGRAPHER: Good morning. We are going on the record at 8:31 a.m., Thursday, September 30th, 2021. This is Media Unit 1 of the videorecorded deposition of Dr. Patrick Lappert as taken by counsel for plaintiff in the matter of Kadel, et al. v. Folwell, et al., filed in the United States District Court for the Middle District of North

Carolina, Civil Action No. 1:19-cv-272-LCB-LPA.

This deposition is being recorded remote via Zoom located in Decatur, Alabama. My name is Andrew Baker from the firm Veritext Legal Solutions. I am the videographer. The court reporter is Lane Butler, also from Veritext Legal Solutions.

Will counsel now state their appearance and affiliations for the record. The court reporter will swear in the witness. Thank you. We may proceed.

MR. TISHYEVICH: This is Dmitriy Tishyevich from McDermott, Will & Emery, LLP, for plaintiffs.

MR. KNEPPER: My name is John Knepper. I represent three of the defendants in this matter: the North Carolina State Health Plan for Teachers and State Employees; Dale Folwell, the treasurer for the State of North Carolina; and Dee Jones, the executive

administrator of the North Carolina State Health Plan. I'll be defending Dr. Lappert's deposition.

PATRICK LAPPERT, M.D.,
having first been duly sworn,
was examined and testified as follows:

EXAMINATION BY MR. TISHYEVICH:

Q. Good morning, Doctor.

A. Good morning, sir.

Q. State your full name for the record.

A. Patrick Walter Lappert.

Q. Any reason you're not able to give complete and truthful testimony today?

A. There is no reason.

Q. You've been retained as an expert by defendants in this case; correct?

A. I have.

Q. You've prepared an expert

report; right?

A. I have.

Q. So, I've premarked Exhibit 1. Open that, and let me know when you have it.

(Exhibit 1 was marked for identification and is attached.)

A. Okay. I have it.

Q. This report contains all the opinions that you intend to offer in this case; correct?

A. It does.

Q. All right. Without telling me any conversations that you had with counsel, what did you do to prepare for your deposition today?

A. Well, I reviewed the -- the documents. I guess it's called the complaint. I reviewed the patient records. And then, I reviewed the literature, pertinent journal articles, publications, and had conversations with -- with counsel, Mr. Kadel [sic], and his

staff at various times.

Q. When you say "patient records," are you talking about the medical records for the individual plaintiffs?

A. Yes. The ones that were -- that were given to me to review.

Q. And when you say "the literature," are you referring to some of the studies that you cite in your report?

A. Yes.

Q. Have you reviewed any studies -- strike that.

In preparing for your deposition today, have you reviewed additional studies that are not cited in your report?

A. No. The report contains all of the studies that I -- that I reviewed that I consider pertinent. I glossed some but didn't see them as germane. So all the ones that were -- that were germane to my opinion are -- are in the -- in the document.

Q. Understood. And you mentioned that you met with or spoke with Mr. Knepper in preparing for today?

A. I have.

Q. Okay. Again, without disclosing any substance of the conversation, how many times did you speak or meet with him?

A. Three or four times, I think.

Q. And when did those conversations take place?

A. Well, as recently as yesterday evening and I think a couple of meetings back in May, I think it was. I'd have to look at my calendar, but.

Q. Last evening, you spoke -- strike that.

You know that Dr. Hruz was deposed yesterday; right?

A. I'd heard, yes.

Q. And so before yesterday, when was the last time that you spoke with Mr. Knepper to prepare for your deposition?

A. I want to say it's a couple of weeks ago. I'm not exactly sure.

Q. How long was the conversation with Mr. Knepper last night?

A. A little less than an hour.

Q. Did he provide you with copies of any of the exhibits that were used at Dr. Hruz's deposition?

A. No, he did not.

Q. Did he provide you with any -- any portions of that deposition transcript?

A. No.

Q. And then going in reverse chronological order, you mentioned you may have spoken a couple of weeks ago?

A. I think. I don't know exactly -- I don't know exactly when that was, Mr. Tishyevich. I want to say three weeks ago perhaps. I'm not exactly sure.

Q. Do you recall roughly how long that conversation was?

A. About the same duration. I

think it was perhaps an hour, perhaps an hour.

Q. Okay. All right. You -- in the course of -- strike that.

In the course of working on this case, have you ever communicated with Dr. Hruz?

A. Not directly. I've spoken with Dr. Hruz, but in the matter at hand, I have not spoken with him about it.

MR. TISHYEVICH: For the court reporter, that's H-R-U-Z. And I'll try and spell things as we go to make it a little easier.

Q. How about Dr. McHugh? M-C-H-U-G-H. Have you spoken with him in the course of working on this case?

A. I've never spoken directly to him, no.

Q. How about Dr. Levine? L-E-V-I-N-E.

A. I have not spoken with Dr. Levine.

Q. But you have met Dr. Hruz before working on this case; right?

A. Yes.

Q. And is the same true for Dr. Levine?

A. I've never met Dr. Levine.

Q. All right. About how many hours do you estimate you've spent working on your expert report?

A. Somewhere around maybe 60 hours. I could -- I could look for that number, but I'm going to estimate it at about 60 hours, something like that.

Q. You're aware that the individual plaintiffs in this case have been deposed; right?

A. Yes, I've heard.

Q. Were you provided with deposition transcripts or any portion of their testimony?

A. I have -- I have not seen those, no.

Q. Okay. You're aware that other

experts in this case have also already been deposed?

A. Yes.

Q. Have you been provided with deposition transcripts or any portion of their deposition testimony?

A. I -- I saw a transcript of Dr. McHugh's.

Q. Was that the only tran- -- strike that.

Was Dr. McHugh's transcript the only expert deposition transcript you've seen?

A. It's the only one I've read. I -- I think that -- yeah, I think it's the only one I read. Yes, sir.

Q. Okay. All right. So throughout your report, you use this term --

A. Could I amend that last answer?

Q. Of course.

A. I -- I did read portions of Dr. Brown's transcript, actually, some days back. My -- my apologies.

Q. No. And I should say that. If at any point in time in your deposition you want to go back and amend your answer, that is totally fine.

A. Thank you.

Q. Okay. So in your report, you use this term "transgender treatment industry." Right?

A. Yes.

Q. And you and Dr. Levine and Dr. McHugh all use this term in your reports. Were you aware of that?

A. Oh, I was aware that the -- no, I wasn't aware that they were using it, actually.

Q. Is it coincidental that the three of you are using this term?

A. I -- I think it's sort of becoming a common term lately. I don't know where it came from. I was trying to think about that. I don't know who originated it, but I've -- I don't know even if it was me that originated it,

actually, since I've been speaking about this subject for some time now. But it seemed like an apt term, so it doesn't surprise me that others are using it.

Q. You don't know who came up with that term?

A. I don't.

Q. It's possible that it was you?

A. It wouldn't surprise me.

Q. And you mentioned that it's becoming more commonly used. Is that right?

A. It seems to be. I don't know. I don't know how common it is, but it's kind of a small circle of people talking about these things.

Q. Are you aware of a single peer-reviewed scientific article that has used the term "transgender treatment industry"?

A. I am not.

Q. Do you know what PubMed is? P-U-B-M-E-D.

A. Yes.
Q. It's a search engine maintained by the National Institute of Health; right?
A. Yes. That's my understanding.
Q. It's a search engine for scientific articles, basically; right?
A. Yes.
Q. So I'll represent to you that I ran a search in PubMed for the phrase transgender treatment industry, in quotation marks, and came back with zero results for that phrase.
MR. KNEPPER: Objection to form.
Q. Do you find that surprising?
A. No.
Q. Okay. What does that lack of results tell you about whether this term is a commonly used term in this field?
MR. KNEPPER: Objection to form.
A. I wouldn't expect it to be a commonly used term, and it doesn't surprise me that you didn't find it.

Q. Yeah. "Transgender treatment industry" is not a commonly used term in the field of treatment and diagnosis of gender dysphoria; right?

MR. KNEPPER: Objection to form.

A. I would agree.

Q. Yeah. It's a term that, as far as I can tell, is fairly idiosyncratic to the opinions that you and the other defendant experts are using in this case. Does that sound right?

MR. KNEPPER: Objection to form.

A. That sounds right to me, yeah.

Q. Okay. Look at page 1 of your expert report, Exhibit 1.

A. All right.

Q. I see it says, "Declaration of Patrick Lappert, MD." You see that?

A. Yes.

Q. Under that, it says, "Board Certified in Surgery and Plastic Surgery." Do you see that?

A. I do.

Q. Let's talk about your certifications. Let's start with plastic surgery. You originally received your board certification in plastic surgery in 1997; correct?

A. That's correct.

Q. Then you got recertified in 2008; correct?

A. That's correct.

Q. That board certificate was only valid for ten years; correct?

A. Correct.

Q. And your plastic board -- strike that.

And your plastic surgery board certificate expired at the end of 2018; correct?

A. Correct.

Q. Well, why did you decide not to renew your board certificate past 2018?

A. Well, I'm a -- I'm a solo practitioner, and the main reason for maintaining that expensive certificate

was that many hospitals required it in order to have privileges. Several years ago, a lot of hospitals started dropping that requirement, so it didn't make sense for a surgeon who is within three years of retirement to expend all that money and time to maintain a certification that was no longer necessary for me in terms of maintaining my practice.

Q. Do you currently have admitting privileges at any hospital?

A. No.

Q. When was the last time you had admitting privileges in any hospital?

A. A year ago.

Q. What hospital was that?

A. Crestwood Hospital, Huntsville, Alabama.

Q. So within the last year at least, I take it you haven't performed any surgeries at a hospital. Right?

A. That's correct. A -- a year ago, I retired from active surgical

practice.

Q. Were you doing surgeries in 2019 after your plastic -- plastic surgery board certificate expired?

A. Yes.

Q. When -- just can we pin this down more? What -- what month do you think you stopped performing surgeries?

A. Let's see. This is November of 2021, so it would have been August of 2020.

Q. All right. You are not currently board-certified in plastic surgery; correct?

A. Correct.

Q. And you have not been board-certified in plastic surgery since 2018; correct?

A. Correct.

Q. For over two and a half years at this point; right?

A. Correct.

Q. So this page 1 of your report

says that you're board-certified in plastic surgery. Do you think it's appropriate for you to make that representation even though you don't have an active certification?

MR. KNEPPER: Objection, form.

A. Well, appropriate in terms of -- I don't understand the question.

Q. Let me be more specific.

A. Okay.

Q. Do you know what the Amer- -- I'll go back.

You know what the American Board of Plastic Surgery is; right?

A. Certainly.

Q. Do you know what the American Board of Plastic Surgery has to say about doctors who represent that they're board-certified when they don't have an active certification?

MR. KNEPPER: Objection, form.

A. They discourage it. I -- I suspect that the -- the document -- well,

I didn't prepare that -- that particular part of the document, although I signed it, certainly. But I see your point, yes.

Q. Okay. I'm going to introduce another exhibit. You'll see it in a minute. Let me know when you have it, Doctor.

(Exhibit 2 was marked for identification and is attached.)

A. I have it.

Q. This is a printout from the -- a web page from the American Board of Plastic Surgery. Go to page 2.

A. All right. I'm there.

Q. Middle of the page, it says in bold letters, "Guidelines for Stating Certification Status." Do you see that?

A. I do.

Q. Look at the third paragraph.

A. All right.

Q. It says, "ABPS does not mandate the specifics of how diplomates state

their certification, except to assert that diplomates should not state or imply that they are certified if their certification has expired."

Do you see that?

A. I do.

Q. All right. You understand that under this guidance from the ABPS, you are not supposed to be representing that you are board-certified in plastic surgery because you do not have a current certification; correct?

MR. KNEPPER: Objection, form.

A. Yes, I understand it.

Q. Let's look at what else it says. Towards the bottom of page 2, it says, "We ask that you follow these guidelines throughout your career to accurately state your ABPS certification." Do you see that?

A. I do.

Q. The first bullet says, "Diplomates of ABPS must accurately state

their certification status at all times." Do you see that?

A. I do.

Q. And you understand what this means; right?

A. I do.

MR. KNEPPER: Objection, form.

Q. Page 3, next bullet says, "Diplomates with expired time-limited certification or those whose certification is revoked may not claim Board certification by ABPS and must revise all descriptions of their qualifications accordingly." Right?

MR. KNEPPER: Objection to form.

A. Yes. Yes, I see that.

Q. And you understand what that means; right?

MR. KNEPPER: Objection to form.

A. I do.

Q. Your expert report is not in compliance with this guidance from the ABPS; correct?

MR. KNEPPER: Objection, form.

A. The -- the one line there under my name is not in compliance. That's correct.

Q. And the same is true of your CV; right?

A. Well, the CV states that I have been board-certified by the American Board of Surgery and have been board-certified by the ABPS in 1997 and 2008, yes. Have been.

Q. And look back at this page 3 from the ABPS. It says, "When a physician misrepresents certification status, ABPS may notify local credentialing bodies, licensing bodies, law enforcement agencies and others." Do you see that?

A. I do.

Q. All right. And you understand what this means; right?

MR. KNEPPER: Objection to form.

A. Yes.

Q. Okay. Are you going to update your expert report so that it comports with this guidance from the ABPS?

MR. KNEPPER: Objection to form.

A. Certainly.

Q. Okay. So that's plastic surgery. Let's talk about your board certification in surgery next. So, go back to your expert report, page 1.

A. Okay.

Q. You received your board certification in surgery in 1992; correct?

A. Was it '92 or '91? '92, yes, sir.

Q. And that certification expired in 2002; right?

A. Yes.

Q. And you had not renewed that after 2002; right?

A. Correct.

Q. You're not currently board-certified in surgery; correct?

A. Correct.

Q. You have not been board-certified in surgery since 2002; correct?

A. Since 2002, yes, sir.

Q. That's over nineteen years; right?

So, I showed you this guidance from the American Board of Plastic Surgery. How about the American Board of Surgery? What do you think they have to say about doctors who make these kind of representations?

MR. KNEPPER: Objection, form.

A. I'm sure it's probably the same.

Q. Yeah. Would it surprise you that the American Board of Surgery does not allow doctors to represent that they are board-certified in surgery unless they have a current board certificate?

MR. KNEPPER: Objection, form.

A. It would not surprise me, no.

Q. All right. You are currently

serving as an expert in another case, Brandt v. Rutledge. B-R-A-N-D-T. Correct?

A. Yes.

Q. That's a case pending in federal court in Arkansas; right?

A. Correct.

Q. In that case, you were retained by the defendants, by the State of Arkansas; right?

A. Yes.

Q. Dr. Hruz, who is one of the defendants -- strike that. Dr. Hruz, who is one of the experts in this case, is also serving as an expert for defendants in that Brandt case; right?

A. That's my understanding, yes.

Q. And the same is true for Dr. Levine; right?

A. I didn't know about Dr. Levine, but.

Q. And you submitted an expert declaration in that Brandt case in July

of this year; correct?

A. I believe that was when I submitted it, yes.

Q. All right. Let's look at it. And let me know when you get the exhibit, Doctor.

(Exhibit 3 was marked for identification and is attached.)

A. Here it is. Let's see. All right.

Q. All right. Page 1 says, "Declaration of Dr. Patrick Lappert." That's you; right?

A. Yes.

Q. Fair to say that there is at least some overlap between the opinions that you're offering in this case and the opinions that you're offering in that Brandt case; right?

MR. KNEPPER: Form.

A. Well, given that the subject matter is the same, I would expect some overlap, yes, sir.

Q. Go to page 5 of that declaration.

A. All right. I'm there.

Q. You say under Section II, "'Gender affirming' treatments are experimental." Right?

A. Yes.

Q. It's basically the same opinion that you offered in this case; right?

A. Yes, sir.

Q. Go to page 29 of your declaration. See there's a paragraph 63?

A. Yes, sir.

Q. And toward the end of that paragraph, you talk about the national reviews in England, Sweden, and Finland and other reviews like Cochrane, Griffin, and Carmichael. You see that?

A. Yes, sir.

Q. You relied -- you relied on all those studies for your opinions in this case as well; right?

A. I did.

Q. Okay. Go to page 38 of your declaration. Do you see that it's the section titled "Concluding Opinions" and it goes through the next --

A. Yes, sir.

Q. -- few pages?

We don't need to go through these individually, but you agree there's a lot of overlap between the opinions you're offering in that Brandt case and the opinions you're offering in this case; right?

MR. KNEPPER: Objection to form.

A. Yes.

Q. The Brandt case involves a challenge to an Arkansas law which bans doctors from providing various types of gender-affirming treatments to adolescents; correct?

A. Yes.

Q. Including puberty blockers and cross-sex hormones and gender-affirming surgery; correct?

A. Yes.

MR. KNEPPER: Objection.

Q. Have you kept up with what's going on in that case in Arkansas?

MR. KNEPPER: Objection, form.

A. I haven't heard anything perhaps in the last several weeks.

Q. Well, are you aware that in July of this year, the judge in that case held that the State is prohibited from enforcing the ban while the case is being decided?

A. I've heard that.

Q. All right. And as part of that order, the judge made some factual findings. Are you aware of that?

A. I'm not -- haven't read the details.

Q. All right. Let me show you.

A. Okay.

Q. Let me introduce one more exhibit.

(Exhibit 4 was marked for identification

and is attached.)

A. I have it now.

Q. Okay. So, this is a supplemental order from Judge Moody in Arkansas dated August 2nd, 2021. Do you see that?

A. I see that, yes.

Q. This first paragraph says, "After further consideration, the Court supplements the ruling made at the conclusion of the July 21, 2021 hearing to include the following findings." Do you see that?

A. I do.

Q. By the way, did you testify live at that July 2021 hearing?

A. No.

Q. Do you know if any of the other experts testified live at that hearing?

A. I don't know.

Q. Go to page 7.

A. All right.

Q. All right. Look at the last

paragraph.

A. Okay.

Q. The second sentence in that last paragraph says, "Gender-affirming treatment is supported by medical evidence that has been subject to rigorous study." Right? Do you see that?

A. That's what it says, yes, sir.

Q. And that finding by the Court in Arkansas is contrary to the opinions that you offered in that case; right?

A. Apparently so, yes.

Q. And it's also contrary to the opinions that Dr. Hruz and Dr. Levine offered in that case; right?

A. Yes.

MR. KNEPPER: Objection to form.

A. It appears to be, yes.

Q. And it's also contrary to the opinions that you and Dr. Hruz and Dr. Levine are offering in this case; right?

A. Yes.

Q. Look at the next sentence. It says, "Every major expert medical association recognizes that gender-affirming care for transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people."

That's what it says; right?

A. That's what it says, yes, sir.

Q. That's also contrary to the opinions that you and Dr. Hruz and Dr. Levine are offering in both these cases; right?

A. Yes, it certainly is.

Q. In fact, according to this order, every major expert medical association disagrees with you because they've all taken a position that this treatment is in fact medically necessary; right?

MR. KNEPPER: Objection to form.

A. Apparently so, yes.

Q. All right. Look at page 6.

Look at the last paragraph. You see it says that -- the third sentence says, "The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care." Do you see that?

A. I do.

Q. You see there's a Footnote 3?

A. Let me get my glasses on here. Footnote 3. I don't see Footnote 3. Let's see.

Q. The bottom of page 6.

A. I see it now, yes.

Q. Footnote 3 has a long list of medical organizations that all have taken the position that gender-affirming care is medically appropriate for individuals with gender dysphoria; right?

MR. KNEPPER: Objection to form.

A. Yeah, the consensus recommendations. Those are consensus

recommendations. And yes, I was aware that those were the positions taken by those organizations even before the judge's opinion.

Q. Yeah. By my count, Footnote 3 lists 18 different professional medical organizations, and as I read this footnote, every single one of them takes the view that's contrary to the opinions that you and Dr. Hruz and Dr. Levine are offering; right?

MR. KNEPPER: Objection to form.

A. Yes. There's a consensus of consensus on this, exactly, yes, sir.

Q. And you're not aware of a single professional medical organization that submitted anything in this Brandt case and said that they agree with the opinions that you and Dr. Hruz and Dr. Levine are offering; right?

A. Well, I'm aware of at least one professional organization that -- that disagrees with that, yeah, the

pediatric -- American Pediatric -- American Association of Pediatricians.

Q. Do you know if they submitted anything to the Court in this Brandt case to that effect?

A. I'm not aware. I don't know.

Q. Okay. Look back to your report, Exhibit 1.

A. Okay.

Q. And go to page 5.

A. Okay.

Q. See there's paragraph 11?

A. Yes.

Q. And you say that "Affirmation Treatments are Currently Experimental." And then you say, "are not generally accepted by the relevant scientific community." Right?

A. Yes, I say that, absolutely.

Q. Well, apparently, there's at least eighteen different professional medical organizations that all say that you and Dr. Hruz and Dr. Levine are wrong

and that these gender-affirming treatments are, in fact, medically appropriate; right?

A. Well, I --

MR. KNEPPER: Object.

A. I would say that part of the difficulty here is a misunderstanding about how those consensus opinions are arrived at. They're not arrived at scientifically. So minus a scientific opinion, those are -- those are consensus opinions.

For example, in plastic surgery, there was a controversy some years ago about the use of fat grafting in breast reconstruction, and there was a concern about whether it would promote malignant degeneration. The American Society of Plastic and Reconstructive Surgeons came out with a consensus statement essentially recommending against, if not outright forbidding, the use of fat grafting in breast reconstruction or

cosmetic surgery. But I was never polled. I was a member of the American Society of Plastic Surgery, but I was never polled.

These consensus statements do not poll the scientific or professional community. They're the work product of a -- of small committees where they perhaps will review scientific literature and come to an opinion within that relatively small group.

So I think the misunderstanding is that because, for example, the American Medical Association or the American Pediatric Society has a statement making this claim, it's not, by definition, supported by the membership of that -- that society. It is the work product of a committee, and it's -- and it doesn't -- it doesn't lay out the scientific basis for those opinions for the membership to review, as was the case in -- and it turns out that seven, eight

years later, the American Society of Plastic and Reconstructive Surgery rescinded their prohibition when the membership basically chimed in and said this is incorrect and this is our evidence, here's the science. And the American Society rescinded that consensus statement that they had made ten years earlier.

So I imagine that similar things are going on here. Committees generates consensus statements. The consensus statements are published. And one gets the impression that the entire membership supports the statement when that in fact is not the case. And when these consensus statements are published, they don't publish the supporting scientific literature. They merely make the statement. So I think this is the case here as well.

Q. You are not a member of the, let's say, American Medical Association;

right?

A. Not -- not any longer, no.

Q. And your -- I hear you speculating that there's a committee that came to this decision at the AMA; right?

MR. KNEPPER: Objection, form.

A. Well, if the AMA functions like the American Society of Plastic Surgery or other -- other professional bodies like that, professional organizations like that, I would expect that's how they make their consensus statements, yes.

Q. You personally do not know how the AMA came to issue this consensus statement, do you?

MR. KNEPPER: Objection.

A. I have no personal knowledge, no.

Q. You have no personal knowledge what scientific literature they reviewed in coming up with that consensus statement, do you?

A. That's the difficulty. Yes,

sir.

Q. Yeah.

A. Correct.

Q. You have no idea, in short, how the AMA came to reach this consensus statement; right?

MR. KNEPPER: Objection to form.

A. I have no personal knowledge of it, no.

Q. How about the American Pediatric Society? You're not a member of that; right?

A. No.

Q. You have no idea how the American Pediatric Society came to support this consensus statement; right?

A. Well, in that case, I do have friends who are members of the American Pediatric Society, I think it is. And they, in conversation, have told me that this is how the process works. I don't have personal -- personal knowledge of it, no.

Q. Are those friends on the committee at the APA that decided to adopt this consensus statement?

A. Not to my knowledge.

Q. So they also -- strike that.

How about the American Psychiatric Association? You're not a member of that --

A. No.

Q. -- right?

A. No.

Q. You have no idea on what basis they decided to support this consen- -- what you call consensus -- consensus statement about the necessity of treatment for gender dysphoria, do you?

A. No.

Q. So, Doctor, I hear you criticizing these organizations, but you do not have firsthand knowledge of how any of those organizations came to reach these positions, do you?

MR. KNEPPER: Objection to form.

A. No.

Q. And you do not know what scientific literature they relied on, do you?

A. No.

MR. KNEPPER: Objection to form.

A. Other than to say that I'm familiar with the current literature, and I -- and whenever these -- these consensus statements are supported with references to the scientific literature, that literature I have reviewed. That was part of the process of generating my expert testimony.

Q. I thought I just heard you say that these position statements are not typically supported by "Here's the study we relied on." Isn't that what you said?

A. Well, no. In the -- in the actual document that they publish, they make -- they make reference to things like that.

What I meant to say, I suppose,

is that -- that I've reviewed the current literature, particularly in the last three to five years, that's germane to the subject of gender affirmation in pediatric patients and adolescents, and I -- and I find that the science is weak, so --

Q. But because you have no firsthand knowledge of how any of these associations came out with these position statements, you do not know to what extent it may have taken that literature into account before adopting these position statements; right?

MR. KNEPPER: Objection.

A. I can only say that if they gave full force to the scientific literature that is used to support their position, I find the scientific literature weak, yeah.

Q. This Brandt case involves a state law that prohibits doctors in Arkansas from providing gender-affirming

medical treatment to anyone under eighteen; correct?

A. Yes.

Q. You yourself support these kind of state law bans; right?

MR. KNEPPER: Objection, form, scope.

A. I do support a control over these kinds of therapies, yes, I do.

Q. Well, not -- not just control, because Arkansas says it will criminally prosecute doctors that do it; right?

A. Right.

MR. KNEPPER: Objection to form, scope.

Q. And you think that's a good idea; right?

A. I do.

MR. KNEPPER: Objection to form, scope.

Q. You think that other states outside of Arkansas should be passing similar bans; right?

MR. KNEPPER: Objection, form, scope.

A. Actually, what I would prefer to see is the -- is the professional societies recommend against these sorts of things, yes. That would be my preference. I would rather that the State did not step in and manage the care of people who are suffering. I'd rather the State stayed out of it. But short of that, I suppose that's the -- the fallback position is to recourse through the law.

It would seem to me that professional organizations should be managing these issues, and practitioners ultimately should be responsible, as was found in the -- in the -- the case in Great Britain at the Tavistock Portman Institute when the Court came back and reviewed the find -- the ruling there and declared that primacy should be given to the decision-making of doctors rather

than the Courts stepping in as -- as managers of medical care.

And I feel the same way. I don't think that the State should have to do this. But -- given that -- given that things are moving at the pace they are.

Q. Are you aware that state legislators in Utah have proposed a similar ban as Arkansas for gender-affirming medical treatment for minors?

A. Yes.

MR. KNEPPER: Objection to form, scope.

Q. You had involvement with those legislative efforts in Utah, didn't you?

A. I think I made some recommendations to them. Yes, I did.

Q. Yeah. Because now I hear you saying you prefer the professional organizations handle it. But the fact is you have actively lobbied to get these kind of bans passed in other states,

haven't you?

A. Yes, I have.

MR. KNEPPER: Objection to form, scope.

A. Yes, I have.

Q. I'm going to introduce another exhibit. Let me know when you have it, Doctor.

(Exhibit 5 was marked for identification and is attached.)

A. I have it.

Q. Exhibit 5 is a document titled: "Transgender 'Transition' Procedures Performed on Minors. Answers to Questions and Information for Joint Interim Committee," dated June 10th, 2021. Do you see that?

A. I do.

Q. It says, "Submitted by Rep Rex P. Shipp," S-H-I-P-P. Do you know who that is?

A. I don't know him personally, but I -- I see he's a representative from

Utah apparently.

Q. Have you ever communicated with Mr. Shipp and his staff?

A. I may have and don't recall.

Q. Why do you say you may have?

A. I have a lot of correspondence with people who ask a lot of questions who are involved in this -- in this issue, and I don't have a great memory for names sometimes. But I know I was in communication at some level with people in Utah, but I don't recall exactly the nature of that conversation, or that interchange.

Q. Go to page 16.

A. Sixteen?

Q. One six.

A. One six. Okay.

Q. Toward the bottom of the page, it says, "We express appreciation to these noted professionals who contributed to this report." Do you see that?

A. I do.

Q. Go to page 17.
A. Okay.
Q. The bottom of the page says, "Patrick Lappert, M.D."
A. Yes.
Q. That's you; right?
A. Yes.
Q. So at some point earlier this year, you were providing information to the Utah State Legislature to support the potential enactment of a ban on gender-affirming healthcare for minors; right?
MR. KNEPPER: Objection, form.
A. Yes.
Q. Look at the fourth name from the bottom on page 17.
A. Fourth name -- I'm sorry?
Q. Fourth name from the bottom.
A. Paul Hruz. Yes.
Q. That's the same Dr. Hruz who's an expert in this case; right?
A. Yes.

Q. Go to page 18. The second name from the top is Stephen B. Levine M.D.; right?

A. Yes.

Q. Same Dr. Levine who is an expert in this case; right?

A. Yes. I think so, yes.

Q. And the next name is Paul McHugh, M.D.; right?

A. Yes.

Q. The same Dr. McHugh who is an expert in this case; right?

A. Yes.

Q. All four of you were providing information to the Utah State Legislature to support this potential ban; right?

MR. KNEPPER: Objection to form.

A. Yes.

Q. How did you get involved with providing this information to the Utah State Legislature?

A. I don't recall. My -- my suspicion is I may have been contacted by

e-mail or some other such thing. In fact, I'm fairly confident it was an e-mail request for assistance, probably.

Q. Do you remember who the e-mail was from?

A. I do not.

Q. Do you remember who at the Utah State Legislature or anyone affiliated with them you were communicating with in this respect?

A. I don't remember, no.

Q. All right. Let's see what you were telling the state legislature in this report. Go to page 5. See there's a section near the top titled "Sex reassignment surgeries"?

A. Yes.

Q. There's some language in quotes -- in quotes and italicized. Do you see that?

A. I do.

Q. And the first portion of the paragraph says: '"Sex reassignment

surgery' is a massive misrepresentation of what these operations actually do. You can't change a person's sex. All that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex."

Do you see that?

A. I do.

Q. And underneath, it says, "Patrick Lappert, M.D." Right?

A. Yes.

Q. These are your words, Dr. Lappert; right?

A. Yes.

Q. You consider gender reassignment surgery to be an intentional mutilation; right?

A. I do. Absolutely.

MR. KNEPPER: Form.

Q. And calling gender reassignment surgery, quote, intentional mutilation, is that commonly accepted terminology in

this field, Doctor?

A. I expect not.

Q. And then you say that when a patient undergoes gender reassignment surgery, all that is happening is, quote, a counterfeit appearance of the other sex; right?

A. Yes.

Q. This phrase, "counterfeit appearance," do you think that's an appropriate term for a doctor to use?

A. Absolutely.

Q. And you stand by these words; right?

A. I do.

Q. All right. So, we've talked about Arkansas, we've talked about Utah. Now, I know there is currently a number of other states that are considering passing similar bans. Outside of Utah, have you done any work whatsoever in connection with these potential bans in other states?

MR. KNEPPER: Objection, form, scope.

A. I have.

Q. Which states?

A. Alabama, Texas.

Q. What else?

A. Texas. I don't know if there were any in the Northwest or not. I think that's all of them. I may be wrong, but I think that's all. Alabama and Texas I would just add to your list.

Q. Okay.

A. There may been something in Arizona. I'm not certain about Arizona as well, but --

Q. Now let me introduce another exhibit. Okay. Let me know when you get this one.

(Exhibit 6 was marked for identification and is attached.)

A. I've got it.

Q. All right. This article is titled, "Alabama bill that would

criminalize treatment for transgender minors headed to full Alabama Senate." You see that?

A. I do.

Q. Alabama, your home state, was considering a ban very similar to Arkansas just this year; correct?

A. Actually over the last couple of years.

Q. Okay. The first paragraph says, "The Alabama Senate Health Committee on Wednesday approved a bill that would outlaw puberty-blocking medications and gender-affirming care for minors, giving" -- "giving it a favorable report in an 11-2 vote." You see that?

A. I do.

Q. Then it says, "An Alabama House committee heard testimony in a public hearing on a companion bill, but the committee did not vote on the" -- "on the measure." You see that?

A. I do.

Q. You testified in support of this bill; right?
A. Yes, sir.
Q. Go to page 2.
A. Okay.
Q. Look at the second paragraph from the bottom.
A. Second from the bottom. Yes.
Q. It says, "Dr. Patrick Lappert, a Decatur plastic surgeon, spoke in favor of the bill."
That's you; right?
A. That's right.
Q. Go to page 3.
A. Okay.
Q. And look at the third paragraph. It says that you've "spoken against the use of medicine and surgery for transgender people as a Catholic deacon in his local diocese." See that?
A. Yes.
Q. You don't deny that you've spoken against the use of medical and

surgical treatment for transgender people in your position as a Catholic deacon; right?

A. That's correct, I do not.

Q. All right. Focus on the last sentence of this third paragraph. It says that when a committee member questioned your medical expertise on this issue, you said that you would not treat a person for gender dysphoria and would instead refer them to a qualified mental health professional. You see that?

A. Yes.

Q. At this hearing, someone on the committee was questioning your medical expertise to offer these opinions; right?

MR. KNEPPER: Objection, form.

A. I don't remember that detail, but I think so, yeah. I think the objection they raised was that I don't do these treatments, how could I know.

Q. You're not a psychiatrist; right?

A. No.

Q. You do not have specialized training or expertise in diagnosing mental health conditions; right?

A. I have limited -- limited training. Yes.

Q. And when you say "limited training," what does that mean?

A. Well, in the training of plastic surgeons, we are -- we are required -- because we offer aesthetic surgery, we get some training in issues, psychological/psychiatric issues relating to people who will seek to modify their bodies in order to achieve a sense of peace or a sense of improvement in their lives. And it's imperative that a plastic surgeon be able to recognize persons who are suffering from psychiatric problems because plastic surgery -- to offer them plastic surgery to modify their bodies is in the category of malpractice, not to mention that very

often, dissatisfied patients will -- will make life very difficult for the practitioner, if not threaten them with physical harm.

I would refer you to an article by -- although we haven't offered it up, -- a friend of mine, Dr. Mark Gorney, who was one of the -- one of the grand old men of plastic surgery, started the Physicians Company to manage physician liability and risk and had -- he discovered that there's an overrepresentation of -- of violence against physicians by aesthetic patients committing violence against plastic surgeons. That's just one of the motivators.

But nonetheless, the issue of body dysmorphic disorder is part of our training, persons who are seeking a remedy to their interior woundedness or their psychological disturbances by changing their outward opinion. And body

dysmorphic disorder is a well-characterized psychiatric diagnosis that impinges greatly upon plastic surgery precisely because aesthetic surgery -- even in its name, you can tell that aesthetic surgery is surgery aimed at the aesthetic, the feelings, esthesia, the feelings that a patient has about themselves, about their life. So it's incumbent upon plastic surgeons to know about these things, and so we get trained in those matters.

So again, I have very limited psychiatric/psychological knowledge, but I do know that that subset of patients should be referred for psychological help rather than offered surgery. Not to mention the fact that such patients can't even give informed consent because of their psychological disturbances.

Q. All right. You're talking about patients who have body dysmorphic disorder; right?

A. That's right.

Q. When did you last receive training in how to diagnose someone with body dysmorphic disorder?

A. I guess it's ongoing training when one's in the -- in the practice of plastic surgery. But I had originally in my residency and then on an ongoing basis I think at conferences through the years.

Formal training in it, I -- I don't recall beyond my residency. All I do is try to keep abreast of the literature.

Q. Yeah. So, let's take that in steps. Outside of -- when was your residency in plastic surgery, Doctor?

A. '92 to '94.

Q. Right. Past '94, you have not received formal training in how to diagnose someone with body dysmorphic disorder; right?

A. There may have been some CME credits at a conference in there

somewhere or remote learning. I don't recall.

Q. But sitting here, you can't recall any of those specifically; right?

A. I cannot, no.

Q. What are the diagnostic criteria for body dysmorphic disorder?

A. Well --

Q. Do you know that sitting here today?

A. Yes. So, a person with body dysmorphic disorder, the diagnostic criteria is the -- is the patient who presents with evidence of a psychological disturbance. In review of their history and physical examination, you may see evidence of a history of substance abuse, maybe evidence of some self-harm, evidence of social isolation in their intake forms, that sort of thing. That would raise the concern.

The second would be the person who attaches tremendous potential benefit

of, psychologically, the -- the quality of the -- sort of a transformative power of cosmetic surgery.

And then the third criteria would be that they -- they see something that you don't see. They see a defect that you don't see. And that's probably the key diagnostic criteria. For example, a man who presents seeking a modification to his nose who has evidence of living a life of social isolation who is adamant that by changing his -- the appearance of his nose, he will -- he will have a much better life. And hearing that, of course, the alarm bells go off and then examining the patient and seeing that there's no objectively definable deformity, only a normal variation that one would expect to see on a man's face.

Those are all red flags. And -- and based upon that, it is -- it is definitely the -- has been

historically the recommendation of the likes of Dr. Mark Gorney and other leaders in the American Society of Plastic Surgery to not offer surgery, but rather to offer referral for psychiatric/psychological support and evaluation.

Q. These diag- -- these diagnostic criteria that you mentioned, where do they come from?

A. They -- I think you can find much of that in the DSM book, if -- if -- if that's the route you want to go. You find it in the literature. There are -- there are references in the scientific literature about it dating back to I think the 1920s. I included some of those, I think, in my discussion, if not on this one, in the Arkansas case.

But -- but there have been papers published through the years that describe the condition and make recommendations about care, and again,

going all the way back even to textbooks in plastic surgery and -- and of course, the residency training that speaks about that as well.

Q. So for diagnosing someone with body dysmorphic disorder, you would rely on the DSM-5; right?

A. I wouldn't rely on it, no. No. I would rely on my -- my clinical experience more than anything else there.

Q. Well, you just rattled off three or four guidelines that I think I heard you say come from the DSM-5; right?

MR. KNEPPER: Objection, form.

A. Well, they're -- they don't come from the DSM-5 but are described in the DSM-5, yeah.

Q. So when I asked you --

A. And 4 -- actually, DSM-4 has a clearer description, I think, than DSM-5.

Q. So when I asked you what criteria you would use to diagnose someone with body dysmorphic disorder,

the source you went to was the DSM; right?

A. No. The source I went to was my training and the -- and the papers that relate to it. I think it's just been subsequently characterized in the DSM. And it's a ready -- it's a volume that's readily accessible to people. The language is readily accessible, so people who are seeking information about that, they can go there for it or they can go to the articles, if they like. Yes.

Q. Outside of whatever training you had on diagnosing someone with body dysmorphic disorder, you do not have specialist training or expertise in diagnosing other mental health conditions; fair?

MR. KNEPPER: Objection, form.

A. Let's see. Well, there's -- I guess there are subcategories of -- of body dysmorphic disorder, like recognizing the anorexic patient, of

course, who presents for body modification. That -- that's a fairly readily and obvious one.

But no, I'm not a -- I'm not formally trained in psychiatry or psychology.

Q. You do not have -- you do not hold yourself out as an expert in diagnosing mental health conditions outside, potentially, of body dysmorphic disorder; right?

A. Correct.

Q. You do not have specialist training or expertise in treating mental health conditions; right?

A. No.

Q. You would refer that person to a qualified mental health professional; right?

A. I would. I would.

Q. Because you yourself are not a qualified mental health professional; correct?

A. Correct.

Q. All right. You've also published an op-ed in May of this year supporting this Alabama ban; correct?

A. Yes.

Q. And you said that Alabama legislators should enact this ban because they have a duty to protect the vulnerable population of gender-confused children. Does that sound familiar?

A. Yes.

Q. So again, earlier you said you had a preference for professional societies dealing with this, but you're out there publishing op-eds calling on state legislatures to pass these bans; right?

MR. KNEPPER: Objection, form.

A. Right. Yes, sir.

Q. All right. How about Texas? Tell me what work you've done supporting this kind of a ban in Texas?

A. It's been similar. I've been in

communication with -- I can't remember if they're on the legislative side or on the justice side. I don't remember exactly where they fit into the -- the government of Texas, but I've corresponded with them and offered them information and advice.

Q. Was it similar information to what we've seen in that Utah packet?

A. I'm sorry, sir?

Q. Was it information similar to what we've seen in that Utah legislation packet?

MR. KNEPPER: Objection, form.

A. Right. The substance -- the substance of the issue at hand is the same wherever you find it. It's this contest between those who -- who promote gender-affirming care versus those who promote, in the case of children, for example, watchful waiting and psychological support and cognitive behavioral therapy and those things, yes. It's the same battle wherever you find it

because it's the same problem, the same science, the same language. All of it's the same.

Q. So earlier, we saw that in addition to you, Dr. Hruz and Dr. Levine and Dr. McHugh were also involved with those Utah legislative efforts; right?

MR. KNEPPER: Objection, form.

A. I -- I don't know their involvement in -- in Texas. I'm -- I'm not aware.

Q. Yeah. Do you know whether any of them have been involved with any of these efforts in any other state?

A. I don't. I don't know.

Q. Okay. Fair to say that you have some strong personal opinions on whether doctors should be providing gender-affirming treatment to minors?

MR. KNEPPER: Objection to form.

A. Very fair to -- very fair to say, yes.

MR. TISHYEVICH: Let's go off

the record.

THE VIDEOGRAPHER: This is the end of Media Unit 1. We are off the record at 9:33 a.m.

(Break taken.)

THE VIDEOGRAPHER: This is the beginning of Media Unit No. 4. We are on the record at 9:44 a.m.

Q. (By Mr. Tishyevich) Doctor, you're familiar with an organization called Alliance Defending Freedom, ADF; right?

A. Yes.

Q. How are you familiar with the ADF?

A. I was invited down there for a conference on the subject of transgender. I was an invited presenter, I should say. They asked me to come and speak from a plastic surgeon's perspective on how I view the current state of transgender medicine and surgery.

Q. Those were -- those were the

meetings in Arizona? Is that right?

MR. KNEPPER: Objection.

A. Yes.

Q. Who invited you?

A. I don't remember who the particular name was. I -- I don't recall who the -- the particular person, the one that sent me the invitation.

Q. Was it --

A. It may have been -- it may have been Gary McCaleb, I want to say. I'm not positive about that, though.

Q. You -- you anticipated my question.

A. Okay.

Q. To your knowledge, what's the view that the FDA takes on providing healthcare treatment to patients with gender dysphoria?

A. The position of the FDA?

Q. The ADF.

A. Oh, the ADF. They -- let's see. So, the sense I get is that the ADF takes

a -- the opinion that the present state of transgender medicine and surgery is not in the interest of the patients or the families.

Q. The ADF has moral objections to doctors performing this kind of surgery and treatment; right?

MR. KNEPPER: Objection, form, scope.

A. I would -- I would characterize the ADF's position as more than just a moral objection. It's both moral and objective scientific objections.

So the -- the -- the sense I got from that conference was that most of the invited speakers came to speak about -- for example, Dr. Hruz was there, and he spoke about endocrinology and the endocrinol- -- endocrinologic basis for sex/gender. And he spoke about the effects of -- the endocrinological effects, the objective changes that are caused by, for example, puberty-blocking

cross-sex hormones.

I was -- there was also another speaker there, I think, on the subject of -- from the family medicine perspective, the overall effects on the health of the child, developmental issues. There was a presenter on the objective psychological issues.

And then, I presented on the realities of the surgery. They wanted me to speak about the technical details of transgender surgery, kind of the evolution of the process of transitioning surgery, and the -- and to give them a summary of the state of the science on it.

So I would characterize the ADF as interested in both the moral -- the moral issues and the objective, and they impinge upon one another. Clearly, to do something that is not in the -- in the objective benefit of the patient is a moral problem.

Did I answer your question?

Q. That's helpful, yeah.

The ADF is not a professional scientific organization; right?

A. Not to my knowledge, no.

MR. KNEPPER: Objection to form, scope.

Q. They're a legal organization; right?

A. Yes. That's my understanding.

Q. ADF is engaged with bringing lawsuits that do things like challenge schools' rights to -- to have transgender persons on their teams; right?

MR. KNEPPER: Objection, form, scope.

A. I don't know the scope, the full scope of their efforts, but yeah, they're one of I guess several legal organizations that are -- that are approaching these matters, as are you, for example.

Q. All right. Let's talk about

these meetings in more detail. So, how many -- strike that.

You've been to two meetings organized by ADF?

A. That's my recoll- -- yeah, two meetings. I think that's right.

Q. All right. Let's start with the first one. This was in 2017?

A. That sounds about right, yeah.

Q. What --

A. I think it was 2017, yeah.

Q. What month roughly?

A. I don't remember now.

Q. Do you know how they came to invite you to that first meeting?

A. I do not.

Q. Before that meeting, you had not published anything about gender dysphoria, had you?

A. No.

Q. Before that meeting, you had not published anything about the risks of use of hormone blockers in minors; right?

A. No. I've given -- I gave some -- some -- I think they may have heard of me not through publications, but through public speaking.

Q. How long have you been doing public speaking on the issues related to gender dysphoria?

A. Since 2014.

Q. Let's start with the first meeting. So, Dr. Hruz was also present at that meeting?

A. Yes.

Q. Was Dr. Levine present at that meeting?

A. I don't think I've ever met Dr. Levine, so I don't -- he couldn't have been there because I would have remembered meeting him, and I don't remember ever having met him.

Q. How about Dr. McHugh?

A. No. I would have remembered him. He's a very famous person.

Q. How many people were present at

this first meeting?

A. Perhaps ten. I'm not certain.

Q. Outside of you and Dr. Hruz, who else do you remember being at that first meeting?

A. I remember meeting a Dr. Andre Van Mol. I believe he was at that meeting. There was a pediatric endocrinologist there by the name of Quentin Van Meter. I think he was there.

There was a -- there was an expert in scientific data and scientific data analysis, medical record data analysis from UC-San Francisco. I don't believe he was a physician. I think he was a -- had a doctorate in science. And he was a -- he was actually a detransitioner. So he was giving not only his knowledge of the medical literature, he was just an incredible resource and reference for medical literature. You could just about ask him anything. But he was also there, I

think, to speak from a personal perspective as well, being a detransitioner.

There was another detransitioner there who I don't remember their name, but they were there to speak. I think they were also an educator as well. I'm not positive about that.

So it's kind of vague for me, but I -- but definitely Paul Hruz stands out because we had a very good conversation there.

Q. What was the format? Were there presentations, a round table discussion? How did the conversations go?

A. There was some introductory remarks, and then -- and then each -- each sort of specialist gave a presentation. I think I gave an hour-long presentation. And there were others like mine on those other subjects we talked about.

Q. Did you use slides as part of

that presentation?

A. I usually do, yes, although I don't know what I've done with that slide deck. I don't keep them very long. They sort of morph all the time.

Q. Do you think you might have an electronic copy of that slide deck somewhere?

A. I don't.

Q. At a very high level, what was the -- what were you trying to convey through your presentation to that group? Let me ask it a different way. Were -- was your presentation broadly similar to the opinions that you're offering in this case and in the Brandt case?

MR. KNEPPER: Objection, form.

A. Well, by the -- by "broadly similar," do you mean the subject matter or the nature of my opinion or the evidence used to support my opinion?

Q. All right. Give me a high-level summary of what your presentation was at

that first meeting.

A. It was a --

MR. KNEPPER: Objection, form, scope.

A. -- a summary, a summary of the present state of transgender medicine and surgery, a review of the scientific literature used to support the treatments that are being offered, a review of the long-term outcomes of treatment that are being offered, with particular attention to the European literature, which is more reliable. I sort of -- I compared the American literature to the European literature because that's one of the great problems we're having in this issue. And it was already evident in 2017 that there was a great disparity between the American literature and the European literature in terms of the quality of the scientific evidence that's being used to support the interventions.

So that was -- really at the

heart of the presentation was what's the state of the science and where is the reliable science coming from and what is it -- what is it showing us, so. But they also -- the audience wanted to have an understanding of what these plastic surgery interventions were. So there was an extensive discussion of the particulars of the surgeries, the details about the surgeries, the typical outcomes of the surgeries, so.

Q. I want to -- strike that.

One of the topics of discussion at that meeting was about the need to have expert witnesses for litigation; right?

MR. KNEPPER: Objection, form, scope.

A. I remember -- I remember a fairly long discussion about the poverty of people who are willing to testify because of the risk that they take in testifying. That was a -- that was a

fairly long discussion. And the difficulty that that -- that people have in finding expert witnesses because of the risks they place themselves in, in testifying.

Q. And people at that meeting were asked whether they would be willing to participate as expert witnesses; right?

A. Yes.

Q. Before that meeting, you had never testified as an expert witness?

A. Before this moment, I never testified as an expert witness.

Q. Who made the introductory remarks at the beginning of this meeting?

MR. KNEPPER: Objection, form, scope.

A. I'm trying to remember. It was a -- it was an attorney whose first name is Jeff, and I'm trying to remember what his last name was. But he seemed to be the -- the -- kind of the emcee, if you will. Yeah, Jeff. I'll see if, in the

course of our conversation today, the name will pop in. This is the difficulty I have with remembering names. They'll just pop in at a moment's notice.

But it was -- yeah, it was an attorney who gave the overall scope of why -- why we were there, to discuss this issue, to see what -- what the -- what the science is showing to see where -- what the -- the moral aspects of good science versus bad science and issues like that, yeah.

Q. Aside from you and Dr. Hruz, do you recall anyone else expressing an interest at that conference about serving as an expert witness?

MR. KNEPPER: Objection, form, scope.

A. You mean someone expressing just generally about having expert witnesses?

Q. No. Other participants saying, "I might consider being an expert witness in one of these cases."

A. I don't recall. I don't, no.
Q. Okay. All right. So then there was a second meeting also in Arizona; right?
A. Right.
Q. And that was also in 2017?
A. I don't remember the date of that as well -- either, no.
Q. What was the purpose of that second meeting?
A. I think it was similar, although it may have been a little bit more refined. There was not as much discussion of the really foundational science as more a review, I think, of -- you know, I -- I guess it was similar in terms of format. I think there were more -- more people there who were speaking from personal experience.
So I think the most important thing I recall from that meeting was that -- that there was a mother -- actually, a couple of family members of persons who

experienced cross-sex self-identification who have gone through various -- various phases of transitioning. And they were giving sort of a personal experience, trying to describe to us what they went through as a family, what they went through with their children. And that's what -- so that was the difference between the first and the second meeting. I think it was more of a personal thing. It had the science as well, but I think it had more of a personal side to it as well.

Q. How many people do you think attended -- attended that second meeting?

A. I'm trying to think how full the room was. I think it was probably comparable maybe, a dozen perhaps. I'm not sure.

Q. Who do you remember being there by name?

A. I think that may have been when I met Dr. Cretella. I can't remember if

I met her at the first meeting or the second meeting.

Oh, also at that second meeting, there was a plastic surgeon. I can't remember his last name. I was -- I remember being very encouraged to meet another plastic surgeon who saw this as an issue. And I do remember that he had been the chairman -- this speaks to the issue of fear about testifying. He had been the chairman of a major plastic surgery department in a large Midwest university, had built that program for many years, had run one of the most successful residency training programs. And he had been fired because he had objections to the transgender services that the hospital administration -- or the university administration wanted to introduce. And I thought it was a very heartbreaking story to see that a man had lost his entire career over his professional opinion. I don't remember

his last name, but I do know that I met him at that second meeting.

Q. Do you remember his first name?

A. I don't.

Q. Do you remember which center he was affiliated with?

A. I believe he was from the Ohio State University. But I haven't seen or heard from him since. He has just disappeared. I tried to reach out to him, I recall, because, again, there's not a lot of plastic surgeons who are willing to speak on this matter. And -- but I haven't heard from him since.

Q. Did participants at the second meeting make presenta- -- make presentations as well?

MR. KNEPPER: Objection, form, scope.

A. I -- I don't -- yeah, I think it was more limited presentations, briefer, sort of reviews sort of thing. But it wasn't -- it didn't have the formality of

the first meeting, as I recall. Again, it's -- it's a little bit murky four years on.

Q. Yeah. I'm just asking for your best recollection. That's fine.

A. Sure. Okay.

Q. Do you remember giving a presentation at that second meeting?

A. I believe I did.

Q. How long do you think that meeting lasted, roughly?

MR. KNEPPER: Objection, form, scope.

A. Well, I remember it -- we went through a full morning, a light lunch, and perhaps into the very early afternoon.

Q. And you mentioned that there was some personal testimony from parents, families. What portion of the meeting was that, roughly?

A. What -- what portion?

MR. KNEPPER: Objection, form,

scope.

Q. What portion, yes.

A. I would be guessing that perhaps a third of the meeting was -- was that.

Q. Okay. After these meetings in 2017, have you continued to stay in touch with the ADF?

MR. KNEPPER: Objection, form, scope.

A. I think perhaps, you know, one or two e-mail exchanges, but nothing -- nothing substantive. I haven't really heard anything from them. I think I got a -- no. Well, I can't -- I can't recall anything other than maybe a thank-you e-mail or hope you're doing well kind of thing, but nothing substantive, no.

Q. How did you come to get involved with being an expert in this case?

A. I was contacted by Mr. Knepper.

Q. Okay.

A. Actually, I was contacted by his staff. He didn't call me himself, but

his -- someone on his staff called me and asked --

Q. I understand.

A. -- if I would be available. Yeah.

Q. How did you come to get involved with the Brandt case in Arkansas?

MR. KNEPPER: Objection, form, scope.

A. I think it may have been similar. I don't recall the particulars, but I -- someone on -- on the legal counsel side contacted me. I don't remember who it was.

Q. Okay. Let me shift gears a bit. You know what the American Society of Plastic Surgeons is; right?

A. Of course.

Q. Are you a current member?

A. No. I -- I let my membership lapse years ago, yeah.

Q. When --

A. About two years ago, I would

say. Maybe two years ago, yeah.

Q. Why did you decide to let your membership lapse?

A. Well, in order to be a member of the American Society of Plastic Surgeons, you have to be board-certified. And so since I declined continuing board certification for the reasons I explained to you, then my membership -- you know, over time, when my subscriptions and membership fees lapsed, so did my membership. And I think that would have been in 2019.

Q. I understand.

A. Yeah.

Q. Is it -- is an active board certification in plastic surgery a prerequisite to being in the American Society of Plastic Surgeons?

A. I seem to remember that when I -- back in the '90s after my residency, there's a -- there's a membership for -- for board-eligible. It's not the full

membership, but then when you get board-certified, then you get full membership and the rights to use the logo and all that sort of stuff, so. Yeah, as I recall. It's been a long time since I read the bylaws. That would have been back in '95, I think, that I read those things.

Q. Yeah. When did you first join the ASPS?

A. I think I joined as a student member when I was in my residency. I want to say it was probably like '92 or '93, somewhere in there.

Q. So you were in the ASPS roughly '92 --

A. I think, yeah.

Q. -- to 2017?

A. I think, yeah. As I recall -- again, it's a little bit murky, but as I recall, there's sort of a provisional membership for residents in training. You sort of get a discounted rate on all

of the expensive things, and the -- and access to the White Journal, as it's called. And then -- and then I -- as I recall, you don't get the full membership until you've been board-certified, which happened for me, as you know, in '97.

Q. Okay. But you were part of the ASPS for a long time; right?

A. Yes. Going to meetings.

Q. You consider the ASPS to be a reputable organization; right?

MR. KNEPPER: Objection, form.

A. Yeah. Well, for the most part, yeah. Certainly, the members, virtually most of the members I've ever known are reputable. And there are some things that the ASPS has done through the years that -- that I've had difficulty with and -- but they're certainly the organization in American plastic surgery.

Q. Yeah. I think one statistic I heard is 93 or so percent of all plastic surgeons are part of the ASPS.

A. Yeah.
Q. Right?
A. That -- that number wouldn't surprise -- I would have thought even higher, actually, but yeah.
Q. Do you think the ASPS would encourage its members to perform surgeries that are not medically necessary?
MR. KNEPPER: Objection, form.
A. Well, the -- as a -- as an organization, they don't encourage particular surgeries, but they may support them with their scientific presentations, their conferences, and that sort of thing.
For example, three or four years ago, I went to a meeting of the California Society of Plastic Surgery, which is -- I think it has sort of a subsidiary relationship with the ASPS. And at that conference, among other things -- I went there because that's one

of the -- the areas of the country where I trained and I had hoped to see some friends there. But -- but for example, in that conference I went to a lot of great presentations, but the last day was devoted almost entirely to transgender surgery.

And so if you're asking me do I -- how do I feel about that, well, I have great difficulty with a professional organization that would support or promote those sorts of interventions knowing what I know about the scientific underpinnings of those medical and surgical procedures. And I had many conversations at that conference on the subject with persons who were providing the services, and I didn't find their answers particularly satisfactory. So that would be an example.

I can't give you carte blanche that everything that the Society says and does is to my liking. I would say

probably most of what they say and do is very much to my liking. But on this matter, I have -- I have a great difficulty. And it's one of the reasons that I -- I -- yeah.

Q. It's one of -- one of the reasons that you what?

A. That I -- that I don't have a lot of heartache about stepping away from the ASPS.

Q. Do you think the AS- -- ASPS advocates in favor of surgical procedures that are not medically necessary?

A. I think that would be probably an overreaching statement. I wouldn't say that. I would say that perhaps they're mute on some of the -- some of the procedures that their members perform, and they certainly have their eyes and ears open for new things. And so when members come forward to make presentations about particular new therapies and new approaches, as they

should, the ASPS is open to those things. So for many years, transgender surgery has been in that category.

I remember when I was a -- even when I was a general surgeon and I was looking for residency programs to train in, I was considering UVA. And I saw that -- that Milton Edgerton, one of the great names in plastic surgery was at UVA doing transgender surgery, both at UVA and at Johns Hopkins. And I remember thinking, well, I'm -- I really need -- it struck me as an unusual operation, and I -- I started doing some research into it.

And I remember starting to think about the issue of transgender surgery back in the -- what would have been 1991, 1990, 1991. And -- and through the years, the ASPS has made room for that intervention, those therapies, in their conferences, in their dialogues, in their publications. And I've reviewed all that

stuff as it has come along. And I think now being twenty, nearly thirty years on since I first started looking at it and they're still just sort of at that stage of -- of putting it out there, although now they're offering more extensive training conferences on how to do those procedures, and they're now encouraging that it be included in residency programs, and so -- yeah.

Q. Do you know what position the ASPS takes on whether gender-affirming surgery is medically necessary?

A. I think that position has changed, and now they're -- they're speaking positively about it.

Q. Yeah. Your own professional organization, or at least your former organization, takes the position that gender-affirming surgery is medically necessary; right?

MR. KNEPPER: Objection, form.

A. Yeah. As I -- as I said before,

this is one of the reasons why I don't have a lot of heartache about having withdrawn my membership. Yeah.

Q. Now let me introduce another exhibit. Let me know when you have it, Doctor.

(Exhibit 7 was marked for identification and is attached.)

A. Okay. Okay. I've got it.

Q. The top of the page says, "American Society of Plastic Surgeons." Right?

A. Yes.

Q. You see this document is dated February 25, 2021; right?

A. Yes.

Q. This is after all the studies that you cite in your report; right?

A. Where does that say that? I'm sorry, you're at a particular paragraph?

Q. No. The date of this --

A. Oh, I see. Oh, the date is after this --

Q. Yeah.

A. Yes. Well, February 25th, yes, 2021.

Q. Yeah. This is -- this is dated after all of the studies that you cite in your report; correct?

A. I don't -- yeah, I don't remember off the top of my head any studies that were dated after. There may have been an April study in there, but okay.

Q. The first sentence says, "Policy around transgender care has recently gained considerable attention amid a growing trend of legislation carrying serious professional, financial or criminal penalties for the provision of gender affirmation care." You see that?

A. I do.

Q. Now, this reference to a growing trend of legislation, that's talking about legislation like the Arkansas ban and the Utah ban and the Alabama ban that

we talked about earlier; right?

A. Right.

MR. KNEPPER: Objection, form.

Q. Go to page 2. Look at the second paragraph. It says that "Less than three months into 2021, 11 pieces of legislation attempting to criminalize gender affirmation therapies have been introduced in 10 states." See that?

A. I do.

Q. And then there's a list of states; right?

A. Yes.

Q. So we talked about Utah and Alabama and Texas before. Looking at this list, does that refresh your recollection whether you've worked on these kind of legislative efforts in any other states?

A. I think -- I think, yeah, my answer has not changed. I think I've only been involved in Alabama, Texas, and Utah. I don't remember anything from

Oklahoma, New Hampshire, Montana, or Missouri or Mississippi. I don't recall any other states in that list, no.

Q. Okay. All right. Now let's look at what position the ASPS takes on whether gender-affirming treatment is medically necessary. Go to page 3. The first sentence says, "ASPS firmly believes that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be and improve their overall mental health and well-being." Do you see that?

A. I do.

Q. The ASPS, your own professional organization, does not agree with your opinions that gender-affirming surgery is medically inappropriate; right?

MR. KNEPPER: Objection, form.

A. Let me just read that. Give me just a moment to look at that. Okay.

Yeah. This is a very --

language used by the other professional organizations, and essentially, the language takes the position that surgical intervention for a subjective problem is medically indicated. And that's the difficulty that I'm having here, is that in this document the ASPS does not -- does not provide medical scientific support. They essentially admit that the surgery is for help with a psychological problem of perception on the part of the patient. So essentially what -- what the ASPS firmly believes in is the use of surgery to manage a psychological problem. And -- and this is -- this is consonant with the -- with the -- the consensus opinions that were offered by the other professional organizations that you listed earlier.

Q. The AS- -- ASPS does not agree with your opinions that gender-affirming surgery is experimental; correct?

MR. KNEPPER: Objection, form.

A. They don't -- let's see, do they say anything about experimental in here? No, they don't. So yeah, I would agree.

Q. Do you agree? Yeah.

A. I would agree, yeah, sure.

Q. Look at the last sentence. It says, "ASPS will continue its efforts to advocate across state legislatures for full access to medically necessary transition care." Do you see that?

A. Yeah. I don't find that statement at all surprising. No.

Q. Yeah.

A. I do see that, yeah. Not surprising. This is legislative --

Q. The ASPS --

A. -- legislative advocacy by the ASPS.

Q. The ASPS considers transition care to be medically necessary; right?

MR. KNEPPER: Objection, form.

A. Again, that returns -- returns to that -- that inherent and

contradictory statement of medical necessity for a subjective condition. And the statement is consistent with what -- yeah. Exactly, yeah.

Q. It's fair to say that the opinions that you and Dr. Hruz and Dr. Levine are offering in this case are very different than the position that the ASPS has adopted on whether gender-affirming surgery is medically necessary; right?

MR. KNEPPER: Objection, form.

A. Absolutely correct.

Q. In fact, let me show you how strongly the ASPS feels about this issue. Let me introduce another exhibit. Okay. Let me know when you -- when you receive it.

MR. KNEPPER: Dmitriy, I -- I will tell you, it seems to be moving more slowly than normal. I don't know if you're seeing the same thing on your end.

MR. TISHYEVICH: I am.

A. So yeah, I have this document.

Again from the ASPS? Is that the one? February 25th?

Q. No. It should be -- it's a one-page document. I think it just says ASPS in your folder.

A. Exhibit 7?

MR. TISHYEVICH: Let me -- let's go off the record for a minute.

MR. KNEPPER: Sure.

THE VIDEOGRAPHER: We are off the record at 10:19 a.m.

(Break taken.)

THE VIDEOGRAPHER: We are back on the record at 10:21 a.m.

Q. (By Mr. Tishyevich) All right. Doctor, before the break, we were talking about the ASPS and the position they take on the medical necessity of gender-affirming surgery. You recall that?

A. Yes.

Q. All right. This is a document from the ASPS titled "2021 State Policy

Priorities." Do you see that?
(Exhibit 8 was marked for identification and is attached.)
A. Yes.
Q. Last sentence of the first paragraph says, "To ensure that our health care system is effective and efficient, ASPS will focus its state advocacy efforts on," and then there's a list. Do you see that?
A. Yes.
Q. And there's three sections: "Core Priorities," "High Priorities," and "Other Priorities." You see that?
A. Yes.
Q. Go to the "High Priorities" section.
A. Okay.
Q. The last bullet says, "Opposing attempts to criminalize gender confirmation." Do you see that?
A. I do.
Q. And you understand what this

bullet means; right?

A. I do.

MR. KNEPPER: Objection to form.

Q. One of the ASPS's high priorities for this year is to oppose legislation like the Arkansas ban and the Utah ban and the Alabama ban that you are supporting; right?

A. Apparently so, yes.

MR. KNEPPER: Objection, form, scope.

Q. The sense that I got from reading your report, Doctor, is that it's supposedly generally accepted that gender-affirming surgical treatment is experimental and should not be performed on anyone; right? That's what you think?

MR. KNEPPER: Objection, scope, form.

A. Right. My opinion -- my opinion in that matter is based on the -- on the world literature rather than advocacy statements by a professional

organization. That's right.

Q. You are suggesting, in fact, that doctors who do these surgeries should be investigated for unethical behavior and potential misconduct; right?

MR. KNEPPER: Objection, form.

A. I -- yes, I do.

Q. And you do not think it's relevant to mention that your own professional society takes a view that is contrary to the opinions that you're offering in this case; right?

A. I'm not sure I understood your question, sir.

Q. Yeah. When you talk about how these doctors should be investigated for misconduct, you don't think it's relevant that your own professional society takes a completely contrary view?

MR. KNEPPER: Objection, form.

A. Well, I think I would -- I would characterize my concern and -- and possibly recommendation of investigation,

I was discussing, I think, consent procedures and getting informed consent. I don't think -- yeah, so -- so I think the object- -- the concerns I raised had to do with the off-label use of drugs in irreversible treatments, the -- the problem of obtaining consent from emotionally compromised people who are threatening suicide. Those were the issues that I raised in terms of, you know, investigation kind of things, or examination would be a better term, examination of -- of how a physician/surgeon conducts their practice, so.

Q. Go -- go back to your report.

A. Okay.

Q. Go to page 15. You with me?

A. Yes, sir.

Q. Look at the second sentence in the bottom paragraph. You say, "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 methodo-" -- "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."

Right? That's your opinion?

A. Yes, sir. And I stand by that.

Q. You know that today there's thousands of plastic surgeons that are performing these surgeries; right?

MR. KNEPPER: Objection, form, scope.

A. I don't know the number of plastic surgeons who do these surgeries.

Q. Hundreds?

A. I'm -- I'm sure the number is large. I don't know what the number is. Yes.

Q. And you think all of those doctors are out there committing misconduct? Is that really what you think?

A. Well, I think that -- that their knowledge might affect their decision-making. So if somebody is going through a residency training program that -- that is teaching these things and they grow up in that world -- let me give you an example.

When I was a surgeon in training in general surgery, the -- the most coveted surgical experience would be, as a chief resident, to do ulcer surgery. At the time, we thought that ulcers were caused by neurologic problems affecting the stomach. And so some of the most complex abdominal surgeries were ulcer

surgeries, and some of the greatest names in general surgery were given to those operations. Subsequent to my residency training, perhaps five years later, it was found to be a medical condition treatable with antibiotics and antacids. Nobody does ulcer surgery any longer.

I would put -- I would put transgender surgery in the same category. Well-meaning persons who are interested in the care of people who are suffering, in this case, transgender persons who are suffering, well-meaning physicians and surgeons are offering them the best care that they've learned in their training. But I -- I would expect that when the science shows that to be not the case, that those same doctors will abandon it. And I think we're at the same stage now. We're at an inflection point in plastic surgery where in the last three years things have changed radically.

If you had asked that question

five, seven years ago, it would have been up for grabs. But things have changed radically with the flood of credible scientific evidence pouring in from Europe to now -- if -- if five years from now, having seen that information, surgeons persist in doing transgender surgery, then I would -- then I would have real issues with that, as I would with a -- with a general surgeon offering a Billroth II ulcer operation today when you could give the patient erythromycin and some -- and some Zantac. You see where I'm going.

So we're at a -- we're at a tipping point in the world of plastic surgery right now, and the last three years have changed everything, because the very, very well-supported -- see, the problem is quality of evidence. Plastic surgeons in America are operating with scientific evidence that even the American Society of Plastic Surgery

characterizes as level 5 evidence, basically, the -- the professional opinions based on personal experience. This is entry-level science for a particular therapy or a particular intervention.

To raise to level 4, you would have to have the same collected cases with -- with before and after tests of the patient. We haven't gotten to that level yet. There are no long-term longitudinal studies in the American literature. It's all in the European literature, and the bulk of it in the last three years.

So the question is a difficult one to answer. As simply as saying that all of these people are immoral, I'm not saying that at all. I'm saying that they're doing the best that they know how according to the training that they've received for people that they very much care for and are hoping to do good by.

But the -- but the world is changing rapidly now, and we've reached a stage now where it's such a controversy that this is -- this is -- this is why I've become so publicly vocal about it, because the controversy is now raging. It's no longer: "Maybe so. Milton Edgerton, interesting guy. You know, the surgery at UVA, the surgery at Johns Hopkins, let's get a look at that kind of thing." We've gone beyond that now, and just in the last three years.

So I -- the people who do these surgeries are not right out of residency training. These are people who have -- you know, who have been in the -- in the business for a number of years now, and they're relying on what they learned and doing the best that they can. But as I say, the science is changing everything, so.

MR. TISHYEVICH: With respect, I'm going to strike that answer as not

responsive.

Q. Here's the -- here's --

MR. KNEPPER: No.

Q. -- the question that I'd like you to answer.

MR. KNEPPER: Go ahead.

Q. Here's the question that I'd like you to answer. Is it your expert opinion that the surgeons that are today performing gender-affirming surgical procedures are committing or potentially committing misconduct, yes or no?

MR. KNEPPER: Objection, form, scope, asked and answered. Dmitriy, you asked him. He gave you a --

MR. TISHYEVICH: I don't need the speaking objections. I do not need the speaking objections.

Q. Answer my question, Doctor.

MR. KNEPPER: He gave you a thoughtful answer.

A. Okay. If you could ask me the question again, I want to be sure that

I -- I answer it as succinctly as I can.

Q. Is it your expert opinion that the surgeons that are performing gender-affirming surgical procedures today are potentially committing professional misconduct, yes or no?

MR. KNEPPER: Objection, form.

A. I would -- I would say, only to the extent that they're familiar with the more recent literature would make them sort of culpable, if you will. Not -- not being aware of that literature, I would not accuse them of such a thing.

Q. All right. Let me introduce another exhibit. Let me know when you get this one, Doctor, Exhibit 9.

(Exhibit 9 was marked for identification and is attached.)

A. All right. The first page of my -- well, that's the CV, I guess. My CV, yes.

Q. This is a copy of your CV; right?

A. Yeah. Yes.
Q. You prepared this?
A. Well, it was prepared for me by -- I gave -- I gave the factual input for it, but I didn't prepare it myself, let's say.
Q. Top of the page says, "Board Certified in Surgery and Plastic Surgery" again; right?
A. Right. Same mistake, yeah.
Q. We agree that's not consistent with guidance from the American Board of Surgery, American Plastic Board of Surgery; correct?
MR. KNEPPER: Objection, form.
A. Yes.
Q. Go to page 3, the bottom of the page. It says, "Publications - Peer Reviewed Medical Journals." You see that?
A. I do.
Q. And then through page 4, it lists six publications; right?

A. Right.
Q. In your professional career, you've published six articles in peer-reviewed medical journals; right?
A. Right.
Q. First one was in 1997; right?
A. '87. Yes.
Q. Most recent one was in 1998; correct?
A. Correct.
Q. That's 23 years ago; right?
A. Right.
Q. You have not published any original research in peer-reviewed literature within the last 23 years; correct?
A. Correct.
Q. All right. Let's go through these in reverse order. All right. Most recent one from '98 is titled "Treatment of an isolated outer table frontal sinus fracture using endoscopic reduction and fixation." Right?

A. Yes.

Q. That publication doesn't relate to gender-affirming surgery or to gender dysphoria; correct?

A. Tangentially, it would relate to it. And I would say this about it. It was one of the first, if not the first, paper demonstrating the use of endoscopic technique to operate on facial bones of the forehead and the use of internal fixation devices for modification or repair of the forehead. Those are the same techniques that are now used by transgender surgeons who are offering top surgery. For example, for feminization of a masculine brow ridge, they use endoscopic technique, which is described in this paper that came out 23 years ago and was written by myself and another Navy surgeon.

Q. Understood.

A. Yeah.

Q. The -- the patient in this

publication was not treated for face -- for gender dysphoria obviously; right?

A. No. She was a sweet pizza maker who had slipped in the kitchen and struck her head on a stainless steel table and had a -- had a displaced fracture of her forehead. But no, she was -- not to my knowledge. I don't know if she was or not, but to my knowledge, she was not.

Q. Next one going backwards is from 1996, and it's titled, "Scarless Fetal Skin Repair: 'Unborn Patients' and 'Fetal Material.'" Do you see that?

A. I do.

Q. All right. That doesn't relate to gender-affirming surgery or to gender dysphoria, I take it?

A. It -- it actually refers to all forms of surgery and particularly, ethical decision-making. So I would say that it's -- it's a -- it's a fairly broad paper that talks about how we treat other human persons. So transgender

surgery is all about how we treat other human persons. That's what that paper is about and how -- how some surgeons are likely -- or possibly physicians and surgeons could characterize someone as less than human, which is a -- which is a danger that transgender persons experience when they're seeking care. And so I would say that in a very tangential way, it does. It does impinge upon the field of transgender medicine precisely for the reason that transgender persons suffer oftentimes from being treated as -- as someone who is less than human.

Q. Aside from that very tangential angle, this paper does not specifically relate to gender-affirming surgery or gender dysphoria; correct?

A. No, it does not.

Q. And the next one before that is in 1995. Do you see that?

A. I do.

Q. You're listed as the third author in this one; right?

A. Yes, sir.

Q. Because you're not the lead author; right?

A. No. The attending surgeon is always the lead author, and I was a resident. I was a resident at that time, yeah.

Q. Understood. This one's titled "Delayed development of an ectopic frontal sinus mucocele after pediatric cranial trauma."

A. Mucocele, yes. Mucocele.

Q. Thank you. This publication doesn't relate to gender-affirming surgery or gender dysphoria; correct?

A. Not directly, no.

Q. Okay. Next one before that is titled "Patch Esophagoplasty"?

A. Very good.

Q. And that's repair or reconstruction of the esophagus; right?

A. Yes.

Q. Does this relate to gender-affirming surgery or gender dysphoria?

A. No.

Q. Next one before that is titled "Modified Skin Incisions for Mastectomy: The Need for Plastic Surgical Input in Preoperative Planning." Do you see that?

A. I do.

Q. And finally, your oldest publication is from 1987, titled "Peritoneal Fluid in Human Acute Pancreatitis." Do you see that?

A. Yes.

Q. Does that relate to gender-affirming surgery or gender dysphoria?

A. It does not. By the way, that -- that second to the last article, your pattern of questions, I wondered if you overlooked asking the same question on that paper.

Q. No. I want to ask you more specific questions about that one, so we'll spend --

A. Oh, okay.

Q. -- more time on that one.

A. Good. Good. Very good. All right.

Q. Don't worry.

A. Yeah. "Peritoneal Fluid in Acute Pancreatitis" was a research paper, animal model, and review of the literature. Yeah.

Q. Okay. You agree there's a difference between a scientific article that reports original research versus a letter to the editor that's published in a scientific journal?

MR. KNEPPER: Objection, form.

A. Yes.

Q. Some of your publications listed here are just letters to editors; right?

A. Yes.

Q. Why is it that your CV doesn't

identify those as letters as opposed to original research?

A. I didn't -- that didn't occur to me to do that. Do we generally list them separately? I don't know. I just put all my publications there.

Q. So we can look at them, but for example, the scarless fetal skin repair, that's a letter to the editor; right?

A. Right.

Q. And so is the 1993 publication on patch esophagoplasty; right?

A. Right.

Q. So out of the six publications that you list in your CV, at least two of them are letters to editors rather than original research; fair?

MR. KNEPPER: Objection, form.

A. Right. Yes.

Q. Okay. Let's talk about your experience treating transgender patients. You retired from the military in 2002; correct?

A. Correct.

Q. In 2002, the U.S. military certainly was not providing any gender-affirming treatment to anyone in the military; right?

A. That's correct.

Q. Or to veterans; right?

A. Correct.

Q. In fact, at that time, there was a policy not to provide gender-affirming treatment to active military or to veterans; correct?

MR. KNEPPER: Objection, form, scope.

A. Correct.

Q. So during your career in the military, you did not provide any gender-affirming treatment to any patients; correct?

A. Correct.

Q. All right. Let's focus on your practice after you left the military in 2002. You currently run the Lappert Skin

Care clinic; right?

A. That's correct.

Q. How long have you operated that clinic?

A. One year.

Q. Did you operate any clinics before opening this one?

A. Yes.

Q. What was that one?

A. That was my plastic surgery office called Lappert Plastic Surgery in Madison, Alabama. And before that, it was under the same name but located in Decatur, Alabama. And before that, it was in Scottsbluff, Nebraska, same name.

Q. How long did you run the Lappert Plastic Surgery clinic?

A. The Madison office was for 15 years. I'm sorry. The Madison office was for ten years. My -- my mistake. Ten years at the Madison office, five years at the Decatur office, and three years at the Scottsbluff office.

Q. So, let me just make sure I have my timing here. So you've had the Lappert Skin Care clinic for a year, since 2020?

A. Right.

Q. And then the Lappert Plastic Surgery ten years in Madison, so roughly 2010 to 2020?

A. That's right.

Q. And then five years before that in Decatur, 2005 --

A. Right.

Q. -- to 2010, roughly?

A. Right.

Q. And then --

A. Scottsbluff was from 2002 through two -- through 2005. That was where I went when I retired out of the Navy.

Q. Your -- your skin clinic currently does treatments like Botox, light therapy, laser hair removal; right?

A. Right. Laser tattoo removal,

injectables, just skin consultations for skin problems like rosacea, acne, that sort of thing. That's right.

Q. Were you performing similar treatments at the Lappert Plastic Surgery clinic?

A. Yes. All I've done is I've just suspend -- I just retired from active surgical practice. I had an operatory in my office in Madison as well as in Decatur previously, so I would do both hospital-based surgeries as well as clinic-based, office-based procedures.

Q. So for example, light therapy services, you've offered that for ten-plus years, I take it?

A. I believe we got that instrument in 2006.

Q. How about Botox? Have you been offering that for more than ten years?

A. Yes.

Q. Have you done forehead injections for more than ten years?

A. With Botox?
Q. Yes.
A. Yes.
Q. How about crow's feet? Is that the right term?
A. Yes.
Q. More than -- more than ten years?
A. Yes.
Q. When was the last time you've performed a surgical procedure?
A. Well, as I said, I retired from surgery in August of 2020, so it was -- I think I was doing some last procedures in that same month, perhaps July, somewhere in there.
Q. And in 2020, roughly how many surgical procedures do you think you've performed?
A. From January to July?
Q. Yes.
A. Let's see. Seven months. Perhaps -- I don't know. Maybe eighty,

something 80 to 100, I'm guessing. I don't know.

Q. And give me examples of common surgeries you would have performed in 2020.

A. Well, among the most common ones that we did in the -- in the office were autologous fat grafting for recon- -- for rejuvenation of the face, autologous fat grafting for breast augmentation, ultrasound -- I'm sorry -- laser lipoplasty for body contouring, and then many in-office surgical procedures for skin cancer and skin cancer reconstruction, particularly of the face and the extremities.

And then on the hospital side, I would be guessing how many, but it was common for me to do breast reductions and abdominoplasties, little local flap reconstructions in the hospital for younger patients who needed anesthesia, reconstruction -- little reconstructive

flaps for trauma or for cancer.

I had a working relationship with a dermatologist who did a lot of what's called Mohs surgery for removal of cancers. He would send me his patients if they -- if they were cancers that involved the face. I would do those reconstructive surgeries.

Yeah, that was probably -- I was definitely throttling back in my last year. I didn't take on a lot of complex cases, so.

Q. Okay.

A. Because I needed -- you need follow-up, and so limited.

Q. I understand. Let's go back to your report. Go to page 4.

A. Okay.

Q. Okay. Five lines down, you see the sentence starting with, "In my private practice"?

A. Yes.

Q. Okay. Let's break this down.

So you reference treated skin pathologies. What skin pathologies are you referring to here?

A. Skin can- -- well, surgically or medically, we're talking two different categories, but. So I'm consulted on -- on a lot of nonsurgical skin pathologies. But as far as surgical skin pathologies, that would include various forms of malignancy and then benign growths and things that are either aesthetically or -- aesthetically problematic or suspicious in appearance, so both proven cancers and things that are suspicious of cancers. So those would be the skin conditions. The medical --

Q. Yeah. Well --

A. -- skin conditions -- I'm sorry?

Q. Yeah. That's all right. I'm asking more specifically.

A. Okay.

Q. Because here, you write, "I've had occasion to treat many

self-identified transgender patients for skin pathologies related to their use of high dose sex steroids."

A. Yeah.

Q. So focusing specifically on that patient population.

A. Okay.

Q. So, what skin pathologies are you referring to here with respect to transgender patients?

A. Well, I've had a few patients who've come in evidencing, you know, acneiform conditions of the facial skin. And so helping people manage acne is a common thing that I do, and a variety of interventions including, you know, the light therapy, but more -- more properly, the use of medications and -- and sometimes laser therapy to manage scarring. But in those particular cases of the trans-identified people, it's mostly just ordinary management of acne. And it's usually the same patients who

come to see me about facial hair removal with laser. I have a couple of patients in that category, people who are transitioning and who are seeking laser removal of hair from their faces.

Q. And you said this is a few patients. How many transgender patients would you estimate you've treated for skin pathologies related to steroids?

A. Related to -- to sex steroids?

Q. Yes.

A. Oh, I don't know. Probably less than half a dozen.

Q. Okay. The acne you're referring to, it's essentially a side effect from the steroids; right?

A. It's a common side effect of -- of -- yeah. Particularly androgen is the most common.

Q. So this -- and so you're treating patients with gender dysphoria after they have already decided to follow a certain course of treatment and started

taking sex steroids; right?

A. Right. Yeah.

Q. Okay. And then you say you've done laser therapies for management of facial hair of also the transgender population?

A. That's right.

Q. Right?

A. That's right.

Q. And is that also in about half a dozen patients? Or what's you're estimate?

A. Yeah. It's not a huge number.

Q. Okay. And finally, you say you've done breast reversal surgeries for detransitioning patients. On how many patients have you performed -- strike that.

On how many detransitioning patients have you performed the surgery?

A. Two.

Q. Two. All right. It's not a commonly performed procedure for you;

fair?

MR. KNEPPER: Objection, form.

A. Yeah, no. They -- they started coming to me in that last year of practice, so. Yeah, that -- it's not a -- yeah, it's not a -- it was never a common procedure for me. I did a lot of, you know, implant removals and stuff through my years. It's the same operation. And I've done a lot of gynecomastectomy surgeries. That's also the same operation. But in terms of as it's applied to a trans- -- a transitioned person who wants to revert back to male presentation, very limited experience. But even though it's the same operation, I have only done it for two people.

Q. And you said both of those patients were in 2020?

A. I believe so, yeah. One of them may have been in 2019. I'm not positive about that.

Q. Before 2019 or 2020, you had never had a detransitioning patient come to you to obtain breast reversal surgery; fair?

A. I think that's correct, yeah. I'm just trying to think if there was any, but I can't -- I can't recall any other.

Q. Okay. Are you aware that modern gender affirmation programs typically have a multidisciplinary team of healthcare providers?

A. Yes.

MR. KNEPPER: Objection, form.

Q. And they usually involve mental health specialists; right?

A. Yes.

MR. KNEPPER: Objection, form.

Q. Endocrinologists?

A. Yes, that's my understanding.

Q. And oftentimes plastic surgeons if the patient wants to go that route; right?

A. Right. That's -- that's my understanding, yes.

Q. You personally have never been part of this kind of a multidisciplinary team for any patient with gender dysphoria; correct?

A. No. I have always -- I have always turned away personal -- for per- -- well, my understanding of those procedures has caused me to reject offering them to my patients because I don't see them as beneficial. So clearly, I wouldn't want to participate in a multidisciplinary team that's offering therapies that I consider to be incorrect treatments for a condition that deserves our care, so.

Q. All right.

A. If you want, I can give you a shorter answer. No.

Q. Yeah, let's -- you personally have never treated a single patient for gender dysphoria; correct?

A. I have never treated a patient with gender dysphoria surgically.

Q. Okay.

A. Other than the detransitioner. I -- I suspect they were still suffering from dysphoria even though they were detransitioning, but I didn't treat them with surgery to -- per se for that condition the way the transgender teams do. Yeah.

Q. When you were providing laser hair removal to trans women, is that providing gender-affirming care?

MR. KNEPPER: Objection, form.

A. I don't get into the affirmation side of the treatment. I'm simply providing a service to -- to people who -- who I want to have as friends. Believe it or not, it's true. I -- I don't turn anyone away whose -- whose request is -- is within the scope of what I consider moral practice of medicine and surgery, so.

Q. So earlier, I asked you, you personally have never treated a single patient for gender dysphoria, and I think you said not surgically. Let me ask more broadly. Not limited to surgery, you have never treated a single patient for their gender dysphoria symptoms; correct?

A. Well, I guess if -- if you were to look at laser facial hair removal and consider that in the -- in the spectrum of care, certainly that's -- that's -- that's clinic care that's probably improving the emotional life of the patient because they're seeking to present as women. So in that sense, I have, yeah.

Q. Nothing outside of laser hair removal?

A. No.

Q. You personally have never --

A. Well, and -- and acne. Because clearly, that's a problem. But in terms of their -- the trajectory of their

transition, acne doesn't enter into it. But certainly laser hair removal, yeah.

Q. You personally have never sat in any meetings between a provider and a patient where the doctor was trying to diagnose whether the patient has gender dysphoria; correct?

A. Correct.

Q. You have never sat in any meetings between a provider and a patient discussing their potential treatment options for gender dysphoria; correct?

A. No.

Q. All right. You're not an endocrinologist; right?

A. Correct.

Q. You're not a psychiatrist; right?

A. Correct.

Q. You're not a licensed mental healthcare provider of any kind; right?

A. Correct.

Q. In your professional day-to-day

practice, you do not diagnose mental health conditions of any kind; right?

MR. KNEPPER: Objection, form.

A. With the exception of what we discussed earlier about body dysmorphic disorder and gender -- gender identity as a subcategory of body dysmorphic disorder, no, I would say I don't.

Q. Okay. If some patient thinks that they may have depression or anxiety, you would expect that patient to go to a mental health professional, not to you; right?

A. That's my expectation. But again, many depressed people come to plastic surgeons seeking a remedy for their depression thinking that their appearance is the cause of their depression. And it's my duty as a plastic surgeon to recognize those patients and -- and send them to the psychologist, psychiatrist, rather than offering them surgical care, yeah, so.

Q. Yeah. I'm asking a slightly different question.

A. Okay.

Q. If a -- if a patient, for some reason, came to you and asked you to diagnose them with depression or anxiety, I assume you would refer them to a train -- trained mental health professional; right?

A. Yes.

Q. Because doctors should not be diagnosing patients with mental health conditions if they do not have training in how to diagnose mental health conditions; right?

MR. KNEPPER: Objection, form.

A. Well, I wouldn't say that, because for example, as a -- as a -- as a surgeon, as a plastic surgeon, we do have to make diagnoses outside of our specialty in order to get people to the right specialist. So to an extent, you have to make that diagnosis.

So for example, as a resident in training, I diagnosed an endocrinological disease and probably saved a woman's life because she was in a psych ward, and -- and -- and the doctors had a question about her -- a lump in her neck. She had been on the psych ward for weeks, and I diagnosed a hyperfunctioning thyroid nodule. I didn't confirm that diagnosis. I sent her to an endocrinologist. But I made the initial diagnosis of hyperfunctioning thyroid nodule, and -- and ultimately, I did her thyroidectomy. But that's an example.

You have to understand pathology outside your specialty because you don't know why the patient is going to present to you, and you have to be ready to start the process that gets them to the specialist, so you have to have a working knowledge of the problems.

Q. Yeah, that's exactly the point. Even for that one example, you still send

this patient to a trained endocrinologist to confirm the diagnosis; right?

A. Right. And then they sent them back to me to give them definitive care.

Q. Yeah. And that's what you would do for any patient that presents to you with a mental health condition; right? You would train -- you would send them to someone who is -- who is trained in how to diagnose mental health conditions; right?

MR. KNEPPER: Objection, form.

A. Yes.

Q. You're not trained in providing psychotherapy counseling; right?

A. Right.

Q. You've never provided counseling, psychotherapy counseling to children or adolescents with gender dysphoria; right?

A. Right.

Q. You've never provided psychotherapy counseling to adults who

have gender dysphoria; right?

A. Right.

Q. You do not have the professional training to provide psychotherapy counseling to adults who have gender dysphoria; right?

MR. KNEPPER: Objection, form.

A. Correct.

Q. Or to children or adolescents with gender dysphoria; right?

MR. KNEPPER: Objection, form.

A. Correct.

Q. Go to page -- back to your -- strike that.

Back to your report on page 4, in this paragraph 9, about six lines down, you say, "I have consulted with families with children who are experiencing gender discordance." Do you see that?

A. Yes.

Q. Describe these consultations for me at a high level.

A. Basically, it was families that wanted to understand what -- the nature of plastic surgery sort of in the future for their children. These were -- these were personal encounters rather than in the office, but fairly lengthy at times, talking to families about -- they wanted to understand what was being offered to their children. They wanted to understand the nature of -- or what the future would look like for their children. They wanted to get some idea of -- basically, they wanted to hear sort of a fuller explanation of the -- of the medical and surgical side of things. So I wasn't giving them psychiatric counseling, but basically offering them my experience as a plastic surgeon, wanting to know what the surgery's about, what the -- the hormone therapy that precedes the surgery's about, that sort of thing.

Q. How many of these consultations

have you done, would you estimate?

A. Perhaps five or six, maybe more. Maybe -- yeah, five or six would be a fair number, I think.

Q. Over what years?

A. Perhaps the last three.

Q. Do you know how these parents know to reach out to you for these consultations?

A. It's -- I think maybe some of them were -- having heard about my public presentations at various venues. People hear about this plastic surgeon in Decatur who's raising objections, I guess. I don't know the particular details about how a particular patient might have come to me. I just -- I just always make myself available when people are anxious for their children and they're looking for an understanding of what transgender is about.

Q. What's the typical advice that you give to parents of children or

adolescents who are considering starting puberty blockers?

A. Well, my advice on that score is based on the -- on the world literature, that the desistance rate for their child, if they don't give them puberty blockers, the likelihood is that by the time they reach mid-adolescence, they have an 80 percent likelihood of desisting in their cross-sex self-identification. And if you follow them into young adulthood, that percentage will be in the 90s.

But essentially, I recommend that they slow everything down, and I recommend against the use of puberty blockade because it's experimental and because the likelihood is very high -- in fact, if I had any medical procedure that gave me 90-plus percent success rate, I would consider that a great victory. So -- so that's -- that's what I speak to them about.

That -- that desistance data is

a very important thing for parents to understand. And very often, the patient -- the parents are experiencing tremendous pressure from the people they've seen in consultation, a tremendous pressure. And usually, the parents are very distressed about what they're hearing, particularly the -- the fear of suicide and self-harm.

Q. Yeah.

A. So --

Q. You encourage -- yeah, no, I got it. You encourage patients of children who -- or adolescents who experience gender dysphoria not to start them on puberty-blocking drugs; fair?

MR. KNEPPER: Objection, form.

A. Yeah, I discourage the use of puberty blockade for anything other than precocious puberty or other endocrinopathies.

Q. And you also discourage them from pursuing surgical procedures for

gender dysphoria; correct?

MR. KNEPPER: Objection, form.

A. Correct.

Q. When you do these consultations, do you talk just to the parents or to the children as well?

A. Both, yeah. I like to meet the children and -- and -- and get to know them, yeah.

Q. And do you convey the same message to the children? Don't start puberty blockers; don't start -- don't do any surgical procedures?

MR. KNEPPER: Objection.

A. I -- I generally don't -- I'm sorry. I generally don't speak about the details of therapy to children. I speak to their parents.

Q. How many children do you think you have consulted with specifically?

A. On this -- on this issue?

Q. Yes.

A. As I say, maybe six. I often --

well, yeah, I would say six is a good number.

Q. Do you know how many of them went on to start hormone-blocking therapy, if any?

A. I don't. I don't know the answer to that question. Yeah, I don't.

Q. Do you know how many of them, if any, went on to start cross-sex hormone therapy?

A. I don't know the answer to that question, no.

Q. You don't know how many of them went on to do any kind of surgical gender-affirming procedures?

A. No.

Q. You haven't done any follow-up with any of these families that you've consulted?

A. As I say, this was an informal thing, so. Yeah. So no, I -- I haven't followed up long-term. This has -- as I say, this has happened over the last

perhaps three years. And so the general course of events there is -- is typically longer than that, so. But I have not seen -- well, I have seen one -- one child twice, actually, with the parents. And actually -- okay. So -- so perhaps she would be an exception.

She was sort of headed in the direction of seeking puberty blockade. And then in our meetings, she has sort of given that up. She was under a lot of pressure at school, you know, being pressured by boys because she was starting to develop secondary sex characteristics, and she developed a tremendous anxiety about it. And someone had told her that -- that if she went through transition care, that that would be avoided. And I had a conversation with her parents, I had a conversation with her, and essentially just encouraged her to slow down and sort of examine her other options. And I think within about

seven months, she came back to me, and she's not even thinking along those lines any longer. In fact, now she's talking about what high school she wants to go to, so.

Q. Okay. So this is one child who was considering, or whose parents were considering starting puberty-blocking, but after consultation with you, decided not to; right?

A. I think that she -- yeah.

MR. KNEPPER: Objection to form.

MR. TISHYEVICH: Okay. All right off the record.

THE VIDEOGRAPHER: This is the end of Media Unit No. 2. We are off the record at 11:06 a.m.

(Break taken.)

THE VIDEOGRAPHER: This is the beginning of Media Unit No. 3. We are on the record at 11:16 a.m.

Q. (By Mr. Tishyevich) Doctor, you know what facial feminization surgery is;

right?

A. Yes, I do.

Q. You have never performed facial feminization surgery for any transgender patient; correct?

A. Correct.

Q. You know what facial masculinization surgery is?

A. Yes.

Q. You have never performed that for any transgender patient; correct?

A. Correct.

Q. Do you know what transfeminine top surgery is?

A. Yes.

Q. You have never performed that on a transgender patient?

A. No.

Q. How about a chest reconstruction surgery? Have you performed that on a transgender patient?

A. No.

Q. You have never performed a

vaginoplasty for a transgender patient?

A. No.

Q. You have never performed a metoidioplasty for any transgender patient?

A. No.

Q. You've never performed what's colloquially known as bottom surgery for any transgender patient; correct?

A. Correct.

Q. Fair to say you've never performed any kind of gender-affirming surgery in transgender patients; right?

A. Correct.

Q. And fair to say you don't have recent and substantive experience in performing gender-affirming -- -affirming surgery for transgender patients; correct?

MR. KNEPPER: Form.

A. I have -- I have substantive experience with all the actual -- the nature of the particular operations but

never performed for transgender patients to transition them, no. But the operations themselves as used in reconstruction, I have considerable experience with.

Q. We talked earlier about the American Society of Plastic Surgeons. You recall that?

A. I do.

Q. You know that the ASPS has a code of ethics?

A. Yes.

Q. And you know that members are required to comply with the code of ethics; right?

A. Yes.

Q. And I know you're not a member now, but you were a member of the ASPS for a considerable amount of time; right?

A. Yes.

Q. And I assume during that time, you followed the ASPS code of ethics; right?

A. To my knowledge, I never violated it. Yes.

Q. When was the last time you reviewed it?

A. I'm sorry, did I lose the sound here?

Q. When was the last time you reviewed the ASPS code of ethics?

A. Oh, gosh. Years ago. Years ago.

Q. Let me introduce an exhibit.

Let me ask you this first. Are you aware that the ASPS code of ethics had some specific rules for members who provide expert testimony?

A. Yes.

Q. Okay. You didn't review those provisions before you formed your expert opinions in this case?

A. No.

Q. Sitting here today, do you know if your opinions in this case are in compliance with what the ASPS code of

ethics says about members who provide expert testimony?

A. I'm not aware that I've violated them in any way, yeah.

Q. Let me introduce an exhibit. Okay. Let me know when you have it.

(Exhibit 10 was marked for identification and is attached.)

A. Okay.

Q. It's still opening on my end.

Okay. So, Exhibit 10 is the Code of Ethics of the American Society of Plastic Surgeons. You see that?

A. I do.

Q. The bottom left corner says, "Updated September 25, 2017." See that?

A. I do.

Q. That's when you were still an active member of the ASPS; right?

A. Yeah, that's right.

Q. Go to page 4.

A. I think I'm on page 4 here. They're not numbered. Oh, here we are,

yes.

Q. Or I'm sorry, page 6.

A. Page 6.

Q. Section IV.

A. Section IV, yes.

Q. Section IV is "Expert Testimony"; right?

A. Yes.

Q. I want to focus you on the last two sentences of this first paragraph. It says, "Members whose testimony, including testimony as to credentials or qualifications, is false, deceptive, or misleading may be subject to disciplinary action, including expulsion." You see that?

A. Yes.

Q. The next sentence says, "Further to help limit false, deceptive and/or mislead" -- "misleading testimony, Members serving as expert witnesses must," and then there's a list of requirements. You see that?

A. I do.

Q. Okay. So "must" means this is a mandatory rule, not an optional suggestion; right?

MR. KNEPPER: Objection, form.

A. I expect that's what it means, yes.

Q. All right. Let's look at these rules. Number 1 says that members serving as expert witnesses must "Have recent and substantive experience (as defined in the Glossary of the Code) in the area in which they testify, including, without limitation, experience in the relevant subspecialty or the particular procedure performed on the plaintiff."

Do you see that?

A. I do.

Q. All right. Without looking at the glossary, do you know, sitting here today, how the glossary defines "recent and substantive experience"?

A. I don't.
Q. Okay. Why don't we look at that definition together. Go to page 8.
A. Okay.
Q. See there's subsection F?
A. Yes.
Q. All right. Read that definition to yourself, and tell me when you're done.
A. Okay.
(Witness reviews document.)
A. Okay.
Q. To be able to provide expert testimony -- well, strike that.
Let me focus you on the very last part of this definition. Okay. To be able to provide expert testimony about a particular surgical procedure, the ASPS Code of Ethics requires a surgeon to have performed a specific procedure in question within three years of being retained as an expert witness; correct?
A. That's what it says, yes, sir.

MR. KNEPPER: Objection, form.
Q. All right. Now, as we've just discussed, you personally have not performed any kind of facial masculinization surgery in the last three years; correct?
MR. KNEPPER: Objection, form.
A. Correct.
Q. Any kind of facial feminization surgery; right?
A. Correct.
MR. KNEPPER: Objection, form.
Q. Vaginoplasty; right?
MR. KNEPPER: Objection, form.
A. Correct.
Q. Metoidioplasty; right?
MR. KNEPPER: Objection to form.
A. Correct.
Q. You personally have not performed any kind of gender-affirming surgical procedure on a transgender patient in the last three years; correct?
MR. KNEPPER: Objection, form.

A. I have never performed such procedures.

Q. All right. Well, given that you have not ever personally performed any kind of surgical procedures in the last three years, I take it you're not offering expert opinions on any of these surgeries because doing so would be inconsistent with the ASPS code of ethics; right?

MR. KNEPPER: Objection, form.

A. Well, so the ethics that informs my opinion here is I don't derive from the ASPS, nor am I subject to their -- their -- what's the word I'm looking for -- their sanctions, I guess, would be the correct word. The expert opinion I offer here is not on -- on complications of an operation that might enter into a litigation. In terms of the -- you know, I guess the -- the question at hand here is transition surgery, the bigger picture. I certainly make record of --

of the known complications as available in the literature. And in my testimony, I did a literature review on the complications of particular surgeries.

But I don't do these operations for a reason, and the reason I don't do these operations is ethical based on my knowledge of the science. I don't derive my ethical decision-making from the ASPS, and this is one of the reasons why, again, I have no heartburn about having withdrawn my membership. I have great issue with -- with the idea that a professional organization would encourage or sanction these operations given the world literature.

Q. Your opinion -- your -- strike that.

Your expert report does offer some opinion, or purports to offer some opinions about surgical risks of some of these gender-affirming surgical procedures, does it not?

A. Yes. Based on my -- my experience in microvascular surgery, on flap reconstruction of the perineum, for example, flap reconstruction of the chest or the -- or the genital area in treatment for traumatic injuries and things. So the operations themselves, I'm quite familiar with. I'm quite familiar with the complications that are peculiar to free flap or local flap reconstructions.

But as far as doing those operations for gender transitioning, I -- I don't do those operations. But the complications are the same: flap loss, flap necrosis, urinary fistulas. All of those things I have -- I have experience with in managing trauma, in managing cancer, in managing infectious destruction of the genital area. But I've never done the operation for transgender per se, correct.

Q. And because you've never done

any of those procedures on transgender patients, can we agree that offering those opinions is inconsistent with the ASPS Code of Ethics?

MR. KNEPPER: Objection, form.

A. I would not agree with that.

Q. Does it bother you that you might be in violation of the Code of Ethics by offering these opinions?

MR. KNEPPER: Objection.

A. No. Not in the least.

Q. Do you think that a judge might be troubled by the fact that your professional organization, former professional organization, says you shouldn't be allowed -- you shouldn't be offering these kind of opinions?

MR. KNEPPER: Objection, form.

A. Yeah, I find -- I find the -- the whole situation troubling, and I would hope that the judge would be troubled by it, yes.

Q. Okay. Yeah, no, I mean, I'm

asking a much more specific question. The judge is going to be asked to find whether your testimony is reliable. Do you think the judge might have some concerns if she -- if they were to conclude that the testimony you're offering in this case is not allowed under the code of ethics of the ASPS?

MR. KNEPPER: Objection, form.

A. I -- I -- I haven't thought about it.

Q. And you haven't thought about it because before today, you didn't know whether or not your testimony complies with the ASPS Code of Ethics; right?

MR. KNEPPER: Objection, form.

A. I was not -- I was not concerned with the ASPS Code of Ethics, for reasons we've discussed earlier.

Q. Did you know that -- did you know that the ASPS Code of Ethics prohibits members from offering expert testimony on topics in which they do not

have recent and substantive experience?

MR. KNEPPER: Objection, form.

A. Could you -- can you -- I want to make sure I answer your question and not something else. Could you offer me that question again, please?

Q. Before I showed you this code of ethics at your deposition today, were you aware that the ASPS Code of Ethics prohibits members from offering expert opinions on topics on which they do not have recent and substantive experience?

MR. KNEPPER: Objection, form.

A. Actually, I dreaded that such a -- such a fact would come to light. I have not read the -- the ethics code in recent years, as I said earlier. But I -- I have dreaded this evolution in the ethics of my former professional society, that they would consider transgender surgery the way they do.

I -- other -- aside from that, I was not concerned that I might be

violating the ethics of the society because in all my previous life, I have never violated the ethics of the society. And I don't -- at present, I don't consider my testimony to be a violation of this policy that we've read together.

Q. I understand. All right. Let's switch gears. You know what the WPATH is? The World Professional Association for Transgender Health?

A. Yes.

MR. TISHYEVICH: And for the court reporter, it's W-P-A-T-H, all capital.

Q. All right. You know that the WPATH publishes standards of care for the health of transgender people; right?

A. They have a publication that they call the standards of care, yes.

Q. And are you aware that they've been publishing those standards since 1979?

A. Yes.

Q. The latest publicly available standard of care is Version 7; correct?

A. Correct.

Q. And that was published in 2012; right?

A. That's right.

Q. All right. Before you wrote your report, did you sit down and review the Standards of Care, Version 7 that you're criticizing?

A. Yes, I did.

Q. All right. You yourself are not part of the WPATH; correct?

A. No, I am not.

Q. You've never been part of the WPATH; right?

A. I would never be part of the WPATH.

Q. You've never advised the WPATH in any capacity; right?

A. They've never asked my opinion. No.

Q. You've never advised the WPATH

in any capacity; correct?

A. I have not.

Q. You personally have not been involved with the development of WPATH's Standards of Care, Version 7; correct?

A. Correct.

Q. You don't know what year the WPATH started working on Version 7; right?

A. My understanding was it was in 2007, but I could be wrong. I think it was 2007. I think it was a five-year process, but I could be wrong on that.

Q. You don't know for sure?

A. I don't know for sure.

Q. You don't know how many different work groups at the WPATH were involved with working on Version 7; correct?

MR. KNEPPER: Objection, form.

A. In reading the -- the introduction to the document, the number nine pops into my mind, but I can't swear

to that.

Q. Okay. You don't know what kind of scientific literature the WPATH conducted as part of drafting Version 7; right?

A. As far as naming the particular papers that they may have reviewed, I can't do that for you because those are -- that happens in closed committee. I -- all I can say to you is my -- based upon my reading of the product and the verbiage that it's used, my suspicion is that it's pretty heavily weighted towards the American literature and -- and does not bring in particular document -- well, being that it was published in 2012, the big inflection point in 2011 probably wasn't available to the committee when they were writing that document.

So given that the document is already out of date and it's -- and the subsequent WPATH 8, no one knows when it's going to come out, yeah, it's --

it's almost -- it's almost irrelevant because of the change in the literature that happened since it was published, so. In particular, the 2011 article by Dhejne, Cecilia Dhejne, and -- and others that kind of changed the view of the scientific evidence.

So yeah, it's an out-of-date document by the standards of what are called standards of care. It's not a standards of care document. It's a -- it's a treatment guideline document is really what it is, and it's a poorly supported treatment guideline at that, so -- gosh, I wandered off.

Did I -- did I answer your question?

Q. Yeah, you anticipated my objection.

MR. TISHYEVICH: Which, again, I'll move to strike most of that as nonresponsive.

Q. Because here's my question. You

don't personally know what kind of scientific literature the WPATH conducted as part of drafting Version 7; correct?

MR. KNEPPER: Objection, form.

A. No. Again, a closed session, so I don't know what documents they used.

Q. You don't know what kind of outside experts the WPATH may have consulted in drafting Version 7; right?

A. No.

Q. You don't know what kind of peer review the WPATH may have conducted as part of developing Version 7; right?

MR. KNEPPER: Objection, form.

A. No.

Q. You don't know what kind of public comments the WPATH may have solicited as part of developing Version 7.

MR. KNEPPER: Objection, form.

Q. Right?

A. No.

Q. You don't know how many

different drafts the Version 7 went through before it was finalized; right?

A. No.

Q. You don't know how many different meetings or conferences the WPATH had to discuss the development of Version 7; right?

A. Correct.

Q. You have no idea what may have gone on during those meetings or conferences; correct?

MR. KNEPPER: Objection, form.

A. No. I was not a part of the conferences that produced the product.

Q. Yeah, you are not an expert in how Version 7 of the WPATH was developed; right?

A. Correct.

Q. And we can go through all these questions again individually for Version 8, but maybe we can shortcut this.

A. Well, no one knows what's in Version 8 except the people who are in

the committee. It's a -- it's a privileged document. There's no one in plastic surgery who knows it apart from the people who serve as members of the WPATH, so that would be the case.

Q. Okay.

A. It's a -- it -- yeah.

Q. So just so we have it on the record, you don't hold yourself out as an expert on how Version 8 of the WPATH Standards of Care are currently being developed; fair?

A. Fair.

Q. Okay. We talked earlier about the DSM; right?

A. Yes.

Q. In your day-to-day practice, you don't use the DSM-5; correct?

A. No.

Q. But you do know the DSM-5 is widely used by psychiatrists; correct?

A. Yes.

Q. The DSM-5 was published in 2013;

correct?

A. I don't know the publication date, but it sounds about right.

Q. Do you know that it was developed by the American Psychiatric Association?

A. Yes.

Q. You're not a member of the APA; right?

A. Correct.

Q. You personally have not been involved with the development of DSM-5; right?

A. No.

Q. You don't know how many different working groups were involved with developing the DSM-5; right?

MR. KNEPPER: Objection, form.

A. Correct.

Q. You don't know how many different members those working groups had; right?

MR. KNEPPER: Objection, form.

A. No.
Q. Or how they were selected; right?
MR. KNEPPER: Objection, form.
A. Correct.
Q. You don't know how many different authors contributed to the development of DSM-5; correct?
A. Correct.
MR. KNEPPER: Objection, form.
Q. You don't know what kind of scientific literature review was done by different work groups as part of developing the DSM-5; correct?
MR. KNEPPER: Objection, form.
A. Correct.
Q. You don't know what kind of public comments the APA may have solicited in developing the DSM-5; correct?
MR. KNEPPER: Objection, form.
A. Correct.
Q. You don't know how many

different drafts the DSM-5 went through before it was finalized; correct?

MR. KNEPPER: Objection, form.

A. Correct.

Q. You don't know how many different meetings or conferences or telephonic conferences the working groups had to discuss the development of the DSM-5; right?

MR. KNEPPER: Objection, form.

A. Right.

Q. You have no idea what was discussed during any of those meetings; right?

A. Right.

Q. Let me ask you specifically about the Sexual and Gender Identity Disorders Work Group. First of all, before today, did you know that the APA had a Sexual and Gender Identity Disorders Work Group as part of the development of the DSM-5?

MR. KNEPPER: Objection, form.

A. Yes.
Q. Do you know how many members were in that work group?
A. No.
Q. You don't know --
MR. KNEPPER: Objection.
Q. -- how those members were selected; right?
MR. KNEPPER: Objection to form.
A. Correct.
Q. You don't know their expertise; right?
A. Correct.
Q. You do not have expert firsthand knowledge of how the DSM-5 was developed; fair?
MR. KNEPPER: Objection, form.
A. Fair.
Q. Are you aware that the DSM-4 used the term "gender identity disorder" instead of "gender dysphoria"?
A. Yes.
Q. Do you know the reason for that

change?

A. From DSM-4 to DSM-5?

Q. Yes.

A. Yes.

Q. What's the reason?

A. In reading the literature and reading the reports of perhaps people who served on the committee, because I don't know how else you would be privy to this information, there was a desire on the part of the APA to de-pathologize the condition, and they wanted to use terminology that didn't sound like medical diagnoses. It was the opinion of the members of that committee that -- that transgenderism is only a diagnostic issue from the standpoint of the discomfort or the sorrow that the patient feels rather than any underlying pathology. So the -- the desire was to move those -- the diagnosis to change the language of diagnosis to de-pathologize it. But the problem that the committee

faces is that having done that, there's no mechanism for providing the services that they felt that the patients needed, so there had to be a diagnose -- a diagnostic code in order to get thirty-part -- third-party payers to pay. So it's a de-pathologize but maintain a diagnostic -- diagnostic code. That's my understanding of it.

Again, I wasn't there. But again, reading the writings of people who could only have gleaned it from having been present because it's closed session, that's my understanding.

Q. Understood. All right. Do you know what the Endo- -- Endocrine Society guidelines for treatment of gender-dysphoric or gender-incongruent persons are?

A. Do I know what they are?

Q. Yeah.

A. Yes.

Q. Do you know when they were

initially published?

A. No.

Q. Do you know when they were last revised?

A. I think it was just a couple of years ago, but I don't know the exact date.

Q. If I tell you it's 2017, does that sound right?

A. That wouldn't -- it wouldn't surprise me if that were true. I -- just within the last couple of years. I think theirs are current, and the expectation is that these standards of care or treatment guidelines will have a five-year revision. So given that they're current, they couldn't be any older than, say, 2017. So I suspect that -- yeah.

Q. All right. Did you review the latest available version of those Endocrine Society guidelines before forming your opinions in this case?

A. Yes. I have read them, yes.
Q. Okay. You yourself are not part of the Endocrine Society; right?
A. Correct.
Q. Have never been part of that society; right?
A. Correct.
Q. You've never advised the Endocrine Society in any capacity; correct?
A. Correct.
Q. You personally were not involved with the development of these original guidelines; correct?
A. That's correct.
Q. Not personally involved with the development of the updated guidelines in 2017; right?
A. Correct.
Q. Do you know how many people at the Endocrine Society were involved with those 2017 updates?
A. I do not know that number.

Q. And you don't know how they were selected to work on the 2017 updates; correct?

A. Correct.

Q. You personally don't know what kind of scientific literature review the Endocrine Society conducted in developing those updates; correct?

MR. KNEPPER: Objection to form.

A. Correct.

Q. You don't know what kind of outside experts they may have used; right?

A. What kind of outside experts? I would imagine they were all endocrinologists. Or are you asking did they have plastic surgeon input or --

Q. Do you know specifically whether the Endocrine Society used any outside experts in updating the -- in implementing the 2017 updates?

A. Well --

MR. KNEPPER: Objection, form.

A. I can only infer that they would, because such -- such statements, in order to be valid, demand review by outside parties to -- to obviate conflicts of interest, whether financial or professional. Those are all issues when generating standards of care, so of necessity, they would have had to have had outside experts to come in, yes.

Q. Okay. Do you know what kind of public comments the Endocrine Society may have solicited as part of developing the 2017 updates?

A. I don't.

MR. KNEPPER: Objection to form.

Q. You don't know how many different drafts there were of those 2017 updates before they were finalized; right?

A. No.

MR. KNEPPER: Objection to form.

A. No, I don't.

Q. Again, you haven't been to any

meetings or conferences or telephonic conferences where those 2017 updates were discussed, where the development of those 2017 updates was discussed; correct?

MR. KNEPPER: Objection to form.

A. Correct.

Q. You don't know what went on during those meetings or conferences; right?

MR. KNEPPER: Objection, form.

A. I do not.

Q. You -- you're not an expert in how the Endocrine Society developed the original 2009 guidelines for treating gender dysphoria; correct?

MR. KNEPPER: Objection to form.

A. That's not -- that's not my area of expertise. That's correct.

Q. Right. And you're also not an expert in how the Endocrine Society then developed the 2017 updates back to those guidelines; correct?

A. Correct.

Q. Okay. All right. Now let's talk about puberty-blocking agents. What puberty blocker drugs are you aware of by name?

A. Well, Lupron is probably the most widely used one. They're -- they're all gonadotropin-releasing hormone agonists. They come by a variety of trade names. But gonadotropin-releasing hormone is the genetic -- I'm sorry, the generic name for the drug that may appear under a variety of, you know, proprietary names, Lupron being the most commonly used.

Q. You've never prescribed Lupron; right?

A. No, I have never. No.

Q. You have never prescribed any puberty-blocking drugs of any kind; right?

A. No. That's not my area of expertise.

Q. Right. Have you ever looked at

the package -- strike that.

You know what a package insert is; right?

A. Yes.

Q. Have you ever looked at a package insert for Lupron?

A. Some time ago, but yes, I have.

Q. Okay. How recently do you think?

A. Gosh, it's probably more than four or five years ago. I think probably when I first started go -- you know, looking into this more carefully back in 2014. It was probably that long ago.

Q. Do you know what Vantas is? V-A-N-T-A-S.

A. Oh, I've read that somewhere before. Let's see. Is it -- it's the adverse events reporting -- is that what I -- I don't --

Q. It's a type of drug.

A. Oh.

Q. So no, that doesn't sound

familiar?

A. It does not sound familiar, no.

Q. How about Triptodur? T-R-I-P-T-O-D-U-R.

A. That sounds like a trade name I'm not familiar with.

Q. Okay. Fensolvil? F-E-N-S-O-L-V-I-L.

A. That sounds like a trade name I'm not familiar with.

Q. Trelstar? T-R-E-L-S-T-A-R.

A. Same.

Q. All right. You're not an expert in the different types of prescription drugs that are used as puberty-blocking agents; fair?

A. I do not consider myself an expert in that area, no. I rely on experts.

Q. All right. You know that puberty blockers are typically prescribed by endocrinologists; right?

A. Yes. Pediatricians and

endocrinologists, yes.

Q. Right. You have no specialized training or expertise in endocrinology; correct?

A. Correct.

Q. You don't hold yourself out as an expert in endocrinology; correct?

A. No, I do not.

Q. You're not planning on offering any expert opinions in endocrinology in this case because that's outside your scope of expertise; right?

A. Yes.

MR. KNEPPER: Objection to form.

Q. All right. Earlier, you said you have never prescribed puberty-blocking agents to anyone, so I take it you have no experience, no firsthand experience with advising your patients about potential risks and benefits of puberty blockers; right?

MR. KNEPPER: Objection, form.

A. Well, I have talked to patients

-- well, families, really, about the risks of puberty blockers in -- in early puberty and into adolescence. I have because I've reviewed the literature and I've spoken with experts in the area. And so, is that the question --

Q. Yeah.

A. -- you're asking, have I spoken to anybody? Yeah, I have. I -- I have, again, knowing that -- for example, that the drug Lupron, as an example, is -- is -- is not cleared by the FDA for application. It's an off-label use when using it in the diagnosed condition of gender dysphoria. So I know that it's an off-label application of the drug, and I know what the effects of the drug are. But nobody knows what the effects of the drug are on otherwise normal children, and that's pretty much all I'd relate to the families on the -- on that subject.

I don't offer myself as an endocrinologist, but I offer myself as a

concerned physician who has spoken with the specialists and read the package insert. Yes.

Q. You think off-label use is improper; right? That's the sense I got from reading your report.

MR. KNEPPER: Objection, form.

A. Off-label use in certain situations. So I use -- I use -- I have applied drugs' off-label use many times. But what the -- what the practitioner has to do is weigh the risk/benefit equation there and what is the expected goal and what are the likely risks.

For example, I used Botox long ago in the treatment of -- of hyperhidrosis before the company that produces it got FDA clearance to use it that way. The risk, very, very low risk; the potential benefit, very, very high. But in this case, we're talking about very significant risks for an unproven benefit. So that's an example of how you

have to weigh off-label use.

And the FDA understands that, and they don't go after off-label use unless there's significant risk. And even then, they might not yet spring into action. It's a pretty slow-moving organization.

Q. All right. We'll come back to that.

A. Okay.

Q. You never sat in on any appointment where an endocrinologist prescribed a puberty-blocking drug to a patient; correct?

A. I have never.

MR. KNEPPER: Objection, form.

Q. You personally don't know what endocrinologists typically tell their patients about risks and benefits of puberty blockers; right?

MR. KNEPPER: Objection, form.

A. Only what I have read in the record. For example, the plaintiffs'

records, I -- I -- I believe I have read that -- that kind of consultation, yeah. But I -- but I wasn't present in the room, if that's what your question is.

Q. Yeah. You don't know what was actually communicated to the patient; correct?

A. Only what was entered in the record, yeah, the medical record.

Q. And just as a more -- outside of these plaintiffs, as a more general matter, you don't personally know what endocrinologists tell their patients about potential risks and benefits of puberty blockers because you're not present on those prescribing decisions; right?

MR. KNEPPER: Objection, form.

A. Well, if -- I assume that they follow the same sort of process that every other medical professional does when getting consent for -- for therapies of various kinds. And so to offer

informed consent to a -- in this case, perhaps a family, parents, that informed consent would have to include -- in order to be valid, it would have to include the potential risks that are enumerated in the package insert. And then they would also, in certain cases, have to enumerate risks that may not be in the package insert but may be expected given the -- the particular case of their child or the particular patient.

So we all have to follow that same general standard, and so to that extent, I have some knowledge of what they would be saying. But the particular words or the particular things they may have emphasized, I have no -- no personal knowledge of.

Q. Your general expectation is that before a doctor prescribes the drugs, they will at least inform the patients of the risks as specifically enumerated in the drug labeling; right?

A. Among other things, yes.

Q. And the doctor may also go beyond the labeling and advise them of potential risks even though they're not specifically disclosed in the drug labeling; right?

A. Yes. Because there -- there are circumstances wherein the underlying conditions of the patient may -- may cause particular risks in particular areas, so that's right.

So there's the general precautions that are included in the package insert, but they usually tend to be exhaustive. They -- they list in the package inserts even remote possibilities, so. But most physicians can't drill down into those details with a patient. You don't want to overwhelm the patient and their family with those minute details. You want to talk about the major risks and then the risks that are peculiar to the patient because of

their underlying condition. And that's generally what everybody does.

Q. Yeah.

A. Although, again, I'm not present in every office on every occasion, but that's generally how we're trained to conduct a consent.

Q. Do you know -- are you aware that patients who are prescribed puberty-blocking agents are typically monitored through blood tests and lab work?

MR. KNEPPER: Objection, form.

A. It -- I don't -- I'm not familiar in all cases to what extent they're monitored. My hope is that they're being monitored. I would expect that they're being monitored.

Q. Yeah. And you don't have experience with monitoring patients who undergoing treatment with puberty blockers; right?

A. No.

Q. And you don't have experience with reviewing blood work, labs, what's normal, what's not, anything in that field; right?

MR. KNEPPER: Objection to form.

A. Oh, no, I am familiar with reviewing labs and interpreting laboratory data --

Q. Sorry.

A. -- as it pertains -- yeah.

Q. Sorry. Let me make -- make my question more specific. I'm still talking about patients who are treated with puberty-blocking agents.

A. Okay.

Q. For those patients in particular, you don't have experience with reviewing their blood work, labs to see -- to check their hormone levels and see if any adjustments are needed; right?

MR. KNEPPER: Objection, form.

A. No. I have some familiarity with the interpretation of hormone levels

in endocrinology. As a -- as a general surgeon and a critical care doctor, these issues were very important to me for a number of years. So I'm familiar with that, although I haven't monitored patients receiving puberty blockers or cross-sex hormones per se. So generally, I am familiar with -- with that and the ramifications of endocrinopathies, again, because I had considerable experience with management of critical care patients and -- yeah.

Q. Yeah. My question is more specific.

A. Okay.

Q. You personally have not monitored blood work from patients who are undergoing puberty-blocking agents; right?

A. Correct.

Q. Okay. And you mentioned cross-sex hormones. You know what those are; right?

A. Yes.
Q. For transgender women, estrogen is a hormone that's typically prescribed; right?
A. Yes.
Q. For transgender men, testosterone is the hormone that's typically prescribed; right?
A. Right.
Q. You've never prescribed cross-sex hormones for treatment of gender dysphoria to anyone; correct?
A. Correct.
Q. You have no firsthand experience with advising your patients about potential risks and benefits of cross-sex hormones when used for treatment of gender dysphoria; correct?
A. Correct.
Q. You personally don't know what doctors who do prescribe estrogen or testosterone to their patients for gender dysphoria tell those patients about the

risks and benefits of that treatment; correct?

MR. KNEPPER: Objection, form.

A. I would answer that question as we did earlier, that my expectation would be that they would cover the -- the risks and benefits of that -- of that particular therapy and that the exploration of potential risks would include the major points that are contained in the package insert and whatever particular risks that the patient may have because of their underlying conditions, medical conditions that may impinge upon them. That would be my expectation.

Q. Okay. So for testosterone and estrogen when used to treat gender dysphoria, you would generally expect doctors to at least give the warning about -- that's in the labeling and potentially give additional warnings outside of that as well; fair?

MR. KNEPPER: Objection to form.

A. That would be my -- that would be my expectation.

Q. All right. We started talking about off-label use, so let's circle back to that. So in your report, you criticize Dr. Brown and Dr. Schechter for not disclosing that the FDA has not approved these hormones for treatment of gender dysphoria. Do you recall that?

A. Yes. My testimony, yes, I do recall that.

Q. All right. Off-label use is when a doctor prescribes a drug outside of its FDA-approved indication; correct?

A. Correct.

Q. And we touched earlier on whether it's proper or improper to prescribe drugs on an off-label basis. There are circumstances where it is appropriate to prescribe a drug on an off-label basis; correct?

A. Yes.

Q. It's a case-by-case decision; right?

MR. KNEPPER: Objection, form.

A. Yes.

Q. It's a case-by-case decision that's made between the doctor and their patient; right?

MR. KNEPPER: Objection, form.

A. Right.

Q. You're not expressing the opinion that doctors should not be prescribing drugs on an off-label basis ever; right?

A. I'm expressing the opinion that -- that drugs that have massive potential side effects should not be off-label prescribed unless those risks warrant -- I mean, those risks are warranted given the underlying condition of the patient and that the patient is being treated as a -- as a -- as a trial or an experimental patient with ethics monitoring and all the rest of it that

attends.

The reason why off-label use is problematic is because it doesn't have a body of proven scientific evidence that the FDA has made use of in order to -- to warrant the use of the drug. So if you're going to go off label, again, the risks have to be low. If the condition you're treating makes -- makes the risks high, then that's where you have to get into ethics panels and experimental trials and things like that. I think that's at the heart of this issue.

We're dealing with a condition where the application of these drugs is not proven and the risks are very high, and that's where my concern lay.

Q. Do you think that off-label use of prescription drugs is, by definition, investigational?

A. To the extent that very often the -- the use of -- the off-label use of drugs begins on the basis of anecdotal

reports. So anecdotal reports, again, are categorized as level 5 evidence. And -- and so when those reports are published and -- and the risks are seen as low, then other physicians may begin the off-label use of those drugs.

But generally, one wants to progress to a more definitive scientific evidence, like level 4 evidence where there's a pre-application test, the use of the drug, and a post-application test, or level 3 where you're looking at longitudinal data to confirm not only the safety but the efficacy of the application of the drug.

In the case of the use of puberty blockade and cross-sex hormones, it doesn't exist beyond level 5 evidence even though the treatment has now been going on off-label for more than a decade, if not approaching twenty years.

Q. All right. You mentioned doctors are prescribing on an off-label

basis after there's case reports. It does happen that doctors prescribe drugs on an off-label basis based on nothing more than case reports; right?

A. That's how it always begins, yeah.

Q. Yeah. The FDA doesn't say that's not permissible, do they?

A. No, they don't.

Q. Okay.

A. I don't know. I don't know what the FDA -- if there's a published policy about that. I would suspect not, given the history in my lifetime of people off-label using, for example, asthma medications for the treatment of breast implant encapsulation, that kind of stuff. That's an example of a very benign drug being used off-label to treat a surgical condition of breast implant encapsulation. So that's my personal experience. I suspect there isn't an FDA policy that utterly prohibits it. I

would agree, yeah.

Q. Okay. The FDA is the federal agency that regulates prescription drugs; correct?

A. Food and drugs, yes.

Q. And they decide whether a particular drug can be marketed for a particular indication; correct?

A. Right.

MR. KNEPPER: Form.

Q. And one of the areas of oversight the FDA has is the safety of prescription drugs; right?

A. Right.

Q. Before forming your opinions in this case, did you investigate what position the FDA takes on off-label use of drugs?

A. No, I did not.

Q. Sitting here today, do you know what that position is?

A. I do not, no.

Q. Do you know whether the expert

opinions you're expressing about off-label use of drugs are consistent or inconsistent with what the -- what the FDA has said about off-label use?

MR. KNEPPER: Objection, form.

A. I remember when the controversy about the use of Singulair in breast implant capsules came up. That was discussed at an ASPS meeting and then some articles that came out. And I think I recall from those -- either the conference or the article that the FDA takes a permissive attitude where risk is low.

Q. You think the FDA only allows off-label use of prescription drugs when the risk is low?

A. I don't know that for a fact.

Q. All right.

A. I would -- I would hope. I would hope low risk/high benefit. So -- so again, it's an equation, it's not just a one-sided thing. So it isn't just the

risk but also the potential benefits. And the potential benefits have to be very high. The higher the risk is, the higher the benefit has to be. And that's kind of a general principle of the medical care. You know, before all else, do no harm. That's what informs all medical care, and I would hope that's what informs the FDA policy, whatever that may be.

Q. Okay. Well, let's look at the policy.

A. Okay.

Q. I'm going to introduce another exhibit. Okay. This is going to be Exhibit 11. Let me know when you have it.

(Exhibit 11 was marked for identification and is attached.)

A. Okay.

Q. Have you ever seen this document before?

A. I have not.

Q. Do you know what the Federal Register is?

A. It's a -- it's a federal list of regulations pertaining to things like this.

Q. Yeah. It's the official publication --

A. Federal code.

Q. -- of federal rules, proposed rules, and notices for federal agencies; right?

A. Yeah. Right.

Q. I see this is dated at the top November 18, 1994. See that?

A. Yes.

Q. Page 1, middle column, see it says, "Agency: Food and Drug Administration, HHS"?

A. Let's see. "Agency: Food and Drug Administration, HHS." Yes.

Q. It says, "Action." It says, "Notice; request for comments." Do you see that?

A. Yes.
Q. All right. Go to page 2.
A. Okay.
Q. In the column all the way to the right, you see there's a section II, and it's titled, "FDA Policy on Promotion of Unapproved Uses." Do you see that?
A. I do.
Q. All right. The first paragraph says, "Over a decade ago, the FDA Drug Bulletin informed the medical community that 'once a [drug] product had been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.'" Do you see that?
A. I do.
Q. What do you understand that to mean?
A. That --
MR. KNEPPER: Objection.
A. I apply that to mean that --

that the -- that the FDA does not -- does not intend to weigh in on off-label use, you know, without restriction, I guess. The sense I get of it is that they're -- they're declining to prohibit the off-label use in -- in other patients at this time, I would -- I would guess. I suppose that if they started to see complications, they might weigh in. This has been the history, for example, with nausea medicines and things like that that created problems after use.

Q. At that time at least, the FDA was telling the medical community that doctors may prescribe drugs for uses outside of FDA-approved indications; correct?

A. Yes. I would say that --

MR. KNEPPER: Objection, form.

A. -- in 1994, the FDA declined to -- to -- I don't know what they've done subsequently. I -- but -- but in 1994, they -- they -- off-label use was not

prohibited.

Q. Well, actually --

A. They finally --

Q. Sorry, finish.

A. No, go ahead.

Q. Well, you see this actually says, "The publication further stated," and then there's a quote. And after the quote, there's a Footnote 4.

Before we get to that, do you see it says -- it cites to the FDA Drug Bulletin from 1982.

A. Right.

Q. Right?

A. Right.

Q. So that original guidance came from a 1982 FDA position; right?

A. Right.

MR. KNEPPER: Objection, form.

Q. And you say that you read this and you don't think that the FDA has taken a position, but let's see what else that quote says. You see the quoted

language starting with "The publication further stated"? Do you see that?

A. That starts with the word "unapproved"?

Q. Yeah. It says, "'unapproved' or, more precisely, 'unlabeled' uses may be appropriate and rational in certain circumstances, and may, in fact reflect approaches to drug therapy that have been extensively reported in medical literature." Do you see that?

A. I do.

Q. You understand what that means; right?

MR. KNEPPER: Objection to form.

A. Yes. Yes.

Q. Off-label use -- strike that.

The FDA has recognized as early as 1982 that off-label use may be based on medical literature, not published indications; right?

A. Right.

Q. And then it says, "Valid new

uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations." Right?

A. Yeah. That's -- that's kind of a -- just a restating of what I related to you about, for example, the use of Botox and hyperhidrosis, as I have done. Yeah, I would totally agree with that.

Q. And then it says, "The agency and its representatives have restated this policy on numerous occasions." Do you see that?

A. I do.

Q. Do you understand that for decades, for three decades at least, the FDA has taken the position that physicians are allowed to prescribe drugs on an off-label basis?

MR. KNEPPER: Objection, form.

A. Yes.

Q. Your report doesn't acknowledge this longstanding position from the FDA, does it?

A. My report does not -- no, it does not.

Q. And I mean, I know I just heard you say, well, maybe this is from the '80s. Let me show you what the FDA says today.

A. Okay.

Q. I'm going to introduce another exhibit. This is Exhibit 12. Let me know when you get it.

(Exhibit 12 was marked for identification and is attached.)

A. Okay. All right. I've got it.

Q. All right. You see that this is a printout from fda.gov, the official website of the FDA; right?

A. Right.

Q. The title is "Understanding Unapproved Use of Approved Drugs 'Off Label.'" Right?

A. Right.
Q. Go to page 2.
A. Okay.
Q. Toward the bottom, it says in bold, "Why might an approved drug be used for an unapproved use?" Do you see that?
A. I do.
Q. Then it says, "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient." Do you see that?
A. I do.
Q. And then skipping one sentence, it says, "One reason is that there" may -- "might not be an approved drug to treat your disease or medical condition." Right?
A. Right.
Q. So the FDA -- the position that the FDA takes is off-label use may be

medically appropriate for patients; right?

A. Right.

Q. That's a position they've taken for thirty years plus; right?

A. Right.

MR. KNEPPER: Objection, form.

Q. All right. And we talked earlier about, you know, is off-label use experimental or investigational. Before forming those opinions, did you look to see what the FDA says on that point?

A. How the FDA classifies experimental or investigational?

Q. Do you know what position the FDA takes on whether off-label use is considered investigational?

A. I don't know what their official position is, no.

Q. All right. Let's look at that. All right. This is going to be Exhibit 13. Let me know when you have it.

(Exhibit 13 was marked for identification

and is attached.)

A. I have it.

Q. This is a guidance document from the FDA from 1998. Generally, are you aware that the FDA issues guidance documents?

A. Generally, yes, I am aware.

Q. Have you ever seen an FDA guidance document before today?

A. I've heard them referred to, but I've never read one, no.

Q. Okay. All right. Well, this one's titled "'Off-Label' and Investigational Use of Marketed Drugs, Biologics, and Medical Devices." You see that?

A. I do.

Q. Okay. All right. The first paragraph, second sentence says, "If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its

use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." You see that?

A. I do.

Q. All right. The next sentence says, "Use of a marketed product in this manner when the intent is the 'practice of medicine' does not require the submission of an Investigational New Drug Application, Investigational Device Exemption or review by an Institutional Review Board." Do you see that?

A. I do.

Q. I understand that what this is saying, according to the FDA, when a doctor prescribes a drug on an off-label basis, that is not necessarily an investigational use of that drug; right?

MR. KNEPPER: Objection, form.

A. I would disagree, because as it says there, when they're -- when they're prescribing in that manner, they have a

responsibility not only to be informed about the product but to do the recordkeeping of its effects, which is really the initial phase of investigation. So in a sense, they are -- they are part of the investigative process now because a new application of the medication has been proposed, and safety and efficacy have -- have to be documented in some measure.

So the FDA is giving you room to broaden the application of the drug, but they're also placing upon you the burden of documenting so that its effects and benefits can be characterized because that's being -- obviously, it's being investigated. That's the point of their wanting the recordkeeping, so --

Q. Do you know what the Institutional Review Board is?

A. Yes.

Q. Clinical trials have to be cleared by IR- -- IRBs; right?

A. Right.

Q. And this says you don't actually have to apply for approval by an IRB when you're prescribing a drug on an off-label basis; right?

MR. KNEPPER: Objection, form.

A. It says that it's not of necessity, so they're not making a blanket requirement. I would imagine that that might be modified in particular cases.

Q. Yeah. Because this is saying that when you're prescribing a drug on an off-label basis, that doesn't mean you're starting up a clinical trial; right?

A. It doesn't necessarily mean you're starting a clinical trial, that's right. It doesn't exclude the necessity for a clinical trial. It just says you're not necessarily starting a clinical trial.

Q. Yeah. And when this says -- when it says doctors should maintain

records of the product's use and effects, it's not telling them that they're enrolling their patients in a clinical trial by starting -- by prescribing a drug on an off-label basis; right?

MR. KNEPPER: Objection, form.

A. Right. But what it -- what it probably is inferring is that if they start seeing complications, then the further application of the drug in that circumstance might be required -- might require an IRB. So yeah. So it's -- what they're saying is it doesn't require an IRB of necessity. It does require recordkeeping. And I would expect that if they were to see complications, problems, lack of efficacy, that -- and the desire for its continued use might require an IRB. In fact, I would -- I would hope it would require an IRB. Yeah.

Q. Yeah. A clinical trial down the line is a "this might be nice to have,"

but it's not a requirement for a doctor to prescribe a drug on an off-label use basis. That's what this says; right?

MR. KNEPPER: Objection, form.

A. That's what that says, yeah.

Q. Yeah. You don't cite this guidance in your report obviously; right?

A. I don't think it's --

MR. KNEPPER: Objection, form.

A. I don't think it's germane to my report. No.

Q. All right. You've also offered opinions on whether it's proper to prescribe drugs on an off-label basis to children and adolescents; right?

A. I've only offered it in the case of this particular therapy. I haven't offered it generally, only in the case of puberty blockade and cross-sex hormones for the purposes of transitioning a child to the appearance of the other sex. That's all I've offered it as an opinion.

Q. All right. Do you know what the

American Pediatrics Association is?

A. Yes.

Q. Before forming your opinions, did you look to see what the APA says about off-label use of drugs in children and adolescents?

A. No.

Q. Sitting here today, you don't know the APA's position on this -- on this topic; correct?

MR. KNEPPER: Objection, form.

A. Correct.

Q. Let's look at that next. Okay. This is going to be Exhibit 14, and let me know when you have it.

(Exhibit 14 was marked for identification and is attached.)

A. Okay. I have it.

Q. You understand this is a policy statement from the APA?

A. I'm reading it now. I see that it is a policy statement from the American Academy of Pediatrics.

Q. It's a policy statement entitled, "Off-Label Use of Drugs in Children." Right?

A. Yes. Yes.

Q. Look at the introduction section toward the bottom of the page.

A. Okay.

Q. It says that, "The purpose of this statement is to further define and discuss the status of off-label use of medic- -- medications in children." And then it talks about a publication of a 2002 statement. You see that?

A. Yes.

Q. All right. So the FDA -- APA has taken a position on off-label use of drugs in children since at least 2002; right?

MR. KNEPPER: Objection, form.

A. I'm reading it now. It appears to be that, yeah.

Q. All right. Look at the abstract towards the top.

A. Okay.

Q. Second sentence says, "However, off-label drug use remains an important public health issue for infants," childrens, and" -- "children, and adolescents, because an overwhelming number of drugs still have no information in the labeling for use in pediatrics." Do you see that?

A. I do.

Q. Okay. And then it says, "The purpose of off-label use is to benefit the individual patient." Right?

A. Yes.

Q. And then it says, "Practitioners use their professional judgment to determine these uses." Correct?

A. Yes.

Q. And then it says, "As such, the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use." Right?

A. That's what it says there, yes.

Q. Yeah. The APA also takes the position that off-label use does not imply investigational use; correct?

MR. KNEPPER: Objection to form.

A. It does not de facto imply off-label use, that's right, yeah. It does not imply, right.

Q. And it does not imply that off-label use is de facto improper or illegal or contraindicated; right?

A. Right.

MR. KNEPPER: Objection, form.

Q. All right. Go to page 2.

A. Okay.

Q. Look at the left column, the very bottom paragraph.

A. Okay.

Q. It says: "The absence of labeling for a specific age group or for a specific disorder does not necessarily mean that the drug's use is improper for that age or disorder. Rather, it only means that the evidence required by law

to allow inclusion in the label has not been approved by the FDA. Additionally, in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children."

Do you see that?

A. I do.

Q. This is the APA recognizing that even in the absence of FDA approval for a particular indication, that use may still be supported by clinical experience and data; right?

MR. KNEPPER: Objection, form.

A. Yeah. I would -- I would say also that the APA recognizes that -- that there's a poverty of evidence. The poverty of evidence is one of the characteristics of off-label use. And that's -- that's what the nature of my expert opinion was about, that the poverty of evidence is what makes the off-label use an issue, and in this case, poverty of evidence for off-label use in

a situation where the harms -- potential harms are great. That's what the concern was, not -- obviously, I use -- I've off-label used drugs in my own practice, as I said before.

I don't have an objection without qualification that -- that the off-label use of drugs is somehow a crime. I'm saying that in this particular instance of this particular application, that the off-label use tells us that there's a poverty of scientific evidence to support its application that way. Clearly, there's anecdotal reports; otherwise, doctors wouldn't be using it. But there's a poverty of evidence, and what we're dealing with here is not a potential trivial complication but potentially permanently life-altering complications.

That was the issue that I was addressing in my concern about the off-label use, that there's a standard

of -- of caution that's required when you go off-label. And that caution isn't being demonstrated by the -- for the persons who are prescribing or applying these drugs in this way. That was my concern.

Q. All right. You think that before these drugs are to be prescribed, they should first be supported by results from clinical trials; right?

MR. KNEPPER: Objection, form.

A. That's the beginning.

Q. That's the beginning.

A. Yeah.

Q. The absolute minimum to prescribe these drugs; right?

MR. KNEPPER: Objection, form.

A. Well, no. No, I -- I didn't say that. As I said, it begins with anecdotal evidence, not clinical trials. So somebody somewhere sees an effect. As it said in that FDA document, it's oftentimes serendipitous. A clinician

will see an effect, and then -- and then they'll, based on that, they'll hopefully check out the potential risks to the patient and then begin that off-label use.

So it begins actually with anecdotal reports, maybe case collections, maybe a number of providers' case collections, maybe it's a -- it's a -- it's an institutional experience. But that leads to clinical trials and the IRB and all the rest of it. So that's just the beginning of it.

Q. It may be appropriate for a doctor to prescribe a drug on an off-label basis without having the results from a clinical trial; correct?

A. Yeah, I would -- I would hope that after thirty years of doing this, that we would beyond -- be beyond institutional or personal experience, that those trials would have already been done. This isn't -- we're not just at

the beginning of puberty blockade and cross-sex hormones. We're well into this now, to the point where the European literature is now vehemently rejecting that.

That's -- these things have changed. In the last three years, it's all changed. With respect to this off-label application of puberty blockade and cross-sex hormones, it's changed utterly. So these general statements about off-label use are important to understand, certainly, when you see a serendipitous result and you consider applying the drug. But we are so far beyond that at this point in the history of transgender therapy, this is where we're concerned. We're concerned with the continued off-label use, the continued absence of clinical trials. We should have been beyond that years ago. And this is what the European literature is now showing us, that the application

of those drugs by -- which is approved by the APA, is now being rejected by the medical services in Great Britain, in Sweden, in Finland, in Holland. And this is where we as American providers have to get.

Q. All right. We'll -- we'll definitely come back to those --

A. Okay.

Q. -- studies. I promise.

A. Okay.

Q. Let's finish this document first, though. All right. Go to page 3. All right.

A. Okay.

Q. Look at the left column.

A. Okay.

Q. It says: "Therapeutic decision-making should always be guided by the best available evidence and the importance of the benefit for the individual patient. Practitioners are in agreement regarding the importance of

practicing evidence-based medicine. However, for the pediatric population, gold standard clinical trials are often not available, so practitioners must rely on either less definitive information, such as expert opinion for the age group that they are treating, or use evidence from a different population to guide practice."

You see that?

A. I do. And I would agree with that, that particularly in pediatric patients, the clinical trial approach oftentimes is -- is not available because of the nature of the condition and so on. But in the -- in this case, there's a -- it's not an all or none, it's got to be clinical trials or -- or nothing.

There's longitudinal population-based studies, long-term results seen in a population that has matured through this therapy, and looking at, you know, cohort studies

longitudinally, cohort study, which is -- which is an alternative when -- when the clinical trial is not available to you for ethical reasons. Like you wouldn't do sham surgery on somebody. That would be ethically untenable. But you can look at population-based studies where you have a cohort to compare. And that's -- that's where we should be. That's where the European literature is now.

So I would agree with that statement that -- that the APA is making there, but I would qualify it by saying that there's an alternative available that brings you to a higher level of evidence that may in fact bring it to on-label use if they were to bother to do it.

Q. The APA recognizes that for the pediatric population in particular, results from clinical trials are often not available; right?

A. Right.

Q. And the answer in those situations is not to stop prescribing these drugs altogether; right?

MR. KNEPPER: Objection, form.

A. Yeah. The "altogether" would be the qualifier there because there are some circumstances where it would be -- I mean, it wouldn't be good to stop its prescription, but there would be others that you would have to examine more carefully because of the risk issue.

Q. Yeah. Instead, what the APA says is that when clinical trial results are not available, doctors have to rely on less definitive -- definitive information; right?

A. That's what -- that's all you have. That's right.

Q. Yeah. The APA says it may be appropriate for doctors to prescribe drugs to pediatric patients on an off-label basis even when that use is not supported by randomized clinical trials;

correct?

A. Right.

Q. Because the reality is that for a lot of conditions, in the pediatric population, there are no randomized clinical trial results available; right?

MR. KNEPPER: Objection, form.

A. Again, so you're holding out randomized clinical trial, or they're holding out randomized clinical trial as the only alternative to the lowest form of evidence. And I -- I agree that randomized clinical trial are not always available, and we have to have recourse to perhaps lesser but nonetheless more convincing forms of evidence to fall back on rather than falling back to the lowest form of evidence as is the case today with the application of these drugs.

Q. All right. Look at the last paragraph in the left column of this page.

A. Okay.

Q. It says: "In most situations, off-label use of medications is neither experimentation nor research. The administration of an approved drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest." Do you see that?

A. I do.

Q. If the physician deems an off-label use to be in the individual patient's best interest, that's not experimental use, according to the APA; right?

MR. KNEPPER: Object to the form.

A. Well, according to the -- according to the APA, in most situations.

Q. Yeah.

A. So in that statement, it acknowledges that there are some

situations where that would be considered. That's the implication in that statement. So "most" is the qualifier, implying that there are situations where it would be considered experimental.

Q. Okay.

A. And that's what we propose in our expert testimony, is that this is one of those situations. This is experimental use.

MR. TISHYEVICH: Now let's go off the record.

THE VIDEOGRAPHER: This is the end of Media Unit No. 3. We are off the record at 12:30 p.m.

(Break taken.)

THE VIDEOGRAPHER: This is the start of Media Unit No. 4. We are on the record at 1:21 p.m.

Q. (By Mr. Tishyevich) All right, Doctor. You know you're still under oath; right?

A. Yes.

Q. Before lunch, we were talking about off-label use of prescription drugs. Do you know how common or uncommon off-label use of prescription drugs is in the overall population?

A. I'm not familiar with that number, no.

Q. All right. You don't know if it's 5 percent or 10 percent or 50 percent of all drugs are prescribed off label; right?

A. I have no idea.

Q. How about pediatrics specifically? Do you know how common or uncommon off-label use is in the pediatric population?

A. I do not.

Q. Let me introduce an exhibit.

MR. KNEPPER: One second.

Dr. Lappert?

THE WITNESS: Yes.

MR. KNEPPER: Your camera has

moved accidentally, yeah.

THE WITNESS: It just allows me to look at the bottom of the other screen here so I can look at the exhibits.

MR. KNEPPER: Okay. I think just for the video recording, we want to make sure that the camera stays on your face.

THE WITNESS: I'll go like this, then.

MR. KNEPPER: Perfect.

Q. (By Mr. Tishyevich) So this is going to be Exhibit 15. Let me know when you have it.

(Exhibit 15 was marked for identification and is attached.)

A. All right. I have it.

Q. All right. This is a study from 2019 by Dr. Yackey, Y-A-C-K-E-Y, titled "Off-label Medication Prescribing Patterns in Pediatrics: An Update." Do you see that?

A. I do.

Q. All right. And the objective is "To describe the frequency of off-label drug use in 2014 as defined by the FDA-approved age ranges in patients 18 or under 18 years of age." Do you see that?

A. I do.

Q. All right. Look at "Methods." Do you see that section?

A. I do.

Q. It says, "This is a retrospective cohort study of an administrative database containing inpatient resource use data from January 1, 2014, to December 31, 2014." And do you see that?

A. I do.

Q. Look at the "Results" section.

A. Okay.

Q. The first sentence says, "At least 1 drug was prescribed off-label in 779,270 of 2,773,770 (28.1%) patient visits during the study period." Do you see that?

A. I do.

Q. And skipping a sentence, then it says: "Off-label usage of certain medications differed between care settings. Rates of off-label medication use were higher in observational (45.5%), inpatient (53.9%), and ambulatory (54.2%) settings." Do you see that?

A. I do.

Q. All right. The study concluded after reviewing 2.7 patient visits that overall, 28.1 percent of patients were prescribed an off-label -- prescribed a drug on an off-label basis; right?

A. Right.

Q. And depending on the setting, off-label prescriptions in the pediatrics context can be as high as 45 to 54 percent; right?

A. That's what the study shows.

Q. All right. The reality is that prescribing drugs to children and adolescents on an off-label basis is a

fairly common practice; right?

MR. KNEPPER: Objection to form.

A. It appears to be, yes.

Q. You did not know this before you formed your expert opinions?

A. I knew that it was more common in children than in adults, and I knew that it was, you know, fairly common, having -- having prescribed off-label myself to children, that it's -- it's probably fairly common. I didn't know the exact numbers, though, until now.

Q. Okay.

A. Again, my -- my expert opinion about this is not about does it happen. It's about the particular case of the transgendered person receiving an off-label use of a -- of a fairly problematic drug in light of the recently changing evidence about its efficacy. So the issue of off-label use that I presented was not about are drugs prescribed off-label. The issue was

these particular drugs in these particular patients off-label in light of the recent change in the world literature about the risk/benefits of doing those things. And the evidence now is that that whole position about puberty blockade and cross-sex hormones, it's falling apart in the last three years, and there's a -- there's a growing wave of evidence that says do not do this. And in fact, that's where the Court stepped in in Great Britain, and it's where the Karolinska Institute stepped in.

It's not that it's off-label use. It's that it's particularly problematic in the case of these drugs in these suffering patients. That's what my expert opinion was about. It was not about drug policy. It was about these patients, these problems, these drugs. And the fact is that when you off-label use, the responsibility falls much more

heavily on the provider. When the FDA approves it, the responsibility falls to the shoulders of the approving authority. But if you're going off-label, it's on you as the provider to be certain that you're doing good to the patient. And up until the last three years, the evidence wasn't there. Now it's there. The continued use of the drugs in this way has become very problematic, and that's -- that's what my expert opinion was about, not about drug policy, but about these drugs, these patients.

Q. Doctor, there's actually no question pending, so I'm going to ask that you stick with listening to my questions and then answering them instead of making speeches. Okay?

All right. You -- we talked earlier about the Botox injections that you've done; right?

A. Yes.

Q. You told me you've been doing

Botox injections in the forehead for over ten years; right?

A. Correct.

Q. You've told me that you've been doing Botox injections for crow's feet for over ten years; right?

A. Yes.

Q. Do you know when the FDA first approved Botox for the use of treating forehead wrinkles?

A. Let's see. I recall that it was when I was the chief of plastics at Portsmouth, Virginia, because we had been using it for dystonias and things like that in children. And it got approved for cosmetic use I'm going to say before we moved to the new hospital, so it had to have been around ninety- -- I want to say '97, somewhere in there. I'm just ballparking it here.

Q. So when you were using Botox to do forehead injections, you think that was an on-label FDA approved use for the

last ten years; right?

A. Yeah. When used in the corrugator and procerus muscles, that's the on-label use for cosmetic botulinum toxin.

Q. Let me introduce another exhibit. All right. This is going to be Exhibit 16, and let me know when you have it.

(Exhibit 16 was marked for identification and is attached.)

A. All right. I have it.

Q. Top right corner, you see it says, "Food and Drug Administration"?

A. Yes.

Q. Below that, do you see it says, "Supplement Approval"?

A. Yes.

Q. You know what this is?

A. It looks to be a -- a letter from the FDA to the Allergan corporation, to a particular Ph.D. there who is the director of regulatory affairs. And it's

a supplemental -- I guess it's an amendment. I haven't read it. Can I have a moment to read it?

Q. I'll -- I'll point you to it. Don't worry.

A. All right.

Q. Allergan is a manufacturer of Botox; right?

A. Allergan, yes, uh-huh.

Q. Go to page 3.

A. Okay.

Q. And you see there's a signature line, and under that, it says, "10/02/2017"?

A. Correct.

Q. You understand this was issued on October 2, 2017; right?

A. That's -- that's what the document appears to show, yeah.

Q. Go back to the first page.

A. Okay.

Q. First paragraph says, "Dear Dr. Richmond: Please refer to your

Supplemental Biologics License Application, dated and received December 2, 2016." Do you see that?

A. I do.

Q. The next paragraph says, "This Prior Approval supplemental biologics application proposes an additional indication for the temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity."

A. Right.

Q. Do you see that?

A. I do.

Q. All right. Then the next section says, "Approval & Labeling." Right?

A. Yes.

Q. It says, "We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon

labeling text." Do you see that?

A. I do.

Q. All right. You understand that Botox was not an FDA-approved treatment for improvement in moderate to severe forehead lines until October 3, 2017 --

MR. KNEPPER: Objection --

Q. -- right?

MR. KNEPPER: -- to form.

A. The sense I get of your question is that you -- you're conflating the injection of corrugator and procerus muscles with the injection of the frontalis muscles. I consider all those muscle groups to be forehead muscles because they all animate the brow. The approval of Botox for the corrugator and frontalis -- I mean, corrugator and procerus muscle that goes way back is, I thought, what you were -- you were asking me about with ten years application to the forehead. So yeah. So I consider the -- the corrugator and procerus

muscles (indicating) forehead muscles. Maybe others would call them glabellar, but glabellar is the lesser-included category. So yeah.

So I was aware of the broadened application, and I was aware that for most of the time it's been on the market, it has been limited, the approval been limited to the corrugator and procerus. And the frontalis marginal radicularis was considered off-label use, as was its use in hyperhidrosis, like we talked about earlier. Yeah.

Q. You have prescribed Botox cosmetic -- or strike that.

You have used Botox for treatment of moderate to severe forehead lines associated with frontalis muscle activity before October 3, 2017; correct?

A. Yes.

MR. KNEPPER: Objection to form.

A. Absolutely.

Q. It's an off-label use; right?

A. As we've talked about before, yes, I've -- I've used it off-label.

Q. And do you know when Botox received this indication for treatment of crow lines?

A. I'm sorry. Of?

Q. Treatment of crow lines.

A. Crow lines?

Q. Yes.

A. Oh, crow's feet (indicating).

Q. Sorry, crow's feet.

A. Yeah. Yeah. I don't know -- I don't know the exact date of that. I just know that it's been broadened.

Q. All right. Before -- strike that.

Before you first started using Botox on an off-label basis, did you do a literature search to see if there was a randomized, double-blinded controlled trial to demonstrate that this forehead use was safe and effective?

A. No.

MR. KNEPPER: Objection, form.

Q. So you were using it without having any idea if there was randomized controlled clinical trials to demonstrate the safety and effectiveness of that use; correct?

MR. KNEPPER: Objection, form.

A. So the question is, was I using it in other than the on-label purposes before the approval was handed down by -- to the -- by the FDA?

Q. No. I already heard the answer to that question.

A. Oh, okay.

Q. I'm asking you a different question.

A. Okay.

Q. At the time you were using Botox on --

A. Oh.

Q. -- an off-label basis --

A. Right.

Q. -- you were doing that without

having results from a randomized controlled trial to demonstrate that this off-label use was safe and effective; correct?

A. Correct. Correct.

MR. KNEPPER: Objection, form.

Q. The same is true for respective cohort studies; right?

A. Correct.

Q. The same is true for case control studies; right?

MR. KNEPPER: Objection, form.

A. Right. And that's an example of what we were talking about earlier where a low-risk application begins with anecdotal experience, shared anecdotal experience, and -- and the literature that comes later leading to the controlled trial that the Allergan company may have done and it's then subsequently approved by the FDA. That's right. So this would fit into that category.

Q. All right. Let's talk more about randomized controlled trials outside of Botox. If I call them RCTs for short, you'll know what I'm referring to; right?

A. Yes.

Q. An RCT typically involves two groups, an experiment group and a control group; right?

A. Yes.

Q. RCTs are typically double-blinded; right?

A. Well, in most cases. But when you're talking about things where there's going to be an outward change in the patient, it's -- it's difficult to blind such studies. You're essentially just -- for example, you couldn't have a double-blinded study of a surgical procedure, or you couldn't have a double-blinded study of a -- of a medical intervention where there's outward change to the patient that would be evident to

both the experimenter and the subject. So yeah.

Q. Yeah. So -- yeah, we'll get to that in a minute. Let me ask just some more general questions first.

A. Okay.

Q. Because I want to figure out your experience with RCTs. You personally have never been the lead investigator for an RCT; correct?

A. That's correct.

Q. You personally -- strike that.

Have you ever been involved with an RCT?

A. Yes. When I was a resident at the University of California-San Francisco working on the neurosurgical trauma unit, we were doing a randomized controlled trial of the medical management of elevated intracranial pressure, and I was -- because I was part of the team, I was responsible for gathering data in the critical care unit

and -- and working with the investigators ensuring the integrity of the data. So I was not the lead investigator, obviously. I was just one of the participants as one of the treating physicians.

Q. The only time you worked on a randomized controlled trial was during your surgery res- -- general surgery residency; correct?

MR. KNEPPER: Objection, form.

A. I'm trying to think if there were other instances here. At UC-Davis -- I'm trying to think. Give me just a moment. I just want to --

Q. Sure.

A. -- make sure I'm not missing any more. I think that's the only one where it was a randomized blinded study. That's right, yeah.

Q. And that residency was '87 through '91?

A. That's right.

Q. Okay. You've never published

any articles in peer-reviewed journals about RCTs; correct?

A. That's correct.

Q. You've personally never designed an RCT; correct?

A. That's correct.

Q. You don't hold yourself out as an expert in RCT design; right?

MR. KNEPPER: Objection, form.

A. Well, I would qualify that answer by saying that part of my training involves me being able to understand and review published literature on the subject even though I'm not the investigator because of my training as a plastic and reconstructive surgeon, as a general surgeon. As just a physician in general, we're trained on how to interpret the validity or the veracity of the medical literature, including how to interpret the randomized controlled trial and -- and understand its validity, which is -- what I'm testifying about is not my

personal experience. It's my opinion of the validity of the scientific data. So I -- so it's not that I -- that I can't express an opinion on it. It's just that I haven't personally conducted one, but I have been trained on how to interpret them.

Q. I understand that distinction you're making.

A. Thank you.

Q. But when it comes to designing RCT, you're not an expert in that aspect of RCT?

MR. KNEPPER: Objection, form.

A. Well, again, part of the evaluation of a randomized controlled trial is to evaluate how the study was designed. That's one of the criteria used for understanding the validity of a published document like a RCT. So you always look at -- that's why it's such an essential part of a -- of a RCT publication is you look at the materials

and methods and you look at the study design, and that's where, really, your analysis begins if you're trying to interpret the data. Did they design the study properly? Does it have the power of discrimination of what they claim that it has? And then you look at the actual results, and it's on -- it's on your shoulders as the -- as the professional, whether you're a -- you know, a researcher or somebody who's seeking to apply it in his practice, you're responsible for interpreting the data quite apart from their interpretation of it.

So an example of that would be the Branström study, where they -- they -- they generated a good -- a reasonable study design, but they misinterpreted the data, and that's what caused the retraction of the Branström study, is that all the other people who were not RCT investigators, but they were

all physicians, endocrinologists, pediatricians, they looked at the data and said, "You've misinterpreted the study."

And that's really what we're talking about here. There are those who perform the study, and then there's us who have to live with it, and we have to be able to understand what they're -- what they're purporting to. So we have to interpret the data even before reading their conclusions.

Q. Do you know what the CONSORT criteria are? C-O-N-S-O-R-T.

A. I've read it sometime before. I can't -- I can't -- I can't quote it for you, but it's -- it's germane to the study design process? I'm not sure.

Q. Okay. Can you describe for me what the CONSORT criteria are in general terms?

A. I cannot.

Q. All right. How about cohort

studies? You've personally never designed a cohort study; correct?

A. No, I have not.

Q. You've personally never been an investigator in a cohort study; correct?

A. Well, so -- so, that experience at -- at UC-San Francisco was a -- well, so are you asking -- by cohort study, are you talking about like a retrospective study of a -- of a population cohort? Is that what you're asking me about?

Q. Prospective or retrospective, either -- either/or.

A. I haven't designed any of those studies, no.

Q. Okay. And outside the one experience in your residency, have you ever been involved with any prospective or retrospective cohort study?

A. No.

Q. And how about case-control studies? Have you ever personally designed a case-control study?

A. No, I have not.

Q. Have you ever been an investigator in a case-control study?

A. I'm just trying to think if the -- if the head trauma investigation would fit the category of a case control. It was a randomized study. It had its own internal controls. So I guess I've assisted in that investigation, but only as a -- as a provider and a -- and a data gatherer.

Q. Outside of that one experience, you have not been involved with any prospective or retrospective cohort study; right?

A. No.

Q. Or a case-control study? Excuse me.

Okay. Let's go back to your report, Exhibit 1, and go to page 13.

A. Okay. Okay.

Q. You see there's a header that says in capital letters, "Anecdotal

Patient Stories Are Not Data." Do you see that?

A. I do.

Q. And you write, "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." Do you see that?

A. I do.

Q. And then you reference personal patient stories, and you say, "This is unreliable Anecdotal Data and it is not credible, scientific information." Do you see that.

A. I do.

Q. All right. You think that case reports are anecdotal evidence; right?

A. Yeah, they're --

MR. KNEPPER: Objection.

THE WITNESS: I'm sorry?

MR. KNEPPER: Objection, form.
Go ahead.
THE WITNESS: I'm sorry.
A. Yeah. And so anecdotal data is personal experience of a -- of a practitioner, for example. So -- so a surgeon reporting on five cases that he did would be considered anecdotal reporting, or case reports and things like that, yeah. That's anecdotal, personal experience, a personal exper- --
Q. And you think --
A. I'm sorry?
Q. Go ahead. Sorry.
A. Personal experience as distinct from more stringent scientific evidence like a longitudinal study or a cohort study or something like that. Or even -- even personal experience with pre- and posttreatment testing rises to a higher level than anecdotal. So you can base -- you can base scientific evidence on that next level, which would be anecdotal

experience elevated to the next level by pretreatment and posttreatment testing. This is -- this is from the guidance that the American Society of Plastic Surgery puts out.

So depending on the -- depending on the type of study, if it's a -- if it's a therapeutic study or a diagnostic study or a prognostic study, depending on what you're looking at, if -- if you -- if you take it to that next level with pre- and posttreatment testing with a validated scientific instrument, you know, a validated study even of subjective reporting from the psychiatric/psychological side of things, that has more validity than the anecdotal reports of a practitioner or even an institution.

Q. Do you think that a case report that doesn't have this before and after comparator that you describe is essentially worthless from the --

A. No.

Q. -- scientific perspective?

A. No, no. Not worthless. Not worthless, but it's what's considered in the -- in the -- in plastic surgery circles, certainly, it's considered the lowest form of evidence. So for a number of years now, the American Society of Plastic Surgery has insisted that publications -- if you're going to publish a case series, for example, that they have to be a sequential -- you can't pick the cases you're reporting on. It has to be a sequential series of patients, and you have to declare in the publication, in your -- in your article, the level of evidence that you're presenting.

So if -- if it's merely a -- case reports, that would be level 5 evidence. If you added to that a review of the literature with a -- you know, a definitive review of the literature

looking at the -- at where the weight of evidence lies, then you raise it to the next level. But we're -- we're now required when we're publishing in -- in the ASPS journal, for example, to state in the -- in the document level of evidence. So a case report is not zero scientific evidence. It's level 5 evidence. It's the lowest form of -- of evidence is what it is.

Q. You personally would not rely on a level 5 case report to decide if a surgical technique is effective?

A. It would be the beginning of my interest in a particular technique. As a surgeon, we tend to be very conservative, and we call upon our personal experience very much and certainly upon our training. So if somebody proposes something radically new and all they have to support it is level 5 evidence, generally -- there's a saying that I learned in training is never be the first

or -- first one to do a procedure or the last one to do a procedure.

And so, yeah, you know, surgeons tend to not jump in early on -- on low-quality evidence. We tend to be conservative about it. And I would number myself among them.

Q. All right. Let me ask the flip side.

A. Okay.

Q. Do you think it's necessary for a surgical procedure to be supported by results from a level 5 RCT before it can be considered effective?

A. No.

MR. KNEPPER: Objection to form.

A. That would -- that would be one of those circumstances where what is the risk to the patient and -- and what's the potential benefit to the patient. That's -- that's what kind of would drive my decision to act on a level 5 case report, offering something like that to

one of my patients.

Q. Do you think that a surgical procedure has to be supported by a level 2 controlled study before that surgical procedure can be considered nonexperimental?

A. Not necessarily. It would depend on what is -- what is -- what is at risk here. Certainly, we're much more willing to -- to proceed with -- with techniques and procedures that aren't hugely supported if there's great risk to the patient of not doing anything. So level of risk and what is at stake kind of drives that and -- and yeah.

Did I answer that question? Is that what you were asking?

Q. Yeah. It's basically a case-by-case decision; right?

MR. KNEPPER: Objection, form.

A. Well, I wouldn't say case by case. I would say, you know, you're relying on -- on -- on a lifetime of

experience possibly, and you're relying also on -- on conversations with your peers, your colleagues, what is their experience in the area and how much of a risk are you going to subject to the patient -- subject the patient to in order to achieve a result. The greater the risk, the greater the expectation of a defined scientifically supported outcome.

So in the case -- in the issue at hand here, great risk of doing, for example, a transition surgery, because you're talking about permanent sterilization, irreversible sterilization, or the removal of the breasts, permanent and irreversible loss of the breasts, that's a huge stake, a huge risk to the patient that the -- the expected outcomes have to be consummately much larger in order to justify something like that if you don't have scientific support. If you're at low levels of

scientific evidence, then clearly, you have an obligation to the patient not to -- not to try something risky if you don't have extensive and very valid scientific -- and that's where we are now. We're at very low-level evidence for these things. That's kind of why we're here today.

Q. I guess I'm asking a more specific question. You're not taking the position that in order to be considered nonexperimental, a particular surgical procedure has to be supported by at least level 1 or level 2 evidence; right?

MR. KNEPPER: Objection, form.

A. Oh, okay. So you're asking me the definition of experimental. Is that -- do I understand you correctly?

Q. Sure.

A. Yes. Am I saying that something is nonexperimental once it reaches level 2 evidence or higher and not before?

Q. Correct.

A. I'm not saying that, no.

Q. Okay. How about level 3? Are you taking the position -- strike that.

Are you expressing the opinion that a surgical procedure can only be considered not experimental if it reaches evidence level 3?

A. Well, it's getting closer. So when you're -- when you're at level 3, you're talking about a retrospective study with a cohort. And if we were talking about some simple technique of reconstructing, say, a wound on the face for cancer therapy, then I certainly wouldn't wait to try a new technique. If it promised to get a better result, I wouldn't wait until I got to level 3 evidence.

But if you're talking about a very drastic operation where I'm amputating healthy parts, then yeah, I'm going to want to go at least to level 3 before I consider that, because again,

you're talk about tremendous risk to the patient, permanently life-altering changes. You better have very strong evidence that you're doing the patient good because you're doing the patient a great harm by, you know, removing their, genitals, permanently sterilizing them, removing their breasts. So again, it's -- it's not a case by case, but let's -- let's say broad categories of -- of techniques or surgery.

If you're talking about something small like reconstructing a facial defect, then yeah, you don't need to get to level 3. But if you're talking about something large and permanently life-altering, then at least level 3.

Q. All right. We talked earlier a while ago about some of the surgical procedure you performed, and I think one of the things you mentioned was breast reductions.

A. Yes.

Q. Right?
A. Yes.
Q. You've done those; right?
A. I have done so many of those.
Q. All right. You've done breast reduction surgery without having the results from a randomized controlled clinical trial; right?
A. I believe the -- the bulk of the evidence in the therapeutic benefit of breast reduction is primarily given to us by a long-term longitudinal cohort study that we actually get from the insurance industry. Because when you do breast reduction surgery, one of the key issues in a breast reduction is, is it going to be efficacious in curing an orthopedic problem. So if you're talking about breast reduction surgery as a quote, unquote reconstructive procedure, then really, it's being applied to an orthopedic condition.
And the insurance companies have

a wealth of evidence about, for example, the weight of the specimen that has to be submitted in order to have a hope of relieving the orthopedic complaint of neck, back, and shoulder pain.

So -- and vir- -- and I can tell you categorically, because I'm very fastidious about this, that all of the breast reduction operations that I've ever done for the orthopedic condition of neck, back, and shoulder pain have met the criteria based upon this long-term longitudinal cohort study that the insurance companies have been running since back in the '80s at least.

Q. All right. Doctor, again, I need you to listen to my questions. I didn't ask about cohort studies. I asked about randomized clinical trial.

A. Oh.

Q. You have done -- you have done breast reductions without having results from a randomized controlled clinical

trial?

A. Oh, forgive me. I -- I misunderstood the question, then. No. The -- I have not, no. The industry -- the plastic surgery community does not rely on a randomized trial for the -- the operation to be merited. That's correct.

Q. Right. Nobody in this industry waits for results from a randomized controlled trial before determining that a particular surgical procedure is nonexperimental; right?

MR. KNEPPER: Objection, form.

A. Well, this gets back to what we were talking about before, what the -- what the level of evidence is, what's at risk, and what are the potential benefits. So in the case of breast reduction surgery, yes, we have not relied on randomized controlled trials because there was such an abundance of level 3 evidence to justify the procedure. And so -- and level 3

evidence is sufficient to answer the question, is this experimental or not? This procedure doesn't rise to the level of level 2 or level 1 in order to be justified. I believe there have been -- well, no, I can't say categorically, so I won't.

So yeah, to answer your question, breast reduction does not rely on randomized trials. It relies on level 3 evidence.

Q. All right. Let's take it out of the realm of breast reduction in particular.

A. Okay.

Q. It is not uncommon for plastic surgeons to perform procedures that are not supported by results from an RCT; correct?

MR. KNEPPER: Objection, form.

A. As a general principle, plastic surgeons are perhaps more innovative than other surgeons, so we're inclined to try

new techniques. And then, of course, you have to exercise some significant prudential judgment about what risk are you placing the patient in before you get experimental with them. Yeah. So yes, we -- we do that all -- we're innovators, as -- as a general principle.

Q. And as a general principle, plastic surgeons will often commonly perform procedures that are not supported by level 2 evidence; correct?

MR. KNEPPER: Objection, form.

A. Yes.

Q. And as innovators, plastic surgeons will often perform surgical procedures that are not level 3 evidence; right?

MR. KNEPPER: Objection, form.

A. Yeah. They -- if you're talking about small like technical improvements in -- in low-risk procedures, then yeah, we -- we do that very commonly.

Q. Okay. You know what the

Plastics and Reconstructive Surgery journal is; right?

A. Yes.

Q. It's the official publication of the ASPS; correct?

A. Correct.

Q. It's a peer-reviewed medical journal; right?

A. Correct.

Q. It's published monthly; right?

A. And plus supplements as well and online. Yes, sir.

Q. One purpose of that journal is to educate members about new surgical techniques; right?

A. Yes.

Q. Would you agree that the journal is the premier peer-reviewed source for current information on reconstructive and cosmetic surgery?

A. I would.

Q. All right. Are you -- I know that you're no longer a member. Are you

still subscribing to the journal?

A. No, I'm not. It's a -- it's for members that you get the journal, so yeah. That's what my subscription relied on, so -- all those years.

Q. I understand. So not -- you haven't had access to it since 2018?

A. Well, I -- no, I go online, and I'll pay for access to particular articles. So yeah. So it's not that I've lost contact with it, it's just that I do literature searches, and if an ASPS citation comes up, I'll pay to look at it.

Q. I understand. Sitting here today, what percent of publications in that journal do you think consist of results from RCTs?

MR. KNEPPER: Objection, scope, form.

A. Yeah, I'm -- I'm not sure I could hazard a guess even.

Q. Ballpark, do you think it's 10

percent? 50 percent?

A. Of their published articles that are randomized controlled trials?

Q. Yes.

MR. KNEPPER: Objection to form, scope.

A. Gosh, I'm going to guess it's probably somewhere -- probably less than 10 percent.

Q. How about cohort studies? If you had to estimate, what percentage of publications in that journal do you think consist of results from cohort studies?

MR. KNEPPER: Objection, form.

A. Again, just ballparking here after, you know, 35 years of reading that article -- that journal for 35 years, I would say that -- I don't -- I may be guessing, but 15 percent maybe are -- are cohorts that are usually single-center studies. There's a lot of those in the -- in the White Journal. There'll be a single-center cohort study of -- of

some operation or technique, and they'll usually report it as three or four surgeons at a single center reporting a -- a longitudinal cohort of, say, breast cancer reconstructions with implants versus breast reconstruction with autologous flaps and comparing satisfaction surveys and things like that. So I'm going to ballpark it at 15 percent, but I don't know. I don't know for a fact.

Q. Let me introduce an exhibit. So this will be Exhibit 17, and let me know when you get it.

(Exhibit 17 was marked for identification and is attached.)

A. Okay. All right. I have it.

Q. All right. This is a study from 2019 by Sugrue, S-U-G-R-U-E, titled "Levels of Evidence in Plastic and Reconstructive Surgery Research." See that?

A. I do.

Q. All right. See there's a "Summary" box on the first page?

A. Yes.

Q. The third sentence says, "The aim of this study is to determine if the quality of evidence in plastic surgery research has improved over the past 10 years. Systematic review of research published in Plastics and Reconstructive Surgery journal over the years, 10-year period (2008, 2013, 2018), was performed." Do you see that?

A. I do.

Q. Now, you understand what this study was trying to accomplish; right?

A. Yeah. They were measuring the level of success that the American Society of Plastic Surgery was having after having applied those criteria we talked about earlier, the -- this requirement of reporting levels of evidence, seeking the clarity on levels of evidence. And so I expect -- I

haven't read this -- this article before, but I guess that's what they're looking at, is how successful have we been as a professional society in publishing --

Q. Yeah.

A. -- these things.

Q. And this references the levels of evidence, LOE, metric; right?

A. Yes.

Q. And that's the same metric that you referenced earlier, levels 1 through 5; right?

A. Right. Well, the levels 1 through 5 that I referenced includes the -- sort of the subcategorizing, depending on if it's a therapeutic trial or a -- or a trial of risk or things like that. So the -- the document that the ASPS published some years ago includes risk studies and diagnostic studies, but they're all ranked 1 through 5. That's right.

Q. And you see a couple of

sentences down, it says 884 studies were included in the final analysis. You see that?

A. Yes, I do.

Q. Okay. Go to page 2.

A. Okay.

Q. You see there's a Table 1?

A. Yes, I do.

Q. Table 1 is "Percentage of Each Level of Evidence Published per Year." Do you see that?

A. I do.

Q. And there's columns for 2008, 2013, and 2018; right?

A. Yes.

Q. All right. Let's start with level 1, and that's randomized control trials or metaanalyses of those trials; right?

A. Right.

Q. In 2018, only 2.1 percent of all publications in the journal were level 1 evidence; right?

A. That's right.

Q. And in 2008 and 2013, those percentages were 0.3 and 1.7 percent respectively; correct?

A. Correct.

Q. Not very common for the journal to report on results of RCTs, according to this summary; right?

MR. KNEPPER: Objection, form.

A. Yeah. And it even goes along with what -- my ballpark earlier, so I'm surprised -- yes, it was less than 10 percent were -- were level 1 evidence and somewhere around -- yeah, so those numbers are consistent. But yeah.

And the other thing to note about it is that they appear to have been successful in choosing what they publish to support higher levels of evidence. So I guess they're to be commended for having done this, yeah.

Q. Okay. All right. Then level 2 are -- level 2 evidence includes

prospective cohort or comparative studies; right?

A. Yes.

Q. With controls; right?

A. Yeah. There's a level of randomization that -- that's there as well --

Q. Okay.

A. -- in those prospective studies. That's right.

Q. And for that level 2 evidence, only 13.6 percent of all publications in the journal in 2018 consisted of that evidence; right?

A. Yes. That's what it says there, yes.

Q. All right. Level of evidence 4 is case series with a pre- or posttest or only posttest; right?

A. Right.

Q. And in 2018, those amounted to 41.7 percent of all publications; right?

A. Right. It looks as though more

of those level 4 have been shifted up into level 3, given that the level 5 has declined. So it looks like they're pushing more of the level 4 up into level 5. Yeah.

Q. Yeah. Much of the research on which your field relies doesn't consist of results from RCTs or controlled cohort studies; right?

A. Well, I wouldn't --

MR. KNEPPER: Objection, form.

A. I wouldn't say that based on this. I would say that much of the published research in this journal is of that -- of what you described, relying on RCTs and so on.

This is a -- this is not a document about what the profession is doing. This is a document about what this journal is publishing. And what they're publishing is more papers of higher value, for which they're to be commended. So this says nothing about

what people are investigating. This says about -- this says something about what this journal is publishing.

Q. Well, this is the journal for the ASPS; right?

A. Right. With limited space for publication. So they're being, apparently, more selective about what they'll publish, that it's not just that well, this is the chief of plastic surgery at NYU, so we're going to publish his paper. It's the chief of plastic surgery has a level 2 case. Let's -- let's present -- let's publish that one. I think that's what this is telling us, that they're being more fastidious about what they publish, whereas before, they might have been more -- well, less selective, let's say.

Q. Have you ever been involved with selecting articles to be published in this journal?

A. I've never been involved in --

in journal publication staff or -- no, I have not.

Q. You don't know the process by which they select what article to publish; right?

MR. KNEPPER: Objection, form.

A. I have some idea, but I'm -- it's not my -- my area of professional expertise.

Q. Yeah.

A. I merely read the journal, and have for approaching forty years now.

Q. Look at Table 2.

A. Okay.

Q. And look at the column under 2018.

A. Yes.

Q. The first two rows, "Systematic review/meta analysis" and "Randomized control trials," account for 3.2 plus 3.8 percent of all publications of the journal in 2018. Correct?

A. Right.

MR. KNEPPER: Objection.

Q. Case series account for 26.3 percent; right?

A. Right.

Q. Okay. Go to page 3 of this exhibit.

A. Okay. I'm there.

Q. All right. First full paragraph, first sentence says, "Case series are the backbone of surgical research." Do you see that?

A. I do.

Q. You don't disagree that case series can be helpful scientific evidence; right?

A. No. As I -- as I testified before, this is the beginning of research. It always begins with perhaps a serendipitous discovery, then to case reports, then to case series, single -- single-provider case series or multiple providers in a -- in a -- an institution. But that's the beginning of surgical

research, yeah. That's how it always begins.

Q. Well, it's a beginning, but sometimes it's also the end; right? Because look at the third sentence. It says: "The absence of a control group justifiably ranks this design at the lower end of the evidence pyramid. Despite this, case series are vital. They may be the only feasible and ethical study methodology obtainable, as seen with craniofacial surgery." You see that?

A. Yeah. And to that -- to that particular point, so I've got extensive experience with craniofacial surgery, and -- and it's -- this is one of those procedures where the outward change to the child can't be blinded. You cannot blind the investigator because, obviously, he's doing the surgery, and you can't blind the patient or the family to it because the results are quite

obvious. And that's what they're saying here. And obviously, they're not saying that it's never useful or is never necessary. They're saying that in many cases, you don't need to rise to that level because you have evident benefit to the patient and the risk is not only manageable but -- but sufficiently low to warrant the application of a particular technique.

So that was certainly the case, for example, when we introduced external fixation devices for advancement of the mid face in certain congenital deformities. Nobody had done a randomized trial because you can't. You've got this hardware sitting on the patient's face. So -- but yet, the -- the luminaries in craniofacial surgery were able to demonstrate through a case series that this was a valid technique, and then the rest of us adopted it. So that's an example of how plastic surgery

works.

Now, if the patient was at risk of death because this technique was being applied or if the patient was at risk of permanent life-altering changes that couldn't be reversed, then yeah, you would have to proceed with much greater caution, and you may be looking at finding some way, longitudinal study-wise, to -- to quantify the benefit of using your technique over using established techniques.

Q. There are some areas in plastic surgery and reconstructive surgery where case series are basically as good as it gets in terms of scientific evidence; right?

MR. KNEPPER: Objection, form.

A. Yeah. I suppose in the newer -- at the newer end of techniques, that's all you got for now until the technique has been applied over a sufficiently long time that you can look at a retrospective

cohort.

So for example, in the case of gender transitioning surgery, the -- the -- the surgeons have been at it now for several decades. And we should be already at the level of level 3 evidence, but -- but we're not.

Q. Well, you --

A. So I wouldn't put that in the category of -- you're talking there about a high-risk procedure that has a long track record that can be examined. And -- and clearly, the examination of that technique in the last three years, give or take, has -- has shown us that that this is in the category of those operations that demand higher levels of evidence than a case series, whether it's single provider, single institution, or even single nation. You've got to -- you've got to look at the data now and -- and prove that you are doing something good for the patient.

And quite frankly, it hasn't been proven in the -- in the American literature. Certainly, WPATH hasn't proven that. But in the European literature, they're looking at it and saying, gosh, you know, the -- the Swedish study shows us that if you only follow patients for five years at the most, you're not even going to see the long-term effect of what you did to them. And if you look at them eight years and beyond, you'll see that you haven't solved the suicidality, the self-harm, the incarceration, psychiatric diagnosis admissions, and things like that.

So -- so yeah, as far as what we're talking about today, yeah, there's a whole spectrum of what's acceptable levels of evidence for a particular procedure. The higher the risk, the higher the level of evidence is demanded. And sometimes you have to wait to get to that level of evidence if you're dealing

with something potentially life-threatening.

Like certainly, the providers were fully justified in considering this because of the high suicide rate of transgender patients. Case series, totally valid reason given that the life of the patient is at risk here, totally valid to go with a case series as the evidence by which you're consenting the patient to surgery. But we're now beyond that. We're now beyond that. We're at -- we're now -- the ethics demands that we look at higher levels of evidence because of the long-term risk to the patient and the fact that the long-term evidence doesn't support the indication for surgery, which is lower suicide rate, lower self-harm, lower drug abuse. That's really what we're talking about here.

Q. I have some other questions. You agree that -- strike that.

Do you agree that it is not possible to perform RCTs for some surgical procedure because you can't blind the patient or the investigator to what the procedure is?

A. Absolutely agree, yeah.

Q. So, let's take phalloplasty; right?

A. Okay. Yeah.

Q. When a surgeon performs a phalloplasty on a patient, both the surgeon and the patient are going to know that the procedure was done; right?

A. Yes.

Q. It's not possible to have a RCT for phalloplasty because you can't blind the participant or the investigator; right?

A. Yeah. That's typical of most surgical interventions. The only exception to that would be intraabdominal or intrathoracic surgeries or even intracranial surgeries. And -- and

that's considered sham surgery, which is considered malpractice and ethical violation of professional standards. So you can pretty much rule out most all surgical procedures from the randomized control trial category. Correct.

Q. And we agree that the same would apply to metoidioplasty, for example; right?

A. Yes.

Q. To all types of, again, colloquially known as bottom surgery; right?

A. Correct.

Q. All right. Let's take puberty-blocking hormones.

A. Okay.

Q. When patients with gender dysphoria treatment start puberty-blocking hormones, they're not going to undergo puberty, basically; right?

A. Well, that's the intended use,

that's correct.

Q. So there's going to be observable physical effects of the hormones that will be apparent to the patient; right?

A. Yes. Within a year, that child is going to look much smaller than his peers. He's going to be developmentally delayed psychologically, neurophysiologically. His -- his movements are not going to be as -- his coordination is going to be less matured. His higher executive functions will be impaired. So it will be very obvious that this child is now different from his peers. So I would agree with you; you couldn't find a way to blind such a study because the evidence of effect is so obvious within the first year that everyone would know that they're taking the -- the puberty-blocking gonadotropin-releasing hormone agonist.

Q. We agree that -- we agree that

it's not possible to do an RCT for puberty-blocking hormones because of these apparent physical effects; right?

MR. KNEPPER: Objection, form.

A. I -- I would agree, yes.

Q. Okay. Let's take cross-sex hormones.

A. And the -- the last question you asked me, did you qualify that as you couldn't do a double-blinded study using puberty-blocking drugs in self-identified transgender children?

Q. Yes.

A. Yeah. Because if you're applying the drug to other conditions like precocious puberty, it -- it may be possible. It may be possible to -- I don't know. I'd have to think about that but -- okay. Sorry.

Q. Let's take cross-sex hormones.

A. Okay.

Q. When somebody -- someone is treated with estrogen or testosterone for

gender dysphoria, there are also going to be physical effects from those treatments; correct?

A. Yes. Given that sex hormones have such a profound effect on every body system, then it's going to be impossible to conceal the fact that the person is on sex hormones because every -- every function of the body is affected by sex hormone levels, particularly at the age of early adolescence.

Q. And given these visible physical effects, it's not possible to design a double-blind RCT for cross-sex hormones for gender dysphoria; correct?

A. It would probably be an invalid study, yes.

Q. All right. Let's go back to your -- actually, you know what? I'm going to move to a different area. It's been about an hour. Let's take a quick break.

MR. TISHYEVICH: Off the record.

THE VIDEOGRAPHER: This is the end of Media Unit No. 4. We are off the record at 2:16 p.m.

(Break taken.)

THE VIDEOGRAPHER: This is the beginning of Media Unit No. 5. We are on the record at 2:24 p.m.

Q. (By Mr. Tishyevich) Let's go back to your report, Exhibit 1.

A. Okay.

Q. Go to page 21.

A. Twenty-one. Okay.

Q. And you see there's a paragraph starting with, "Failure to discuss the failure to conduct"?

A. Yes.

Q. Okay. So in the second line, you reference the "unknown number and percentage of patients who drop out of transitioning or reverse the process parentheses (Detransitioners)."

A. Right.

Q. You see that?

A. I do.

Q. All right. You agree that the number and percentage of patients with gender dysphoria who drop out of transitioning or who reverse the process is currently unknown; right?

A. Well, it depends on if you're asking that question about the general population or in a particular study. So in particular studies, that number is known, but in the general population, it's an unknown.

Q. Yeah.

A. And the reason -- the reason it's unknown in the general population is because the people doing the research aren't following those patients. That's why we don't know.

Q. In the overall population, the number and percentage of patients who drop out of transitioning or reverse the process is unknown; agree?

A. Yeah. I would agree that's

unknown, yeah.

Q. All right. Given that, obviously, you're not offering any expert opinions on what that number or percentage is in the general population; right?

A. Yeah, I don't -- I don't think it's possible for anyone to break out the difference, for example, between somebody who isn't followed up because they've detransitioned or somebody who isn't followed up because they've taken their own life. We have no way of knowing because nobody's following up.

Q. All right. Look toward the bottom of this page 21. You cite a case series from I believe it's Djordjevic, D-J-O-R-D-J-E-V-I-C. Do you see that?

A. I do.

Q. And you say, "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." Right?

A. I see that, yes.

Q. Okay. Now, this article was not an RCT, obviously; right?

A. Right, right.

Q. It was not a cohort study; right?

A. No. This would be a case -- a case series.

Q. Yeah. The lowest level of evidence; right?

A. No. Actually, the lowest level of evidence would be sort of single patient -- well, it's sort of somewhere between 4 and 5, I suppose. I'd have to look at the article again to see what the -- what the denominator is, but --

Q. Yeah. Well, generally, you think that anecdotal patient stories like these are not reliable scientific

information; right?

MR. KNEPPER: Objection, form.

A. No. They're the first clue to a problem or the first clue to a solution. That's exactly right. So that -- that sort of points to the controversial nature of these therapies, is that -- is that we don't have the answer. We can't explain why these detransitioners weren't predicted preoperatively because we don't have a test instrument to figure that out.

So when you see a series like this -- this is what we talked about earlier, about the -- the history of progression of levels of evidence. You start out with reports like this. This leads to further research. And I'm just trying to remember, when I read the article, where that study was done. I don't have it in front -- I'm just trying to remember what -- what country that was done in.

Q. Yeah. I'll -- I'll show it to you.
A. Okay.
Q. Hold on. Let me introduce it.
A. Thank you.
Q. You did read these -- this article in full before you cited it; right?
A. Yeah. That -- it was -- it was probably about seven months ago, but yes, I did.
Q. Sure.
THE COURT REPORTER: I didn't hear anything. So it's just --
THE WITNESS: Okay.
THE COURT REPORTER: We're losing it in Zoom. Thank you.
THE WITNESS: Forgive me. I'm sorry.
THE COURT REPORTER: No, that's okay. It's awkward.
Q. (By Mr. Tishyevich) Okay. This is going to be Exhibit 18, and let me

know when you have it.
(Exhibit 18 was marked for identification and is attached.)
A. Okay. Okay. Yeah, there it is. Yes. Yeah, right. Okay. It's coming back to me now. And this was published out of the -- Amsterdam. That's right. Okay. All right. Yeah.
Q. All right. Let me ask you -- strike that.
Bottom of the page, there's a section titled "Introduction." You see that?
A. The bottom of the first page?
Q. Yes.
A. Yes, I see that.
Q. Look at -- look to the column on the right.
A. Okay.
Q. The last sentence says, "In general, most researchers have reported their patients are extremely satisfied overall with their surgical outcomes,

with a low rate of complications." You see that?

(Witness reviews document.)

A. Right. I see -- I do see that, yes.

Q. Then it cites three footnotes, 5 through 7; right?

A. Right.

Q. You don't acknowledge this portion of the article in your report; right?

A. Well, it is in the discussion, I think. Well, actually, probably maybe in the summary of the -- of the medical evidence. The -- I would put this in the category of subjective reporting and short -- subjective reporting and short follow-up. Right. That's what --

Q. Well, you --

A. I'm sorry. Go ahead.

Q. No, no, go ahead.

A. So I think the reason I included this was to show that there are -- you

know, that there's a growing pool of patients who are returning for reversal surgery. I don't think I discussed in this part of my report -- yeah. I'm just talking about increasingly visible community and patient -- increasing number of patients requesting reversal surgery. And as an example of that, again, going to a single-center case collection as an example, early evidence, we're starting to see this now as numbers of patients who have surgically transitioned increases, the numbers of patients who regret is going to increase, particularly in light of what these authors speak about here.

Let me see if I -- yeah. So in the second sentence of the abstract in the introduction, it says, "However, misdiagnosed patients sometimes regret their decisions." And one of the reasons for including this article is the fact that misdiagnosis is not measured. The

world literature doesn't present error rates. This would be what I would consider an error rate, that an erroneous diagnosis was acted upon surgically, leading to this complication of regret and a -- and a desire for reversal. Yeah.

Q. Your expert testimony is that there's no data available on the percentage of people who have received treatment for gender dysphoria who experience regret?

A. Yeah. It's very, very low -- low-level evidence right now. It's basically we're in the -- we're in the case collection study, whereas actually in the -- well, that's not regret. But -- but perhaps in the category of misdiagnosis would be the -- the reports out of Sweden, certainly the -- yeah, so beginning with the Swede -- Swedish studies by Cecilia Dhejne and others that shows us a lack of efficacy. Whether or

not the patient presented for reversal is definitely an unknown number, definitely.

Q. All right. That study doesn't quantify anything about patient regret; right?

A. The Swedish study does not. It quantifies lack of -- of effect from the surgical interventions. Lack of benefit, I should say.

Q. Go to page -- PDF page 7 of this document and look at the Conclusions --

A. Okay.

Q. -- section.

A. All right. Let's see that page. Conclusions. Okay. I'm there.

Q. The first sentence says, "The vast majority of properly diagnosed transsexual patients are satisfied with their decision to undergo SRS, with only a few coming to regret it." Right?

A. Right. So this -- the other reason why this study is useful to our conversation is that this is the same

language and the same metrics that's used to describe the success of cosmetic surgery. They don't include in here, apart from the regret number that they're actually publishing here -- not number but the examples, I should say. They don't include in their -- in their conclusions any statement about objective quantifiable benefit from the surgery. They talk about subjective reporting.

So this is an example of a -- of a peer-reviewed journal article that measures the efficacy of this surgery based solely upon a satisfaction survey of patients who have returned for follow-up, so this would be an example of that. Yes, sir.

Q. Do you know what metric was used to measure satisfaction or nonsatisfaction in these studies?

A. I'd have to reread the -- the methods and materials here, but I would -- I would guess it was one of the

approved instruments for measuring satisfaction. There are a variety of test instruments used for -- in satisfaction surveys, particularly in the world of plastic surgery.

Let's see. They used the -- these are the kind of things I don't keep in my long-term memory here for a particular article. Okay.

(Witness reviews document.)

A. Okay. There's the outcomes measures. Forgive me for eating up your time.

Q. Let me -- let help you, Doctor. Go to page --

A. Okay. There it is.

Q. -- PDF page 5.

A. Yeah. Fif- -- yeah.

Q. Yeah.

A. Fifteen, right.

Q. Question on the page --

A. So there's a -- there's a test instrument there. Right.

Q. Yeah. There's a test instrument that measures things like erectile function, sexual desire, orgasmic function, intercourse satisfaction, and overall satisfaction; right?

A. Right.

Q. They don't just ask the patient, "Hey, are you happy with the surgery?" There's five criteria that are applied; right?

A. Right.

Q. This is an approved instrument for measuring this type of satisfaction for surgery; right?

MR. KNEPPER: Objection, form.

A. This is -- this is -- yeah, it's definitely a valuable instrument for measuring things, but none of them are the -- are the indication for surgery, which is things like reduced suicidality, reduced self-harm, reduced alcohol use, all of those other things which are -- which are the reason, the indication for

the operation. So you generally try to match the surgical procedure with the indication for the surgery.

They're measuring things that weren't involved in the indications for surgery. They didn't get, you know, reconstructive surgical approval so that they could achieve erections, for example. This was approved because of the risk of self-harm, suicide, those sorts of things. Yeah. But none of those are measured. They -- it is -- it is they do have objective measures, and this is one of the -- one of the values of this study. But I don't think they report the complication rate in this study, as I recall.

Q. This -- this study specifically did not purport to seek out anything about suicidality or mortality or other adverse outcomes of that nature; right?

A. Let's see. I'm trying to remember in their introduction.

(Witness reviews document.)

A. Yeah. I think their indications used language that was more consistent with -- with aesthetic, aesthetic surgery rather than the reconstructive language. So yeah.

(Witness reviews document.)

A. Yeah. So --

Q. Yeah. Here's --

A. Yeah, I would --

Q. Here's what I find interesting, Doctor.

A. Okay.

Q. Your report cites this one case series of seven patients to make the point that there's this regret occurring without even mentioning that there's multiple case series that say the vast majority of these patients end up being satisfied with this type of surgery?

A. No. I don't think --

Q. You don't think that's appropriate to mention?

A. No. I -- actually, what I present these examples to show, that -- that the literature in support of these surgeries is characterized by very short follow-up and subjective reporting. So this is an example of some objective reporting, mostly subjective reporting. And most of the articles, for example, that you just asked me about involve subjective reporting and short follow-up. That's right, yeah.

Q. All right.

A. And in this case, you also -- I'm -- I'm pleased that they reported that one, two, three, four, five, six, seven -- so nearly half of their patients had a surgical complication of a urethral fistula, and if you have a urethral fistula and you have a malleable prosthesis, probably they went on to remove the prosthesis as well. But that's -- I mean, I -- props for this -- this team that they reported their

complications.

Q. Where -- what page is the complications portion you're looking at?

A. That's on -- just before you get -- the last page before the -- the same page as the conclusions. There's a table at the top, and they have the seven patients, and you can see -- what's also interesting here, too, is -- is that if you look at the period after sex reassignment surgery, that the -- that the dissatisfaction level really kicks in when you're beyond eight years. Actually, if you look at even six years beyond.

Initially, there's no patients reporting dissatisfaction at anything less than five years, and so this is actually further evidence of the -- of the inadequacy of the -- the papers that are in the literature right now which have follow-ups that are typically two to three years. So none of these patients

would have been seen, with most of the literature that supports these techniques, as a way to, you know, avoid -- avoid dissatisfaction or -- or suicidality or drug use or anything else like that. So that's an interesting -- I hadn't noticed that before, but yeah.

Q. Yeah. Are you reading Table 1 to say that these complications like urethral fistula and stricture were from the original surgery?

A. Well, I'm -- I'm merely --

Q. Or is it from the reversal surgery that was being done later?

A. So they're talking here about flaps. They're talking about complications from the -- the -- the surgeries. Yeah. So this --

Q. Yeah. This is --

A. They're speaking about urethral fistulas and strictures are the main problem after total phalloplasty. So that's the construct of the counterfeit

phallus because of insufficient vascular supply. I also discuss that in my complications section. These are characteristic complications of these free flaps, radial forearm free flaps, and you see those complications here. And you even see them later in -- in the case, so. Some of them are step procedures. In fact, all of them are.

Q. All right. Let me -- let me show you another study.

A. Okay.

Q. Let me reintroduce this with an exhibit -- exhibit stamp. Give me a second. All right. I'm reintroducing this as Exhibit 20. Let me know when you have it.

(Exhibit 20 was marked for identification and is attached.)

A. I just got Exhibit 19. Is there another? There's a 20 to follow?

Q. It -- it should load momentarily. Yeah.

A. Oh, I'm sorry.

MR. KNEPPER: Are 19 and 20 the same, just one's missing the little stamp?

MR. TISHYEVICH: Correct.

THE WITNESS: Okay. I'll just go to 20, then, when it comes in.

Q. Okay. This is a study titled "The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets." Do you see that?

A. I do.

Q. And then it's by an author, let's say Wiepjes, W-I-E-P-J-E-S.

A. Yeah.

Q. Right?

A. I agree.

Q. Have you seen this study before?

A. I'm trying to gloss it to see if I've read this before. I -- I may have. Give me just a moment, if that's okay.

Q. Sure.

(Witness reviews document.)

A. Yeah, this looks familiar.

Q. I don't think I saw this in your report, but tell me if you remember otherwise.

(Witness reviews document.)

A. Yeah, no. I remember this being evidence of the growing population of self-reported transgender patients, and it's a retro- --

Q. Okay. Let me --

A. -- retrospective trial. Yeah.

Q. Yeah. Let's go through this.

A. Retrospective study, I should say.

Q. All right. You see the "Abstract" section on the first page?

A. I do.

Q. See the "Results" section?

A. I do.

Q. It says, "6,793 people (4,432 birth-assigned male, 2,361 birth-assigned female) visited our gender identity

clinic from 1972 through 2015." See that?

A. I do.

Q. All right. So you understand that as part of this study, the authors reviewed medical records of 6,793 people who visited this gender identity clinic from 1972 to 2015; right?

A. I do.

Q. All right. And you see the "Strengths and Limitations" section?

A. Yes, I do.

Q. And you understand that this Dutch gender identity clinic treats more than 95 percent of the transgender population in the Netherlands; right?

A. Right.

Q. Pretty comprehensive study; right?

MR. KNEPPER: Objection, form.

A. As of 2015, yes. So it's a 7-year-old study, and it's -- it's certainly large in numbers, that's for

sure. So it's a retrospective chart review of patients visiting the -- the center in the Netherlands, and it's -- it concludes in 2015.

Q. This is certainly a better study than that seven series case report that you cited in your report; right?

A. It's a different type of study. Yes, it is. Right.

Q. Yeah. This study reports on 6,793 people, whereas the case series on which you rely has seven what you call anecdotes; right?

A. I wouldn't say I relied on that study. I merely presented it as an example of -- of reporting on transgender regret. I didn't present it as a study that I relied all my opinions on. Certainly, there's other study types and other studies in the literature that -- that one might rely more heavily on.

Q. Well, let the --

A. A retro- -- a retrospective

chart review, for example, might be more useful.

Q. Yeah.

A. But not -- not definitive. And again, we've got to examine the fact that we're looking at old data here.

Q. Well, let's see what this 30-year retrospective review found. Look at the "Results" section.

A. Scroll down. Okay.

Q. Look at the last two sentences. "The percentage of people who underwent gonadectomy within 5 years after starting HT remained stable over time" --

A. Right.

Q. -- "(74.7% of transwomen and 83.8% of transmen). Only 0.6% of transwomen and 0.3% percent of transmen who underwent gonadectomy were identified as experiencing regret." Do you see that?

A. I do. And that has caused me to want to look back and see -- okay. So

they started with the 6,800, roughly, and they report on 6,000 -- 7,000 almost. Okay. And clinic. Okay. And increase.

So I'm just trying to see if they reported the average follow-up. They're reporting when they underwent gonadectomy after starting hormone therapy, but they don't report the length of follow-up, which is one of the key reporting points there, because regret, as we talked about earlier, is a -- tends to be a function of time postsurgically. So, let's just scroll down because it's been a long time since I looked at this article. Transwomen, transmen total underwent gonadectomy.

Yeah. As I recall, they don't report average follow-up time. Every five-year cohort. So they're looking -- they -- they did look at when they entered the system. Prevalence and treatment. Confidence interval.

Yeah, as I -- yes. So I think

that's -- this is coming back to me now. I think they didn't report the average follow-up or the -- let's see if I'm missing something here. Age for each year, so they did break them out in age that they -- they entered the -- the process, the years during which they entered the process, age groups. And yeah, I think that's -- that was one of the -- one of the issues.

And this is -- consonant with -- with a lot of the literature, is they don't report the follow-up interval. And that's what the Swedish study is showing us, that if -- if you don't have a handle on the length of follow-up after sex reassignment surgery, then you don't have a -- you don't have any way to fully understand the issue of lack of efficacy or regret.

If you're asking the questions is the surgery effective in correcting the most calamitous problems that a

transgender person has, which is suicidality, self-harm, and all those things that we talked about earlier, then you have to look at the interval postsurgery in order to have a full understanding of the efficacy of the procedure. And as I recall now, looking it over again, this study does not report on the follow-up period. The median age at first visit was younger, 25. Yeah. So they talk about age. They talk about the years in which they were cared for, but they don't talk about the length of the follow-up interval, so.

Q. All right. Let me move on --

A. Okay.

Q. -- to save time.

A. All right.

Q. Go to page 4 and where it says "Regret."

A. Okay.

Q. You with me?

A. I am.

Q. Third sentence says -- fourth sentence says, "Reasons for regret were divided into social regret, true regret, or feeling non-binary." You see that?

A. I do.

Q. And social regret -- strike that.

It says, "Transwomen who were classified as having social regret still identified as women, but reported reasons such as 'ignored by surroundings' or 'the loss of relatives is a large sacrifice' for returning to the male role." Do you see that?

A. I do.

Q. All right. So some of the persons who are being counted as experiencing regret in the study did not experience regret in the sense of they're realizing they're not transgender; right?

A. Realizing they're not transgender? I'm -- I'm trying to understand your question here. So you're

-- you're pointing me to the -- social regret, true regret, feeling non-binary is what's stated here.

"Transwomen who were classified as having social regret still identified as women, but reported reasons such as 'ignored by surroundings' or 'the loss of relatives is a large sacrifice' for returning to the male role."

Okay. Yeah. So -- so it's -- it's reporting without quantifying the reasons for regret and the -- basically all of them, subjective reporting again, so -- okay.

Q. Well -- well, let's go to page 6.

A. That's the next page, isn't it? Am I on the right page?

Q. On page 6, it has a large vertical table on the left side.

A. Okay. There we are.

Q. And you may want to rotate it so that you can see that table 6.

A. When I got -- let's see. There's a way to do that, isn't there?

THE COURT REPORTER: Yeah. If you put your cursor over the document, a black rectangle will come up at the bottom.

THE WITNESS: I see it now. Yes.

THE COURT REPORTER: There you go.

THE WITNESS: All right. There we are.

Q. Table 4 is titled "Characteristics of people with regret."

A. Okay.

Q. According to this table, out of 6,793 patients who received treatment, 14 of them reported regret of any type; right?

A. Okay.

Q. And all the way on the right, you see there's a "Reason for regret" column; right?

A. Right.

Q. And you're welcome to count it, but by my count, only 7 of those 14 reported, quote, unquote, true regret; right?

A. Yeah. And what's interesting about that is that those are the same criteria that were used to seek transgender surgery to solve their interior problems. So many patients will present for care because they feel socially isolated and because they have, you know, issues of -- well, for example, being non-binary and so on, those -- those -- like social acceptance and feeling non-binary is among the indications for the procedure. So it's interesting to note also that time after surgery, the regretters seem to favor -- postsurgical, you start to see them, what, maybe 50 to 90 months out and a lot of them, years -- ten years out. Yeah. So that -- that speaks to what we talked

about earlier, that you see these regrets and these problems beyond five years.

Q. All right. Whatever criticism you have of the methodology, what the study reports is -- are rates of regret that are below 1 percent; right?

MR. KNEPPER: Objection, form.

A. Yeah. Again, so as we talked about earlier, that's the problem with this study, is that -- is that the -- the denominator is a much larger number than these 14 patients, and they don't address the length of follow-up out of which they extracted these 14 patients. So it makes it difficult to interpret the study, and the claim that it's a small number is hard to support by their own evidence because they didn't follow them long enough. As their own data shows, you got to follow them longer to see the regret in most patients. And they don't tell us what that number is.

Q. Are you aware that there are

studies on patient regret outside of the treatment for gender dysphoria?

A. Am I aware of -- of transgender transition regret outside of --

Q. No. I'm going to ask -- I'm going to ask this again.

A. I'm sorry.

Q. Are you aware there are studies on rates of patient regret outside of surgical treatment for gender dysphoria?

A. Yes. Absolutely, yeah. So --

Q. Okay.

A. One of the -- one of the most important --

Q. Okay. Let me ask -- yeah, Doctor, let's -- this is going to be a long day. Just listen to my questions.

Did you do a literature search to find out what the average rates of patient regret are for other surgical procedures compared to surgical treatment for gender dysphoria?

A. I did not.

Q. Do you know if those rates are higher, lower, or about the same as the rates of regret for surgical treatment for gender dysphoria?

A. I would say there's no way of knowing because we don't have the -- the rate of regret in transgender regretters. We don't have that number, so there's no way to compare or to know which is the higher number.

Q. Okay.

A. Like we talked about earlier, we don't have this number.

Q. Well, this one study I just showed you showed a finding of 0.3 percent to 0.6 percent; right?

A. Right. And I -- and as I said, this is -- this is -- it's difficult to use this to compare to other regret cases because of the poor quality of this study. So I can't use this to compare it to the other studies on regret because this is not -- not useful to that end. I

mean, it's useful in seeing that 14 -- 14 regretters had these complications, 14 regretters had these -- these explanations for their regret.

And so it's kind of like a case collection, and retrospective reviews of -- of patient records are helpful in getting a sense of the size of the problem. Certainly, this study shows us that there's an increasing patient pool of people who self-identify as transgender. So in that regard, this publication is very useful. But in terms of comparing the regret rate based on this paper, I'd say this paper is useless.

Q. Okay. Open Exhibit 21.

(Exhibit 21 was marked for identification and is attached.)

A. Okay.

Q. Let me know when you have it.

A. Okay.

Q. All right. This is a

publication from 2017 by Wilson, W-I-L-S-O-N, titled "Regret in Surgical Decision Making: a Systematic Review of Patient and Physician Perspectives." See that?

A. I do.

Q. All right. Look at the abstract. You with me?

A. I'm -- I'm looking -- I'm just reading it now.

Q. The third sentence says, "We performed a systematic review of the literature focused on patient and physician regret in the surgical setting." See that?

A. I do.

Q. Now look at "Results." See that?

A. I'm there now, yes.

Q. It says, "Of 889 studies identified, 73 patient studies and 6 physician studies met inclusion criteria." Do you see that?

A. I'm reading it now, yes.
Q. I understand this is a systematic review of 73 patient studies and 6 physician studies on regret and surgical decision-making; right?
A. That's what it says here, yes.
Q. Then the third sentence of "Results" says, "Interestingly self-reported patient regret was relatively uncommon with an average prevalence across studies of 14.4%." Right?
A. Right.
Q. And then "Conclusion" says, "Self-reported decisional regret was present in about 1 in 7 surgical patients." You see that?
A. I do.
Q. All right. So according to this systematic review, one out of seven surgical patients, on average, report having decisional regret; correct?
MR. KNEPPER: Objection, form.

A. Right. So actually, I would go a little deeper than that. The first thing to note about this study -- and again, this is my first reading of it, so I'm on the fly here.

The first thing to note about it is that they looked at nearly 900 studies, of which only 73 qualified as having sufficient validity to include in their study. So this -- this speaks to a problem in the literature. I'd have to read lower to see what particular -- if they even examined what kind of surgeries were performed, because regret can happen for a number of reasons, including postsurgical complications and so on, types of surgery.

Q. We don't need --

A. Yeah.

Q. We don't need to dig into this too deeply. But, I mean, you don't dispute that regret is not uncommon for patients who have any kind of surgical

procedure; right?

MR. KNEPPER: Objection to form.

A. No. You know, there's -- there's -- it's such a life-changing event that the potential for regret is very high, so that's why you have to be careful in consenting the patient.

Q. Okay. Let me -- let's go back to your report.

A. Okay.

Q. Because I hear you criticizing all this evidence, and I want to see the stuff that you're relying on. Go to page 22.

A. All right.

Q. All right. About halfway down this paragraph, you say, "As reported by one author in 2021, 60,000 testimonies of personal de-transition can be found on the Internet."

A. Yeah, that's a typo. That's a typo. That should have been 16, not 60.

Q. Okay. Well, I think it's more

than that.

A. Okay.

Q. So we'll look at this in a second.

A. Sure, sure.

Q. And you cited this article from Pablo Exposito-Campos.

A. Yes.

Q. E-X-P-O-S-I-T-O, dash, C-A-M-P-O-S. Right? That's what you rely on; right?

A. Not relying. I'm basically just putting that out there as an example of a growing number of patients regretting transitioning, yeah.

Q. Well, no. What you say in your report is that according to this publication, you can find 60,000 -- or let's call it 16,000 testimonies of personal de-transition on the Internet; right? That's the point you're making?

A. Sixteen thousand, right. Yeah.

Q. Let's look at what that article

actually says.

A. Okay.

Q. Okay. This is going to be Exhibit 22. And let me know when you get it.

A. Doesn't seem to be coming through.

Q. Yeah, it may be stuck on my end. Okay. Just went through, so you should see it shortly.

(Exhibit 22 was marked for identification and is attached.)

A. There it is. Okay. Right.

Q. All right. This is the article that you're citing in your report; right?

A. Uh-huh.

Q. All right. So before we get there, you know that what this author was talking about was a Reddit website; right?

A. Yeah. That was -- that was their data source, yeah. Right.

Q. Reddit is not a peer-reviewed

publication, obviously; right?
A. Clearly.
MR. KNEPPER: Objection.
A. Yeah.
Q. Right?
A. Yes. It's not a peer-reviewed.
Q. It's a social website that anyone can access; right?
A. Right. Correct.
Q. Anyone can post -- can register an account on Reddit and post whatever they want; right?
A. Right.
Q. A post on Reddit is not something that you would consider reliable scientific evidence, I assume; right?
A. Yeah, no.
MR. KNEPPER: Objection, form.
A. I would -- I would put that as self-reporting anecdotal-level evidence, that's right. So it's -- it's not definitive, but it's suggestive of an

area in need of examination. And that's the reason I include it here, is not as definitive evidence of a particular level of problem but the -- the presence of a problem that needs to be addressed. So the substance of my testimony there where I call this study up is to show that there's a growing body of patients, as we talked about earlier, a growing body of patients who regret their transition and are seeking reversal. So that's what this is about.

It's not a quantification of the phenomenon. It's not a level 3 evidence of the phenomenon. It's a level 5, self-reported, anecdotal stuff that -- that is basically just calling us to look more carefully at what promises to be a controversial area of medical care. So this is just part -- part of the controversy is what we're looking at here. We're not looking at a definitive scientific document, so.

Q. It's not even level 5 because at least a case report that's published in a peer-reviewed journal has someone looking at that case report to figure out if it's a real thing; right?

A. Right.

MR. KNEPPER: Objection, form.

A. What we have here is a clinical psychologist who's looking at something going on online, and the clinical psychologist is -- is reporting this, that's right.

Q. Go to page 4 of this article.

A. One, two, three, four. Okay.

Q. See there's a second paragraph under "Further clarifications"?

A. Yes, I do.

Q. All right. And it references this Reddit/detrans subreddit; right?

A. Right.

Q. And it says it's "a subreddit for detransitioners to share their experiences with more than 16,000

members."

A. That's correct.

Q. Right?

A. Uh-huh.

Q. Then it says, "one can find several stories of people who call their transgender status into question." You see that?

A. Right.

Q. All right. This author is not saying that there's 16,000 separate testimonies of people tran- -- detransitioning on that subreddit; right?

A. I think the author is saying that there's a pool of 16,000 people among whom are evidence of regret or cessation of transition. That's what -- I think that's what the author's saying.

Q. Well, let's be more specific, because what he actually says is "one can find several stories." Right?

A. Right.

Q. There's a very big difference

between, quote, several stories and 16,000 stories of detransitioning; right?

A. I think what the author is saying is that -- that there are -- let's see. Subreddit -- detran- -- experiences -- more than 16- -- one can find several stories of a particular kind of transgender -- persons who call their transgender status into question after stopping transition.

So the several stories have to do with people who call their transgender status into question. Not people who regret the surgery, but these are people who regret the diagnosis. So he's talking about several stories of regretters of the diagnosis. It doesn't speak about regretters of the transition. He doesn't address that in that.

Q. All right. A bunch of posts on a social website is not scientifically reliable evidence to show the number of different people who actually

detransition; right, Doctor?

MR. KNEPPER: Form.

A. Yeah. As we said before, we have no way of -- at present, of knowing the number of people.

Q. Okay. Go back to your report.

A. Okay.

Q. Go to page 40.

A. All right. Okay.

Q. All right. Your first paragraph at the top of this page says, "A currently unknown percent-" -- "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." Right?

A. That's right.

Q. I take it you're not aware of any peer-reviewed studies that quantifies the number of people with gender dysphoria that are being, quote, unquote,

manipulated by social contagion or social pressure; right?

A. Again, as I said before, we don't know the numbers because that's not -- it's not adequately reported in the literature. But what we do know is that the social -- Lisa Littman's article, for example, in 2017 shows us that there's a significant factor in this new demographic of self-reported transgender patients, the new demographic being adolescent to young adult females without prior history of gender dysphoria or gender discordance suddenly reporting transgender self-identification.

And -- and what it shows us, what Lisa -- Lisa Littman's publication from Brown University shows us is that underlying these outbreaks is peer group networks of people online, peer groups online, social media, a modeled speech, a rehearsed speech, and -- and these -- these sudden outbreaks of -- of

self-identified transgender patients.

So we know it's there, but we can't quantify it yet. It's just it's -- but it's -- we have at present no other explanation for why the demographic of self-reported transgender patients has suddenly shifted from virtually all young boys to 50 to 60 percent of the new cases being adolescent to young adult females. And that's -- that's what we're -- what we're talking about here. This just speaks to the controversial nature of this -- medical and surgical interventions is that we don't even understand the origin of that phenomenon. And -- and what that Littman article shows us is precisely these things: that there's an element of social contagion, that there's peer pressure, there's rehearsed speech, online networks that cause these outbreaks of these new kind of patients, adolescent young adult females who previously had no

self-reporting of trans- -- cross-sex self-identification.

MR. TISHYEVICH: This is not responsive to my question, and I move to strike it.

Q. Here's my question, Doctor. You are not aware of any peer-reviewed study that quantifies the number of people with gender dysphoria who are being manipulated by social contagion or social pressure; correct?

A. No. We're at the -- we're at the level of level 4/5 evidence now. Lisa Littman's article is a level 5, possibly 4. A level 5. So --

Q. It's not a -- you're also not aware of any peer-reviewed study that quantifies the percentage of people with gender dysphoria who are being manipulated by social contagion or social pressure; correct?

A. No. That's part of the -- part of the problem with the literature.

Exactly right.

Q. Yeah.

A. Exactly right.

Q. Given this lack of reliable studies, do you agree that this phenomenon of social contagion is currently hypothetical?

MR. KNEPPER: Objection, form.

A. I would not agree with that. It's not hypothetical.

Q. Do you -- did you read the response from Lisa -- from Littman to the criticisms to that article?

A. I did. And -- and I also noted that the -- the -- the organization under which she published that article put considerable pressure on her. But she can't retract her data. She can retract her conclusions, but she can't retract her data, and she can't retract the findings in the paper itself that show the rehearsed speech, that show the networks that are involved, that showed

the -- the character of the -- the rehearsed speech, like, you know, if you're talking to the psychologist, tell them you've been thinking about suicide; if you're talking to the endocrinologist, tell them you feel better now that you're started on T, that sort of stuff. So -- so it's not hypothetical, it's actual.

The -- the size of the phenomenon can only be compared to the change in the demographic. Why are 60 percent of patients fitting into that category suddenly, whereas before, only 20 percent of patients were females?

Q. Do you remember --

A. That's what --

Q. Okay. Do you remember the part of the correction from Ms. Littman where she said that this is a hypothesis-generating article?

A. Hypothesis as to -- as to mechanism of -- of action, and some of the hypotheses are what's listed there:

social network peer -- media -- I'm sorry -- peer pressure, social media, role modeling, social contagion. So she admits that is a -- it is not understood. She admits that those phenomena are there, but it -- at present, we're hypothesizing about the actual cause. And this speaks again to the controversial nature of even the diagnosis, much less the treatment.

Q. Go back to your report.

A. Okay.

Q. Page 40.

A. I'm there.

Q. Toward the bottom, you say, in capital letters, "Not Generally Accepted." You see that?

A. I do.

Q. And you say, "Affirmation medical treatments -- hormones and surgery -- for gender dysphoria and transitioning have not been accepted by the relevant scientific communities." Do

you see that?

A. I do.

Q. It's your expert opinion that it's generally accepted that puberty blockers are not medically necessary; right?

A. No.

MR. KNEPPER: Objection, form.

A. I would say puberty blockers in the setting of a self-identified transgender is not medically necessary, but puberty blockers are often medically necessary, just not in that particular patient population.

Q. Is it also your expert opinion that it's generally accepted that hormone treatment for gender dysphoria is not medically necessary?

A. Well, the scientific evidence now shows that it is -- is not useful. That's what I said --

Q. Answer my question. Is it your expert opinion that it's generally

accepted that hormone treatment for gender dysphoria is not medically necessary?

A. Yes.

Q. Is it also your expert opinion that it's generally accepted that gender-affirming surgery for gender dysphoria is not medically necessary?

A. Yes. I would say so, yeah. I can't put a number on it, but yeah.

Q. All right. Let me -- let me show you another document. Okay. Let me introduce this. Okay. This is going to be Exhibit 23. And let me know when you get it.

(Exhibit 23 was marked for identification and is attached.)

A. Okay. All right. I'm there.

Q. Okay. Top of the page says, "BlueCross BlueShield of North Carolina." Right?

A. Correct.

Q. You know what Blue Cross and

Blue Shield is; right?

A. Right.

Q. It's a healthcare insurer; right?

A. Yes.

Q. Are you aware that Blue Cross Blue Shield is the largest private insurer in the state of North Carolina?

A. I am now.

MR. KNEPPER: Objection, form.

Q. All right. This document is titled "Corporate Medical Policy," "Gender Affirmation Surgery and Hormone Therapy." Right?

A. Right.

Q. Do you know what this is?

A. Do I know what what is?

Q. Do you know what this document is?

A. It appears to be an insurance company document concerning the coverage of certain services. I would have to read it to know what it is specifically,

but I think it's probably a policy statement about what is covered and what is not covered and what the diagnostic criteria are.

Q. Yeah.

A. What the policy of the company is. Yeah. So, shall I read it or?

Q. I'll walk you through it.

A. Okay.

Q. You see it says "Last Review" near the top?

A. Right.

Q. It's 3/2021. That's March 2021; right?

A. Yes.

Q. All right. You understand this policy was a -- strike that.

In your report, you cite a number of articles that you say Dr. Brown and Dr. Schechter overlooked, like a bunch of 2020 articles; right?

A. Right.

Q. You understand this was

published -- updated after all those studies that you cited were published; right?

A. It appears to be.

Q. Okay. Go to page 7. You see it says "Scientific Background and Reference Sources"?

A. Right.

Q. You understand this section of the policy provides some of the scientific background on which the policy is based; right?

A. I see that, yes.

Q. And if you go to page -- the next page, page 8, you see there's a bunch of references to Specialty Matched Consultant Advisory Panel; right?

A. I see that, yeah.

Q. And there's some references to sen- -- Senior Medical Director reviews; right?

A. I see that, yeah, from 2016.

Q. Yeah. Well, if you keep

looking, there's a bunch from 2020; right?

A. I see medical director review in 2020. Yes, I do. I see that.

Q. And then including a medical director review in March 2021; right?

A. I see it. That's probably what generated this document. Am I right?

Q. Yeah. Good guess. Now, obviously --

A. That's why they pay me the big bucks. Sorry.

Q. Obviously, you had no involvement with the development of this policy from BlueCross BlueShield of North Carolina; right?

A. Correct.

Q. You have no idea how BlueCross BlueShield of North Carolina came to decide what gender affirmation surgeries or hormone therapy they're going to cover or not; right?

A. Wrong. I -- I have now some

idea of what they used because you've listed -- or they've listed the scientific background and reference sources for coming to their company policy. And what I would point you to is the fact that every one of the documents, the scientific documents that support their decision-making, I think the most recent one is 2014. You've got some that go back to the year 2000. So you've got 21-year-old DSM-4 characterizations. You've got 2001 Harry Benjamin Gender Dysphoria Association publications. The most recent thing is a -- is a -- well, that's actually an advisory panel. So the most recent medical article is the Cohen-Kettenis Hembree article from 2016. So what's used to support a March 2021 document is essentially six-year-old information. And as we talked about earlier, it hasn't -- it's changed a lot. It's changed a lot since then.

The fact that Blue Cross Blue

Shield is slow off the mark would be troublesome to the shareholders, I suppose. But as far as what I'm here to talk about, the scientific basis for this, the scientific basis is old data.

Q. Doctor, you don't know whether this is an exhaustive list of every scientific resource that Blue Cross Blue Shield considered in making the March 2021 update; right? You have no idea?

MR. KNEPPER: Objection, form.

A. I can only go by what they've disclosed.

Q. Right.

A. And what they've disclosed -- which I would assume they would be leading with their best information rather than their worst -- I would call that -- the scientific support of low quality because of the -- the better-quality data that's now available in the last three years.

Q. You don't know personally

whether Blue Cross Blue Shield considered any of the articles that you've cited when they're making this policy change in 2021; right? You don't know that?

A. I have no way of knowing how --

Q. Yeah.

A. -- that committee worked. I only -- I only assume that they would have put out their best scientific support rather than their weakest.

Q. Yeah. Bottom of this page, by the way, see there's a section that says, "Policy Implementation/Update Information"?

A. Yes, I see that.

Q. And it says, "7/19/11" --

A. Yeah.

Q. -- "New policy developed." Right?

A. Right.

Q. You understand that Blue Cross Blue Shield has had some form of this policy for gender affirmation surgery

since July 2011?

MR. KNEPPER: Objection, form.

A. I can see that they have had a policy, according to their own reporting, since July of 2011.

Q. All right. So, let's look at what Blue Cross Blue -- Blue Cross Blue Shield thinks about whether these procedures are medically necessary. Go to page 5.

A. Let's see. So we're at page 8. We're going up to page 5? Okay. Okay.

Q. Give me a second. Actually, let me start you on page 1. You see there's a description of -- let me know when you get there.

A. I'm there.

Q. Okay. Now, the beginning says, "Gender Dysphoria is the formal diagnosis used by professionals to describe persons who experience significant gender dysphoria (discontent with their biological sex and/or birth gender)."

Right?

A. Yes, I see that.

Q. All right. You understand what this policy is addressing; right?

A. Yeah. It's addressing a psychiatric classification, not medically classified as a medical illness. So they're -- yeah.

Q. Okay. Go to page 2.

A. Can you give me just a moment to reread that sentence for just a second.

(Witness reviews document.)

A. Okay. Yeah. So that's boilerplate. I'm sorry. Sorry for slowing you down here.

Q. That's fine. Go to page 2.

A. Okay.

Q. Top of the page says, "Policy." Right?

A. Correct.

Q. And it says, "Services for gender affirmation surgery and hormone therapy may be considered medically

necessary when the criteria below are met." You see that?

A. Right. So that's -- that's language that insurance companies use. If you're not in the category of medical necessity, there's no insurance coverage. So whether or not one could classify it as a medical diagnosis is not at issue. What's at issue is, is the insurance company going to cover this -- this benefit.

Q. Yeah. Because insurers typically are not in the business of covering services that are not medically necessary; right?

A. No. I wouldn't --

MR. KNEPPER: Objection, form.

A. -- characterize it that way.

THE WITNESS: I'm sorry.

A. I wouldn't characterize it that way. Insurance companies are in the business of -- certainly, they're in the business of -- of paying for covered

benefits. But that's the problem with the insurance industry, is their primary fiduciary duty is to their investors. And so the question of coverage has more to do with are we going to make an insurance policy that earns us money or are we going to be paying for something and not seeing the money. Okay? Does that make sense?

Q. Doctor, you --

A. I think that's what -- that's what this language here is talking about is -- is medical necessity is the language that's used when an insurance company will cover. They will not cover cosmetic surgery, but they're -- they're proposing to cover transgender surgery beginning by attempting to define it as a medical diagnosis. That's what's at stake here is.

Q. No. What -- what this policy says is that when certain criteria are met --

A. Right.

Q. -- gender affirmation surgery and hormone therapy may be considered medically necessary; right? That's what it says in black and white.

MR. KNEPPER: Objection, form.

A. Yeah, again, so medically necessary from the standpoint of an insurance company is if you meet these criteria, we'll pay for it; if you don't meet these criteria, we won't pay for it. That's -- that's --

Q. Right. And the difference is whether the surgery is considered to be medically necessary or not; right?

MR. KNEPPER: Objection, form.

A. Well, again, so medically necessary in this case is has the insurance company decided that they're going to cover this benefit. It says nothing about the scientific support for the efficacy of the procedure. They haven't said anything in that about it.

They've just called it medically necessary.

Q. All right. Let's -- let's go off the record.

A. Okay.

THE VIDEOGRAPHER: This is the end of Media Unit No. 5. We are off the record at 3:25 p.m.

(Break taken.)

THE VIDEOGRAPHER: This is the beginning of Media Unit No. 6. We are on the record at 3:36 p.m.

Q. (By Mr. Tishyevich) All right. I'm going to introduce another exhibit, Doctor.

A. Okay.

Q. It's being slow on my end. Bear with me. Okay. This will be Exhibit 24. Let me know when you have it.

(Exhibit 24 was marked for identification and is attached.)

A. I will. Okay. I've got it.

Q. Okay. You've seen this study

before; right?

A. Yes, I have.

Q. How do you pronounce the lead author's name?

A. That's the subject of great debate, but I think it's Dhejne or -- I think it's Dhejne, Cecilia Dhejne, but I -- I -- I'm not -- I'm not a Swissophone.

Q. I'll use Dhejne as well.

A. Okay.

MR. TISHYEVICH: And for the court reporter, it's D-H-E-J-N-E.

Q. Okay. This is a study from 2011; right?

A. Yes.

Q. And you cited this study in several places in your report --

A. I do.

Q. -- right?

And one of the points for which you cite this study is to say that Swedish patients who underwent

gender-affirming surgery had a 19.1 times greater suicide rate than the control group; right?

A. Yeah. The hazard ratio for -- well, for all reassigned persons is 19.1, and they further break out the -- that into subgroups of female-to-male and male-to-female.

Q. Yeah. And you understand how the control group in this study was defined; right?

A. Yes.

Q. The control group did not consist of patients with gender dysphoria who did not undergo gender-affirming surgery; correct?

A. Correct.

Q. The control group consisted of patients without gender dysphoria; right?

A. Yeah. That's kind of the point of the -- of the research, yes. That's right.

Q. Yeah. What this Dhejne study

compared was the suicide rate for patients who underwent gender-affirming surgery against the general Swedish population; right?

A. Right.

Q. And you know there's many studies that find that patients with gender dysphoria, as a population, have a higher risk of suicide compared to the general population; right?

A. Very much accepted fact, yes.

Q. Yeah. All right. We'll go to page 7.

A. Let's see here.

Q. You see there's a "Strengths and limitations of the study" section?

A. Two, three, four, five, six, seven. Yes, I'm there.

Q. All right. Look at the third full paragraph in that column.

A. Okay.

Q. All right. Second sentence says: "The caveat with this design is

that transsexual persons before sex reassignment might differ from healthy controls (although this bias can be statistically corrected for by adjusting for baseline differences). It is therefore important to note that the current study is only informative with respect to transsexual persons health after sex reassignment; no inferences can be drawn as to the effectiveness of sex reassignment as a treatment for transsexualism."

You see that?

A. Right. Yeah.

Q. Then it says: "In other words, the results should not be interpreted such as sex reassignment per se increases morbidity and mortality. Things might have been even worse without sex reassignment." Correct?

A. Yeah. It's -- the -- let's see. The -- yeah, so -- and I don't think I ever make the claim that the surgery

increases the risk of morbidity and mortality. Yeah, I -- I would agree with that.

Q. Yeah, no --

A. But I would -- I would also wonder on what basis they -- there's nothing to support that it might have been worse either. It's for the same reason.

Q. Yeah. This study does not support the conclusion that sex reassignment surgery by itself increases risk of suicide; correct?

A. That's what they -- they say, yes.

Q. And they also say that this study does not support the conclusion that surgical procedure for gender dysphoria by themselves increase risk of morbidities other than suicide; right?

A. Right.

Q. Okay. All right. Let me -- you mentioned that -- in your report the 2020

Finland guidelines. You recall that?

A. I do.

Q. Let me ask you a couple of questions on those.

A. Okay.

Q. So I'll introduce another exhibit. This will be Exhibit 25, and let me know when you get it.

(Exhibit 25 was marked for identification and is attached.)

A. Okay.

Q. Let me ask you before we get into this, look at page 46 of your report.

A. Okay.

Q. Near the top, there's a "2020 - Finland" reference. You see that?

A. I see that, yeah.

Q. You say, "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." You see that?

A. I do.

Q. And then you say in the last sentence, "The Finland National Guidelines appear quite contrary to the opinions of Drs Brown and Schechter and WPATH." Do you see that?

A. I do.

Q. Is it your opinion that the WPATH guidelines recommend that children who experience gender dysphoria should transition to a different gender role?

MR. KNEPPER: Objection, form.

A. No. I would say that the WPATH guidelines essentially leaves us with affirmation care only, that it does -- it does, you know, recom- -- recommend all of the psychological support but all of it in support of transition. I would say that. Yeah.

Q. Yeah. The WPATH guidelines do not recommend that children with gender dysphoria automatically be put on puberty

blockers; right?

A. They don't make that recommendation, no. They don't state that recommendation, no.

Q. Yeah. Let's look at what they actually say.

A. Okay.

Q. I'm going to introduce one more exhibit.

A. So we're going to leave the Finland article for now and go to --

Q. Yeah. We'll come back to it. I want to show you the WPATH --

A. Okay.

Q. -- Standards of Care Version 7 first.

A. Uh-huh.

Q. All right. This will be Exhibit 26. Let me know when you have it.

(Exhibit 26 was marked for identification and is attached.)

A. Okay.

Q. This is a larger file, so this

may take an extra minute or so.

A. Okay. I've got it.

Q. Okay. These are the WPATH Standards of Care Version 7; right?

A. Yes.

Q. Turn to page 23.

A. Okay.

Q. All right. There's a section titled "Social Transition in Early Childhood." You see that?

A. I must be on the wrong page. Did you say page 23?

Q. It's PDF page 23, which is going to be page 17 in the standards.

A. Oh, I'm sorry. Okay. Let's go back, then. Page 17. Okay. I'm there. Right. "Social Transition in Early Childhood."

Q. All right. It says: "Some children state that they want to make a social transition to a different gender role long before puberty. For some children, this may reflect an expression

of their gender identity. For others, this could be motivated by other forces."

You see that?

A. I do.

Q. And then a couple of sentences down, it says: "This is a controversial issue, and divergent views are held by health professionals. The current evidence base is insufficient to predict the long-term outcomes of completing a gender role transition during early childhood." You see that?

A. I do.

Q. All right. The WPATH Standards of Care Version 7 is not making any clinical recommendations encouraging children in early childhood to go through gender transition roles; correct?

A. Yeah, I would -- yes. I would add to that that they're also not offering any clinical guidance on how to distinguish who might or who might not be suitable for transition. Right.

Q. Do you know whether that's explored somewhere else in this Standards of Care Version 7?

A. Yeah. I think it's discussed.

Q. Okay.

A. But -- but it's -- but I -- yeah. So what's -- what's important, I think, in what you cite here is that the current evidence base is insufficient to predict the long-term outcome. Yes.

Q. Okay. Go to the next page.

A. Okay.

Q. Page 18, PDF page 24.

A. Okay.

Q. There's a section titled "Physical Interventions for Adolescents."

A. Right.

Q. Right?

A. Yes.

Q. You understand that adolescents are different than children; right?

MR. KNEPPER: Objection, form.

A. Well, yeah. So, adolescents are

treated in pediatric clinics, but they're different from prepubertal children, yes.

Q. Yeah. This section does not provide any clinical recommendations for hormone therapy in prepubescent children; right?

A. Let's see. I've just got to refresh my memory here on the verbiage.

(Witness reviews document.)

A. Yeah. So it -- it addresses the important issue of gender fluidity in adolescents, potential for shift to conformity and -- that may not persist. Yeah. Right.

Q. Okay. And this section also does not provide any clin- -- clinical recommendations for surgical intervention in prepubescent children; right?

A. This section doesn't address prepubescent children. It addresses adolescents.

Q. Yeah, exactly. And you don't know of any other section in these

Standards of Care Version 7 that provide those guidelines for prepubescent children; right?

A. No.

Q. Okay. Go to the next page, PDF page 25, page 19 in the document.

A. Okay.

Q. And you see there's a section that says, "Criteria for Puberty-Suppressing Hormones"?

A. Yes.

Q. It says, "In order for adolescents to receive puberty-suppressing hormones, the following minimum criteria must be met." You see that?

A. Yes.

Q. And then there's four items; right?

A. Yes.

Q. Number 4 says, "The adolescent has given informed consent and, particularly when the adolescent has not

reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescents throughout the treatment process."

You see that?

A. Yeah. That -- in fact, that was one of the most troubling things I read when I reviewed this whole document from the WPATH guidelines, is that -- yeah, that using those words in the same sentence, an adolescent giving informed consent, is a -- is a non sequitur because I -- I don't think -- in all my years of practice as a surgeon, which amounts to greater than 35, the idea of obtaining consent from an adolescent was never accepted by the surgical community or the medical community, to my understanding.

Q. Well, this also talks about getting informed consent from the parents or other caretakers or guardians; right?

A. Yeah. So in their role supporting the adolescent's decision. It doesn't say -- yeah. So the parents or other caregivers have consented in support. Right.

Q. Yeah. What the guidelines contemplate is that it's not just the adolescent that's going to give an informed consent, it's also the parents or other caretakers or guardians; right?

A. Yeah. But again, that's the problem I have with it, because that's -- the introductory sentence has -- has no meaning -- or the introductory part of the one sentence has no meaning. If the beginning point of the process is adolescent consent, that's -- that's not an ethical thing to do because --

Q. Yeah.

A. -- because an adolescent can't grasp -- they don't have enough executive function or development, particularly if they have been through a period of

puberty suppression before they begin the period of cross-sex hormones, that it's -- it's already quite evident that these patients, these children do not have enough -- and it's just known in society at large that adolescent children don't have the capacity for long-term reckoning of things like risk and outcomes and neither do they have the executive capacity in their brains to make an informed consent decision. So that part of it is meaningless to me. Yeah.

Q. Yeah. But you understand there's two components to this requirement; one is informed consent by the adolescent, and two is informed consent by parents or other caretakers or guardians. Right?

A. Yes.

Q. Okay.

A. That's what it says.

Q. All right. Let's now go back to the Finland guidelines. It's Exhibit 25.

A. Okay.

Q. And go to PDF page 9 which has Section 8, "Summary" -- "Summary of the Recommendations." Let me know when you get there.

A. Okay.

Q. All right. This page provides recommendations for treatment of minors with gender dysphoria in Finland; right?

A. Yes.

Q. All right. Look at number 2 at the bottom.

A. At the bottom. Okay. Okay.

Q. All right. So it starts with, "If a child is diagnosed prior to the onset of puberty with a persistent experience of identifying as the other sex and shows symptoms of gender-related anxiety, which increases in severity in puberty." You see that?

A. Yes, I do.

Q. All right. And then next sentence says, "Based on these

assessments, puberty suppression treatment may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications."

Do you see that?

A. I do.

Q. All right. You understand that these Finland guidelines do not categorically prohibit the use of puberty-blocking agents in minors; correct?

MR. KNEPPER: Objection, form.

A. Right. They don't categorically, but what they do is they express uncertainty about the data that -- that's been used to support the use of those drugs in children.

Q. Yeah. But -- but despite that data, what the guidelines recognize is that puberty-blocking treatment may still

be initiated for some minor patients in certain circumstances.

A. Right.

Q. Right?

A. Agree.

MR. KNEPPER: Objection, form.

Q. All right. Let's go back to your report. Go to page 46.

A. I'm there.

Q. So in your discussion of these Finland guidelines, you cite something called -- it's a website, genderreport.ca.

A. Correct.

Q. Do you see that?

A. I do.

Q. And I saw at least two other references to this source in your report. All right. This is -- genderreport is not a peer-reviewed publication, Doctor; right?

A. No. It's a data collection site. Yeah.

Q. It's a data collection site?
A. I think that's what the -- so, let me just review what I wrote here.
(Witness reviews document.)
A. All right. Okay. Yeah. Okay. Yeah, no. I agree they're not peer-reviewed to my knowledge, no.
Q. It's a blog; right?
A. Right. It's on -- it's online, exactly.
Q. Blogs are not generally considered reliable scientific evidence, I take it. Right?
MR. KNEPPER: Objection, form.
A. No, they're not.
Q. Okay. Do you know who started this genderreport blog?
A. I do not.
Q. Do you know this person was a doctor?
A. I don't know the person, no.
Q. You don't know they're a scientist?

A. I'm sorry?
Q. You don't know whether they're a scientist; right?
A. I don't know.
Q. Did you know that this blog was started by a parent who was upset that her daughter was told in school that girls are not real and who filed a lawsuit about it?
MR. KNEPPER: Objection, form.
A. I did not know those details, no.
Q. Assuming that's true, do you think this is an unbiased, objective resource?
MR. KNEPPER: Objection to form.
A. I -- I don't know. I don't know the answer to that question.
Q. Do other experts in your field rely on blogs like this one to support their opinions?
MR. KNEPPER: Objection, form.
A. And I don't, and neither did I

rely on this as sole support for my opinion. This -- again, this is just evidence of -- of controversy that exists out in the literature, or that exists out in the -- in the greater world, I should say, in this case because this is not medical literature, but in the wider world.

Q. Well, as I read this, your page 46, you're -- you're citing this gender report for your analysis of the 2020 Finland guidelines.

MR. KNEPPER: Objection, form.

Q. Right?

A. I think I'm using the Finland guidelines as a standalone and just referencing this gender report as evidence of events in Finland rather than scientific support for the conclusions of the Finland review.

Q. Okay. Another article you cite is the Carmichael 2021 study.

A. Right.

Q. Let's look at that one. I'll introduce it as Exhibit 27. Let me know when you have that.

(Exhibit 27 was marked for identification and is attached.)

A. Okay. Okay. I have it.

Q. Okay. This is titled, "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."

A. Right.

Q. Right?

A. Yeah.

Q. All right. Look at the -- on page 1, you see there's an abstract?

A. Yes.

Q. Under "Methods," it says, "We undertook an uncontrolled prospective observational study." Right? Do you see that?

A. Right.

Q. All right. This is not a

randomly controlled clinical trial; right?

A. Right.

Q. Not a cohort study --

A. Right.

Q. -- right?

A. Right.

Q. There's no control group; right?

A. Correct.

Q. You don't mention any of that in your report even though you spend a lot of time discussing the limitations of other studies. Why is that?

MR. KNEPPER: Objection, form.

A. I -- we include this to one to show the raging controversy in the world of transgender medicine, and this is an example of that, the -- the evidence of uncertain result or no result, no change from baseline effect.

Let's see. Let me just review because I've reviewed so many of these articles lately.

(Witness reviews document.)

A. Right. Yeah. So -- yeah. So that's right. So they were unable to quantify benefit or harm from puberty suppression.

Q. Go to page 21. See there's a "Strength and Limitations" section?

A. I see it. Yes, I do.

Q. The second sentence says: "The study size and uncontrolled design were key limitations. The small sample size limited our ability to identify small changes in outcomes. This was an uncontrolled observational study and thus cannot infer causality." See that?

A. I do.

Q. Again, you don't acknowledge any of these limitations in your report; right?

MR. KNEPPER: Objection, form.

A. Right. I believe I made reference to this in terms of it's evidence of -- of controversy in the

literature, that they could not see a benefit from it. So again, at lower levels of evidence, evidence of benefit would suggest further study. This shows that further study is needed because, at the observational level, you don't see effect.

Q. All right. Another study -- not a study, a review that you cite is this Cochrane 2020 --

A. Yes.

Q. -- review; right?

A. Right.

MR. TISHYEVICH: And for the court reporter, that's C-O-C-H-R-A-N-E.

Q. I'm going to introduce that one next.

A. Okay.

Q. All right. I'm introducing this as Exhibit 28, and let me know when you get it.

(Exhibit 28 was marked for identification and is attached.)

A. I will. Okay.
Q. Okay. This is from the Cochrane Library. This is the review that you cite in your report; right?
A. Right.
Q. Go to page 2.
A. Okay.
Q. All right. You see there's the section titled, "Authors' Conclusions"?
A. Okay. Yes, I do.
Q. All right. Toward the end, do you see it says, "We will include non-controlled cohort studies in the next iteration of this review, as our review has shown that such studies provide the highest quality evidence currently available in the field." You see that?
A. Yes, I do.
Q. All right. So the Cochrane review is not saying they're just going to ignore all those studies going forward; right?
A. Right.

MR. KNEPPER: Objection, form.

Q. They rec- -- they recognize that those noncontrolled studies currently represent the best available evidence; right?

MR. KNEPPER: Objection, form.

A. Well, yeah. Before they say best available evidence, they speak about the level of the evidence now. And what's -- what's interesting about this Cochrane review, because it's a worldwide review of the literature on the subject of cross-sex hormones and hormone blockade in transwomen, is that they found over a thousand references, and by the time they got through qualifying those references for suitability, they got down to thirteen studies. And when they fully screened the text, they got down to a single study. And that's -- that's kind of characteristic of -- of the data used to support hormonal transitioning.

And so yeah, they -- they have to -- they have to backpedal in order to get any data because what they have in hand now is -- is not supportive of -- of the use of cross-sex hormones in transwomen, so.

Q. All right. Let me introduce another exhibit.

MR. TISHYEVICH: Can we go off the record?

THE VIDEOGRAPHER: We are off the record at 4:07 p.m.

(Break taken.)

THE VIDEOGRAPHER: We are back on the record at 4:20 p.m.

Q. (By Mr. Tishyevich) All right. Doctor, let me ask you about what experience you have with the individual plaintiffs in this case specifically.

You personally did not meet with any of the plaintiffs in this case; correct?

A. No. I did a review of their

charts and nothing more. Yeah.

Q. All right. You've personally never spoken with any of the plaintiffs; correct?

A. I have not.

Q. You obviously were not present in any meetings that any of these plaintiffs may have had with their mental health professionals; right?

A. I was not.

Q. And you don't know specifically what was said or not said during those meetings; correct?

A. The only information I have about those meetings was what's entered in the medical record that was given to me to review.

Q. Yeah. You were also not present in any meetings any of the plaintiffs may have had with their endocrinologists; right?

A. Correct.

Q. And outside of reading medical

records, you don't know what was said or not said during those meetings; correct?

A. Correct.

Q. And finally, for plaintiffs who had undergone surgical procedures, you were also not present in any meetings between these plaintiffs and their surgeons; correct?

A. Correct.

Q. And outside of medical records, again, you don't know what was said or not said during those meetings; correct?

A. Correct.

Q. Okay. You should see a new exhibit pop up, Exhibit 29.

A. Okay.

(Exhibit 29 was marked for identification and is attached.)

Q. And if you can go to PDF page 54.

A. PDF page 54. Okay.

Q. First of all, you understand what this document is; right?

A. I didn't get to see the header on it. I haven't seen this before, I don't think.

Q. Oh, feel free -- yeah, feel free to go back to the first page if you want to.

A. Okay.

(Witness reviews document.)

Q. All right. This is the --

A. Okay. Okay. So it's --

Q. Yeah.

A. -- a benefits booklet for the State health plan. Is that right?

Q. For North Carolina, right.

A. Yes. The teachers union -- teachers and employ- -- and State employees, right. Okay.

Q. You know what a benefit plan is; right?

A. Yes, uh-huh.

Q. At a high level, it sets out what the insurer is going to cover or not cover; right?

A. Correct.

Q. Among other things. Okay. And earlier, we talked about medical necessity. You recall that?

A. Yes.

Q. All right. Go to -- now go back to PDF page 54 of this plan.

A. Okay. I'm there.

Q. You see at the top, it says, "What is not Covered?" And it's a list of items?

A. Am I on the right page? I'm on -- on PDF page 54?

Q. Yeah.

A. That's the -- the -- oh, I'm sorry.

Q. Plan page 46, so that's --

A. Plan page 46. Let me back up real quickly here. Sorry. Okay. I'm there.

Q. At the top or near the top, it says, "What is not Covered?" You see that?

A. I do.
Q. There's a list of items alphabetically. See that?
A. Yes.
Q. And under M, it says, "Services or supplies deemed not medically necessary." "Medically necessary" is in bold; right?
A. Right.
Q. All right. Let's look at that definition. Go to PDF page 89, which is page 81 of the plan.
A. Okay.
Q. All right. At the bottom, you see there's a definition of "Medically Necessary (or Medical Necessity"; right?
A. Yes.
Q. And it says, "those covered services or supplies that are: a) Provided for the diagnosis, treatment, cure, or relief of a health condition, illness, injury, or disease; and, except for clinical trials as described under

this health benefit plan, not for experimental, investigational, or cosmetic purposes." Right?

A. Okay.

Q. I understand that as part of determining what the benefit plan is going to consider medically necessary, whether or not the treatment is experimental is one of the factors; right?

A. As would be defined -- so all of the definitions here are determined by the insurance provider. So they've defined these listed necessities as covered under their plan, yes.

Q. Yeah. So under this definition, if a treatment is experimental, it is likely not going to be covered under the plan; right?

A. Right. According to their definition, it doesn't appear they would cover experimental surgery or cosmetic surgery.

Q. Conversely, if a treatment is not experimental, it may be covered by the plan in some circumstances; right?

A. It would seem --

MR. KNEPPER: Objection, form.

Q. Yeah. And I showed you earlier a policy from BlueCross BlueShield of North Carolina from March 2021 that says that gender-affirming hormone and surgical treatment is considered medically necessary; right?

MR. KNEPPER: Objection, form.

A. Yeah, no. As we talked about before, these are definitions formulated by the insurance company to define coverage, not medical definitions in terms of medical care. This is strictly coverage by insurance. Yeah.

Q. Well, one of the factors that goes into that consideration is whether or not that treatment in question is experimental; right?

MR. KNEPPER: Objection, form.

A. Right. The plan excludes experimental or investigational or cosmetic procedures.

Q. Okay. All right. We're talking about BlueCross BlueShield of North Carolina. Let me ask you about another insurer, Aetna, A-E-T-N-A. You've heard of Aetna; right?

A. Yes.

Q. Are you aware that Aetna is one of the five largest health insurance -- insurers in the U.S.?

A. It would not surprise me to learn that.

MR. KNEPPER: Form.

Q. Do you have any idea whether Aetna considers gender-affirming surgery and hormone therapy to be medically necessary?

MR. KNEPPER: Objection, form, scope.

Q. Would it surprise you if Aetna --

THE COURT REPORTER: I'm sorry. I didn't hear the answer over the objection.

THE WITNESS: I haven't answered yet.

THE COURT REPORTER: Okay.

THE WITNESS: Sorry.

A. So as to the size of Aetna or the -- that they cover --

Q. Yeah, let me just ask -- I'll ask the question again.

A. Okay.

Q. Do you have any idea whether Aetna considers gender-affirming surgery and hormone therapy to be medically necessary?

MR. KNEPPER: Objection, form, scope.

A. I don't.

Q. Well, let me show you. I'm going to introduce another exhibit. Okay. This is going to be Exhibit 30. Let me know when you have it.

(Exhibit 30 was marked for identification and is attached.)

A. Okay. All right. I have it.

Q. All right. This is a policy from Aetna titled "Gender Affirming Surgery." You see that?

A. I do.

Q. You see there's a "Policy History" on the right?

A. Yes.

Q. Under "Last Review," it says January 12th, 2021; right?

A. Yes.

Q. So you understand this was revised within this year; right?

A. Yes.

Q. And under Policy, it says, "Aetna considers gender affirming surgery medically necessary when all of the following criteria are met." Right?

A. Right.

MR. KNEPPER: Form.

Q. All right. So according to this

policy, in Aetna's view, gender-affirming surgery is medically necessary, therefore nonexperimental; right?

MR. KNEPPER: Objection, form.

A. Yeah, Aetna's definition of what is medically necessary appears to allow for gender-affirming surgery.

Q. Okay. Go to page 3.

A. Okay.

Q. Look at the bottom of the page.

A. Okay.

Q. The second to the last paragraph says, "Aetna considers gonadotropin-releasing hormone medically necessary to suppress puberty in trans identified adolescents if they meet World Professional Association for Transgender Health (WPATH) criteria." Do you see that?

A. I do.

Q. Okay. According to Aetna, puberty-blocking hormones are medically necessary to suppress puberty in

trans-identified adolescents if they meet the WPATH criteria; right?

MR. KNEPPER: Objection, form.

A. That -- that's what it states there, yes.

Q. By the way, look at the next paragraph. See it says, "Aetna considers reversal of gender affirming surgery for gender dysphoria not medically necessary."

MR. KNEPPER: Objection.

Q. Do you see that?

A. I do.

Q. Okay. We talked about Blue Cross Blue Shield, talked about Aetna. Do you know what Cigna is?

A. Yeah. It's one of the largest health insurance providers.

Q. Do you know what position Cigna takes on whether gender dysphoria treatment is medically necessary?

MR. KNEPPER: Objection, form, scope.

A. I have not read their policies.
Q. You don't know; right?
A. Correct.
Q. Let me show you that policy.
A. Okay.
Q. All right. This is going to be Exhibit 31. Let me know when you have it.
(Exhibit 31 was marked for identification and is attached.)
A. Okay. Okay. I have it.
Q. All right. This is a Cigna medical coverage policy titled "Treatment of Gender Dysphoria." Do you see that?
A. Yes, I do.
Q. On the right top, it says "Effective Date," May 18th, 2021; right?
A. Yes.
Q. Also recently updated; right?
A. Yes.
Q. Go to page 2. Under "Coverage Policy," look at the third paragraph in bold. It says, "Medically necessary

treatment for an individual with gender dysphoria may include any of the following services, when services are available in the benefit plan." Do you see that?

A. I do.

Q. All right. And then there's five different bullets of different categories of services; right?

A. One, two, three, four, five. Yes.

Q. Number two is "Hormonal therapy, including but not limited to androgens, anti-androgens, Gn-" -- "GnRH analogues, estrogens, and progestins." Right?

A. Yes.

Q. That's a medically necessary benefit in Cigna's view; right?

MR. KNEPPER: Objection, form.

A. It is a -- medically necessary as defined by a insurance company for purposes of a policy.

Q. Yeah.

A. Yes.

Q. And the last bullet point says, "Gender reassignment and related surgery (see below)." Do you see that?

A. I do.

Q. According to this policy, in Cigna's view, gender reassignment and related surgery is a medically necessary service; right?

MR. KNEPPER: Objection, form.

A. Again, so -- so the insurance company makes a distinction between medically necessary, meaning things that they will cover, versus not medically necessary, meaning things they won't cover. It's not based on an actual medical diagnosis but a -- a managerial diagnosis, because if it's not medically necessary, it's not covered by insurance. So if they choose to cover it, they will call that medically necessary. And that's what they're detailing here, what they will cover and what they won't

cover.

Q. Okay.

A. And they call what they will cover medically necessary.

Q. Let me show you one last policy. Do you know -- strike that.

You know what UnitedHealthcare is; right?

A. Yes, I do.

Q. It's another health insurer; right?

A. Yes.

Q. They're the largest health insurer in the country; right?

A. I don't know that for a fact. I'll assume if you're telling me so.

Q. All right. Well, do you have any idea whether United considers gender-affirming surgery and hormone treatment to be medically necessary for gender dysphoria?

A. I have a dawning suspicion that they do.

Q. Yeah. I think you can probably tell where this is heading at this point; right?

A. Sure. The insurance industry likes these services.

Q. Let me introduce this next exhibit. This is going to be Exhibit 32. All right at the top it says, "United Healthcare." You see that?

(Exhibit 32 was marked for identification and is attached.)

A. I don't have it yet.

Q. Oh, I apologize.

A. That's okay.

Q. Let me know when.

A. Okay. Yes.

Q. All right. Top right says "United Healthcare" -- "Healthcare Commercial Medical Policy." Right?

A. Yes.

Q. Under that, it says, "Gender Dysphoria Treatment." Right?

A. Yes.

Q. See there's an effective date of April 1, 2021; right?
A. Yes.
Q. Also fairly recently updated; right?
A. Yes.
Q. Okay. And then you see there's a bunch of bullet points setting forth criteria for the services on page 1; right?
A. Yeah. Yes.
Q. Then go to page 2.
A. Okay.
Q. And the first full paragraph says, "When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit." Do you see that?
A. I do.
Q. Okay. So United also covers -- also considers this treatment to be medically necessary; right?

MR. KNEPPER: Objection to form.

A. Yeah, again, so the interesting thing about this that I'm just reading -- because, again, this is the first time I've seen this -- is that the same policy declares that the policy does not apply to individuals with objectively ambiguous genitalia or disorders of sexual development. So that's an example of the insurance company choosing what to call medically necessary based upon an insurance definition rather than a medical definition. Because under, you know, plastic surgical/general medical wisdom, ambiguous genitalia and disorders of sexual development are objective medical surgical -- well, medical conditions, at least, that would be covered -- would be considered medically necessary to treat, you know, because disorders of sexual development can include emergencies like adrenal hyperplasia. So that's a -- you've given

an example of how insurance companies make their own definitions for the sake of distinguishing what they will cover and what they will not cover.

Q. Go to page 9.

A. Okay.

Q. You see there's a section toward the bottom that says, "Benefit Considerations"?

A. Yes.

Q. Third paragraph says, "Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy." Do you see that?

A. I do.

Q. You understand that United considers not just surgery but all these other services, including cross-sex hormone therapy and puberty suppressing

medications, to be medic- -- medically necessary for the treatment of gender dysphoria; right?

MR. KNEPPER: Objection, form, scope.

A. Yeah, again, the same -- same issues of definition. So they -- they can define it any way they choose for the sake of the business of insuring people, yeah. So they -- they definitely have defined all of the services associated with gender dysphoria as covered benefits.

Q. And not just as covered benefits, as medically necessary; right?

A. Again --

MR. KNEPPER: Objection, form and scope.

A. Again, they use -- the use of the word "medically necessary" is defined by the insurance company to distinguish covered benefits from not covered benefits, and it's not based in medical

evidence of efficacy or anything else. It's just an internal definition for the sake of their business model.

Q. You think that insurers do not look at scientific literature in deciding whether or not to cover something?

MR. KNEPPER: Objection, form.

Q. Is that really what you think?

A. Your -- your first example that we've gone through is a -- is an example of the level of literature they've been using, and that example showed that the most recent paper that they used to support it was 2016. So in my mind, it's in doubt. I don't know for a fact what this particular policy used as references. All I have is what you've shown me on that particular policy. And the evidence there was they're not current in the -- in the literature. But they're still doing good business, apparently, because they continue even after reviewing.

Q. Okay. Go to page 10.
A. Okay. All right.
Q. See there's a section at the bottom that says, "Clinical Evidence"?
A. Yes.
Q. Do you know what that means?
A. Yes, I do.
Q. You see then the first thing that's said -- cited is a study from 2019 and the second thing is a study from 2019, the third thing is a study from 2019. You see that?
A. I do.
MR. KNEPPER: Objection, form.
Q. Do you under- -- do you understand what this section represents?
MR. KNEPPER: Objection, form.
A. Permit me to just look at the particular names and the particular cited articles, if I could.
(Witness reviews document.)
A. Sorry. I just wanted to see if there were any -- and then they go to --

okay. Okay. Could I ask you to ask your question again? I'm sorry to have to do that. I just wanted to see what you were referring to.

Q. Yeah. You understand that this "Clinical Evidence" section provides an overview of some of the scientific evidence on which United based its policy; right?

MR. KNEPPER: Objection, form.

A. Yes. They -- they have listed some of the scientific evidence available in the literature.

Q. Including studies as recently as 2019 --

A. Yes.

Q. -- right?

A. Right.

Q. And because you weren't involved with writing this policy or updating for United, you don't know what else they may have considered outside of this policy; right?

A. I have no way of knowing what they would have considered. That's right.

Q. Okay. All right. Let's shift gears a little bit. You've heard the term "Christian anthropology." Right?

A. Yes, I have.

Q. You've used that term yourself; right?

A. Yes, I have.

Q. The view that Christian anthropology takes is that the -- a person's sex assigned at birth is intrinsic and unchangeable; correct?

A. No.

MR. KNEPPER: Objection, form, scope.

A. I would not say that.

Q. What would you -- how would you describe it?

A. Well, your use of the term "sex assigned at birth" is not -- is not contained within Christian anthropology.

Q. Let me try this --
A. By the -- by the way, I don't -- I don't use definitions in Christian anthropology to confect my expert opinion. My opinion is based in the scientific literature, my review of that literature, and my 30-plus years' experience as a reconstructive surgeon.
Q. I understand. The view that Christian -- to use your words, the view that Christian anthropology takes is that a person's biologic sex is intrinsic and unchangeable; right?
A. Yes.
MR. KNEPPER: Objection, form, scope.
Q. You think that people with gender dysphoria should be welcomed, but they should be told that they're biological sex cannot be changed; right?
MR. KNEPPER: Objection, form, scope.
A. Yeah. So, persons who

self-identify as transgender are to be welcomed and are to be cared for because they suffer greatly, and they -- they deserve, in justice -- they deserve, out of justice, I should say, our -- our care and support. But that care and support must always be rooted in the truth of the nature of the human person, the nature of the biology that informs our understanding of that, because that has to drive our medical and surgical decision-making.

So that's why my -- my expert opinion is based in the objective scientific evidence. I don't make reference to my -- any faith statements when I'm -- when I'm developing my expert opinion on transgender medicine and surgery.

Q. In your expert report, you refer to plaintiff Julie -- Dr. Julie McKeown; right?

A. Could you walk me to where I

speak about her?

Q. Yeah. Go to -- go to page 54 of your report.

A. Fifty-four. Thank you.

MR. TISHYEVICH: And the spelling is M-C-K-E-O-W-N.

A. Fifty-four. Okay. I'm there.

Q. Give me a second. Yeah. This is -- this is you discussing one of the plaintiffs; right?

A. Yes. Yes. I'm on page 53, 54.

Q. Yeah. And the second full paragraph on page 54, you refer to Dr. McKeown as a he; right?

(Witness reviews document.)

A. Am I looking at the right -- oh, yes. Okay. I'm sorry. Right at the very beginning. Yes.

Q. Page 48 of your report, this is you discussing minor plaintiff CB; right?

A. Right.

Q. And you refer to minor plaintiff as a she; right?

A. Correct.
Q. Go to page 51.
A. Fifty-one?
Q. Five one.
A. Okay. All right.
Q. This is you talking about plaintiff Connor Thonen-Fleck; right?
A. Let me go to the preceding page because I've got to see where the names -- oh, I only used the initials. Yes. CT-F, yes.
Q. It's T-H-O-N-E-N, dash, F-L-E-C-K. And you refer to him as a she; right?
A. Yes.
Q. Now, you personally do not believe that a person's sex assigned at birth can ever be changed?
MR. KNEPPER: Objection.
Q. Sorry, let me -- let me use your terms. You personally do not believe that a person's biological sex can ever be changed; right?

MR. KNEPPER: Objection, form.

A. A person's biological sex can never be changed, yes.

Q. Do you know what the term "misgendering" is?

A. It's a -- it's a political term, yes. It's a political, cultural term, I should say. Political, cultural term.

Q. Misgendering means referring to a person in a way that doesn't align with their gender; right?

MR. KNEPPER: Objection, form.

A. In -- within their hearing, I could see a problem with that. But from the standpoint of offering medical evidence, I'm obliged to honor objective biological realities when I speak about an examination of their medical record.

There's so many things at stake relating to the sex of the patient that impinge upon the effects of drugs, the effects of time, the effects of hormones that I -- I cannot incorrectly report the

sex of the patient when I'm talking about objective medical care.

Now, speaking with the patients themselves, I wouldn't do that. As we talked about earlier, I have a number of transgender patients, and I don't misgender them. We're talking here about something that's not within their hearing or I assume they -- I assume that they wouldn't be reading this. We're speaking as a professional to a professional review of this stuff, among other experts. So I think it's essential that we stick to the biological reality that -- that biological sex is immutable.

Q. In your expert report, you are misgendering several of the individual plaintiffs in this case; correct?

MR. KNEPPER: Objection, form.

A. I would say incorrect, because misgendering is something that's done to the person themselves or is something that they're going to read or hear or

see. And that's an abuse of the person's right to their name, and I don't do that to people. I don't misgender people.

Q. Well, in this report at least, you are referring to several of these plaintiffs, including a minor, in a way that does not align with their gender; right?

A. I would be --

MR. KNEPPER: Objection, form.

A. Again, I would be concerned to not do that if it was going to be something they were going to read or hear. But this expert testimony, in my understanding, is for the Court and for the other experts to review, in which case, I insist upon the -- the prevailing necessity of sticking to objective truths when talking about medical opinions, scientific opinions.

Again, I -- I'm not in the habit of -- of offending people or using names that they haven't chosen, because, again,

I treat transgender patients and I don't subject them to that kind of abuse. But when reviewing medical and biological realities like this, I have to insist upon it because medical care is not served by incorrectly naming biological realities and confusing people. I can give you an example if you like.

Q. That's all right.

A. Of a --

Q. That's all right.

A. Okay.

Q. You've used the phrase before, "You can't heal an interior wound with external surgery." Right?

A. Yes, I have.

Q. Do you remember giving a presentation at the Gospel of Life conference in Denver in 2018?

A. Yes.

Q. And that presentation was titled "Transgender Surgery & Christian Anthropology." Right?

A. Yes.

Q. All right. Let me introduce an exhibit. This will be Exhibit 33. Let me know when you have it.

(Exhibit 33 was marked for identification and is attached.)

A. Okay. Yes, I have it.

Q. Go to page 2.

A. Okay.

Q. These are slides you prepared; right?

A. Yes.

Q. On the bottom left corner, there's a red logo for Courage International. You see that?

A. I do.

Q. Why did you include that logo in this presentation?

MR. KNEPPER: Objection, form, scope.

A. This was a presentation for the Archdiocese of Denver, the Catholic Archdiocese of Denver, and it was to an

audience of pastors, teachers, school administrators, and so on. And I was there representing my position in the Catholic apostolate of courage, and so making a presentation to a church group, I wanted them to understand the resource so that they could investigate it themselves if they wanted to. So I put that up there for their benefit.

Q. Well, some of the topics you covered also included your views on what the scientific evidence on these issues is; right?

A. Yeah. The -- the talk is a combination of both the scientific evidence and the historic Catholic teachings on the nature of the human person.

Q. For example, go to page -- go to page 87, for example.

A. Okay. Let me hustle down there. Boy, no wonder people get bored when I give this talk. It's so long; right?

Let's see. 87. Here we are. Is that -- let's see. This is -- I want to make sure I'm on the same page as you are. It's of the --

Q. It's titled "The Swedish Study" --

A. Yes.

Q. -- at the top.

A. Yes, yes.

Q. And go to the next page.

A. Okay. Yeah.

Q. You cite from the abstract on that study; right?

A. Yes. Well, I -- I'm not citing it. I'm showing them what this study looks like if they search for it online.

Q. So part of the talk was your recitation of what you think the scientific evidence on these issues shows; right?

MR. KNEPPER: Objection, form, scope.

A. Yeah, I was asked to talk on

this -- on -- on both subjects, as I said earlier, both the -- the teaching in human anthropology as well as the scientific evidence that's used to support these services of transgender medicine and surgery. That's right.

Q. Courage International is an organization that offers support for persons who experience same-sex attraction; right?

A. Yes.

MR. KNEPPER: Objection, form, scope.

Q. Courage International says that people should not act on same sex attraction and should strive for chastity instead; right?

MR. KNEPPER: Objection, form, scope.

A. Actually, it's broader than that. So, Courage addresses chastity as something that's required of everyone. But it -- it particularly addresses the

struggles that persons who experience same-sex attraction experience in trying to maintain the same chastity that all of us are called to. So it's not an exceptional case; it's a particular apostolate to a particular group of people.

Q. There's a chapter of Courage International in Birmingham, Alabama; right?

A. That's correct.

MR. KNEPPER: Objection, form, scope.

Q. And their website lists you as the main contact for that chapter; right?

A. I'm not only the contact, I'm the chaplain for that chapter.

Q. Okay. Go to page 3 of this presentation.

A. Okay.

Q. Let me know when you get there.

A. Okay. Two, three. Yes. The Challenge?

Q. It's titled "The Challenge"?
A. Yeah.
Q. The first bullet says, "'Male and female He created them.'" Right?
A. Right.
Q. That's a quote from Genesis; right?
A. Correct.
Q. The capitalized "He" refers to God; right?
A. Yes.
Q. And this bullet reflects the church's position that God has created each individual as either a man or a woman; right?
A. Well, actually, so this -- these slides serve as jumping-off points for a discussion that I have at each slide. In this case, the point of the discussion was to disabuse the audience of the idea that they can rely on scripture when addressing this problem because the majority of the people that are seeking

to serve do not speak in Biblical language. So the point of this slide is to -- is to encourage them to understand that they have to learn a new language in order to be able to speak effectively to people suffering from gender discordance and to speak to their families on this same issue. That's what this slide is about. It's not a -- it's not a declaration about what God has said. It's a -- it's an explanation of the problem they're going to have if they're going to seek to serve people who experience same-sex -- I'm sorry, who experience cross-sex identification.

Q. All right. You say, "'Male and female He created them' has been replaced by a confusion of exceptional cases." Right?

A. Yes.

Q. And by the phrase "confusion of exceptional cases," one of the things you're referring to are patients with

gender dysphoria; right?

MR. KNEPPER: Objection, form, scope.

A. Right. I'm referring to the -- the recently growing list of exceptional cases that is enumerated in the -- the acronyms of -- of this topic, LGBTQ add a plus and so on, which can be very confusing to people who are trying to help. And so I'm acknowledging that the -- the likelihood that they may be confused by those terms, and I'm also acknowledging the sources of those confusing terms. And the point of the slide, again, is to help them understand there's a language they need to learn and to not be daunted by the confusion that they may experience when they first look into this topic. Yeah. That's what this is.

Q. Go to slide 11. It's titled "Human Nature."

A. So slide 11, Human Nature, yes.

Okay.

Q. So the first two bullets say, "Why must we consider first the nature of the human person?" Then it says, "Defines the 'end' of medical and surgical care."

A. Yes.

Q. What does it mean that it "defines the 'end' of medical and surgical care"?

MR. KNEPPER: Objection, form, scope.

A. Okay. So that's a -- that's a term that dates back to Aristotelian philosophy. And what it has to do is what is the purpose or what is the ultimate arc of a particular thing. So the "end" meaning what are you seeking to accomplish, what is the final goal of that -- of that medical or surgical treatment.

So -- and the examples I use are you have to have an understanding, for

example, of normal blood pressure in order to know when to treat it and why normalizing blood pressure is important. Or we have to know that, you know, the human person has two legs, and if he has a poverty of legs, he has a poverty of human flourishing. And so in the one case, I might be treating with blood pressure medicine, and in the other case, I might be fitting him for a prosthesis. But the point is we have an objective understanding of the nature of the human person, which defines the goals of treatment, whether you're talking about orthopedics or transgender medicine.

Q. Yeah. You think this concept also applies to the concept of treatment for gender dysphoria; right?

A. It does. Yes, it does.

MR. KNEPPER: Objection, form, scope.

Q. All right. Go to slide 23.

A. Okay. Okay.

Q. The top left says, "Shaping the Conversation, & Grooming a Generation."

A. Right.

Q. You see that?

A. Right.

Q. What do you mean by "grooming a generation"?

A. Grooming is a -- is a process by which ideas are introduced that make subsequent actions possible, so that's what -- that's what grooming is, yeah.

Q. Grooming is sometimes used to refer to preparing to -- strike that.

Grooming is sometimes used as preparing children for sexual abuse. Isn't that true?

A. That's one of the --

MR. KNEPPER: Objection, form, scope.

A. That's one of the uses of grooming, yeah, but it's not exclusive use of grooming. Yeah. And I discuss this in this -- in this slide. Yes, I

do.

Q. And you think that discussing gender identity issues with children means sexualizing them; right?

A. Yes, I do. Absolutely, I do.

MR. KNEPPER: Objection, form, scope.

Q. And you think that discussing gender identity issues with children means grooming them for potential later sexual abuse; right?

MR. KNEPPER: Objection, form, scope.

A. No. No. What we're talking about here is grooming them for -- for future -- what's the word I would want to choose carefully? It's preparing them for these interventions is what it does. It lays the groundwork for it by sexualizing their thoughts in a way that's -- is not consonant with their best interest. That's what this slide is about, so --

Q. Let me introduce another exhibit.

A. Okay.

Q. This will be Exhibit 34.

(Exhibit 34 was marked for identification and is attached.)

A. Could I back up to that last one? Would that be all right?

Q. Sure.

A. Before we -- before we press on. One of the things I'm just recalling, the -- the -- the urgency of having that particular slide there is that when people take care of transgender persons, children in particular, we always -- but including adults. But -- but children and adults, one always has to be on the lookout for signs of sexual abuse because it's a very -- it's a very commonly reported comorbidity in persons who experience these self-identifications. It's not uncommon to discover that they've suffered some form of abuse that

may be sexual but not necessarily sexual. And so this is -- one of the things I talk about in that slide is -- is for the people who are care providers, counselors, school administrators, to be alert to that possibility.

So I'm sorry, we were going to move on to the next one.

Q. Do you have the next exhibit?

A. And that is Exhibit 34?

Q. Yeah.

A. Okay.

Q. All right. This is a printout from LifeSite, and the title is "Plastic surgeon: Sex-change operation 'utterly unacceptable' and a form of 'child abuse.'" Right?

A. Yes.

Q. And it says, "Dr. Patrick Lappert, a Catholic deacon in Alabama, says changing a person's sex is a lie and also a moral violation for a physician." Right?

A. Yes.
Q. And you hold those views --
A. I do.
Q. -- correct?
A. I do.
MR. KNEPPER: Objection, form, scope.
Q. Go to page 2.
A. Okay.
Q. This was published in September 2019; right?
A. Yes.
Q. This is reporting on you appearing on a broadcast of something called the "Relevant Radio's Trending With Timmerie."
A. Yes.
Q. Right?
A. Yes.
Q. You made that appearance; right?
A. On the radio, yes.
Q. Okay. Look -- look to the fifth paragraph on page 2.

A. Okay.

Q. It says, "He called it 'utterly unacceptable' on moral grounds for a plastic surgeon, because it disregards the surgeon's call to balance respect for both form and function of the body in his or her work."

A. Right.

Q. Right?

A. Yes, sir.

Q. You don't deny saying that; right?

A. Right. You should understand, though, that the use of the term "moral grounds" here is strictly from the standpoint of my training as a plastic surgeon. I'm not using this as a platform for a religious discussion. Speaking -- I'm speaking about form and function, which are both very crucial to an understanding of what plastic surgery means.

And again, that speaks to the

end of plastic surgery, which is -- when you're speaking about reconstructive surgery, it's the restoration of form and function. And these operations lack moral basis precisely because they destroy essential human functions for the sake of achieving a cosmetic result, which is morally unacceptable. And I say that without reference to any religious teaching. This is strictly my training as a plastic surgeon, morally unacceptable. And from the first moments of my training as a reconstructive surgeon, that was drilled into me, that if you're planning a reconstructive operation and it involves the movement of tissue on the patient's body, you never do something that's going to compromise or destroy an essential human function.

You may challenge that function a little bit, as you do, for example, in a radial forearm flap, the same flap that's used to recon- -- to construct a

phalloplasty. I've used that flap many times to reconstruct head and neck cancer defects, the same neurotized vascular flap. And I would never dream of using that flap, for example, if I was going to compromise hand function. So it obliges me to be careful, to make sure that when I raise the flap, I don't harm the blood supply to the hand. That's an example of that.

In the example of transgender surgery, by definition, you're destroying fertility for life, which is an immoral act in the eyes of plastic surgery as I learned it through 30-plus years of training.

Q. I understand. Let me just ask you about the next two paragraphs --

A. Okay.

Q. -- of this article.

A. Okay.

Q. Then it says: "Regarding children, Lappert said, sexualizing them

at a young age with these ideas is grooming them for later abuse. 'It's atrocious,' he said. 'And no one even knows how that's going to play out. There's no body of scientific evidence to even support the safety of doing that to children. But it's being done.'" Right?

MR. KNEPPER: Objection, form, scope.

A. Okay. So, let's go through that. So in this case -- we talked about multiple uses of the word "grooming." In this case, the abuse that they're -- it's grooming them for is the abuse we just finished discussing, what I consider to be the abuse of transgender medicine and surgery and what it does to the life of that child. So that's the abuse I'm referring to here. I'm not speaking about this in terms of sexual abuse, I'm speaking about in terms of medical/surgical abuse of a child. So if you get a child -- if you sexualize a

child's thinking and encourage them to believe, for example, if -- if -- if I -- and I don't want to take up your remaining time, but we can go into it in more detail if you wish. But the point I'm making here is this is grooming them for medical and surgical abuse.

Q. Okay.

MR. TISHYEVICH: We can go off the record.

THE VIDEOGRAPHER: This is the end of Media Unit 6. We are off the record at 5:07 p.m.

(Break taken.)

THE VIDEOGRAPHER: This is the beginning of Media Unit No. 7. We are on the record at 5:14 p.m.

Q. (By Mr. Tishyevich) Doctor, that's all the questions I have for you today. Thanks for your time.

A. Thank you. This was my first ever deposition, and you were very kind to me. Thank you for that.

Q. Okay.

MR. TISHYEVICH: All right. Mr. Knepper?

MR. KNEPPER: Yeah, I'm ready to go. I'm sorry. I actually had you turned down, because when I put you on mute, I could still hear Lane and Andrew. I thought I saw their lips moving.

THE COURT REPORTER: Yeah, he said he was finished asking questions.

MR. KNEPPER: Oh, I'm sorry. I didn't hear that. I'm sorry, Dmitriy. I apologize. I had -- you know, Lane and -- and Andrew were talking to one another, and so I was -- I had to turn down my speaker.

So I guess why don't we -- why don't we take a -- I've got 4:15. Why don't we take a 15-minute break, and then I'll see if I have anything on redirect, and we'll come back at I guess it would be 6:30 your time, Dmitriy?

MR. TISHYEVICH: Yeah.

MR. KNEPPER: Okay.

MR. TISHYEVICH: Sounds good.

THE VIDEOGRAPHER: We are off the record at 5:15.

(Break taken.)

THE VIDEOGRAPHER: We are back on the record at 5:29 p.m.

EXAMINATION BY MR. KNEPPER:

Q. Dr. Lappert, I wanted to ask you a couple of questions about your CV and your biography.

A. Okay.

Q. On your biography, you identify yourself as the Specialty Leader for Plastic and Reconstructive Surgery, the Office of the Surgeon General - United States Navy, from 1997 to 2002. Could you describe what that position involved?

A. Yeah. So I advised the Surgeon General, first of all, with regard to the selection of physicians for advanced training in plastic surgery. I also

advised the Office of the Surgeon General on policy matters pertaining to the movement of patients and the availability of services in the various treatment facilities. I also advised him on policy relating to coverage of particular medical problems versus sending them out into the community for care or declining care.

So part of it was resource management, part of it was personnel management, and part of it was financial management. And all the time, it required to review the state of the literature regarding reconstructive surgery for combat-injured and as well as medically retired personnel and other retired people.

Q. And I -- I note that also in your resumé is that from 1996 to 2002, you were the Chairman of the Department of Plastic and Reconstructive Surgery at Naval Hospital Portsmouth. Could you

describe that -- that facility and its role within the United States military?

A. Okay. Well, that -- as department head, I was -- I had a five -- five staff plastic surgeons working for me. I had I think seventeen hospital corpsmen working for me. And we provided services, reconstructive surgical services on a referral basis from -- essentially from the eastern Mediterranean all the way to Appalachia and from North Carolina -- I'm sorry, from -- from Maryland all the way down to Florida. So all persons requiring reconstructive surgery, including combat-injured or other, would be referred to us, people with congenital deformities, peop- -- you know, pediatric patients and -- and adults. And this was in a -- in the facility which at the time was the largest medical treatment facility in -- I think in the world, certainly in -- in the American purview.

I also -- I also established and ran congenital craniofacial deformity treatment. We ran a limb salvage treatment that involved a great deal of microvascular reconstructive surgery for wounds, cancer, that sort of thing. We also established the -- the wound care center for that facility, and that -- again, we served that large catchment area with advanced wound care services.

Q. Dr. Lappert, you served as a -- as a plastic and reconstructive surgeon for the United States Navy. Is that correct?

A. Correct.

Q. And you also served as a plastic and reconstructive surgeon in private practice. Is that correct?

A. Correct.

Q. Could you describe the -- or contrast or describe the similarities and differences in those two practices.

A. Certainly. Well, so both

practices involved both reconstructive surgery and aesthetic cosmetic surgery. But the difference is that in the military, because of the nature of the requirements, the experience level grows much more rapidly in the military than it does in the civilian world. So within the first couple of years of my practice as a reconstructive surgeon in the Navy, I was doing the most advanced reconstructive procedures, such as the mi- -- the neurotized microvascular flap operations that are often used, for example, in the phalloplasties of transgender surgery, or the perineal vaginal reconstruction for cancer, same operations that are used in the vaginoplasty for transgender self-identified persons. So a very advanced complexity.

In fact, when I sat for my boards, my oral boards, we had to present ten selected cases that the board

selected, and both of my examiners were startled at the level of complexity for a second-year person out of training, doing craniofacial surgery, free flap operations, massive limb salvage surgery. So that's the distinct difference, what you get in civilian versus what you get in the military. But both of them involved reconstructive as well as aesthetic cosmetic surgery.

Q. Sure. Now earlier, you were asked about whether you had performed certain procedures in the context of transgender surgery. Is that correct?

A. Yes, sir.

Q. And your answer was that you had not. Is that correct?

A. That's correct.

Q. Have you done those procedures in the context of your practice of plastic surgery?

A. I have.

Q. Could you describe that --

those -- those circumstances.

A. Well, as an example, a -- a very memorable case, a patient with what's called Fournier's gangrene, where essentially, they had a massive uncontrollable infection of the perineum that destroyed the scrotum, destroyed major portions of the penis, required what amounts to a reconstructive phalloplasty/scrotoplasty to reconstitute them after a long period of wound care. But the -- the operations to reconstruct the urethra is the same operation that's used to construct the urethra in a phalloplasty or construct the urethra in a metoidioplasty, same operations involving local flaps, mucosal grafts, tubularized flap operations. All of those are the same. Just the indication for the surgery is reconstructive rather than the surgeries for transgender.

Same thing with the vaginoplasty. Again, often --

oftentimes, reconstruction for radiation injuries secondary to management of vagineal -- vaginal perineal malignancies that require removal of large areas of soft tissue, again reconstruction of the -- the perineum, the external genitalia, the vaginal introitus, the vaginal canal, same operations using flaps, grafts to reconstruct as are used in the transgender surgery world.

Q. So, do you feel that your professional experience and qualifications allow you to comment on the -- the medical operations involved in surgery for a transgender individual?

A. Yes. I'm -- I'm very familiar with all of those operations.

Q. And -- and you've performed those operations?

A. Yes, I have.

Q. Okay. Just not in the context of gender transition?

A. That's correct.

Q. Okay. There was a -- there was a brief question, and -- and we didn't get back to it, about one of the articles on your CV on breast reconstruction. Is that -- is that correct?

A. Right. Yeah, that's one of my listed articles. That's right.

Q. Great. Did you want to -- did you want to say more about that article?

A. Yeah. So, that's -- was really my entrance into the breast reconstruction world. That actually started when I was still a general surgeon and I was collaborating with a plastic surgeon, and we examined the surgical planning for mastectomy in the setting of breast cancer or other causes and -- and the surgeon's role in designing those operations to get the best possible outcome. And it was actually a seminal article, up until recently was the most quoted article in the literature on breast reconstruction.

And that was actually the first article that spoke about conservation surgery in surgical planning for the treatment of breast malignancies or other breast problems.

Q. Dr. Lappert, you were asked questions about the policy or position statements of several professional organizations. Do you recall those questions?

A. I do.

Q. Did those exhibits or any of the questions change your opinion that affirmative hormonal treatment and surgery remains unproven and experimental?

A. It has not changed my opinion.

Q. You were asked questions about the evidence supporting the provision of hormonal therapy and surgical interventions for the treatment of gender dysphoria. Is that correct?

A. Yes.

Q. Were any of the questions or any of the studies that were presented to you, did they change your opinion that the existing medical evidence supporting those interventions is of very low quality and has methodological defects?

A. That did not change my opinion about those, no.

Q. And just to clarify, what is your opinion about the -- about the current state of the evidence supporting hormonal therapy for treatment of gender dysphoria?

A. My opinion is that all of these published studies that are used to support or to justify the use of puberty blockade, cross-sex hormones, or transgender -- gender-affirming surgery are of the lowest quality scientific evidence and are not sufficient to support care and interventions that have such far-reaching and lifelong effects on the patient.

Q. Are your opinions on that -- on that issue in this case based on anything other than your review of the scientific and medical literature and your training as a -- as a physician?

A. No, they're not.

Q. Dr. Lappert, you were asked about off-label use of Botox for certain muscle -- muscle groups. Is that correct?

A. Yes, I was.

Q. And you -- and you described -- and you stated that you've actually used Botox off label for treatment of those muscle groups before that was approved by the FDA. Is that correct?

A. That's correct.

Q. But you have also said that you believe that it is significant and -- and relevant to this case that the use of hormone and puberty blockers for treatment of gender dysphoria is off-label. Is that correct?

A. Yes.

Q. Could you disting- -- distinguish between why you hold the view that off-label uses of some pharmaceuticals is acceptable by a -- by a physician and when you consider that to be unacceptable by a physician?

A. Right. So, the off-label use of medications when there's a low risk to the patient or that the -- the possible adverse effect may be brief and that a favorable result is likely where risk is low, then that's justifiable to go off label with medications. But when you're -- when you're talking about significant risk to the patient and irreversible changes, that the off-label use places a tremendous burden on the practitioner to -- to have scientific evidence to support his decision to do that. And to not have sufficient evidence when doing that is a -- is a -- is a great difficulty in terms of consent and in terms of just general

medical/surgical decision-making.

So the distinction is the risk/benefit equation. How much risk are you placing the patient under, is it irreversible, and is the benefit so great that it's worth taking the risk.

Q. Sure. Just to follow up, and these are going to be my final questions, is it your view that there are no -- and does it continue to be your view that there are no -- currently no competent -- competently conducted long-term, peer-reviewed, reliable, and valid research studies documenting the number or percentage of patients who receive gender-affirming medical interventions who are helped by such procedures?

A. It's still my position that -- that the medical literature does not support those interventions of medical and surgical treatment for self-identified transgender persons.

Q. Is it still your view that there

are no published, reliable, and valid research studies that document a valid or reliable biological, medical, surgical, radiological, psychological, or other objective assessment of a -- of a patient's gender identity or gender dysphoria?

A. Yes. It's still my position that there are no tests that will confirm or refute the diagnosis of transgender, a diagnosis made by the patient. There's no way to test for that.

Q. All right. Is it still your view, after the evidence and the questions that you've been presented, that an unknown percentage of patients who present with gender dysphoria also suffer from mental illnesses that complicate and may distort their judgments and perceptions of gender identity?

A. Yes. The -- the world literature demonstrates a consistent and

significant level of comorbidities, including severe anxiety, major depression, self-harm. The patient is very likely to be on the autism spectrum. Suicidal ideation. And -- and the world literature supports that. So -- and those are -- those are serious issues, not only in terms of decision-making, but even on the question of consent and competence for consent.

Q. Just one -- one more thing I wanted to follow up with. Your testimony -- we didn't cover this, but I want to make sure that it's still your view that medical treatments may differ significantly by sex according to your chromosomal assessment but not based on your gender identity and that misinforming physicians of a patient's biological sex could have deleterious effects on treatment for medical conditions?

A. Yes, that's correct. And when

we discuss the issue of misgendering, that's what we were talking about. We were talking about placing the patient at risk. If you're having a -- a discussion or conversation about medical decision-making, you have to distinguish between biological male and female because you run -- there -- there are illnesses that predominate in females that don't exist in males; there are conditions that affect males that do not affect females, and you have to know that if you're going to offer care. But again, that hasn't been changed by -- by what I've seen or heard here today. That's still -- is still the case.

Q. Okay. And it's still your view that the use of hormones and surgery to treat gender dysphoria is not supported by the relevant scientific communities as discerned by your literature review and your training as a physician in reconstructive and plastic surgery?

A. Yes.

MR. KNEPPER: Those are my questions. I don't think I have anything else. Did you have follow-ups you wanted, Dmitriy?

MR. TISHYEVICH: Very, very briefly.

MR. KNEPPER: Okay.

EXAMINATION BY MR. TISHYEVICH:

Q. Doctor, you were just asked about your views on why it's okay to use Botox off-label but you have a different view of puberty blockers. Do you recall that?

A. I do.

Q. And one of your considerations is the risk/benefit profile of Botox; right?

A. Right.

Q. Do you know what a black box warning is, Doctor?

A. Yes.

Q. It's the strongest warning that the FDA can require; right?

A. That's -- that's right.

Q. And that warning is typically only used if studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects; right?

A. Yes.

Q. Do you know that Botox has a black box warning?

A. Yes, I do.

Q. It's for distant spread of toxin effect; right?

A. Yes.

Q. And the use of Botox has -- has resulted in reports of life-threatening injuries and death; right?

A. I'm even familiar with the case reports that reported that. Yes, sir.

Q. Okay. That's all I've got for you.

MR. KNEPPER: Okay. Thank you,

Dr. Lappert.

THE WITNESS: Thank you.

MR. KNEPPER: We're finished with your testimony.

Thank you, Dimitry. Thank you, Lane. Thank you, Andrew.

We can go off the record.

THE VIDEOGRAPHER: This is the end of Media Unit No. 7. We are off the record at 5:47 p.m. Thursday, September 30th, 2021, and this concludes today's testimony given by Dr. Patrick Lappert.

END OF DEPOSITION

(5:47 p.m.)

C E R T I F I C A T E

STATE OF ALABAMA)
COUNTY OF JEFFERSON)

I hereby certify that the above and foregoing proceeding was taken down by me by stenographic means, and that the content herein was produced in transcript form by computer aid under my supervision, and that the foregoing represents, to the best of my ability, a true and correct transcript of the proceedings occurring on said date at said time.

I further certify that I am neither of counsel nor of kin to the parties to the action; nor am I in anywise interested in the result of said case.

/s/ Lane C. Butler
LANE C. BUTLER, RPR, CRR, CCR
CCR# 418 -- Expires 9/30/22
Commissioner, State of Alabama
My Commission Expires: 2/11/25

John G. Knepper, Esquire
john@knepperllc.com

October 13, 2021

RE: Kadel, Et Al v. Folwell
9/30/2021, Patrick Lappert, M.D. (#4814384)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at erratas-cs@veritext.com

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Yours,
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Kadel, Et Al v. Folwell

Patrick Lappert, M.D. (#4814384)

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Patrick Lappert, M.D. Date

Kadel, Et Al v. Folwell

Patrick Lappert, M.D. (#4814384)

ACKNOWLEDGEMENT OF DEPONENT

I, Patrick Lappert, M.D., do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____

Patrick Lappert, M.D. Date

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.

EXHIBIT 3

- +About Us
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- +Hand Surgery Exam (HSE)
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- Guidelines for Stating Certification Status

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  - American Board of Medical Specialties
  - Federation of State Medical Boards

- Contact Us

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GUIDELINES FOR STATING CERTIFICATION STATUS

The American Board of Plastic Surgery (ABPS) is very proud of its diplomates who have achieved Board Certification, Hand Surgery subspecialty certification or recertification and those who are participating in the Continuous Certification in Plastic Surgery Program.

Many diplomates include information about their certification status on letterhead, business cards and other materials. Board certification is an important marker of your competence and skill, and the ABPS encourages you to showcase this accomplishment with your patients, your colleagues and the public.

ABPS does not mandate the specifics of how diplomates state their certification, except to assert that diplomates should not state or imply that they are certified if their certification has expired. If you have multiple certifications by ABMS member boards and allow one of them to lapse, you should revise your public materials (letterhead, business cards, advertisements, websites, etc.) to reflect those certifications that are currently valid.

We ask that you follow these guidelines throughout your career to accurately state your ABPS certification.

- Diplomates of ABPS must accurately state their certification status at all times. This includes descriptions in Curriculum Vitae, advertisements, publications, directories, letterhead and websites.

- Diplomates with expired time-limited certification or those whose certification is revoked may not claim Board certification by ABPS and must revise all descriptions of their qualifications accordingly.

When a physician misrepresents certification status, ABPS may notify local credentialing bodies, licensing bodies, law enforcement agencies and others.

Note: The Board does not allow the use of its trademarked logo on diplomate or candidate websites or for any other commerical purposes.

Examples of accurate statements of certification:

Once you have successfully passed your initial certification examination or renewed your certification through the Continuous Certification program, you may represent that you are “ABPS Board Certified in Plastic Surgery (with a sub-specialty certification in Hand Surgery – if applicable)" or a “Diplomate of the American Board of Plastic Surgery”:

- **John Doe, M.D., ABPS Board Certified in Plastic Surgery**

or

- **John Doe, M.D., a Diplomate of the American Board of Plastic Surgery**

Important: Please be sure to correctly state your certification status in your Medical Licensing Board Profile. In addition, pay close attention to your group practice listings. A blanket statement that everyone in a group is Board certified may be misleading if multiple specialties are listed and some group members are certified in certain specialties and others are not currently certified. ABPS expects that certifications will be listed individually or stated in a way that is not misleading. Aside from accuracy and ABPS requirements, inaccurate statements of certification may create embarrassment or legal issues. ABPS understands that maintaining currency in stating the certification status of groups of physicians may not be easy. We encourage you to work with your colleagues to be sure the certifications you represent to the public are current and accurate.

Refer to the Board's **Advertising Policy**.

Feel free to contact ABPS whenever you have a question about stating your certification.

Call the Board Office at 215-587-9322, or send an e-mail to info@abplasticsurgery.org.

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Philadelphia, PA 19103-2204

Tech Support

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EXHIBIT 4

CODE OF ETHICS OF THE AMERICAN SOCIETY OF PLASTIC SURGEONS

(PLEASE NOTE: All complaints regarding possible ethical misconduct must be in writing and sent to:
EthicsComplaints@plasticsurgery.org or
ASPS Ethics Committee, 444 East Algonquin Road, Arlington Heights, IL 60005.)

PREAMBLE

As stated in its Bylaws, the American Society of Plastic Surgeons (ASPS) is organized:

To benefit humanity by advancing the art and science of plastic and reconstructive surgery; to promote the highest standard of professional skill and competence among plastic surgeons; to promote the exchange of information among plastic surgeons; to promote the highest standard of personal and professional conduct among plastic surgeons and other Members; to provide the public with information about the scientific progress in plastic and reconstructive surgery; to promote the purpose and effectiveness of plastic surgeons as is consistent with the public interest.

Membership in ASPS is granted to those surgeons who are competent practitioners of the art and science of plastic surgery. Competence in plastic surgery involves attainment and maintenance of high standards of medical and ethical conduct. Medical competence is fostered by successful completion of the examinations of the American Board of Plastic Surgery, The Royal College of Physicians and Surgeons in Canada and/or the Corporation Professionelle des Médecins du Québec. Ethical competence is fostered by the adoption and enforcement of a Code of Ethics, adherence to which is prerequisite for admission to and maintenance of membership in ASPS. Members are expected to act in accord with the General and Specific Principles of the Code of Ethics of ASPS in all their contacts with patients, peers and the general public. Further, Members are individually responsible and accountable for their actions and words, as well as the use of their names, by any individual or entity. Members shall be subject to disciplinary action, including expulsion, for violation of any of the General or Specific Principles of this Code.

Section 1: General Principles

I. The principal objective of the medical profession is to render services to humanity with full respect for human dignity. Members should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion.

II. Members should strive continually to improve medical knowledge and skill, and make available to their patients and colleagues the benefits of their professional achievements. Members have an affirmative duty to disclose new medical advances to patients and colleagues.

III. Members should practice a method of healing founded on a scientific basis, and should not voluntarily associate professionally with anyone who violates this principle.

IV. Members should observe all laws, uphold the dignity and honor of the profession, and accept its self-imposed disciplines. They should expose, without hesitation, illegal or unethical conduct of fellow Members of the profession.

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V. Members may choose whom to serve. In emergency situations, however, Members should render service to the best of their ability. Having undertaken the care of a patient, a Member may not neglect the patient; and until the patient has been discharged, a Member may discontinue services only after giving adequate notice.

VI. Members should provide services under the terms and conditions which permit the free and complete exercise of sound medical judgment and skill.

VII. A Member should seek consultation upon request, in doubtful or difficult cases or whenever it appears that the quality of medical service may be enhanced thereby.

VIII. A Member may not reveal a patient's confidence, any observed characteristics of the patient, or any information obtained from the patient in a professional capacity, without such patient's consent or unless required to do so by law or unless it becomes necessary in order to protect the welfare of the patient or of the community.

IX. The honored ideals of the medical profession imply that the responsibilities of the Member extend not only to the patient, but also to society. Activities, which have the purpose of improving both the health and well-being of the patient and the community, deserve the interest and participation of the Member.

X. To assist the public in obtaining medical services, Members are permitted to make known their services through advertising. Advertising, however, entails the risk that the Member may employ practices that are false, fraudulent, deceptive, or misleading. Regulation is, therefore, necessary and in the public interest. Subsection II of the Specific Principles permits public dissemination of truthful information about medical services, while prohibiting false, fraudulent, deceptive or misleading communications, and restricting direct solicitation.

XI. In their public and private communications with or concerning patients and colleagues made in a professional capacity or environment, Members shall strive to use accurate and respectful language and images.

Section 2: Specific Principles

I. Each Member may be subject to disciplinary action, including expulsion, if:

A. The member's right to practice medicine is limited, suspended, terminated, or otherwise affected in any state, province, or country for violation of a medical practice act or other statute or governmental regulation or the Member is disciplined by any medical licensing authority.

B. The Member fails to inform ASPS that the member's right to practice medicine has been limited, suspended, terminated, or otherwise affected in any state, province, or country for violation of a medical practice act, other statute or governmental regulation or, the Member has been disciplined by any medical licensing authority.

C. The Member is convicted of (or pleads guilty to) a felony or any crime relating to or arising out of the practice of medicine or involving moral turpitude.

D. The Member engages in sexual misconduct in the practice of medicine.

E. The Member is involved in improper financial dealings including, but not limited to:

1. Dividing a fee for medical service with another person licensed to practice medicine who is not a partner or associate of his or hers, unless

(a) The patient consents to employment of the other person licensed to practice medicine under a full disclosure that a division of fees will be made; and

(b) A division is made in proportion to the services actually performed and responsibility assigned to each; and

(c) The total fee charged by all persons licensed to practice medicine is not increased solely by reason of provision for the division of fees.

2. Payment and/or acceptance of rebates or referral fees to or from any person, including agents and employees of the member, in exchange for the referral of patients. Nothing in this Principle shall be construed to prohibit a Member from participating in a referral service, in which the member's paid participation is disclosed, where permitted by state law.

3. Charging exorbitant fees, particularly of a non-contractual nature (e.g., emergency care). Fees, whether for professional fees or associated with the use facilities owned in whole or in part by the Member, are exorbitant when they are wholly disproportionate to the services rendered and care provided. The reasonableness of fees depends upon the novelty and difficulty of the procedures involved; the skill required to provide proper care; the time and labor required; the fee charged for similar services by similarly situated peers; and whether or not the patient had agreed in advance to the fee. Members are responsible for ensuring the reasonableness and appropriateness of fees charged to patients and payors on such Member's behalf either directly or through third party billing services.

4. Except in instances of emergencies or urgent and life threatening disease or injury, nothing in this Principle shall be construed to prohibit a Member from requiring prepayment of professional fees for all elective surgical operations.

5. Nothing contained in this provision shall be construed to limit price competition among Members.

F. The Member uses, participates in or promotes the use of any form of public communication (as defined in Glossary to the Code) or private communication (as defined in the Glossary to the Code) containing a false, fraudulent, deceptive, or misleading statement or claim, including a statement or claim which:

1. Contains a misrepresentation of fact, or fails to state any fact that is necessary to make the statement not deceptive or misleading, when considered as a whole.

2. Omits facts or information of which the public ought to reasonably be informed before selecting a qualified plastic surgeon.

3. Contains photographs, images, or facsimiles of persons that falsely or deceptively portray a physical or medical condition, injury, disease, including obesity, or recovery of relief therefrom.

4. Contains photographs, images, or facsimiles of persons who have received the services advertised, but who have experienced results that are not typical of the results obtained by the average patient, without clearly and noticeably disclosing that fact.

5. Contains photographs, images, or facsimiles of persons before and after receiving services, which use different light, poses, or photographic techniques to misrepresent the results achieved by the individual.

6. Contains a testimonial or endorsement pertaining to the quality of the member's medical care if the experience of the endorser does not represent the typical experience of other patients or if, due to the infrequency and/or complexity of such care, results in other cases cannot be predicted with any degree of accuracy.

7. Contains a testimonial or endorsement pertaining to the quality of the member's medical care or the member's qualifications if the endorser has been compensated by the Member or a third party retained by the Member for making such testimonial or endorsement.

8. Is intended or is likely to create false or unjustified expectations of favorable results.

9. Contains a representation or statement of opinion as to the superior quality of professional services which is not susceptible to verification by the public or contains a statement representing that the Member possesses skills or provides services superior to those of other physicians with similar training unless such representation can be factually substantiated.

10. Appeals primarily to layperson's fears, anxieties, or emotional vulnerabilities.

11. Contains, in reference to any matter material to a patient's decision to utilize a member's services, a representation of fact or implication that is likely to cause an ordinary prudent person to misunderstand or be deceived, or fails to contain reasonable warnings or disclosures necessary to make a representation or implication not deceptive.

12. Contains a guarantee that satisfaction or a cure will result from the performance of the member's services.

13. States or implies that a Member is a board-certified specialist unless the Member is certified by a board recognized by the American Board of Medical Specialties, The

Royal College of Physicians and Surgeons in Canada and/or the Corporation Professionelle des Médecins du Québec.

14. Is not identified as a paid advertisement or solicitation unless it is apparent from the context that it is a paid advertisement or solicitation.

15. Is intended or is likely to attract patients by use of exaggerated claims.

G. The Member performs an unjustified surgical operation or a surgical operation that is not calculated to improve or benefit the patient.

H. The Member performs a surgical operation or operations (except on patients whose chances of recovery would be prejudiced by removal to another hospital) under circumstances in which the responsibility for diagnosis or care of the patient is delegated to another who is not qualified to undertake it.

I. The Member participates in a charity raffle, fund raising event, contest or other promotion in which the prize is any procedure, or an integral component of a procedure (e.g. breast implants), as defined in the Glossary to the Code.

J. The Member seeks or obtains a patent for any invention or discovery of a method or process for performing a surgical procedure or employs trade secrets, confidentiality agreements or other methods to limit the availability of medical procedures and the dissemination of medical knowledge.

K. The Member engages in unprofessional conduct in violation of the General Principles of the Code.

II. Advertising

A. Subject to the limitations of Section 2, I, F, a Member may advertise, including advertising through public communications media (as defined in the Glossary of the Code).

B. A Member shall not compensate or give anything of value directly or indirectly to a representative of the press, radio, television, or other public communication media in anticipation of or return for recommending the member's services. A Member shall approve all advertisements before dissemination or transmission, and shall retain a copy or record of all such advertisements in their entirety for one year after its dissemination. A Member shall be held personally responsible for any violation of the Code of Ethics incurred by a public relations, advertising or similar firm which he or she retains, or any entity that advertises on the member's behalf.

C. A Member may use photographs of models in his or her advertisements or other promotional materials. If photographs of models who have not received the services advertised are displayed in a manner that would suggest the model received the services advertised, the advertisement or other promotional material shall clearly and conspicuously state that the model has not received the advertised services.

III. Solicitation

A. A Member shall refrain from engaging in systematic verbal solicitation (as defined in the Glossary of the Code) of patients in person, by telephone, or through agents.

B. A Member shall not initiate contact with a prospective patient knowing that the physical, emotional, or mental state or degree of education of the person solicited is such that the person could not exercise reasonable judgment in employing a member.

C. A Member who has given unsolicited, in-person advice to a layperson that the individual should have medical or health care shall not accept employment resulting from that advice if:

1. The advice embodies or implies a statement or claim that is false, fraudulent, deceptive or misleading within the meaning of Article I, Section F.

2. The advice involves the use by the Member of undue influence, coercion, duress, harassment, intimidation, unwarranted promises of benefits, over-persuasion, overreaching, or pressure for immediate response.

3. The Member has been given notice that the individual non-patient does not want to receive a communication from the member.

IV. Expert Testimony

It is in the public interest that medical expert testimony be readily available, objective and unbiased. Members have an obligation to testify as expert witnesses when appropriate. However, Members may not accept compensation contingent upon the outcome of the litigation, nor agree to testify in any case where the Member has a conflict of interest (including, without limitation, where the Member is or has been the treating physician for the patient at issue or where the physician has a personal or professional relationship with the patient or plaintiff in the case). Members whose testimony, including testimony as to credentials or qualifications, is false, deceptive, or misleading may be subject to disciplinary action, including expulsion. Further to help limit false, deceptive and/or misleading testimony, Members serving as expert witnesses must:

1. Have recent and substantive experience (as defined in the Glossary of the Code) in the area in which they testify, including, without limitation, experience in the relevant subspecialty or the particular procedure performed on the plaintiff;

2. Thoroughly review the medical facts and testify to their content fairly, honestly, and impartially;

3. Be familiar with the standards of practice prevailing at the time of the occurrence,

4. Provide evidence-based testimony regarding the standard of care, citing peer-reviewed plastic surgery literature where possible and identifying personal opinion as such;

5. Demonstrate (or be prepared to demonstrate) a causal relationship between an alleged substandard practice and a medical outcome;

6. Neither condemn performance that clearly falls within the standard of care in the community nor endorse or condone performance that clearly falls outside of such standard of care; and

7. Not testify that a maloccurence is malpractice.

V. Conflicts of Interest

A Member's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises or other actual or potential conflicts of interest. Disclosure of professionally-related commercial interests and any other interests that may influence clinical decision-making is required in communications to patients, the public, and colleagues. When a Member's interest conflicts so greatly with the patient's interest as to be incompatible, the Member should make alternative arrangements for the care of the patient.

In the context of Member ownership interest in a commercial venture, the Member has an obligation to disclose the ownership interest to the patient or referring colleagues prior to utilization; the Member's activities must be in strict conformance with the law; and the patient should have free choice to use the Member's facility or therapy or to seek the needed services elsewhere.

VI. Enforcement

Any Member charged with a violation of any ethical standard set forth herein may be subject to disciplinary measures, including censure, suspension or expulsion, as described in Article XXII of the Society's Bylaws.

VII. Glossary

For purposes of this Code and unless the context otherwise requires,

A. "Electronic Media" includes websites, social media forums, blogs, video streams, discussion boards, digital platforms and any means of communication over the internet or similar virtual technology or networks.

B. "Private communication" includes any information, written or otherwise, that is disseminated by a Member and not made known to the general public or nor intended to be made known to the general public at the time it was made.

C. "Procedure" for the purposes of Section 2, Article I(I) of the Code, is defined as a medical service that requires an incision. Examples of services that require an incision include, but are not limited to, facelift, breast augmentation, blepharoplasty and liposuction. Examples of medical services that would not be considered procedures for purposes of Section 2, Article I(I) include, but are not limited to, injections (botulinum toxin, hyaluronic acid), microdermabrasion and other skin surface treatments.

D. “Public communication” includes any information transmitted orally, in writing, or through Electronic Media, the primary purpose of which is to communicate with the public, or a segment thereof.

E. “Public communications media” includes, but is not limited to, Electronic Media, television, radio, recorded video or motion picture, telephone, written correspondence, electronic mail/e-mail (other than those which are which are Private Communications), print (i.e. newspaper, magazine, book), marketing materials and branding (i.e. directory, business card, professional announcement card, office sign, letterhead, telephone directory listing or professional notice).

F. “Recent and substantive experience” means that the Member is familiar with the practice of plastic surgery and the particular procedure performed at the time of the occurrence that is the subject of legal action, was engaged in the practice of plastic surgery for a period of not less than three (3) years prior to the date of the occurrence and has performed the specific procedure in question within three (3) years of the date of being retained as an expert witness.

G. “Solicitation” is a communication to a specific individual to attract him or her as a patient.

STATEMENT OF PRINCIPLE OF INFORMED CONSENT

The American Society of Plastic Surgeons recognizes the Member-patient relationship as one of shared decision-making. Through a process of communication and dialogue the Member provides information that allows a patient and/or the patient's authorized representative to make individual choices about his or her medical treatment.

Shared decision-making is at the heart of the doctor-patient relationship and is based on the ethical principles of respect for individual autonomy and dignity.

The process by which Members and patients make decisions together is informed consent. For any surgical operation or treatment, relevant information must be provided, discussed, and understood by the patient and/or the patient's authorized representative. Relevant information for proper informed consent for any procedure may include, but is not limited to:

- Nature of the surgery or treatment
- Indications for the operation
- Expected benefits
- Consequences and side effects of the operation
- Potential risks and adverse outcomes with their probability and severity
- Alternatives to the procedure being considered, and their benefits, risks, and consequences
- Outcome anticipated
- Whether the operation or treatment is experimental or being applied in a manner not approved by the relevant regulatory authorities (e.g. an off-label use or without approval of an Institutional Review Board)

The patient and/or the patient's legally authorized representative(s) should sign a written consent form before any surgical procedures are performed.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DYLAN BRANDT, et al.,

PLAINTIFFS,

v. **No. 4:21-CV-00450-JM**

LESLIE RUTLEDGE, et al.,

DEFENDANTS.

DECLARATION OF DR. PATRICK W. LAPPERT

Pursuant to 28 U.S.C. 1746, I declare:

I. 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, which 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,

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Dr. Lappert

1991-1992. I also served as a Plastic and Reconstructive Surgeon, Naval Medical Center, Portsmouth, Virginia, 1994-2002 and as Chairman, Department of Plastic and Reconstructive Surgery, Naval Hospital Portsmouth, Virginia, 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, Virginia, 1996-2002 also as the Founding Director, Wound Care Center, Naval Hospital Portsmouth, Virginia, 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. I also served on the teaching faculty of the Via College of Osteopathic Medicine, 2017-2020.

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 I 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. I was 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, and I 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. Plastic 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 transi-

tioners 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 the State of Arkansas for the defense in connection with this 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. To formulate opinions in this case I have reviewed many scientific publications, case filings, and the plaintiffs' witness declarations.

11. **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 are 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.

II. GENDER AFFIRMING TREATMENTS ARE EXPERIMENTAL.

12. "Gender affirming" treatments remain experimental as the historic Branstrom study and National Reviews in England, Sweden, and Finland indicate. "Gender affirming" treatments (i.e., hormones and surgery) have not been proven effective, or even competently tested. Such "treatments" are not generally accepted by the relevant scientific community and have no documented error rates (See, Daubert/Kumho). 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 of the etiology of this condition, of the risks and benefits of the current experimental (unproven, untested) medical interventions, and of the long-term success of various "affirmation" treatments in achieving the primary desired goal of reducing mental illness including reductions in suicide risk.

13. Multiple 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 significant defects in the "low quality," contradictory, and controversial existing evidence. As we strive to provide real, effective, and sustained treat-

ment 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" are properly viewed as experimental. (See detailed citations in the "Notes" section of this report below).

14. 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, the Cochrane Review, and other reviews, and the collapse and recantation of the 2020 Branstrom long-term treatment outcome study (which proved *no benefits* to these "treatments") claims, all

appear contrary to the opinions of plaintiffs' experts, WPATH, and the endorsements of professional associations. (See detailed citations in the "Notes" section of this report below).

15. 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. The plaintiffs' experts failed to even discuss the serious defects and methodological limits of transgender medicine data and experimental practices. Fifty years of experimenting is enough. It is time for the transgender treatment industry to come up with real, competently constructed scientific evidence that they help more people than they hurt. As the recent national science reviews from England, Sweden, the Cochrane Review, and Finland have all noted, it is time to step back, slow down, and prudently investigate a range of approaches — including years of careful psychotherapy prior to experimental sterilizing "treatments" — to vulnerable patients struggling with gender discordance issues. (See detailed citations in the "Notes" section of this report below).

III. THE ETHICS OF PLASTIC SURGERY

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

16. When mastectomy is performed for the management of breast cancer, or to mitigate the proven risk of developing breast cancer in women, it is done on the basis of objective diagnoses either by pathological examination of biopsy tissue, or as in the case of prophylactic mastectomy, on the basis of genetic analysis that shows known markers of increased risk of developing breast cancer. These tests (microscopic examination of tissue specimens, detection of cell surface markers with proven association with malignancy, and genetic screening of at-risk patients) have known positive predictive value for the diagnosis of breast cancer, and these tests

have known error rates that can be used when obtaining informed consent for mastectomy. The validity of these tests has been proven using scientific methodologies that produce high quality evidence in longitudinal population studies with control populations, and very long follow up. As the result, when a woman gives consent for mastectomy to control or prevent the potentially lethal disease, it is with a clear and proven evaluation of the risks and benefits that consent is obtained. Mastectomy is being performed based upon an objective diagnosis of a potentially lethal condition, and the surgical procedure has proven benefit in management of that condition.

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

18. The best data presently available on the long-term effects of medical and surgical transitioning are long-term, longitudinal, population based studies. For example, Dehjne, et al., examined the putative long-term benefit of full transitioning (including hormonal and surgical treatments) found in the Swedish medical database. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). That database includes

all persons in the Swedish medical system, from pre-natal to death. It reports all episodes of care and all demographic information in a uniform vocabulary. Furthermore, Sweden has been on the forefront of "gender affirmation" long before the American medical system seriously considered its claims. Because of the nature of Sweden's database, it is possible to study a cohort of patients that exactly matches the inquiry group with regards to age, sex, economic status, etc. It is possible to ask precisely such questions as, "What is the likelihood that a fully transitioned transgender male will be hospitalized for psychiatric illness when compared to the age/sex matched control group?" or "What is the relative risk of suicide in transgender persons, when compared to age/sex matched controls?"

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

20. What did this Swedish study show us? It showed us that the risk of completed suicide in all transgender persons is *19.1 times higher* than in the control cohort. If you look only at patients who have transitioned — patients after "treatment" — from female to "male presentation," the risk of completed suicide is *40 times higher* than in the general population.

(Note: this finding is consistent with the historic Branstrom 10yr follow up study, which found no benefits to "transitioning treatments" but did note an increased risk of serious suicide attempts and anxiety disorders AFTER "treatment." (Correction to Bränström and Pachankis, Am J Psychiatry 177:8, August 2020; see detailed citations in the "Notes" section of this report below).

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

22. Similar issues of very poor, low quality scientific support for chest masculinization surgery can be seen in a recent article by Tolstrup et al. published in the journal Aesthetic Plastic Surgery (See Anders Tolstrup, Dennis Zetner, Jacob Rosenberg, Outcome Measures in Gender-Confirming Chest Surgery: A Systematic Scoping Review, Aesthetic Plast Surg 2020 Feb;44(1):219-228. doi: 10.1007/s00266-019-01523-1. Epub 2019 Oct 29). The article reports a comprehensive review of the world literature concerning the efficacy of "gender confirming" chest surgery in transgender patients. The authors found 849 articles on the subject, published in peer reviewed medical journals. Of these 849 articles, only 47 could be included in the review. This means that only 5.5% of all the published, peer-reviewed transgender surgery articles

demonstrated even rudimentary scientific rigor. Of those 47 articles, the authors report that only 29 of the articles addressed mental health outcomes (3.4% of all the articles). What is startling is that the mental health outcomes were judged only on the basis of uncooroborated, untested, and unassessed patient subjective reporting with descriptors that varied so widely from article to article that results could not even be compared. The authors summarize by saying, "Evaluation of outcomes in gender-confirming chest surgery showed large variations in reporting, and further streamlining of reporting is therefore required to be able to compare surgical outcomes between studies." None of these negligent articles even bothered to examine rates of psychiatric hospitalization, substance abuse, self-harm behaviors, and suicide. This tells us that the main reason for performing these surgeries (psychological distress and suicide risk) isn't even evaluated with regard to efficacy.

23. An example of an article with very low quality data, reckless (now banned practices), and methodology, published in a "leading journal," and promoted as evidence for the efficacy of "chest masculinization" surgery makes this fact very clear. The lead author (Olson-Kennedy, a leading national advocate for the transgender treatment industry) is a board certified pediatrician who leads the gender clinic for the Los Angeles Children's Hospital. The article appeared in 2018 (See J. Olson-Kennedy, J. Warus, MD1, et al., *Chest Reconstruction and Chest Dysphoria in Transmasculine Minors and Young Adults; Comparisons of Nonsurgical and Postsurgical Cohorts*., JAMA Pediatr. 2018;172(5):431-436. doi:10.1001/jamapediatrics. 2017.5440). In their summary of findings, the authors reported that "chest dysphoria" is common among "trans males" (natal females seeking to present as males), and claimed that dysphoria is "decreased by surgery." They claim that regret for surgery is "rare." The article reports breast removal surgery on at least one girl aged *13 years*. (Note that this reckless, experimental

practice has now apparently been abandoned as unethical/experimentation on children by England, Sweden, and Finland). The average age of patients in the study was 19. Children were entered into the study through recruitment from among patients visiting the clinic and by telephone over a six month period. The authors found that of the patients recruited from among visitors to the clinic (convenience sampling) there was an abundance of non-operated patients, so they were forced to reach out to all the post-surgical patients by phone. Twenty-six percent of the clinic's post-surgical patients could not be reached for various reasons including no working phone, or failure to respond to multiple messages. The 26% drop-out rate is never even questioned by these authors. Were surgical patients lost to follow up because of dissatisfaction, psychiatric hospitalization, or *suicide*? This problem is called "self-selection bias," and it is evidence of careless study design. Of the remaining 74% of patients, only 72% completed the survey. This is a second example of self-selection bias. Why would some post-surgical patients who had been successfully contacted, not complete the survey? The authors — demonstrating multiple levels of confirmation bias — do not even ask such essential questions. (See detailed citations in the "Notes" section of this report below).

24. In the study, dysphoria was evaluated using what the author called "a novel measure," which amounted to a series of subjective questions about happiness that was in part designed by the adolescent test subjects themselves. Essentially, the methodology used an entirely unvalidated ("junk science") test instrument, with no known error rates and no proven predictive power. Furthermore, the post-surgical patients were administered the survey at widely varying time intervals post-surgery. The longest interval between surgery and the satisfaction survey was 5 years, but children less than a year post-surgery were included in this obviously flawed sample, and yet the authors claim evidence of "negligible regret." This is a remarkable, misleading, and

deceptive claim given that long-term, longitudinal population studies show that there is a dramatic rise in post-surgical problems such as depression, hospitalization, substance abuse, and suicide beginning at around 7 years post-surgery (Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). Surely the authors are familiar with the world literature on transgender outcomes?

25. Having deceptively or negligently promised in the introduction to their paper that "chest dysphoria" is reduced by surgery, at the conclusion the authors confessed to the fact that the study design and execution produced very low quality data that is not useful for patient selection, or prediction of outcomes. They even confessed that the study does not address the efficacy of surgery in improving outcomes regarding the single most compelling reason for performing the operation: mitigation of depression and suicide. The authors write: "An additional limitation of the study was the small sample size. The nonsurgical cohort was a convenience sample, recruited from those with appointments during the data collection period. There could be unknown imbalances between the nonsurgical and postsurgical cohorts that could have confounded the study findings."

26. Finally, the authors did not even bother to validate their "Chest Dysphoria Scale." Such a "made-up" scale is unlikely to accurately represent distress or correlate with properly validated measures of quality of life, depression, anxiety, or functioning." Their own analysis at the conclusion or the paper directly contradicts their own deceptive claim made in their introduction.

27. This is the kind of "junk science" that is used to support transgender medicine and surgery. It was written by board certified physicians who practice in one of the nation's largest pediatric gender clinics and published in a peer-reviewed medical journal. It is essentially useless in making any clinical decisions regarding who should be offered surgery, what is the likelihood they will benefit from it, what is the likelihood they will regret their decision, and most importantly, whether their risk of suicide would be reduced.

28. Because of the very low quality scientific support for mastectomy in the management of gender dysphoria, valid consent would require that these procedures be described as experimental, would need the approval of ethics panels to monitor human experimentation, and would require the use of valid controls found in long-term, longitudinal population based study models. These are the kinds of patient protections now endorsed in England, Sweden and Finland but still ignored in the US environment where proper scientific critiques of such studies can get faculty "cancelled." (See detailed citations in the "Notes" section of this report below).

29. Even though the transgender treatment industry has been performing these surgeries for over 50 years, gender treatment centers continue to publish the same low quality, methodologically defective studies based upon collected cases that are degraded in value by self-selection bias, confirmation bias, and short-term follow-up, while continuing to deceptively claim that such defective research provides a sufficient scientific basis for performing irreversible, disfiguring, and ultimately sterilizing hormonal treatments and surgeries**.** (See detailed citations in the "Notes" section of this report below).

B. "Chest Masculinization" in Natal Females is Not Ethically Equivalent to Gynecomastectomy.

30. Gynecomastectomy is the surgical treatment of gynecomastia, a fairly common condition in which males develop female-type breast gland tissue. Proponents of "masculinization" mastectomy in natal females erroneously equate the ethics of removing healthy breast tissue from these patients with the removal of abnormal breast tissue in men (gynecomastia). In the case of gynecomastectomy in male patients, the operation is performed to remove the objectively diagnosed presence of female type glandular breast tissue present in a male patient. Physical examination demonstrates the presence of a dense retro-areolar mass which is tender and sometimes disfiguring. Pathological examination of the removed tissue will demonstrate the presence of female-type fibroglandular tissue in a male patient. This is an objectively abnormal condition. It should further be noted that in the absence of such abnormal, female-type fibroglandular tissue, chest recontouring is considered to be cosmetic, and is typically not paid for by third-party payors.

31. I have never read a peer reviewed journal article which discusses the indications for gynecomastectomy that included any claim to reduce major depression and suicide. This is because any male patient seeking removal of abnormal, female-type, breast tissue who reported suicidal ideation would be considered incompetent to give consent, and would require a psychiatric evaluation and treatment to manage suicidal thinking before being considered for surgery.

C. **"Chest Masculinization" in Natal Females is Not Ethically Equivalent to Breast Reduction.**

32. It should be obvious that "Chest Masculinization" surgery in natal females is not ethically equivalent to breast reduction surgery in non-transgender females. In the case of breast reduction for females with excessively large breasts (macromastia, or gigantomastia), the operation is performed to relieve a debilitating orthopedic complaint of neck, back, and shoulder pain

associated with the postural/mechanical effects of the weight of the breasts. These patients experience significant activity restriction and chronic pain that is not relieved by medical management or physical therapy. Furthermore, there is voluminous actuarial data, based upon many years of longitudinal population based study by medical insurance agencies that is used to predict who will benefit from surgery, and who will not. These physical, objective tests, based upon the actual measurement of the breasts, and the patient's overall body habitus, have known error rates that can be used to predict the likelihood that a breast reduction will relieve the orthopedic complaints of neck, back, and shoulder pain. When the tissue specimens are submitted to pathology, they are weighed in order to ensure that enough tissue has been removed so that there will be a very high likelihood that the surgery will relieve the orthopedic condition of neck, back, and shoulder pain (Accuracy of Predicted Resection Weights in Breast Reduction Surgery, Theodore A. Kung, MD, Raouf Ahmed, MBBS1 Christine O. Kang, MPH,1 Paul S. Cederna, MD, and Jeffrey H. Kozlow, MD; Plast Reconstr Surg Glob Open. 2018 Jun; 6(6): e1830.

33. Based upon that, adequate pre-operative consent can be obtained. The supporting data is based in very high quality methodology. There is no quality research data, no pre-operative test or study, and no known error rates, that can be used to predict the likelihood that any child suffering from gender dysphoria will benefit from the experimental procedures of mastectomy and chest "masculinization." As noted above, because of the very low quality data, transgender chest masculinization is at best experimental and at worst, should be viewed as a form of medical child abuse — it is important to note that Finland, Sweden, and the UK appar-

ently now all agree with this analysis, as they have all retreated from such reckless surgical procedures for minors — similar to what Arkansas's science-informed, responsible legislature has now done. (See detailed citations in the "Notes" section of this report below).

34. It is crucial to remember that "chest masculinization" of healthy breast tissue results in a complete loss of function, that this loss is two-fold (breast feeding and erotic sensibility), and the cause of the loss is two-fold (gland removal and severing of the intercostal nerve). (See Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, (Breast Reduction with Use of the Free Nipple Graft Technique; Stephen R. Colen, MD; Aesthetic Surgery Journal, Volume 21, Issue 3, May 2001, Pages 261–271, https://doi.org/10.1067/maj.2001.116439.

35. If a patient who undergoes "chest masculinization" should regret the surgery, they do have the option of breast reconstruction. But all that will be produced is the appearance of a breast. The patient will have lost the function of breast feeding. Additionally, the most commonly performed "masculinization" surgery involves the removal of the nipples, and subsequent re-attachment in the form of a nipple graft. Those nipples will have lost their native nerve connections that provoke erotic sensibility. All that can be hoped for is the eventual random ingrowth of local skin sensation, but there will never be erotic sensation because the particular branch of the fourth intercostal nerve which communicates with particular centers in the brain responsible for oxytocin release and erotic provocation will have been permanently severed. This means that breast function has been completely and irreversibly sacrificed for the sake of producing a cosmetic result (a masculine appearing chest). This is the exact opposite of the goals of any reconstructive surgery. It must therefore be understood that "chest masculinization"

is a cosmetic procedure that has violated the most essential principle of cosmetic surgery: never sacrifice function for the sake of a cosmetic result.

D. Masculinizing and Feminizing Chest Surgeries are Not "Medically Necessary."

36. Supporters of "transitioning" treatments justify surgical treatment based upon "medical necessity." They claim that 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, in the studies they cite no measures are made of the effects of surgery on what is claimed to constitute the "medical necessity" for these procedures.

37. In contrast, the Branstrom study cited in detail in the Notes Section of this declaration documented no reliable benefits for transgender surgery/hormonal treatments and no reduction in suicide and even an *increase* in serious suicide attempts requiring hospitalization in patients receiving surgery. These recent, long-term, published, peer reviewed, credible research findings are quite contrary to the claims of supporters of "transitioning treatments" — as are the National Science Reviews in this area from England-NICE, Sweden, and Finland. (See detailed citations in the Notes section in this declaration).

38. 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. One paper does ask these crucial questions concerning efficacy is a very comprehensive, long term, longitudinal population cohort study which actually shows the opposite of what plaintiffs' experts' claims for these patient outcomes. When followed beyond 8 years post operatively, this paper shows patients receiving plaintiffs 'experts' 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 plaintiffs 'experts, 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 remarkably strong (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885

39. 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."

40. 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.

41. 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 typically cited by supporters of "transitioning treatments" 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.

E. Virtually All Transgender Patients are Born with Normal, Healthy Sex Organs and No Scientifically Validated Reason to Surgically Damage Them.

42. 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.

F. Detransitioners are Real and Surgeons Have No Diagnostic Tools to Identify Who They Will Be.

43. 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. But it is a real phenomenon. I myself have worked with multiple individuals who have abandoned a trans female identity after living in it for years, and who would describe their experiences as "regret." More dramatically, a surgical group prominently active in the sexual reassignment 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. Further, there is an increasingly visible online community of young women who have desisted after claiming a male gender identity at some point during their teen years. See, e.g., https://our-duty.group/2020/04/29/the-detransition-advocacy-network/. 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.

44. Transgender surgeons have no objective, reliable 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 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.

45. 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.

46. But the transgender treatment industry, employing scientifically unsupported WPATH guidelines essentially (and unethically) 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 requires only 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 objective, reliable means by which to anticipate who might benefit or who might be harmed by surgery.

47. By the time a patient presents to a transgender surgeon, they have been the subject of affirmation processes that include everything from social transitioning, to hormonal manipulation. 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-psychiatric 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 objective, reliable means of confirming or rejecting the diagnosis.

G. I Do Not Engage in Experimental Treatments Lacking Reliable, Credible Scientific Support.

48. 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. Due to the 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 scientific research supports such methods.

49. The transgender treatment industry generates considerable income for hospitals, clinicians, and pharmaceutical companies. Members of the transgender treatment industry have a vested interest in believing that science has already justified their existence. Further, as sterilization is the expected adult outcome of endocrine and surgical treatments of the procedures undertaken in youth prior, the transgender treatment industry 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

50. In summary, proponents of "affirmation care" for self-identified transgender patients have no body of quality scientific evidence that proves benefit from their interventions. They rely on low to very low quality data when they recommend affirmation therapy. Consensus statements by professional bodies are based upon the lowest category of evidence available. Advocates of "affirmation care" have no long term data to support their therapeutic recommendations, and they never compare their data to the historically proven approach of "watchful waiting." Advocates for "affirmation care" including medical and surgical intervention, have no objective test, with published error rates, that can be employed to determine who will benefit from their treatments. They rely only on subjective reporting by the patient. Transgender surgery, including "chest masculinization" does not meet the criteria for reconstructive surgery. Because the sole aim of the surgery is the claimed, but unsupported, emotional benefit, it is *by definition* aesthetic (feelings) or cosmetic (appearance) surgery. Chest "masculinization" surgery fails on professional moral grounds because informed consent is impossible (given that there is no way to predict who will benefit), and because function is utterly destroyed in order to achieve a counterfeit form.

IV. PLASTIC SURGERY IS CONCERNED WITH PSYCHOLOGY.

A. Why is Plastic Surgery Concerned with Psychology?

51. Plastic surgery has two areas of activity with broad overlap. The practice of plastic surgery includes reconstructive as well as aesthetic (often called cosmetic) surgery.

52. Reconstructive surgery is ordered to the establishment, or restoration, of normal body structures and their associated functions. The reconstructive process aims at deformities caused by trauma, disease or the management of disease such as cancer surgery, and congenital

deformities. The goal is the restoration of form and function. Sometimes functional restoration is given priority over form, as with the reconstruction of a hand injury in a man. Sometimes functional restoration is impossible, and all that can be offered is aesthetic, as with reconstruction of a facial wound that has resulted in the loss of an eye, where vision cannot be restored, and all that can be offered is a prosthetic eye.

53. Aesthetic (cosmetic) surgery on the other hand is surgery to modify the appearance of an area of the body that is functionally normal, and that has an appearance that, even though it is within the range of normal, causes some degree of annoyance or discomfort to the patient. (For example, prominent ears on a boy.) The ears are functionally normal, and their prominence may even be a recurring family trait, but their prominence is a daily annoyance to the boy; he may even have been given a pejorative nick name. A simple and safe procedure can be performed that reduces the prominence of his ears *without sacrificing any function,* and his daily annoyance is resolved. Form is changed within the range of normal, function is preserved, and the aesthetic (feelings) problem is solved.

54. In the clinical training of plastic surgeons, we learn to carefully evaluate aesthetic patients, not only for the sake of surgical planning, but because we have to understand their motivation for the surgery and how to anticipate potential complications. It is axiomatic in plastic surgery that the most avoidable complication in aesthetic surgery is disappointment and regret on the part of the patient. We are taught that disappointment is first and foremost managed by ensuring that the doctor understands what the patient is seeking to achieve, that the goal is worthy of pursuing, and that the surgeon is likely to achieve the goal.

55. Plastic surgeons are trained to recognize a particular subset of aesthetic patients who at first appear to be seeking some ordinary improvement in appearance, but upon further

evaluation discovers that the patient is seeking cosmetic surgery because they are convinced they are horribly disfigured — and *this* is the reason they feel alone, isolated and depressed. If such a patient has an otherwise normal physical appearance, then the diagnosis of Body Dysmorphic Disorder must be entertained. See (5) Body Dysmorphic Disorder, Andri S. Bjornsson, PhD, Elizabeth R. Didie, PhD, Katharine A. Phillips, MD; Dialogues Clin Neurosci. 2010 Jun; 12(2): 221–232; and Body Dysmorphic Disorder and Cosmetic Surgery Crerand, Canice E. Ph.D.; Franklin, Martin E. Ph.D.; Sarwer, David B. Ph.D. Plastic and Reconstructive Surgery: December 2006 - Volume 118 - Issue 7 - p 167e-180e.

56. Persons who suffer with this condition are seeking a physical explanation for a psychological wound. They are trying to explain their isolation, anxiety, depression, and despair by pointing to their appearance as the cause of their sorrows. Plastic surgeons learn that such patients may be elated at first with their surgery, but they return with complaints that "you didn't do the surgery right." They are disappointed because they still experience the anxiety, isolation, depression, and despair, which should not be surprising given the obvious fact that *you cannot heal a psychological wound with cosmetic surgery*.

57. Indeed, to offer cosmetic surgery to a person suffering from Body Dysmorphic Disorder is considered a failure of diagnosis. *To know that a person is suffering from body dysmorphic disorder, and to offer them surgery in spite of that knowledge is malpractice*. The surgeon is taking advantage of a psychologically vulnerable patient for the sake of financial gain. See Cosmetic Surgery and Body Dysmorphic Disorder – An Update B S. Higgins, MD and A. Wysong, MD, MS, Int J Womens Dermatolv. 4(1); March 2018.

58. Gender dysphoria is a diagnosis that is based upon the subjective reporting of the affected child. There is no objective test, with known error rates, that can be employed to confirm the diagnosis, or predict who will benefit from any putative therapeutic interventions. There is no chromosomal study, no genetic marker, no gene product, no hormonal abnormality, or any dynamic brain scan that can be used to confirm the diagnosis. Essentially, the transgender treatment industry is offering permanently life altering hormonal manipulation and irreversible surgery based upon a diagnosis that is made by an emotionally stressed adolescent, or even prepubertal child who is being socially transitioned. (See Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria Paul Hruz, MD, PhD. Linacre Quarterly 2020 Feb 87 (1)34-42. doi10.1177/0024363919873762. Epub 2019 Sep 20.)

B. **Gender Dysphoria or Gender Identity Disorder is a Logical Subcategory of Body Dysmorphic Disorder.**

59. Body dysmorphic disorder is a subcategory of obsessive compulsive disorder. What distinguishes gender identity disorder from other forms of body dysmorphic disorder is that the content of the obsessive thought is the sexed appearance of the patient. The obsessive thought is that they have the wrong genitalia, that they are really the other sex, and if they could change that, their anxiety, isolation, depression, and despair would resolve. Given that the patient is physically normal, and that the patient is seeking a change in appearance in order to resolve a feeling (aesthetic), all transgender surgery, by definition, is cosmetic surgery**.**

60. To call a "chest masculinization" mastectomy a "chest reconstruction" is not just an imprecision of language. It is intentional deception. Such mastectomy is in no way a restoration of form and function. It is rather the willful destruction of function for the purposes of producing a counterfeit form. What is more, because these mastectomies involve the irreversible destruction of normally functional parts, with associated loss of function, these operations violate

the first and most important principle of plastic surgery: It is bad surgical planning if you compromise function for the sake of a cosmetic result. In this case the compromise of function is actually a 100% loss.

C. There Are Multiple Pathways to Gender Dysphoria.

61. The 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 these groups are sufficiently different that data developed in connection with one of them 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., Intl J. of Transgenderism at 10, DOI: 10.1080/15532739.2018.1468293 ("Myth of Persistence").

V. OPINIONS REGARDING THE SHOCKING OMISSIONS OF PLAINTIFFS' REPORTS

62. 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 the prudential review of scientific publications and my being familiar with the ongoing methodological and scientific debates in the field.

63. I have reviewed the plaintiffs' declarations from Drs. Adkins and Antommaria in this case. Those declarations demonstrate an stunning lack of knowledge or candor regarding the ongoing, raging, international scientific debates over the safety and effectiveness of "gender affirming" medical procedures. Those reports offer no proper disclosure of these controversies and demonstrate no apparent awareness of the serious methodological and ethical defects and controversies exposing the lack of scientific foundations for the transgender treatment industry. Over the past few years, multiple methodological exposes and national reviews in England (NICE), Sweden, and Finland, plus other reviews (e.g., Cochrane, Griffin, Carmichael, etc), have all raised urgent warnings and serious questions about the quality and the integrity of the scientific foundation for this very controversial field.

64. It is troubling that the plaintiffs' experts both appear to have significant financial and professional conflicts of interest as they themselves have reported in their appended curriculums vitae that much of their practices and incomes are derived from these experimental, unproven, potentially harmful methods and procedures of "gender affirmation transitioning" medical treatments. Further, not only their incomes but their professional reputations, academic positions, journal publications, and association memberships would all collapse if the transgender treatment industry collapsed due to widely noted missing evidence of safety and effectiveness.

65. The following are among the shocking errors, omissions, and failures of the plaintiffs' expert reports.

A. Failure to Disclose Multiple International Controversies and the Poor Quality of the Evidence

66. The plaintiffs' experts failed to properly disclose and discuss the international debates and controversies surrounding transgender affirmation methods and procedures discussed above. Indeed, it is difficult to imagine a more inaccurate summary of the state of the embattled,

experimental transgender treatment industry that that reflected in their reports. (See detailed citations in the "Notes" section of this report below).

67. The plaintiffs' experts failed to properly disclose and discuss multiple peer-reviewed, published exposés of significant methodological defects in research on transgender affirmation methods and procedures. Further, the plaintiffs' experts 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. (See detailed citations in the "Notes" section of this report below).

B. **Failure to Acknowledge Comorbidities**

68. Plaintiffs' experts fail to recognize how the existence of comorbidities complicate the treatment of gender dysphoric patients. It is well established in peer-reviewed medical literature that children who experience gender discordance have a very high likelihood of major anxiety disorders, major clinical depression, self-harming behaviors such as cutting, substance abuse. They also have a greater than 30% likelihood of being on the autism spectrum. Under the "affirmation care" model, these issues are more often than not ignored, ascribing all of the child's problems to their self-diagnosed gender dysphoria. (See Elevated rates of autism, other neurodevelopmental and psychiatric diagnoses, and autistic traits in transgender and gender-diverse individuals, Varun Warrier, David M. Greenberg, Elizabeth Weir, Clara Buckingham, Paula Smith, Meng-Chuan Lai, Carrie Allison & Simon Baron-Cohen ; Nature Communications volume 11, Article number: 3959 (2020), https://www.nature.com/articles/s41467-020-17794-1.

C. Failure to Acknowledge the Radically Changing Patient Demographics and Problems for the "Affirmative" Model

69. Plaintiffs' experts fail to recognize that the demographics of transgender patients have seen a radical transformation in the last several years. Historically, the condition was rare (less than 0.2% of children), had initial presentation in pre-puberty, was almost exclusively boys, and showed a desistance (i.e., abandonment of cross-sex self-identification) rate of over 80% by mid-adolescence, and over 90% when followed into adulthood. See A Follow-Up Study of Boys With Gender Identity Disorder; Devita Singh, Susan J. Bradley, and Kenneth J. Zucker, Front. Psychiatry, 29 March 2021.

70. Currently, the majority of newly diagnosed transgender children are natal females (over 50%), initial presentation is in early adolescence to young adulthood, and some reports have the overall prevalence rate rising to somewhere between 2 and 10% of school age children. See Evidence for a Change in the Sex Ratio of Children Referred for Gender Dysphoria: Data From the Gender Identity Development Service in London (2000-2017) Nastasja M de Graaf , Polly Carmichael , Thomas D Steensma , Kenneth J Zucker, J Sex Med 2018 Oct;15(10):1381-1383 and also Characteristics of Referrals for Gender Dysphoria Over a 13-Year Period Melinda Chen, M.D., John Fuqua, M.D., and Erica A. Eugster, M.D J Adolesc Health. 2016 Mar; 58(3): 369–371. doi: 10.1016/j.jadohealth.2015.11.010). This means that the diagnosis among females has risen by nearly 50-fold in the last five years (See Gender dysphoria in adolescence: current perspectives, Riittakerttu Kaltiala- Heino, Hannah Bergman, Marja Työläjärvi, and Louise Frisén; Adolesc Health Med Ther. 2018; 9: 31–41. Published online 2018 Mar 2. doi: 10.2147/AHMT.S135432).

71. Additionally, there appear to be "outbreaks" of clusters of adolescent females that are connected either by school, or social media that suddenly appear. This was first reported by

Dr. Lisa Littman of Brown University in her 2018 paper which coined the diagnostic term of Rapid Onset Gender Dysphoria. (See Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria, Littman, L. PLOS One, August 16, 2018; https://doi.org/10.1371/journal.pone.0202330). She found evidence suggesting that these subjects developed transgender self-identification through a social contagion process that included highly rehearsed speech to be used when speaking to psychologists, counselors, pediatricians, and surgeons. A moment's reflection on this single fact should be enough to dissuade anyone from the idea that transgender self-identification is a biologically determined condition. Has there been a mass mutation in the human genome that would cause a fifty-fold increase among girls? Is there some substance abroad in the world that has radically and swiftly altered childhood brain development? The numbers of affected children would easily place this in the category of a pandemic, given the geographic range of the condition in the western world.

72. The transgender treatment industry has not shown the slightest interest in examining alternative causes, and it offers precisely the same treatment model to children whether they experience gender dysphoria from their first days of character formation in early childhood or at age 14 when their psychosexual development is under the tremendous pressures of puberty. All patients are given "affirmation care" in spite of the fact that we are dealing with wildly different psychological processes. The only variation in treatment plan, from the youngest patient to the oldest, is where along that single line of care they are brought in: social transition, puberty blockers, cross-sex hormones, then surgery.

73. Psychological evaluation and treatment, even of the known psychological comorbidities such as depression and anxiety, bipolar disorder, etc., is a priori decried by the American Psychological Association and other political allies as "conversion therapy," even if the therapy

is used to reduce depression and anxiety. Therapists are *barred* by "political correctness" from seeking alternative causal explanations and thus less able to avoid confirmation bias. Properly exploring the possibility of alternative diagnoses, such as anxiety disorder, major depression, or autism spectrum, even though part of the standard of care, is labelled as" trans-phobic."

74. Because the alternative causal explanations identify disorders that are far more treatable, cross-sex identification may, for many patients, be treatable using safe, proven methodologies such as Cognitive Behavioral Therapy (CBT). Instead, "affirmation" advocates claim that CBT — the most tested and validated form of psychotherapy for depression and anxiety relief — is nothing more than" conversion therapy", or even "psychological torture." (See APA Resolution on Gender Identity Change Efforts Feb. 2021 https://www.apa.org/about/policy/resolution-gender-identity-change-efforts.pdf). The transgender treatment industry maintains emotional chaos in these vulnerable patients, giving rise to a continuing "need" for irreversible, sterilizing, unproven, controversial "transitioning" treatments.

D. The Existence of the "Watchful Waiting" Model of Care

75. Plaintiffs' expert witnesses failed to acknowledge even the very existence of the "watchful waiting" model of care.

76. Historically, Gender Identity Disorder (now called Gender Dysphoria) was recognized as a sub-category of Obsessive Compulsive Disorder where the child has a persistent, intrusive thought that they are the wrong sex. This makes sense because the content of the thought meets the three criteria of a delusional thought: It is 1) held with absolute certainty, 2) unpersuadable by contrary evidence, and 3) impossible. In the case of the gender discordant child, the content of the delusional thought relates to their sexed self. These children typically presented in pre-puberty, and care were directed at several important issues: Experiences or perceptions that have provoked fear or anxiety (e.g. child abuse including sexual assault) that might be causing

the child to seek safety in the opposite sex presentation; misinterpretation of family dynamics that may have caused a desire to be the other sex; actual abuse events that may have provoked and habituated the obsessive thought.

77. Individual and family counseling directs the child's thoughts and coping processes in the direction of the truth of their nature, which includes their biological sex. Historically, this "watchful waiting" approach resulted in a complete resolution of symptoms in 80% of children by mid-adolescence, and over 90% resolution by early adulthood. (See Psychosexual outcome of gender-dysphoric children. Madeleine S. C. Wallien, P. Cohen-Kettenis 2008 Psychology, Medicine Journal of the American Academy of Child and Adolescent Psychiatry 10.1097/CHI.0b013e31818956b9; and A Follow-up Study of Girls with Gender Identity Disorder, Kelley D Drummond 1, Susan J Bradley 2, Michele Peterson-Badali 1, Kenneth J Zucker; Dev Psychol. 2008 Jan;44(1):34-45. doi: 10.1037/0012-1649.44.1.34).

78. The "watchful waiting" approach is based upon a recognition that at the heart of the transgender process lies a psychological problem, and this perspective finds strong support in both its natural history (80+% resolution without medical or surgical intervention), and the fact that no objective test, having known error rates, has yet been found that can affirm or reject a "transgender" diagnosis.

79. In contrast to the highly successful results of "watchful waiting," we have the presently regnant "affirmation" model. Under the "affirmation" model, the treating physician is essentially forbidden to consider the transgender condition to be a psychological disturbance apart from the unhappiness and associated impaired social functioning caused by the discordance between their objective biological sex and their interior sense of their gender. Treating profes-

sionals, including pediatricians, endocrinologists, psychologists, and surgeons are strongly discouraged from examining alternate theories concerning the diagnosis and causes, such as clinical anxiety apart from gender discordance, major depression, or the social contagion model of causation. The affirmation model proposes that the child's interior sense of their gender is "their true self," and that the problem demands that the appearance of the body must be radically changed so that it "aligns" with the child's subjective sense of being the opposite sex.

80. The startling difference in outcomes between "watchful waiting" and "affirmation" provides a compelling counter argument to the WPATH guidelines. As stated above, "watchful waiting," which includes individual and family counseling, yields successful resolution of gender discordance by natural maturation in over 80% of children by mid adolescence, and over 90% by young adulthood. This is in stark contrast, with "affirmation care" where we find that children who are enrolled in gender clinics are nearly 100% likely to persist in their cross-sex self-identification through childhood into adulthood. Essentially, at least 80% of affected children who would have resolved their problem and gone onto gender congruence, are instead trapped in the transgender treatment enterprise. The proponents of "affirmation care" have no proven test, with known error rates, by which to distinguish the 90% that will resolve their problem from the 10% that will experience persistence of symptoms into adulthood. The probability of misdiagnosis — the error rate for this process — is 90%. This places the transgender treatment enterprise, including endocrinologists and surgeons, in the category of gross malpractice.

81. Plaintiffs' experts claim that in the case of transgender patients, it would be unethical to randomize patients into control groups and treatment groups, given the high rate of self-harm. This is a specious argument for two reasons. First, randomized case/control studies are

not the only alternative to unreliable, retrospective, biased collected case reports with short follow up on which the transgender industry rests. Longitudinal, population based, long term data is available in the world literature that allows us to evaluate the claims made by the gender affirmation treatment model. (See Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden; Cecilia Dhejne, Paul Lichtenstein, Marcus Boman, Anna L. V. Johansson, Niklas Långström, Mikael Landén; PLOS One February 22, 2011 https://doi.org/10.1371/journal.pone.0016885). In fact, that long-term population based data is very the reason why the Tavistock Institute in London and the Karolinska Institute Hospital in Sweden — in a dramatic change — have *restricted* the use of puberty blockers, cross-sex hormones, and transgender surgery in minors. The famed Swedish hospital's new patient protections require the involvment of research monitoring to protect children from "transitioning" experimental procedures. (See detailed citations in the "Notes" section of this report below).

82. Essentially, the "control group" already exists in the world literature, however the transgender treatment industry ignores this control group, and continues to publish low-quality case-collection studies without controls, with short follow up and massive self-selection biases.

83. Secondly, there is a very long history of results from the "watchful waiting" model against which the "affirmation model" can be compared. But Plaintiffs' experts entirely ignore this data which shows that the historically proven "watchful waiting" model has a "cure" rate of approximately 90%. The "affirmation care" model hasn't even proven basic efficacy, much less high rates of efficacy, given the low to very low quality evidence that they continue to rely on. Its proponents publish only subjective results to which they assign numerical values using unproven test instruments that have no known error rates or predictive value. (E.g., as noted

above, the historic Branstrom study and recantation documented no reliable benefits to patients in a 10yr+ follow-up study.) (See detailed citations in the "Notes" section of this report below).

E. Failure to Acknowledge that Relying on "Consensus Statements" is Not Relying on Evidence.

84. As can be seen in the Complaint in this case and the plaintiffs' expert reports, the primary supports for the "affirmative" approach are the repeated references to "consensus statements" from medical and other associations and the WPATH guidelines. It should be noted that the quality of scientific evidence in medicine can be graded based upon the methodology employed. The methodology of professional consensus seeking is in the lowest category. (See The Levels of Evidence and their role in Evidence-Based Medicine Patricia B. Burns, MPH, Rod J. Rohrich, MD, and Kevin C. Chung, MD, MS. Plast Reconstr Surg. 2011 Jul; 128(1): 305–310.)

85. It should further be noted that consensus statements from such organizations as the American Pediatric Association and the Endocrine Society are not obtained by polling the membership of the entire society, but are instead the product of consensus seeking methodology applied to a very small, self-selected sample of members that happen to be on that particular policy committee. Nonetheless, the "consensus statement" is incorrectly presented as though there is majority if not universal agreement by pediatricians and endocrinologists.

86. Furthermore, WPATH intentionally mis-labels its guidelines, calling them "Standards of Care" (See http://www.wpath.org/publications/soc). Guidelines are a suggested course of treatment that may or may not produce the desired results, and are therefore not mandatory. Labeling their document as "Standards of Care" implies that they are proven treatment methods of very high efficacy that must be adhered to in order to achieve a known and positive outcome, and that deviations from the "standards of care" has a high probability of a poor outcome, and possible legal consequences.. Given that the guidelines offer no scientifically verified

evidence that their outcomes are consistently and overwhelmingly positive, this is a clear misrepresentation of their actual value. For this reason, whenever the acronym "WPATH" is used in conjunction with the words "standards of care," the author of such words is intentionally misleading the reader.

87. The WPATH guidelines also seek to define a "professional" in transgender health. In order to be classified as a "professional" you must simply agree with what the WPATH documents state. (See WPATH Standards of Care section VI p.13 – section VII p.33 (defining the "professional" in terms of compliance with WPATH "standards of care")). This is more characteristic of a cult than a scientific body. Science demands unflinching, ongoing, debate and re-evaluation of hypotheses, quality of data, methodologies, and best practices. In contrast, WPATH demands consensus and compliance with a single, unproven model of care, even when the patients have wildly differing presentations (pre-pubertal vs. adult, co-morbid association with other illness such as autism spectrum etc.).

88. As it happens, among the lead authors of the WPATH guidelines, and their board members, are physicians and surgeons whose practices largely depend on the revenue stream found in transgender services. (WPATH Standards of Care. Pp.109-112 (describing the composition of the committee members, and their consensus methodology used in generating the document)). Essentially, they are saying, "mastectomy is justified in transgender teenage natal females because I said so in the WPATH document that I wrote." This is a classic *ipse dixit* opinion.

VI. CONCLUDING OPINIONS

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. A currently unknown percentage and number of patients reporting gender dysphoria are suffering social contagion and social pressure processes brought on by a peer group, social media, YouTube role modeling, and/or family dynamics.

95. 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.

96. 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 "affirmative" treatments.

97. 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.

98. 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.

99. 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.).

100. "Gender affirmation" assessments and treatments — hormones and surgery — for gender dysphoria and "transitioning" have no known, peer reviewed and published error rates.

101. Political advocates, activist physicians, and 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 are easily swayed by political ideologies rather than evidence-based scientific methodologies.

102. 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, Plaintiffs' experts failed to disclose and discuss the serious controversies, complex issues, debates, and contrary national science review recommendations in this field. It is difficult to imagine a more inaccurate summary of the state of the embattled, experimental transgender treatment industry. (See detailed citations in Notes section below).

VII. 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 gender transition industry have been exposed for all the world to see.

See, 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." The study shows that there is no agreement concerning the causes of gender dysphoria, which give rise to very different treatment strategies that are at times in diametric opposition. As a result of this confusion of explanations, "consensus" regarding treatment is ipso facto impossible. 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 plaintiffs' experts somehow both failed to properly report this ongoing international debate within their claimed filed of expertise.

See, 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 period found 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.

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. 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.

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/ACHANCHA_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.

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), 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, Bränström and Panchankis long term surgical results. NO benefit (data suggests and suggests an increased risk of serious suicide attempts). 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., and Gillberg, C., Methodological Shortcomings Undercut Statement in Support of Gender-Affirming Surgery, Am J Psychiatry 2020; 177:764–765; doi: 10.1176/appi.ajp.2020.19111117.

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 discussed here, 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 somehow ignored this most essential finding] …" See, Curtis, 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 the plaintiffs' experts in this case. https://genderreport.ca/finland-strict-guidelines-for-treating-gender-dysphoria/ The Swedish National Guidelines appear quite contrary to the opinions of Plaintiffs Experts 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 Plaintiffs Experts 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.

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

Executed on July 8, 2021.

Patrick W. Lappert, MD

Curriculum Vitae

Patrick W. Lappert, MD
Board Certified in Surgery and Plastic Surgery
Decatur, AL 35603

Education and Training :

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

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

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

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

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

Board Certifications in Medicine :

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

— Board Certified in Plastic Surgery — American Board of Plastic Surgery, 1997; American Board of Plastic Surgery, 2008.

Medical Staff Appointments :

EXHIBIT A

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

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

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

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

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

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

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

— Staff Plastic Surgeon in Nebraska, and Alabama.

U.S. Surgeon General Service:

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

Faculty Appointments:

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

Military Service :

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

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

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

— Flight Surgeon, Marine Fighter/ Attack Squadron-451

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

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

— Service in the US Navy for 24 years

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

— Retired with the rank of Captain, USN in 2002

Military Awards:

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

— Meritorious Unit Citation- 3rd award

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

Publications - Peer Reviewed Medical Journals :

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

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

— 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.

Publications - Medical Textbooks:

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

Operations and Clinical Experience - Consultations and Discussions : As a physician and surgeon, I have treated many thousands of patients in 7 states and 4 foreign nations. My practice has included Primary Care, Family Medicine, Aerospace Medicine, General Surgery, Reconstructive Surgery for combat injured, cancer reconstructive surgeries including extensive experience with microvascular surgery, Pediatric Congenital Deformity, and the care of chronic wounds. I have practiced in rural medicine, urban trauma centers, military field hospitals, university teaching hospitals, and as a solo private practitioner. In my private practice I have had

occasion to treat many self-identified transgender patients for skin pathologies related to their use of high dose sex steroids, laser therapies for management of facial hair both in transitioners and detransitioners. I have performed breast reversal surgeries for detransitioning patients. My practice is rated as "LGBTQ friendly" on social media. I have consulted with families with children who are experiencing gender discordance. I have given many presentations to professional meetings of educators and counselors on the subject of transgender, and the present state of the science and treatment. I have discussed the scientific issues relevant to the case with many physicians and experts over a number of years and also discussed related issues with parents and others.

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

DYLAN BRANDT, ET AL **PLAINTIFFS**

V. **4:21CV00450 JM**

LESLIE RUTLEDGE, ET AL **DEFENDANTS**

SUPPLEMENTAL ORDER

After further consideration, the Court supplements the ruling made at the conclusion of the July 21, 2021 hearing to include the following findings:

On April 6, 2021, the Arkansas Legislature passed House Bill 1570, Act 626 of the 93rd General Assembly of Arkansas, to be codified at Ark. Code Ann. §§ 20-9-1501 to 20-9-1504 and 23-79-164 ("Act 626"). Act 626 prohibits a physician or other healthcare provider from providing or referring any individual under the age of 18 for "gender transition procedures."

> "Gender transition procedures" means the process in which a person goes from identifying with and living as a gender that corresponds to his or her biological sex to identifying with and living as a gender different from his or her biological sex, and may involve social, legal, or physical changes;
>
> (6)(A) "Gender transition procedures" means any medical or surgical service, including without limitation physician's services, inpatient and outpatient hospital services, or prescribed drugs related to gender transition that seeks to:
>
> (i) Alter or remove physical or anatomical characteristics or features that are typical for the individual's biological sex; or
>
> (ii) Instill or create physiological or anatomical characteristics that resemble a sex different from the individual's biological sex, including without limitation medical services that provide puberty-blocking drugs, cross-sex hormones, or other mechanisms to promote the development of feminizing or masculinizing features in the opposite biological sex, or genital or nongenital gender reassignment surgery performed for the purpose of assisting an individual with a gender transition.

AR LEGIS 626 (2021), 2021 Arkansas Laws Act 626 (H.B. 1570). The Defendants asserts that Arkansas has a compelling government interest in protecting the health and safety of its citizens, particularly "vulnerable" children who are gender nonconforming or who experience distress at identifying with their biological sex. *Id.*

Plaintiffs are minors, Dylan Brandt, Sabrina Jennen, Brooke Dennis, Parker Saxton (the "Patient Plaintiffs"), their parents, Joanna Brandt, Lacey and Aaron Jennen, Amanda and Shayne Dennis, Donnie Saxton (the "Parent Plaintiffs") and their healthcare providers, Dr. Michele Hutchison, and Dr. Kathryn Stambough (the "Physician Plaintiffs"). Plaintiffs have filed suit claiming the Act violates the Equal Protection Clause, Due Process Clause, and the First Amendment. They seek a preliminary injunction to enjoin Defendants and their successors in office from enforcing Act 626 during the pendency of this litigation. Plaintiffs contend that Act 626 categorically prohibits transgender adolescents with gender dysphoria from treatment, that the patient, their parents, and their medical providers agree, is medically necessary and in the adolescent's best interest. They allege that the Act singles out individuals in need of medically necessary gender-affirming care solely because the individual's gender identity does not conform to their assigned sex at birth.

I. Rule 12(b)(1) Motion to Dismiss

As stated on the record, the Court finds that the Patient and Parent Plaintiffs have standing under the Equal Protection Clause to challenge Act 626's prohibition of "gender transition procedures" as that term is defined in Ark. Code Ann. §§ 20-9-1501(6). They also have standing to challenge the Act's authorization of private rights of action. "Where an unconstitutional statute provides for enforcement both through official acts and private suits, Plaintiffs with standing to seek an injunction against the official acts may also challenge the

constitutionality of private suits." *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 887-88 (1992).

The Court finds that Physician Plaintiffs have standing in their own right to challenge the Act's unequal treatment between healthcare providers who provide gender-affirming care to transgender patients, which would be prohibited by Act 626, and other healthcare providers, who provide all other medically accepted care, including gender-affirming care to non-transgender patients, which is not prohibited. *See Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin.*, 472 F. Supp. 3d 183, 206 (D. Md. 2020).

The Court finds that Physician Plaintiffs have third-party standing to challenge Act 626 on behalf of their patients based upon the Supreme Court's opinion in *June Med. Serv's. LLC v. Russo,* 140 S. Ct. 2103, 2118-2119 (2020) ("[W]e have generally permitted plaintiffs to assert third-party rights in cases where the 'enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' rights.'") (quoting *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004)). Further, Physician Plaintiffs have alleged a close relationship with their patients and a hindrance to their patients' ability to protect their interests because of the risk of discrimination and their patients' desire to protect their privacy. *See Singleton v. Wulff,* 428 U.S. 106, 117 (1976) (patient may be "chilled" from asserting their rights "by a desire to protect the very privacy of [their] decision from the publicity of a court suit.").

II. Preliminary Injunction

"The primary function of a preliminary injunction is to preserve the status quo until, upon final hearing, a court may grant full, effective relief." *Ferry-Morse Seed Co. v. Food Corn, Inc*., 729 F.2d 589, 593 (8th Cir. 1984). The Court considers four factors in evaluating Plaintiffs' request for a preliminary injunction: (1) the likelihood of success on the merits; (2) the likelihood

of irreparable harm in the absence of an injunction; (3) the balance of equities; and (4) the public interest. *Sanborn Mfg. Co., Inc. v. Campbell Hausfeld/Scott Fetzer Co*., 997 F.2d 484, 485-86 (8th Cir. 1983). "When the government is a party, these last two factors merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

A. Equal Protection

To analyze Plaintiffs' facial challenge to Act 626, the Court must determine what level of scrutiny applies and whether Act 626 survives that scrutiny. The Court concludes that heightened scrutiny applies to Plaintiffs' Equal Protection claims because Act 626 rests on sex-based classifications and because "transgender people constitute at least a quasi-suspect class." *Grimm v. Gloucester Cty. Sch. Bd.,* 972 F.3d 586, 607 (8th Cir. 2020); *accord Bostock v. Clayton County*, 140 S. Ct. 1731, 1741 (2020) (discrimination for being transgender is discrimination "on the basis of sex"). Defendants argue that Act 626 does not specifically refer to transgender individuals. It does, however, refer to gender transition which is only sought by transgender individuals. *See Bray v. Alexandria Women's Health Clinic,* 506 U.S. 263, 270 (1993) ("Some activities may be such an irrational object of disfavor that, if they are targeted, and if they also happen to be engaged in exclusively or predominantly by a particular class of people, an intent to disfavor that class can readily be presumed.").

Under heightened scrutiny, Act 626 must be substantially related to a sufficiently important governmental interest. A policy subject to intermediate scrutiny must be supported by an "exceedingly persuasive justification." *United States v. Virginia*, 518 U.S. 515, 531 (1996). The policy must serve important governmental objectives, and the government must show "that the discriminatory means employed are substantially related to the achievement of those objectives." *Id*. at 533 (citation omitted).

Defendants contend that Act 626 is substantially related to the State's important governmental objectives of protecting vulnerable children from experimental treatment and regulating the ethics of the medical profession. Defendants contend that there is a lack of credible scientific evidence that gender-transition procedures improve children's health. They also contend that the consequences of performing these procedures on Arkansas children are too great to allow physicians and healthcare providers to continue performing them. Defendants state that the Arkansas General Assembly passed Act 626 in response to a recent judicial ruling of the U.K. High Court of Justice of England and Wales and an Arizona district court. *See Bell v. Tavistock and Portman Nat'l Health Serv. Found. Trust,* [2020] EWHC (Admin) 3274; *Hennessy-Waller v. Snyder*, 2021 WL 1192842, at *1 (D. Ariz. Mar. 30, 2021).

In *Tavistock*, the U.K. High Court considered the "narrow" issue of whether "a child or young person under the age of 16 [can] achieve *Gillick* [1] competence in respect of the decision to take PBs [puberty blockers] for GD [gender dysphoria]" *Id*. at ¶133. Although Defendants argue that this case is evidence that the U.K. Court is on the forefront of ethics by banning all gender transitioning procedures, *Tavistock* does not categorically prohibit individuals from all "gender transition procedures." The U.K. Court merely concluded that it is "unlikely" that a 13-year-old or under would be competent to give *Gillick* consent to puberty blockers and doubtful that a 14- or 15-year-old could give consent. However, a 16-year-old or older is presumed to have the ability to consent to these procedures. Act 626 prohibits anyone under the age of 18 from receiving treatment without regard to informed consent.

[1] *Gillick* refers to a U.K. High Court case where the House of Lords held by a majority that a doctor could lawfully give contraceptive advice and treatment to a girl aged under 16 if she had sufficient maturity and intelligence to understand the nature and implications of the proposed treatment and provided that certain conditions were satisfied. *See Gillick v. West Norfolk and Wisbech Health Authority* [1986] AC 112.

The Arizona district court case, *Hennessy-Waller v. Snyder*, which is on appeal to the Ninth Circuit Court of Appeals, denied plaintiffs' motion to enjoin the director of the Arizona Health Care Cost Containment System "from further enforcement of" a regulation that excludes gender reassignment surgery from Arizona's Medicaid coverage and to "order AHCCCS to cover male chest reconstruction surgery for D.H. and John." *Hennessy-Waller v. Snyder*, 2021 WL 1192842, at *1 (D. Ariz. Mar. 30, 2021). The *Hennessy-Waller* plaintiffs are not prohibited from all gender-transition treatments and their healthcare providers are not prohibited from providing gender-transition treatments to them. The Court does not find either "authority" to be persuasive or precedential.

Plaintiffs argue that Act 626 does not protect children. Instead, it bans potentially life-saving treatment to transgender adolescents given in accordance with widely accepted medical protocols for treatment of adolescent gender dysphoria.[2] The consensus recommendation of medical organizations is that the only effective treatment for individuals at risk of or suffering from gender dysphoria is to provide gender-affirming care.[3] According to the Medical Organizations, the goal of gender-affirming care is to provide patients who struggle with their gender identity the time and support they need to resolve that struggle and to mitigate the distress

[2] Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Soc'y Clinical Practice Guideline*, 1029110 J. Clinical Endocrinology & Metabolism, Vol. 103, Issue 11, pgs. 3869-3903 (Nov. 2017) [hereinafter "Endocrine Soc'y Clinical Guidelines"]; Eli Coleman et al., *The World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People* 13, 19 (7th ed. 2012), https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341 [hereinafter "WPATH Standards of Care"].

[3] *See* Brief for American Medical Association, American Pediatric Society, American Academy of Pediatrics, American Academy of Child and Adolescent Psychiatry, American Psychiatric Association, American Association of Physicians for Human Rights Inc, American College of Osteopathic Pediatricians, Arkansas Chapter of the American Academy of Pediatrics, Arkansas Council on Child and Adolescent Psychiatry, Arkansas Psychiatric Society, Association of Medical School Pediatric Department Chairs, Endocrine Society, National Association of Pediatric Nurse Practitioners, Pediatric Endocrine Society, Society for Adolescent Health and Medicine, Society for Pediatric Research, Society of Pediatric Nurses, and World Professional Association for Transgender Health (the "Medical Organizations") as Amici Curiae Supporting Plaintiffs at ECF No. 30, p.16.

that can be associated with that condition.[4] Gender-affirming care seeks to minimize the incongruence between a transgender person's gender identity and their sex assigned at birth, thereby minimizing or eliminating gender dysphoria. *Id.* In addition, Plaintiffs argue that the State's contention that gender transition treatments cause irreversible and dangerous consequences is belied by the fact that the same medical treatments banned for transgender adolescents for "gender transition" by Act 626 are permitted for non-transgender adolescents for any other purpose, including to bring their bodies into alignment with their gender.

At this point in the proceedings, the Court finds that Act 626 is not substantially related to protecting children in Arkansas from experimental treatment or regulating the ethics of Arkansas doctors and Defendant's purported health concerns regarding the risks of gender transition procedures are pretextual. The State's reliance on the U.K. High Court's ruling is not credible. If the State's health concerns were genuine, the State would prohibit these procedures for all patients under 18 regardless of gender identity. The State's goal in passing Act 626 was not to ban a treatment. It was to ban an outcome that the State deems undesirable. In other words, Defendants' rationale that the Act protects children from experimental treatment and the long-term, irreversible effects of the treatment, is counterintuitive to the fact that it allows the same treatment for cisgender minors as long as the desired results conform with the stereotype of their biological sex.

The Court finds the Act's ban of services and referrals by healthcare providers is not substantially related to the regulation of the ethics of the medical profession in Arkansas. Gender-affirming treatment is supported by medical evidence that has been subject to rigorous study. Every major expert medical association[5] recognizes that gender-affirming care for

[4] *See* Brief for Medical Organizations as Amici Curiae, *supra* note 3, ECF No. 30 at 16-17.
[5] *See* Brief for Medical Organizations as Amici Curiae, *supra* note 3. ECF No. 30 at 16.

transgender minors may be medically appropriate and necessary to improve the physical and mental health of transgender people. Act 626 prohibits most of these treatments. Further, the State's goal of ensuring the ethics of Arkansas healthcare providers is not attained by interfering with the patient-physician relationship, unnecessarily regulating the evidence-based practice of medicine and subjecting physicians who deliver safe, legal, and medically necessary care to civil liability and loss of licensing.[6] If the Act is not enjoined, healthcare providers in this State will not be able to consider the recognized standard of care for adolescent gender dysphoria. Instead of ensuring that healthcare providers in the State of Arkansas abide by ethical standards, the State has ensured that its healthcare providers do not have the ability to abide by their ethical standards which may include medically necessary transition-related care for improving the physical and mental health of their transgender patients. The Court finds that Act 626 cannot withstand heightened scrutiny and based on the record would not even withstand rational basis scrutiny if it were the appropriate standard of review. Plaintiffs are, therefore, likely to succeed on the merits of their Equal Protection claim.

Next, the Court finds that Plaintiffs will suffer irreparable harm if Act 626 is not enjoined. The Act will cause irreparable physical and psychological harms to the Patient Plaintiffs by terminating their access to necessary medical treatment. Plaintiffs who have begun puberty blocking hormones will be forced to stop the treatments which will cause them to undergo endogenous puberty. Plaintiffs who will soon enter puberty will lose access to puberty blockers. In each case, Patient Plaintiffs will have to live with physical characteristics that do not

[6] *See* Statement, American Academy of Family Physicians, American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American College of Physicians, American Osteopathic Association, and American Psychiatric Association, *Frontline Physicians Call on Politicians to End Political Interference in the Delivery of evidence Based Medicine*, (May 15, 2019), https://www.acog.org/news/news-releases/2019/05/frontline-physicians-call-on-politicians-to-end-political-interference-in-the-delivery-of-evidence-based-medicine.

conform to their gender identity, putting them at high risk of gender dysphoria and lifelong physical and emotional pain. Parent Plaintiffs face the irreparable harm of having to watch their children experience physical and emotional pain or of uprooting their families to move to another state where their children can receive medically necessary treatment. Physician Plaintiffs face the irreparable harm of choosing between breaking the law and providing appropriate guidance and interventions for their transgender patients.

The Court finds that the State's interest in enforcing Act 626 during the pendency of this litigation pales in comparison to the certain and severe harm faced by Plaintiffs. The "State has no interest in enforcing laws that are unconstitutional. . .." *Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1322 (E.D. Ark. 2019), *aff'd in part, appeal dismissed in part and remanded*, 984 F.3d 682 (8th Cir. 2021). Because Plaintiffs have demonstrated at least at this preliminary stage that they are likely to prevail on the issue of Act 626's unconstitutionality, an injunction preventing the State from enforcing the Act does not irreparably harm the State.

B. Due Process

The Due Process Clause of the Fourteenth Amendment forbids states to "deprive any person of life, liberty, or property, without due process of law...." U.S. Const. amend. XIV, § 1. The Clause also includes a substantive component that "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Washington v. Glucksberg*, 521 U.S. 702, 719-20 (1997). "The liberty interest at issue in this case—the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court." *Troxel v. Granville*, 530 U.S. 57, 65 (2000); *see also Kanuszewski* v. *Mich. Dep't of Health and Human Serv's*, 927 F.3d 396, 419 (6th Cir. 2019) ("[P]arents' substantive due process right to make decisions concerning the care,

custody, and control of their children includes the right to direct their children's medical care."). Parents are presumed to be acting in the best interest of their children. *Parham v. J.R.*, 442 U.S. 584, 602 (1979).

The Court finds that the Parent Plaintiffs have a fundamental right to seek medical care for their children and, in conjunction with their adolescent child's consent and their doctor's recommendation, make a judgment that medical care is necessary. So long as a parent adequately cares for his or her children, "there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children." *Troxel*, 530 U.S. at 68-69.

Strict scrutiny is the appropriate standard of review for infringement of a fundamental parental right. *Glucksberg*, 521 U.S. at 719-20. In applying strict scrutiny, the Court finds that Defendants have not met their burden of showing that Arkansas has a compelling state interest in infringing upon parents' fundamental right to seek medical care for their children, or that Act 626 is narrowly tailored to serve that interest. As stated, the State has not shown that Act 626 serves the stated goal of protecting Arkansas's children. The goal in this context is pretextual because Act 626 allows the same treatments for cisgender minors that are banned for transgender minors as long as the desired results conform with the stereotype of the minor's biological sex. Based on these findings, the State could not withstand either heightened scrutiny or rational basis review.

The Court finds that Plaintiffs have shown irreparable harm. The State suffers little harm from maintaining the status quo through the litigation of this case. The risk of irreparable harm to the Plaintiffs tips the balance of equities in favor of a preliminary injunction of Act 626.

C. First Amendment

Plaintiffs claim that Act 626 prevents healthcare professionals from speaking, and their patients and parents from hearing, about medically accepted treatments for gender dysphoria in violation of their First Amendment rights. Defendants argue that Act 626 is not a regulation of speech but rather a regulation of professional conduct. Further, they argue that the Act does not restrict any right to receive information.

The Court finds that Act 626's ban on referrals by healthcare providers is a regulation of speech. The Supreme Court has held that "the creation and dissemination of information are speech within the meaning of the First Amendment." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 570 (2011) (citing *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001) ("[I]f the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct")). "[A] State may not, under the guise of prohibiting professional misconduct, ignore constitutional rights." *Nat'l Ass'n for Advancement of Colored People v. Button*, 371 U.S. 415, 439 (1963); *see also Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361, 2371–72 (2018) ("[T]his Court has not recognized 'professional speech' as a separate category of speech. Speech is not unprotected merely because it is uttered by 'professionals.'").

The Court further finds that Act 626 is a content and viewpoint-based regulation because it restricts healthcare professionals only from making referrals for "gender transition procedures," not for other purposes. As such, it is "presumptively unconstitutional" and is subject to strict scrutiny. *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015). To meet the strict scrutiny standard, Defendants assert that Arkansas has a compelling interest in protecting children from experimental gender-transition procedures and safeguarding medical ethics.

However, the Supreme Court has held that the government does not have a legitimate interest in protecting against the "fear that people [will] make bad decisions if given truthful information." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002); *see also Brown v. Entm't. Merch. Ass'n,* 564 U.S. 786, 794 (2011) (while states can protect children from harm, that "does not include a free-floating power to restrict the ideas to which children may be exposed"). In this case, the State believes that a transgender adolescent who, along with their parents and health care providers, decides to receive gender transition treatment is making a bad decision. The State believes it can keep these individuals from getting this treatment if healthcare providers are not allowed to refer their patients to providers in other states who can prescribe the treatment. Because the Court finds that Act 626 cannot survive strict scrutiny or even rational scrutiny, Plaintiffs are likely to succeed on the merits of their First Amendment claim.

The Court also finds that Plaintiffs will suffer irreparable harm if Act 626 is not enjoined. "It is well-established that "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Powell v. Noble*, 798 F.3d 690, 702 (8th Cir. 2015) (*Elrod v. Burns*, 427 U.S. 347, 373 (1976)). The balance of equities so favors the Plaintiffs that justice requires the Court to preserve the status quo until the merits of the case are determined.

III. Rule 12(b)(6) Motion to Dismiss

As for the Defendants motion to dismiss for failure to state a claim, it is inherent in the Court's decision to grant the preliminary injunction that the Plaintiffs have stated claims for violations of their Equal Protection, Due Process, and First Amendment rights.

IV. Conclusion

Defendants and successors in office are enjoined from enforcing any provision of House Bill 1570, Act 626 of the 93rd General Assembly of Arkansas, to be codified at Ark. Code Ann. §§ 20-9-1501 to 20-9-1504 and 23-79-164 during the pendency of the litigation of this case.

IT IS SO ORDERED this 2nd day of August, 2021.

James M. Moody Jr.
United States District Judge

EXHIBIT 7

OPEN

PRS GLOBAL OPEN

SPECIAL TOPIC

Levels of Evidence in Plastic and Reconstructive Surgery Research: Have We Improved Over the Past 10 Years?

Conor M. Sugrue, FRCS
Cormac W. Joyce, FRCS
Sean M. Carroll, FRCS, MD

Summary: Levels of evidence (LOE) aid in the critical appraisal of evidence by ranking studies based on limitation of its design. Analyzing LOE provides insight into application of evidence-based medicine. The aim of this study is to determine if the quality of evidence in plastic surgery research has improved over the past 10 years. Systematic review of research published in *Plastics and Reconstructive Surgery* journal over the years, 10-year period (2008, 2013, 2018), was performed. LOE for each article was determined using the American Society of Plastic Surgeons (ASPS) guidelines. Each level was calculated as percentage of publications per year and compared yearly and between different topics. Eight hundred eighty-four studies were included in the final analysis. The LOE of the research improved over the study period. Level 4 evidence was the most frequent published (50.6%, 447/884), with a decline from 63.2% in 2008 to 41.3% in 2018. Level 1 evidence improved each year and accounted for 2.1% of all research in 2018. Aesthetic surgery was the most frequent published topic with upper limb research demonstrating an 18.5% increase in high-quality evidence over the study period. Increased awareness of evidence-based medicine has improved the quality of plastic surgery research over the past decade. It is vital this continues to provide gold standard patient care. *(Plast Reconstr Surg Glob Open 2019;7:e2408; doi: 10.1097/GOX.0000000000002408; Published online 30 September 2019.)*

Exhibit
0017
9/30/2021
Dr. Lappert

INTRODUCTION

Advances in technology, improved understanding of disease pathogenesis, and superior interventions have enhanced plastic surgery patients' outcomes over the past decade.[1,2] To support these advancements, up to date research endeavors are mandatory. The resultant increase in studies has generated an overwhelming amount of evidence. To assist clinicians in critical appraisal of this evidence, a conceptual tool known as evidence-based medicine (EBM) was developed.[3]

Levels of evidence (LOE) is the foundation of EBM. It is a hierarchical appraisal system which grades research (levels 1–5) based on inherent limitations of study methodology.[4] LOE enables clinicians to rapidly appraise evidence before translating into clinical practice.[5] It is also a reliable method of evaluating the quality of evidence published. High-quality research is a prerequisite in maintaining optimal patient care. The aim of this study is to determine if the quality of evidence in plastic surgery research has improved over the past 10 years.

METHODOLOGY

A systematic review of published research articles was performed in *Plastic and Reconstructive Surgery* (PRS) journal. Articles were selected from this journal, as it is the highest impact factor plastic surgery journal, publishing on a wide variety of plastic surgery topics. To evaluate any trends, articles were initially reviewed from 3 years, covering a 10-year period (2008, 2013, 2018). Editorials, letters, announcements, reflections, book reviews, Continuing Medical Education (CME) articles were excluded from this study. Review articles and laboratory studies (animal, cadaver, basic science) were included in the initial review but excluded from the final analysis, as no LOE can be allocated to these studies.

Each clinical article was allocated an LOE based upon published American Society of Plastic Surgeons (ASPS) guidelines.[6] First, the research aim was broadly divided into 3 categories: therapeutic, risk, and diagnostic. Within these

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categories, evidence was ranked from 1 to 5 mirroring the hierarchal research pyramid. This ranking is based upon the probability that the research design has reduced the potential bias. Highest quality evidence (level 1) is produced from randomized control trials or systematic reviews/meta-analysis of these. Articles of limited study design with biases, such as expert opinions, are ranked the lowest (level 5).

Two authors (C.M.S., C.W.J.) independently evaluated published research articles. Discrepancies in the assignment of LOE were discussed with the senior author (S.M.C.). Information obtained from the articles included year of publication, topic, study design, and LOE. Each LOE was expressed as percentage of the overall publications that year and to the other years. Study design was also assessed. Further analysis on the different topics published in the journal was performed. The percentage of higher-level evidence (levels 1 and 2) was calculated for each topic and compared over the 10-year period.

RESULTS

Two thousand six hundred sixty-four articles were published in the PRS journal in the years 2008, 2013, 2018. By applying the inclusion criteria, a total of 1,369 articles were reviewed. Review articles and laboratory studies accounted for 14.7% and 20.7% of the remaining articles. These were excluded from the final analysis as they are not part of LOE hierarchy. A LOE rank was applied to 884 articles (2008 = 313, 2013 = 291, 2018 = 280) (Fig. 1).

Therapeutic studies were the most frequent research aim, accounting for 83.6% of all research. Level 4 evidence was the greatest level published across the years (50.6%, 447/884). There was a decline in the percentage of level 4 evidence from 63.2% in 2008 to 41.3% in 2018. Twelve publications accounted for level 1 evidence, with 11 of these published in the past 5 years (Table 1).

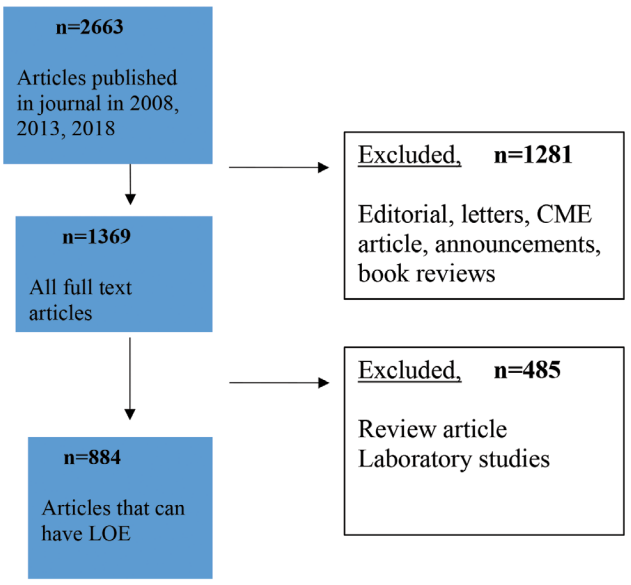

Fig. 1. Flow diagram of study methodology. CME indicates continuing medical education; LOE, levels of evidence.

Table 1. Percentage of Each Level of Evidence Published per Year

Levels of Evidence	2008	2013	2018
1	0.3	1.7	2.1
2	6.3	11.3	13.6
3	19.6	33.3	34.5
4	63.2	45.5	41.7
5	11.3	8.5	7.9

Table 2. Evaluation of Each Study Methodology Used in Research, per Year

	2008 n (%)	2013 n (%)	2018 n (%)
Systematic review/meta analysis	5 (1.1)	21 (4.6)	15 (3.2)
Randomized control trials	8 (1.7)	5 (1.1)	18 (3.8)
Cohort study	4 (0.9)	10 (2.2)	8(1.7)
Case–control	44 (9.7)	75 (16.7)	93 (19.9)
Case series	219 (48.3)	156 (34.7)	123 (26.3)
Case report	10 (2.2)	9 (2.0)	9 (1.2)
Expert opinion	25 (5.5)	15 (1.1)	12 (2.1)
Review article	45 (9.3)	61 (15.8)	99 (22.2)
Laboratory study	96 (21.1)	97 (21.6)	90 (19.3)
	n = 453	n = 449	n = 467

Table 3. Percentage Comparison of High-quality Evidence (Levels 1 and 2) per Plastic Surgery Topic, per Year

Topics	2008	2013	2018
Aesthetics	6.3	6.2	15.3
Breast	19.2	13.7	18.7
Craniofacial	1.5	8.3	8.5
Upper limb	11.5	11.1	25

Case series was the most common study design (36.4%, 498/1,369). This study designed decreased over time from 48.3% in 2008 to 25.5% in 2018. Case–control studies increased from 9.7 % to 19.9% (Table 2).

Aesthetic (21.6%), breast (17.3%), craniofacial (4.2%), and upper limb surgery were the most frequently published topics in PRS journal. The percentage of higher LOE (levels 1 and 2) published in these topics over the years is seen in Table 3. The largest percentage increase over the 10-year period was demonstrated by upper limb surgery (18.5%).

DISCUSSION

The application of EBM involves merging individual clinical experience with the best scientific evidence.[7] The interrogation of EBM into plastic surgery practice has been limited.[8] By evaluating trends in LOE of published research, the utilization of EBM principles can be measured. This study has shown that the LOE in plastic surgery research has improved over the past decade. There has been a growth in levels 1, 2, and 3 evidence, with a reduction in the publication in lower-quality evidence. In 2018, high-quality evidence (levels 1 and 2) accounted for 15.7% of all plastic surgery research. This was marginally lower than orthopedic literature (21.6%),[9] but higher than neurosurgical (10.3%)[10] and maxillofacial research (2%).[11] Within the PRS journal, up-

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per limb and aesthetics surgery demonstrated the largest increase in high-quality evidence over the 10-year period.

Case series are the backbone of surgical research. By evaluating a similar group of patients undergoing a common intervention, this study design replicates everyday surgical practice.[12] The absence of a control group justifiably ranks this design at the lower end of the evidence pyramid. Despite this, case series are vital. They may be the only feasible and ethical study methodology obtainable, as seen with craniofacial surgery.[13] In our study, craniofacial research accounted for the lowest percentage publication (8.4%) of high-quality evidence, with no improvement over the past 5 years. The rarity of craniofacial pathology coupled with a small number of patients makes it difficult to produce higher quality research. Case–control studies are an upgrade from case series, with the addition of a control group significantly reducing study bias.[14] Case –control studies increased in our study period. In a specialty where obtaining high-quality evidence is challenging, the evolution from case series to case–control studies is an important indicator of EBM application.

The concept of LOE was originally described 50 years ago.[15] Yet, its application in plastic surgery research has been underwhelming,[16] with lack of awareness a probable reason.[17] To overcome this, PRS journal, in 2011, made it mandatory for authors submitting manuscripts to attach an LOE rating. This is then displayed as a small pyramidal graphic on the abstract page, providing immediate context for the reader. This editorial policy could account for the greater increase in LOE between 2008 and 2013, in comparison to the past 5 years of this study. Other journals have a similar requirement, but the LOE is allocated by the editorial board, out of fear of authors over infiltrating their own research.[18] However, good interobserver and intraobserver reliability has been reported when grading LOE.[19] By placing the responsibility of LOE ranking with the submitting author, knowledge of EBM has improved along with the quality of evidence published.

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EXHIBIT 8

AMERICAN SOCIETY OF PLASTIC SURGEONS

Exhibit
0007
9/30/2021
Dr. Lappert

State Focus on Gender Affirmation Intensifies

Thursday, February 25, 2021

Policy around transgender care has recently gained considerable attention amid a growing trend of legislation carrying serious professional, financial or criminal penalties for the provision of gender affirmation care. Conversely, although less extensively, efforts to expand coverage for transgender services among both public and third-party payer programs are also taking place.

This period of focused conversation centered on transgender care has been marked by both significant challenges and notable gains in the fight for full access to medically necessary affirming health care.

Background

Gender affirmation is a developing field of medical and surgical practice in which plastic surgeons play a pivotal role, leading the field in many of the physical transformative procedures often involved in gender affirmation.

Like many conditions, gender dysphoria and the process of gender affirmation requires a multidisciplinary approach. Physical, psychological and psychosocial treatment are all components of the gender affirmation process. These components of care – and particularly psychological assessment of gender dysphoria – often begin in childhood and early adolescence. Legislation that seeks to criminalize gender therapy targets this part of the care continuum.

A growing legislative trend

State legislation designed to criminalize gender affirming care first emerged in 2016. The frequency of such bills increased in the years that followed, but 2020 was a particularly active year, seeing six states with bills introduced on the issue. The volume and intent of the legislation between 2016 and 2020 resulted in transgender advocacy groups classifying the bills as "hostile." Last year was also notable because it marked the first instance in which one of the aforementioned bills successfully passed a state legislative chamber.

In 2020, the South Dakota House of Representatives passed legislation prohibiting gender-affirming care for minors and leveling serious consequences for physicians found in violation of the law, including possible jail time. The state's Senate ultimately defeated the bill and prevented it from being enacted into law, but the relative success of the legislation was concerning and may have inspired a number of similar bills that would soon follow.

Less than three months into 2021, 11 pieces of legislation attempting to criminalize gender affirmation therapies have been introduced in 10 states. Alabama, Indiana, Iowa, Mississippi, Missouri, Montana, New Hampshire, Oklahoma, Texas and Utah have each introduced bills seeking to regulate the practice of medicine by banning certain procedures for minors and criminalizing the actions of health care providers who elect to administer gender affirmation care.

While the legislative concepts vary by state, the common threads include a prohibition of gender affirmation care for minors, identification of specific procedures and therapies that cannot be performed by the state's health care practitioners and a stipulation that it is illegal for a minor's parents or guardians to consent to the procedures. Penalties for health care providers, guardians and even school counselors found in violation of the laws vary widely and range from a fine of up to $500,000, to notifying child protective services and even classification of the guilty party as a felon.

Efforts to expand coverage

Contrary to the disturbing trend of legislation looking so severely at limiting gender-affirming care that it seeks to make criminals out of some of those involved, concerted efforts are also underway to expand coverage for the transgender community.

In one notable example, Aetna announced in January the expansion of its coverage for gender-affirming surgeries for transgender women. The insurer now covers gender-affirming breast augmentation in most plans, bringing coverage for the procedure into alignment with coverage for other surgeries common in transgender patients, such as breast removal or gender-reassignment.

Additionally, several states have worked to expand gender affirmation coverage. On February 12, ASPS wrote a letter in support of an emergency rule from the Wisconsin Department of Health Services that would repeal current restrictions and expand coverage for transgender Medicaid members. Similar amendments were proposed to the Washington Administrative Code and received the support of the Society via public comment in late January after ASPS involvement in the development of the policy that dates back to 2018.

ASPS involvement

ASPS firmly believes that plastic surgery services can help gender dysphoria patients align their bodies with whom they know themselves to be and improve their overall mental health and well-being. In 2021, the Society has actively opposed legislation seeking to criminalize actions by physicians and guardians when minors receive gender affirmation surgery in Missouri, Montana and Alabama and is readying engagement in other states where the issue has emerged. ASPS will continue its efforts to advocate across state legislatures for full access to medically necessary transition care.

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EXHIBIT 9

BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Gender Affirmation Surgery and Hormone Therapy

File Name:	gender_affirmation_surgery_and_hormone_therapy
Origination:	7/2011
Last CAP Review:	5/2020
Next CAP Review:	5/2021
Last Review:	3/2021

Description of Procedure or Service

Gender Dysphoria (GD) is the formal diagnosis used by professionals to describe persons who experience significant gender dysphoria (discontent with their biological sex and/or birth gender). Although it is a psychiatric classification, GD is not medically classified as a mental illness.

In the U.S., the American Psychiatric Association (APA) permits a diagnosis of gender dysphoria in adolescents and adults if the diagnostic criteria in the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition, (DSM-5™) are met. The criteria are:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six month's duration, as manifested by at least **two** of the following:

   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics); **OR**
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics; **OR**
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender; **OR**
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender); **OR**
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender); **OR**
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender); **AND**

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Gender dysphoria is a medical condition when the elements of the condition noted above are present. Gender affirmation surgery is one treatment option. Gender Affirmation Surgery is not a single procedure, but part of a complex process involving multiple medical, psychiatric, and surgical modalities performed in conjunction with each other to help the candidate for gender affirmation achieve successful behavioral and medical outcomes. Before undertaking gender affirmation surgery, candidates need to undergo important medical and psychological evaluations, and begin medical/hormonal therapies and behavioral trials to confirm that surgery is the most appropriate treatment choice. Gender affirmation surgery presents significant medical and psychological risks, and the results are irreversible.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your provider.***

Exhibit
0023
9/30/2021
Dr. Lappert

Gender Affirmation Surgery and Hormone Therapy

Policy

Services for gender affirmation surgery and hormone therapy may be considered medically necessary when the criteria below are met.

Please see the following section "Benefits Application" regarding specific benefit and medical management requirements.

Benefits Application

Gender affirmation surgery and hormone therapy may be specifically excluded under some health benefit plans. Please refer to the Member's Benefit Booklet for availability of benefits.

When benefits for gender affirmation surgery and hormone therapy are available, coverage may vary according to benefit design. Some benefit designs for gender affirmation surgery may include benefits for pelvic and/or breast reconstruction. Member benefit language specific to gender affirmation should be reviewed before applying the terms of this medical policy. This medical policy relates only to the services or supplies described herein.

Prior review and certification are required by most benefit plans, and when required, must be obtained or services will not be covered. Some benefit plans provide coverage without a requirement for prior approval or medical necessity review. Please refer to the Member's Benefit Booklet for specific prior approval or medical necessity review requirements.

If prior authorization and medical necessity review are required for hormone therapy, and related surgical procedures for the treatment of gender dysphoria, the medical criteria and guidelines shown below will be utilized to determine the medical necessity for the requested procedure or treatment.

When Gender Affirmation Surgery and Hormone Therapy is covered

Gender affirmation surgery and hormone therapy may be considered medically necessary when all the following candidate criteria are met and supporting provider documentation is provided:

Candidate Criteria for Adults and Adolescents age 18 years and Older for Gender Affirmation Surgery

1. The candidate is at least 18 years of age; and
2. Has been diagnosed with gender dysphoria, including meeting all of the following indications:
    a. A strong conviction to live as some alternative gender different from one's assigned gender.
        - Typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
    b. The new gender identity has been present for at least 6 months; and
    c. If significant medical or mental health concerns are present, they must be reasonably well-controlled; and
    d. The gender dysphoria causes clinical or social distress or impairment in social, occupational, or other important areas of functioning.

3. For those candidates without a medical contraindication, the candidate has undergone a minimum of 12 months of continuous hormonal therapy that is (Note: for those candidates requesting female to male surgery see item 4. below):
    a. Recommended by a mental health professional and

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b. Provided under the supervision of a physician; and the supervising physician indicates that the patient has taken the hormones as directed.

4. For candidates requesting female to male surgery only:
   a. When the initial requested surgery is solely a mastectomy, the treating physician may indicate that no hormonal treatment (as described in criteria 3. above) is required prior to performance of the mastectomy. In this case, the 12 month requirement for hormonal treatment will be waived only when all other criteria contained in this policy and in the member's health benefit plan are met.
5. The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This requirement must be demonstrated by living in their new gender while:
   a. Maintaining part- or full-time employment; or
   b. Functioning as a student in an academic setting; or
   c. Functioning in a community-based volunteer activity as applicable. (For those candidates not meeting this criteria, see item 6. below.)
6. If the candidate does not meet the 12 month time frame criteria as noted in item 5. above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria in item 5. will be waived unless the criteria noted in item 5. above are specified as required in the candidate's health benefit plan.

Provider Documentation Criteria for Gender Affirmation Surgery:

The treating clinicians must provide the following documentation. The documentation must be provided in letters from the appropriate clinicians and contain the information noted below.

1. The letters must attest to the psychological aspects of the candidate's gender dysphoria.
   a. One of the letters must be from a licensed behavioral health professional with an appropriate degree (Ph.D., M.D., L.C.S.W., Ed.D., D.Sc., D.S.W., psychiatric physician assistant, Psy.D, or psychiatric nurse practitioner under the supervision of a psychiatrist) with established competence and clinical expertise in the assessment and treatment of gender dysphoria, who is capable of adequately evaluating if the candidate has any co-morbid psychiatric conditions. When patients with gender dysphoria are also diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder) an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated. Reevaluation by a mental health professional qualified to assess and manage psychotic conditions should be conducted prior to surgery, describing the patient's mental status and readiness for surgery. It is preferable that this mental health professional be familiar with the patient. No surgery should be performed while a patient is actively psychotic.

   b. One of the letters must be from the candidate's established physician or behavioral health provider. The letter or letters must document the following:
      1. Whether the author of the letter is part of a gender dysphoria treatment team and/or follows current WPATH Standards of Care or Endocrine Society Guidelines for the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons for evaluation and treatment of gender dysphoria; and
      2. The initial and evolving gender, sexual, and other psychiatric diagnoses (if applicable); and
      3. The duration of their professional relationship including the type evaluation that the candidate underwent; and
      4. The eligibility criteria that have been met by the candidate according to the above Standards of Care; and
      5. The physician or mental health professional's rationale for hormone therapy and/or surgery; and
      6. The degree to which the candidate has followed the treatment and experiential requirements to date and the likelihood of future compliance; and

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7. The extent of participation in psychotherapy throughout the 12 month real-life trial, (if such therapy is recommended by a treating medical or behavioral health practitioner) and
8. That during the 12 month, real-life experience (for candidates not meeting the 12 month candidate criteria as noted in 6 and 7, the letter should still comment on the candidates ability to function and experience in the desired gender role), persons other than the treating therapist were aware of the candidate's experience in the desired gender role and could attest to the candidate's ability to function in the new role.
9. Demonstrable progress on the part of the candidate in consolidating the new gender identity, including improvements in the ability to handle:
   - Work, family, and interpersonal issues
   - Behavioral health issues, should they exist.

c. If the letters specified in 1a and 1b above come from the same clinician, then a letter from a second physician or behavioral health provider familiar with the candidate corroborating the information provided by the first clinician is required.
d. For members requesting surgical treatment, a letter of documentation must be received from the treating surgeon. If one of the previously described letters is from the treating surgeon, then it must contain the documentation noted in the section below. All letters from a treating surgeon must confirm that:
   1. The candidate meets the "candidate criteria" listed in this policy and
   2. The treating surgeon feels that the candidate is likely to benefit from surgery and
   3. The surgeon has personally communicated with the treating mental health provider or physician treating the candidate, and
   4. The surgeon has personally communicated with the candidate and the candidate understands the ramifications of surgery, including:
      - The required length of hospitalizations,
      - Possible complications of the surgery, and
      - The post-surgical rehabilitation requirements of the various surgical approaches and the planned surgery.

Candidate Criteria for Children and Adolescents under Age 18 years

Pubertal delay and gender affirming hormone therapy may be considered medically necessary when all the following candidate criteria are met and supporting provider documentation is provided:

Candidate Criteria (based on World Professional Association for Transgender Health (WPATH) Standards of Care):

1. The patient has been diagnosed with gender dysphoria, including meeting all of the following indications:
   a. A strong conviction to live as some alternative gender different from one's assigned gender,
      - Typically accompanied by the desire to make the physical body as congruent as possible with the identified sex through surgery and hormone treatment; and
   b. Any co-existing psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; and
   c. The gender dysphoria causes clinical or social distress or impairment in social, occupational, or other important areas of functioning.

2. The candidate has completed a minimum of 12 months of successful continuous full time real-life experience in their new gender, with no returning to their original gender. This requirement must be demonstrated by living in their new gender while:
   a. Maintaining part- or full-time employment; or
   b. Functioning as a student in an academic setting; or
   c. Functioning in a community-based volunteer activity as applicable. (For those candidates not meeting this criteria, see item 3. below.)

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3. If the candidate does not meet the 12 month time frame criteria as noted in item 2. above, then the treating clinician must submit information indicating why it would be clinically inappropriate to require the candidate to meet these criteria. When submitted, the criteria in item 2. will be waived unless the criteria noted in item 2. above are specified as required in the candidate's health benefit plan.

Provider Documentation Criteria for Pubertal Delay and Gender Affirming Hormonal Therapy:

The treating clinicians must provide the following documentation. The documentation must be provided in letters from the appropriate clinicians and contain the information noted below.

1. The letters must attest to the psychological aspects of the candidate's gender dysphoria
   a. One of the letters must be from a licensed behavioral health professional with an appropriate degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., psychiatric physician assistant, Psy.D, or psychiatric nurse practitioner under the supervision of a psychiatrist) with established competence and clinical expertise in the assessment and treatment of gender dysphoria, who is capable of adequately evaluating if the candidate has any co-morbid psychiatric conditions.
   b. One of the letters must be from the candidate's established physician or behavioral health provider. The letter or letters must document the following:
      1. Whether the author of the letter is part of a gender dysphoria treatment team and/or follows current WPATH Standards of Care or Endocrine Society Guidelines for the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons for evaluation and treatment of gender dysphoria; and
      2. The initial and evolving gender, sexual, and other psychiatric diagnoses (if applicable); and
      3. The duration of their professional relationship including the type evaluation that the candidate underwent; and
      4. The eligibility criteria that have been met by the candidate according to the above Standards of Care; and
      5. The physician or mental health professional's rationale for hormone therapy; and
      6. The degree to which the candidate has followed the treatment and experiential requirements to date and the likelihood of future compliance; and
      7. The extent of participation in psychotherapy throughout the 12 month real-life trial, (if such therapy is recommended by a treating medical or behavioral health practitioner); and
      8. That during the 12 month, real-life experience (for candidates not meeting the 12 month candidate criteria as noted in 6 and 7, the letter should still comment on the candidates ability to function and experience in the desired gender role), persons other than the treating therapist were aware of the candidate's experience in the desired gender role and could attest to the candidate's ability to function in the new role.

Prepubertal children do not require medical or surgical treatment, but do require mental health services as listed above.

Criteria for Adolescents Entering Puberty

Adolescents, having reached puberty (tanner 2), and who have met eligibility and readiness criteria can be treated with GnRH analogues.

The definition of puberty is having reached Tanner stage 2/5 and/or having LH, estradiol levels or testosterone levels, within the pubertal range. These LH, estradiol and testosterone ranges are well-known and published and are broken down by biological male vs. biological female Tanner stage, and nocturnal and diurnal levels. Adolescents are ***eligible*** for GnRH treatment, (for suppression of puberty) by these eligibility criteria: (same for adults)

1. Have an established diagnosis for GD based on DSM V or ICD-10 criteria;
2. Have experienced puberty to at least Tanner stage 2, which can be confirmed by pubertal levels of LH, estrogen or testosterone;
3. Have experienced pubertal changes that resulted in an increase of their gender dysphoria;
4. Do not suffer from psychiatric comorbidity (that interferes with the diagnostic work-up or treatment);

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5. Have adequate psychological and social support during treatment, to include having parental/guardian consent;
6. Demonstrate knowledge and understanding of the expected outcomes of GnRH analogue treatment, cross-sex hormone treatment, and gender affirmation surgeries, as well as the medical and social risks and benefits of gender affirmation; and have been counseled regarding fertility options.

Criteria for Postpubertal Adolescents under the Age of 18 Years
Post-pubertal adolescents under age 18 must meet the same criteria and documentation requirements for treatment as listed above for adults. If those criteria are met, they are eligible for gender affirmation hormonal treatment and treatment for menstrual suppression when gender affirming hormones are not successful in eliminating menses.

Gender affirmation surgery is rarely appropriate for patients under the age of 18. Requests for mastectomy for female to male transgender individuals age 17 or older may be considered only in exceptional circumstances on an individual consideration basis.

A limited number of electrolysis or laser hair removal sessions are considered medically necessary to prepare for approved genital surgery when the surgeon makes a recommendation documented in the medical record.

When Gender Affirmation Surgery and Hormone Therapy are not covered

Gender Affirmation Surgery and hormone therapy are non-covered benefits when the member does not have benefits for the services requested contained in their health benefit plan.

Gender Affirmation Surgery and hormonal therapy are considered not medically necessary for plans offering gender affirmation services when the candidate criteria and provider documentation criteria are not met.

Gender Affirmation Surgery Exclusions:

Services and procedures that are considered Cosmetic in all benefit plans are considered non-covered benefits, including but not limited to:

- Cosmetic services that may be used for gender affirmation, including, but not limited to, procedures such as: plastic surgery of the nose; face lift; lip enhancement; facial bone reduction; plastic surgery of the eyelids; liposuction of the waist; reduction of the thyroid cartilage; hair removal ; hair transplants; and surgery of the larynx, including shortening of the vocal cords; chin implants; nose implants, and lip reduction.
- Fertility preservation, including but not limited to: sperm banking and embryonic freezing.

Autologous tissue flap breast reconstructions are considered not medically necessary for gender affirmation surgery.

Policy Guidelines

Gender affirmation surgery and hormone therapy candidate criteria and care standards are based, in part, on the World Professional Association for Transgender Health (WPATH) and Endocrine Society Guidelines for Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the

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Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

ICD-10 diagnosis codes: F64.0, Z87.890

Applicable codes: 17380, 19304, 19316, 19318, 19324, 19325, 19340, 54400, 54401, 54405, 54406, 54408, 54410, 54411, 54415, 54416, 54417, 54660, 55175, 55180, 55970, 55980, 56800, 56805, 57291, 57292, 57295, 57296, 57335, C1813, C2622, J1950, J3315, J9217, J9219, J9226.

Applicable non-covered procedure codes, including, but not limited to: 11950, 11951, 11952, 11954, 15775, 15776, 15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793, 15820, 15821, 15822, 15823, 15824, 15825, 15826, 15828, 15829, 15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879, 21120, 21121, 21122, 21123, 21125, 21127, 21208, 21210, 21270, 30400, 30410, 30420, 30430, 30435, 30450, 67900, 92507, 92508.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Medical Director review 3/2021

Policy Implementation/Update Information

7/19/11 New policy developed. When benefits for gender reassignment surgery are available, coverage may vary. Some benefit plans provide coverage without a requirement for prior approval or medical necessity review. Benefits for upper and/or lower body gender reassignment procedures vary by benefit plan. If prior authorization and medical necessity review are required for hormone therapy, breast augmentation surgery (mammoplasty), and mastectomy for the treatment of gender identity disorders, the medical criteria and guidelines outlined in the policy will be utilized to determine the medical necessity for the requested procedure or treatment. (adn)

9/18/12 Added diagnosis codes 302.0, 302.5, 302.50 – 302.53, 302.6, 302.85, 302.9, 313.82, 752.7 to Billing/Coding section. (sk)

1/1/13 Reference added. Specialty Matched Consultant Advisory Panel review 12/4/12. No change to policy statement. (sk)

7/1/13 ICD-10 diagnosis codes added to Billing/Coding section. (sk)

10/29/13 Reference added. Replaced DSM-IV TR criteria with DSM-5™ criteria. Removed "Sex change surgical procedures other than breast augmentation surgery (mammoplasty) and mastectomy" from the When Not Covered section. Added "pelvic reconstruction" to the When Covered section. Applicable Service Codes removed from Billing/Coding section. Senior Medical Director review. (sk)

7/1/14 Removed ICD-10 effective date from Billing/Coding section. (sk)

12/9/14 Reference added. Specialty Matched Consultant Advisory Panel review 11/24/14. No change to policy statement. (sk)

12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)

9/30/16 Specialty Matched Consultant Advisory Panel review 9/2016. Policy re-titled to Gender Confirmation Surgery and Hormone Therapy. Information regarding coverage of services for adolescents added to the "When Covered" section. Fertility preservation, including but not limited to: sperm banking and embryonic freezing added to Non-covered section. ICD 9 codes removed from Billing/Coding section. ICD 10 codes, covered codes and non-covered codes added to Billing/Coding section. Policy noticed 10/1/2016 for policy effective date 1/1/2017. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

7/16/19 Specialty Matched Consultant Advisory Panel review 6/28/2019. (sk)

6/23/20 Reference added. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)

8/25/20 Medical Director review. Provider Documentation Criteria updated to include "licensed" behavioral health professional, and "with established competence and clinical expertise in the assessment and treatment of gender dysphoria". (sk)

11/10/20 Medical Director review. Policy title changed from "Gender Confirmation Surgery and Hormone Therapy" to "Gender Affirmation Surgery and Hormone Therapy". The word "confirmation" changed to "affirmation" throughout the policy. In the When Covered section, Candidate Criteria for Adults and Adolescents age 18 years and older, criteria 2, wording changed from "the desire to live and be accepted as a member of the opposite sex" to "A strong conviction to live as some alternative gender different from one's assigned gender". In the When Covered section, Candidate Criteria for Children and Adolescents under age 18 years, criteria 1a, wording changed from "the desire to live and be accepted as a member of the opposite sex" to "A strong conviction to live as some alternative gender different from one's assigned gender". When Covered section updated to include information on medically necessary hair removal prior to genital surgery. References updated. (sk)

3/23/21 Medical Director review. Removed "That the candidate has, intends to, or is in the process of acquiring a legal gender-identity appropriate name change and" from the list of Provider Documentation Criteria for Gender Affirmation Surgery. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

EXHIBIT 10

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(https://www.aetna.com/)

Gender Affirming Surgery

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

Number: 0615

Policy

Aetna considers gender affirming surgery medically necessary when all of the following criteria are met:

I. Requirements for breast removal:

A. Single letter of referral from a qualified mental health professional (see Appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. For members less than 18 years of age, completion of one year of testosterone treatment; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Note: A trial of hormone therapy is not a pre-requisite to qualifying for a mastectomy in adults.

II. Requirements for breast augmentation (implants/lipofilling):

Policy History

Last Review
01/12/2021
Effective: 05/14/2002
Next Review: 06/24/2021

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes

State Information

California

Exhibit 0030
9/30/2021
Dr. Lappert

A. Single letter of referral from a qualified mental health professional (see Appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Member is 18 years of age or older; *and*
E. Completion of one year of feminizing hormone therapy prior to breast augmentation surgery (unless the member has a medical contraindication or is otherwise medically unable to take hormones); *and*
F. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Note: More than one breast augmentation is considered not medically necessary. This does not include the medically necessary replacement of breast implants (see CPB 0142 - Breast Implant Remova (../100_199/0142.html)l).

III. Requirements for gonadectomy (hysterectomy and oophorectomy or orchiectomy):

A. Two referral letters from qualified mental health professionals, one in a purely evaluative role (see appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age 18 years or older; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones).

IV. Requirements for genital reconstructive surgery (i.e., vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, placement of a testicular prosthesis and erectile prosthesis,

penectomy, vaginoplasty, labiaplasty, and clitoroplasty)

A. Two referral letters from qualified mental health professionals, one in a purely evaluative role (see appendix); *and*
B. Persistent, well-documented gender dysphoria (see Appendix); *and*
C. Capacity to make a fully informed decision and to consent for treatment; *and*
D. Age 18 years and older; *and*
E. If significant medical or mental health concerns are present, they must be reasonably well controlled; *and*
F. Twelve months of continuous hormone therapy as appropriate to the member's gender goals (unless the member has a medical contraindication or is otherwise unable or unwilling to take hormones); *and*
G. Twelve months of living in a gender role that is congruent with their gender identity (real life experience).

Note on gender specific services for the transgender community:

Gender-specific services may be medically necessary for transgender persons appropriate to their anatomy. Examples include:

1. Breast cancer screening may be medically necessary for transmasculine persons who have not undergone chest masculinization surgery;
2. Prostate cancer screening may be medically necessary for transfeminine persons who have retained their prostate.

Aetna considers gonadotropin-releasing hormone medically necessary to suppress puberty in trans identified adolescents if they meet World Professional Association for Transgender Health (WPATH) criteria (see CPB 0501 - Gonadotropin-Releasing Hormone Analogs and Antagonists (../500_599/0501.html)).

Aetna considers reversal of gender affirming surgery for gender dysphoria not medically necessary.

Aetna considers the following procedures that may be performed as a component of a gender transition as cosmetic (not an all-inclusive list) (see also CPB 0031 - Cosmetic Surgery (../1_99/0031.html)):

- Abdominoplasty
- Blepharoplasty
- Body contouring (liposuction of waist)
- Brow lift
- Calf implants
- Cheek/malar implants
- Chin/nose implants
- Collagen injections
- Construction of a clitoral hood
- Drugs for hair loss or growth
- Face lifting
- Facial bone reduction
- Facial feminization and masculinization surgery
- Feminization of torso
- Forehead lift
- Jaw reduction (jaw contouring)
- Hair removal (e.g., electrolysis, laser hair removal) (Exception: A limited number of electrolysis or laser hair removal sessions are considered medically necessary for skin graft preparation for genital surgery)
- Hair transplantation
- Lip enhancement
- Lip reduction
- Liposuction
- Masculinization of torso
- Mastopexy
- Neck tightening
- Nipple reconstruction
- Nose implants
- Pectoral implants
- Pitch-raising surgery
- Removal of redundant skin
- Rhinoplasty
- Skin resurfacing (dermabrasion/chemical peel)

- Tracheal shave (reduction thyroid chondroplasty)
- Voice modification surgery (laryngoplasty, cricothyroid approximation or shortening of the vocal cords)
- Voice therapy/voice lessons.

Background

Gender dysphoria refers to discomfort or distress that is caused by a discrepancy between an individual's gender identity and the gender assigned at birth (and the associated gender role and/or primary and secondary sex characteristics). A diagnosis of gender dysphoria requires a marked difference between the individual's expressed/experienced gender and the gender others would assign him or her, and it must continue for at least six months. This condition may cause clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender affirming surgery is performed to change primary and/or secondary sex characteristics. For transfeminine (assigned male at birth) gender transition, surgical procedures may include genital reconstruction (vaginoplasty, penectomy, orchidectomy, clitoroplasty), breast augmentation (implants, lipofilling), and cosmetic surgery (facial reshaping, rhinoplasty, abdominoplasty, thyroid chondroplasty (laryngeal shaving), voice modification surgery (vocal cord shortening), hair transplants) (Day, 2002). For transmasculine (assigned female at birth) gender transition, surgical procedures may include mastectomy, genital reconstruction (phalloplasty, genitoplasty, hysterectomy, bilateral oophorectomy), mastectomy, and cosmetic procedures to enhance male features such as pectoral implants and chest wall recontouring (Day, 2002).

The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery (Coleman, et al., 2011).

It is recommended that transfeminine persons undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

In addition to hormone therapy and gender affirming surgery, psychological adjustments are necessary in affirming sex. Treatment should focus on psychological adjustment, with hormone therapy and gender affirming surgery being viewed as confirmatory procedures dependent on adequate psychological adjustment. Mental health care may need to be continued after gender affirming surgery. The overall success of treatment depends partly on the technical success of the surgery, but more crucially on the psychological adjustment of the trans identified person and the support from family, friends, employers and the medical profession.

Nakatsuka (2012) noted that the third versions of the guideline for treatment of people with gender dysphoria (GD) of the Japanese Society of Psychiatry and Neurology recommends that feminizing/masculinizing hormone therapy and genital surgery should not be carried out until 18 years old and 20 years old, respectively. On the other hand, the sixth (2001) and the seventh (2011) versions of the standards of care for the health of transsexual, transgender, and gender non-conforming people of World Professional Association for Transgender Health (WPATH) recommend that transgender adolescents (Tanner stage 2, [mainly 12 to 13 years of age]) are treated by the endocrinologists to suppress puberty with gonadotropin-releasing hormone (GnRH) agonists until age 16 years old, after which gender-affirming hormones may be given. A questionnaire on 181 people with GID diagnosed in the Okayama University Hospital (Japan) showed that female to male (FTM) trans identified individuals hoped to begin masculinizing hormone therapy at age of 15.6 +/- 4.0 (mean +/- S.D.) whereas male to female (MTF) trans identified individuals hoped to begin feminizing hormone therapy as early as age 12.5 +/- 4.0, before presenting secondary sex characters. After confirmation of strong and persistent trans gender identification, adolescents with GD should be treated with gender-affirming hormone or puberty-delaying hormone to prevent developing undesired sex

characters. These treatments may prevent transgender adolescents from attempting suicide, suffering from depression, and refusing to attend school.

Spack (2013) stated that GD is poorly understood from both mechanistic and clinical standpoints. Awareness of the condition appears to be increasing, probably because of greater societal acceptance and available hormonal treatment. Therapeutic options include hormone and surgical treatments but may be limited by insurance coverage because costs are high. For patients seeking MTF affirmation, hormone treatment includes estrogens, finasteride, spironolactone, and GnRH analogs. Surgical options include feminizing genital and facial surgery, breast augmentation, and various fat transplantations. For patients seeking a FTM gender affirmation, medical therapy includes testosterone and GnRH analogs and surgical therapy includes mammoplasty and phalloplasty. Medical therapy for both FTM and MTF can be started in early puberty, although long-term effects are not known. All patients considering treatment need counseling and medical monitoring.

Leinung and colleagues (2013) noted that the Endocrine Society's recently published clinical practice guidelines for the treatment of transgender persons acknowledged the need for further information on transgender health. These investigators reported the experience of one provider with the endocrine treatment of transgender persons over the past 2 decades. Data on demographics, clinical response to treatment, and psychosocial status were collected on all transgender persons receiving gender-affirming hormone therapy since 1991 at the endocrinology clinic at Albany Medical Center, a tertiary care referral center serving upstate New York. Through 2009, a total 192 MTF and 50 FTM transgender persons were seen. These patients had a high prevalence of mental health and psychiatric problems (over 50 %), with low rates of employment and high levels of disability. Mental health and psychiatric problems were inversely correlated with age at presentation. The prevalence of gender affirming surgery was low (31 % for MTF). The number of persons seeking treatment has increased substantially in recent years. Gender-affirming hormone therapy achieves very good results in FTM persons and is most successful in MTF persons when initiated at younger ages. The authors concluded that transgender persons seeking hormonal therapy are being seen with increasing

frequency. The dysphoria present in many transgender persons is associated with significant mood disorders that interfere with successful careers. They stated that starting therapy at an earlier age may lessen the negative impact on mental health and lead to improved social outcomes.

Meyer-Bahlburg (2013) summarized for the practicing endocrinologist the current literature on the psychobiology of the development of gender identity and its variants in individuals with disorders of sex development or with transgenderism. Gender reassignment remains the treatment of choice for strong and persistent gender dysphoria in both categories, but more research is needed on the short-term and long-term effects of puberty-suppressing medications and cross-sex hormones on brain and behavior.

Irreversible Surgical Interventions for Minors

The World Professional Association for Transgender Health (WPATH) recommendations version 7 (Coleman, et al., 2011) states, regarding irreversible surgical interventions, that "[g]enital surgery should not be carried out until (i) patients reach the legal age of majority in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention." The WPATH guidelines state that "Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression."

Note on Breast Reduction/Mastectomy and Nipple Reconstruction

The CPT codes for mastectomy (CPT codes 19303 and 19304) are for breast cancer, and are not appropriate to bill for reduction mammaplasty for female to male (transmasculine) gender affirmation surgery. CPT 2020

states that “Mastectomy procedures (with the exception of gynecomastia [19300]) are performed either for treatment or prevention of breast cancer.” CPT 2020 also states that "Code 19303 describes total removal of ipsilateral breast tissue with or without removal of skin and/or nipples (eg, nipple-sparing), for treatment or prevention of breast cancer.” There are important differences between a mastectomy for breast cancer and a mastectomy for gender reassignment. The former requires careful attention to removal of all breast tissue to reduce the risk of cancer. By contrast, careful removal of all breast tissue is not essential in mastectomy for gender reassignment. In mastectomy for gender reassignment, the nipple areola complex typically can be preserved.

Some have tried to justify routinely billing CPT code 19350 for nipple reconstruction at the time of mastectomy for gender reassignment based upon the frequent need to reduce the size of the areola to give it a male appearance. However, the nipple reconstruction as defined by CPT code 19350 describes a much more involved procedure than areola reduction. The typical patient vignette for CPT code 19350, according to the AMA, is as follows: “The patient is measured in the standing position to ensure even balanced position for a location of the nipple and areola graft on the right breast. Under local anesthesia, a Skate flap is elevated at the site selected for the nipple reconstruction and constructed. A full-thickness skin graft is taken from the right groin to reconstruct the areola. The right groin donor site is closed primarily in layers.”

The AMA vignette for CPT code 19318 (reduction mammaplasty) clarifies that this CPT code includes the work that is necessary to reposition and reshape the nipple to create an aesthetically pleasing result, as is necessary in female to male breast reduction. "The physician reduces the size of the breast, removing wedges of skin and breast tissue from a female patient. The physician makes a circular skin incision above the nipple, in the position to which the nipple will be elevated. Another skin incision is made around the circumference of the nipple. Two incisions are made from the circular cut above the nipple to the fold beneath the breast, one on either side of the nipple, creating a keyhole shaped skin and breast incision. Wedges of skin and breast tissue are removed until the desired size is achieved. Bleeding vessels may be ligated or cauterized. The physician elevates the nipple and its pedicle of subcutaneous tissue to its new position and sutures the nipple pedicle

with layered closure. The remaining incision is repaired with layered closure" (EncoderPro, 2019). CPT code 19350 does not describe the work that that is being done, because that code describes the actual construction of a new nipple.

Thus, Aetna considers nipple reconstruction, as defined by CPT code 19350, as cosmetic/not medically necessary for mastectomy for transmasculine gender reassignment, and that CPT code 19318 includes the extra work that may be necessary to reshape the nipple and create an aesthetically pleasing male chest.

Vulvoplasty versus Vaginoplasty as Gender-Affirming Genital Surgery for Transgender Women

Jiang and colleagues (2018) noted that gender-affirming vaginoplasty aims to create the external female genitalia (vulva) as well as the internal vaginal canal; however, not all patients desire nor can safely undergo vaginal canal creation. These investigators described the factors influencing patient choice or surgeon recommendation of vulvoplasty (creation of the external appearance of female genitalia without creation of a neovaginal canal) and evaluated the patient's satisfaction with this choice. Gender-affirming genital surgery consults were reviewed from March 2015 until December 2017, and patients scheduled for or who had completed vulvoplasty were interviewed by telephone. These investigators reported demographic data and the reasons for choosing vulvoplasty as gender-affirming surgery for patients who either completed or were scheduled for surgery, in addition to patient reports of satisfaction with choice of surgery, satisfaction with the surgery itself, and sexual activity after surgery. A total of 486 patients were seen in consultation for trans-feminine gender-affirming genital surgery: 396 requested vaginoplasty and 39 patients requested vulvoplasty; 30 Patients either completed or are scheduled for vulvoplasty. Vulvoplasty patients were older and had higher body mass index (BMI) than those seeking vaginoplasty. The majority (63 %) of the patients seeking vulvoplasty chose this surgery despite no contraindications to vaginoplasty. The remaining patients had risk factors leading the surgeon to recommend vulvoplasty. Of those who completed surgery, 93 % were satisfied with the surgery and their decision for vulvoplasty. The authors concluded that this was the first study of factors impacting a patient's choice of or a

surgeon's recommendation for vulvoplasty over vaginoplasty as gender-affirming genital surgery; it also was the first reported series of patients undergoing vulvoplasty only.

Drawbacks of this study included its retrospective nature, non-validated questions, short-term follow-up, and selection bias in how vulvoplasty was offered. Vulvoplasty is a form of gender-affirming feminizing surgery that does not involve creation of a neovagina, and it is associated with high satisfaction and low decision regret.

Autologous Fibroblast-Seeded Amnion for Reconstruction of Neo-vagina in Transfeminine Reassignment Surgery

Seyed-Forootan and colleagues (2018) stated that plastic surgeons have used several methods for the construction of neo-vaginas, including the utilization of penile skin, free skin grafts, small bowel or recto-sigmoid grafts, an amnion graft, and cultured cells. These researchers compared the results of amnion grafts with amnion seeded with autograft fibroblasts. Over 8 years, these investigators compared the results of 24 male-to-female transsexual patients retrospectively based on their complications and levels of satisfaction; 16 patients in group A received amnion grafts with fibroblasts, and the patients in group B received only amnion grafts without any additional cellular lining. The depths, sizes, secretions, and sensations of the vaginas were evaluated. The patients were monitored for any complications, including over-secretion, stenosis, stricture, fistula formation, infection, and bleeding. The mean age of group A was 28 ± 4 years and group B was 32 ± 3 years. Patients were followed-up from 30 months to 8 years (mean of 36 ± 4) after surgery. The depth of the vaginas for group A was 14 to 16 and 13 to 16 cm for group B. There was no stenosis in neither group. The diameter of the vaginal opening was 34 to 38 mm in group A and 33 to 38 cm in group B. These researchers only had 2 cases of stricture in the neo-vagina in group B, but no stricture was recorded for group A. All of the patients had good and acceptable sensation in the neo-vagina; 75 % of patients had sexual experience and of those, 93.7 % in group A and 87.5% in group B expressed satisfaction. The authors concluded that the creation of a neo-vaginal canal and its lining with allograft amnion and seeded autologous fibroblasts is an effective method for imitating a normal vagina. The size of neo-vagina, secretion, sensation, and orgasm was good and proper.

More than 93.7 % of patients had satisfaction with sexual intercourse. They stated that amnion seeded with fibroblasts extracted from the patient's own cells will result in a vagina with the proper size and moisture that can eliminate the need for long-term dilatation. The constructed vagina has a 2-layer structure and is much more resistant to trauma and laceration. No cases of stenosis or stricture were recorded. Level of Evidence = IV. These preliminary findings need to be validated by well-designed studies.

Pitch-Raising Surgery in Transfeminine Persons

Van Damme and colleagues (2017) reviewed the evidence of the effectiveness of pitch-raising surgery performed in male-to-female transsexuals. These investigators carried out a search for studies in PubMed, Web of Science, Science Direct, EBSCOhost, Google Scholar, and the references in retrieved manuscripts, using as keywords "transsexual" or "transgender" combined with terms related to voice surgery. They included 8 studies using cricothyroid approximation, 6 studies using anterior glottal web formation, and 6 studies using other surgery types or a combination of surgical techniques, leading to 20 studies in total. Objectively, a substantial rise in post-operative fundamental frequency was identified. Perceptually, mainly laryngeal web formation appeared risky for decreasing voice quality. The majority of patients appeared satisfied with the outcome. However, none of the studies used a control group and randomization process. The authors concluded that future research needs to investigate long-term effects of pitch-raising surgery using a stronger study design.

Azul and associates (2017) evaluated the currently available discursive and empirical data relating to those aspects of trans-masculine people's vocal situations that are not primarily gender-related, and identified restrictions to voice function that have been observed in this population, and made suggestions for future voice research and clinical practice. These researchers conducted a comprehensive review of the voice literature. Publications were identified by searching 6 electronic databases and bibliographies of relevant articles. A total of 22 publications met inclusion criteria. Discourses and empirical data were analyzed for factors and practices that impact on voice function and for indications of voice function-related problems in trans-masculine people.

The quality of the evidence was appraised. The extent and quality of studies investigating trans-masculine people's voice function was found to be limited. There was mixed evidence to suggest that trans-masculine people might experience restrictions to a range of domains of voice function, including vocal power, vocal control/stability, glottal function, pitch range/variability, vocal endurance, and voice quality. The authors concluded that more research into the different factors and practices affecting trans-masculine people's voice function that took account of a range of parameters of voice function and considered participants' self-evaluations is needed to establish how functional voice production can be best supported in this population.

Facial Feminization Surgery

Raffaini and colleagues (2016) stated that gender dysphoria refers to the discomfort and distress that arise from a discrepancy between a person's gender identity and sex assigned at birth. The treatment plan for gender dysphoria varies and can include psychotherapy, hormone treatment, and gender affirmation surgery, which is, in part, an irreversible change of sexual identity. Procedures for transformation to the female sex include facial feminization surgery, vaginoplasty, clitoroplasty, and breast augmentation. Facial feminization surgery can include forehead re-modeling, rhinoplasty, mentoplasty, thyroid chondroplasty, and voice alteration procedures. These investigators reported patient satisfaction following facial feminization surgery, including outcome measurements after forehead slippage and chin re-modeling. A total of 33 patients between 19 and 40 years of age were referred for facial feminization surgery between January of 2003 and December of 2013, for a total of 180 procedures. Surgical outcome was analyzed both subjectively through questionnaires administered to patients and objectively by serial photographs. Most facial feminization surgery procedures could be safely completed in 6 months, barring complications. All patients showed excellent cosmetic results and were satisfied with their procedures. Both frontal and profile views achieved a loss of masculine features. The authors concluded that patient satisfaction following facial feminization surgery was high; they stated that the reduction of gender dysphoria had psychological and social benefits and significantly affected patient outcome. The level of evidence of this study was IV.

Morrison and associates (2018) noted that facial feminization surgery encompasses a broad range of cranio-maxillofacial surgical procedures designed to change masculine facial features into feminine features. The surgical principles of facial feminization surgery could be applied to male-to-female transsexuals and anyone desiring feminization of the face. Although the prevalence of these procedures is difficult to quantify, because of the rising prevalence of transgenderism (approximately 1 in 14,000 men) along with improved insurance coverage for gender-confirming surgery, surgeons versed in techniques, outcomes, and challenges of facial feminization surgery are needed. These researchers appraised the current facial feminization surgery literature. They carried out a comprehensive literature search of the Medline, PubMed, and Embase databases was conducted for studies published through October 2014 with multiple search terms related to facial feminization. Data on techniques, outcomes, complications, and patient satisfaction were collected. A total of 15 articles were selected and reviewed from the 24 identified, all of which were either retrospective or case series/reports. Articles covered a variety of facial feminization procedures. A total of 1,121 patients underwent facial feminization surgery, with 7 complications reported, although many articles did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors concluded that facial feminization surgery appeared to be safe and satisfactory for patients. These researchers stated that further studies are needed to better compare different techniques to more robustly establish best practices; prospective studies and patient-reported outcomes are needed to establish quality-of-life (QOL) outcomes for patients.

Reversal of Gender Affirming Surgery for Gender Dysphoria

The WPATH Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming Peoples describe reversible and irreversible interventions, and the ideal order and timing of these approaches. Surgery as an intervention is considered irreversible by WPATH.

Appendix

DSM 5 Criteria for Gender Dysphoria in Adults and Adolescents

I. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by two or more of the following:

   A. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or, in young adolescents, the anticipated secondary sex characteristics)
   B. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or, in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   C. A strong desire for the primary and/or secondary sex characteristics of the other gender
   D. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
   E. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
   F. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)

II. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Format for referral letters from Qualified Health Professional: (From SOC-7)

1. Client's general identifying characteristics; *and*
2. Results of the client's psychosocial assessment, including any diagnoses; *and*
3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date; *and*

4. An explanation that the WPATH criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery; *and*
5. A statement about the fact that informed consent has been obtained from the patient; *and*
6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

Note: There is no minimum duration of relationship required with mental health professional. It is the professional's judgment as to the appropriate length of time before a referral letter can appropriately be written. A common period of time is three months, but there is significant variation in both directions. When two letters are required, the second referral is intended to be an evaluative consultation, not a representation of an ongoing long-term therapeutic relationship, and can be written by a medical practitioner of sufficient experience with gender dysphoria.

Note: Evaluation of candidacy for gender affirmation surgery by a mental health professional is covered under the member's medical benefit, unless the services of a mental health professional are necessary to evaluate and treat a mental health problem, in which case the mental health professional's services are covered under the member's behavioral health benefit. Please check benefit plan descriptions.

Characteristics of a Qualified Mental Health Professional: (From SOC-7)

1. Master's degree or equivalent in a clinical behavioral science field granted by an institution accredited by the appropriate national accrediting board. The professional should also have documented credentials from the relevant licensing board or equivalent; *and*
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Disease for diagnostic purposes; *and*
3. Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; *and*
4. Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; *and*

5. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

Code	Code Description
CPT codes covered if selection criteria are met:	
Laser hair removal - no specific code	
17380	Electrolysis epilation, each 30 minutes
19318	Reduction mammaplasty
19324 - 19325	Mammaplasty, augmentation
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400 - 54417	Penile prosthesis
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopic, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	complicated
55970	Intersex surgery; male to female [a series of staged procedures that includes male genitalia removal, penile dissection, urethral transposition, creation of vagina and labia with stent placement]

Code	Code Description
55980	female to male [a series of staged procedures that include penis and scrotum formation by graft, and prostheses placement]
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
56810	Perineoplasty, repair of perineum, nonobstetrical (separate procedure)
57106 - 57107, 57110 - 57111	Vaginectomy
57291 - 57292	Construction of artificial vagina
57335	Vaginoplasty for intersex state
58150, 58180, 58260 - 58262, 58275 - 58291, 58541 - 58544, 58550 - 58554	Hysterectomy
58570 - 58573	Laparoscopy, surgical, with total hysterectomy
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral
CPT codes not covered for indications listed in the CPB [considered cosmetic]:	
Tracheal shave - no specific code:	
11950 - 11954	Subcutaneous injection of filling material (e.g., collagen)
15200	Full thickness graft, free, including direct closure of donor site, trunk; 20 sq cm or less [nipple reconstruction]
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780 - 15787	Dermabrasion

Code	Code Description
15788 - 15793	Chemical peel
15820 - 15823	Blepharoplasty
15824 - 15828	Rhytidectomy [face-lifting]
15830 - 15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15876 - 15879	Suction assisted lipectomy
17380	Electrolysis epilation, each 30 minutes
19301	Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)
19303	Mastectomy, simple, complete
19316	Mastopexy
19350	Nipple/areola reconstruction
21087	Nasal prosthesis
21120 - 21123	Genioplasty
21125 - 21127	Augmentation, mandibular body or angle; prosthetic material or with bone graft, onlay or interpositional (includes obtaining autograft)
21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
21194	with bone graft (includes obtaining graft)
21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
21196	with internal rigid fixation
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400 - 30420	Rhinoplasty; primary
30430 - 30450	Rhinoplasty; secondary

Code	Code Description
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, two or more individuals
Other CPT codes related to the CPB:	
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)
+90785	Interactive complexity (List separately in addition to the code for primary procedure)
90832 - 90838	Psychotherapy
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance of drug); subcutaneous or intramuscular
HCPCS codes covered if selection criteria are met:	
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
J1071	Injection, testosterone cypionate, 1 mg
J3121	Injection, testosterone enanthate, 1 mg
J3145	Injection, testosterone undecanoate, 1 mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J9202	Goserelin acetate implant, per 3.6 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg
S0189	Testosterone pellet, 75 mg
HCPCS codes not covered for indications listed in the CPB:	
G0153	Services performed by a qualified speech-language pathologist in the home health or hospice setting, each 15 minutes
S9128	Speech therapy, in the home, per diem
ICD-10 codes covered if selection criteria are met:	
F64.0 - F64.1	Transexualism and dual role transvestism

Code	Code Description
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment
ICD-10 codes not covered for indications listed in the CPB:	
F64.2	Gender identity disorder of childhood

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EXHIBIT 11

Medical Coverage Policy

Effective Date..... 5/18/2021
Next Review Date..... 3/15/2022
Coverage Policy Number 0266

Treatment of Gender Dysphoria

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Exhibit 0031
9/30/2021
Dr. Lappert

Overview

This Coverage Policy addresses treatment of gender dysphoria. Gender dysphoria is defined as discomfort or distress that is caused by a discrepancy between a person's gender identity and the person's assigned sex at birth (World Professional Association for Transgender Health, [WPATH], 2012).

Coverage Policy

Coverage for treatment of gender dysphoria varies across plans. Coverage of drugs for hormonal therapy, as well as whether the drug is covered as a medical or a pharmacy benefit, varies across plans. Refer to the customer's benefit plan document for coverage details. In addition, coverage for treatment of gender dysphoria, including gender reassignment surgery and related services may be governed by state and/or federal mandates.[1]

Unless otherwise specified in a benefit plan, the following conditions of coverage apply for treatment of gender dysphoria and/or gender reassignment surgery and related procedures, including all applicable benefit limitations, precertification, or other medical necessity criteria.

Medically necessary treatment for an individual with gender dysphoria may include ANY of the following services, when services are available in the benefit plan:

- Behavioral health services, including but not limited to, counseling for gender dysphoria and related psychiatric conditions (e.g., anxiety, depression)
- Hormonal therapy, including but not limited to androgens, anti-androgens, GnRH analogues*, estrogens, and progestins (Prior authorization requirements may apply).
  ***Note:** If use in adolescents, individual should have reached Tanner stage 2 of puberty prior to receiving GnRH agonist therapy.
- Laboratory testing to monitor prescribed hormonal therapy
- Age-related, gender-specific services, including but not limited to preventive health, as appropriate to the individuals biological anatomy (e.g., cancer screening [e.g., cervical, breast, prostate]; treatment of a prostate medical condition)
- Gender reassignment and related surgery (see below)**.**

Gender Reassignment Surgery

Gender reassignment surgery is considered medically necessary treatment of gender dysphoria when the individual is age 18 years or older and when the following criteria are met.

Note: For New York regulated benefit plans (e.g., insured): case-by-case review by a medical director for individuals under the age of 18 years of age will be given.

- **For reconstructive chest surgery (i.e., initial mastectomy, breast augmentation):** one letter of support from a qualified mental health professional

  NOTE: The Women's Health and Cancer Rights Act (WHCRA), 29 U.S. Code § 1185b requires coverage of certain post-mastectomy services related to breast reconstruction and treatment of physical complications from mastectomy including nipple-areola reconstruction.

- **For hysterectomy, salpingo-oophorectomy, orchiectomy:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy, AND recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required.

[1] New York regulated benefit plans do not include exclusions or plan language that limit coverage.

- **For reconstructive genital surgery:**
  - documentation of at least 12 months of continuous hormonal sex reassignment therapy, AND
  - recommendation for sex reassignment surgery (i.e., genital surgery) by two qualified mental health professionals with written documentation submitted to the physician performing the genital surgery (If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both [for example, if practicing within the same clinic] are required AND
  - documentation the individual has lived for at least 12 continuous months in a gender role that is congruent with their gender identity

Table 1: Gender Reassignment Surgery: Covered Under Standard Benefit Plan Language

The procedures listed below are considered medically necessary under standard benefit plan language when the above listed criteria for gender reassignment surgery have been met, unless specifically excluded in the benefit plan language.

Procedure	CPT / HCPCS codes (This list may not be all inclusive)
Female to Male reconstructive genital surgery:	55980
Vaginectomy**/colpectomy	57110
Vulvectomy	56625
Metoidioplasty	58999
Phalloplasty	58999
Electrolysis of donor site tissue to be used for phalloplasty	17380
Penile prosthesis (noninflatable / inflatable), including surgical correction of malfunctioning pump, cylinders, or reservoir	54400, 54401, 54405, C1813, C2622
Urethroplasty /urethromeatoplasty	53430, 53450
Hysterectomy and salpingo-oophorectomy	58150, 58260, 58262, 58291, 58552, 58554, 58571, 58573, 58661
Scrotoplasty	55175, 55180
Insertion of testicular prosthesis	54660
Replacement of tissue expander with permanent prosthesis testicular insertion	11970
Testicular expanders, including replacement with prosthesis, testicular prosthesis	11960, 11970, 11971, 54660
Female to Male reconstructive chest surgery:	
Initial mastectomy	19303
Nipple-areola reconstruction (related to mastectomy or post mastectomy reconstruction)	19350*
Breast reduction	19318
Pectoral implants	L8600, 17999
Male to Female reconstructive genital surgery:	55970
Vaginoplasty**, (e.g, construction of vagina with/without graft, colovaginoplasty)	57291, 57292, 57335
Electrolysis of donor site tissue to be used to line the vaginal canal for vaginoplasty	17380
Penectomy	54125
Vulvoplasty, (e.g., labiaplasty, clitoroplasty, penile skin inversion)	56620, 56805
Repair of introitus	56800
	44145, 55899

Coloproctostomy Orchiectomy	54520, 54690
Male to Female reconstructive chest surgery: Initial breast reconstruction including augmentation with implants	 15771-15772 (when specific to breast), 19325, 19340, 19342, C1789

***Note: CPT 19318 (breast reduction) includes the work necessary to reposition and reshape the nipple and areola. Therefore, CPT 19350 (nipple and areola reconstruction) is considered integral to CPT 19318. Thus, these two codes cannot be billed together for "mastectomy" for the purpose of gender reassignment. However, 19350 would be covered if requested along with 19303 as per the federal mandate.**

****Note: For individuals considering hysterectomy/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures a total of 12 months continuous hormonal sex reassignment therapy is required.**

Table 2: Gender Reassignment Surgery: Other Procedures

The procedures listed below are considered not medically necessary under standard benefit plan language. However, some benefit plans may expressly cover some or all of the procedures listed below for gender reassignment surgery.

Note: For New York regulated benefit plans (e.g., insured):The procedures listed below will be further reviewed on a case-by-case basis by a medical director with particular consideration given to whether the proposed procedure(s) advance an individual's ability to properly present and function in the identified gender role.

Facial Feminization/Masculinization Procedures	CPT/HCPCS Code
Blepharoplasty	15820, 15821, 15822, 15823
Brow lift	67900
Cheek/malar implants	17999
Chin/nose implants, chin recontouring	21210, 21270, 30400, 30410, 30420, 30430 30435, 30450
Collagen injections	11950, 11951, 11952, 11954
Face lift	15824, 15825, 15826, 15828, 15829
Forehead reduction and contouring	21137
Facial bone reduction (osteoplasty)	21209
Hair removal/hair transplantation	15775, 15776, 17380
Jaw reduction, contouring, augmentation	21120, 21121, 21122, 21123, 21125, 21127
Laryngoplasty	31599
Lip lift and lip filling	40799
Rhinoplasty	21210, 21270, 30400, 30410, 30420, 30430, 30435, 30450
Skin resurfacing (e.g., dermabrasion, chemical peels)	15780, 15781, 15782, 15783, 15786, 15787, 15788, 15789, 15792, 15793
Thyroid reduction chondroplasty	31750
Neck tightening	15825
Electrolysis, other than when performed pre-vaginoplasty as outlined above	17380
Removal of redundant skin when performed as part of facial reconstruction	15830, 15832, 15833, 15834, 15835, 15836 15837, 15838, 15839
Suction assisted lipoplasty, lipofilling, and/or liposuction	15830, 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879
Voice therapy/voice lessons	92507
Voice modification surgery	31599, 31899

General Background

The causes of gender dysphoria and the developmental factors associated with them are not well-understood. Treatment of individuals with gender dysphoria varies, with some treatments involving a change in gender expression or body modification. The term "transsexual" refers to an individual whose gender identity is not congruent with their genetic and/or assigned sex and usually seeks hormone replacement therapy (HRT) and possibly gender-affirmation surgery to feminize or masculinize the body and who may live full-time in the crossgender role. Transsexualism is a form of gender dysphoria. Other differential diagnoses include, but are not limited to, partial or temporary disorders as seen in adolescent crisis, transvestitism, refusal to accept a homosexual orientation, psychotic misjudgments of gender identity and severe personality disorders (Becker, et al., 1998). Individuals that are transsexual, transgender, or gender nonconforming (i.e., gender identity differs from the cultural norm) may experience gender dysphoria.

Treatment of gender dysphoria is unique to each individual and may or may not involve body modification. Some individuals require only psychotherapy, some require a change in gender roles/expression, and others require hormone therapy and/or surgery to facilitate a gender transition.

Behavioral Health Services

Licensing requirements and scope of practice vary by state for healthcare professionals. The recommended minimum credentials for a mental health professional to be qualified to evaluate or treat adult individuals with gender dysphoria has been defined in the literature. There is some consensus that in addition to general licensing requirements, a minimum of a Master's or more advanced degree from an accredited institution, an ability to recognize and diagnose coexisting mental health concerns, and an ability to distinguish such conditions from gender dysphoria is required.

Mental health professionals play a strong role in working with individuals with gender dysphoria as they need to diagnose the gender disorder and any co-morbid psychiatric conditions accurately, counsel the individual regarding treatment options, and provide psychotherapy (as needed) and assess eligibility and readiness for hormone and surgical therapy. For children and adolescents, the mental health professional should also be trained in child and adolescent developmental psychopathology.

Once the individual is evaluated, the mental health professional provides documentation and formal recommendations to medical and surgical specialists. Documentation for hormonal and/or surgery should be comprehensive and include the extent to which eligibility criteria have been met (i.e., confirmed gender dysphoria, capacity to make a fully informed decision, age ≥ 18 years or age of majority, and other significant medical or behavioral health concerns are well-controlled), in addition to the following:

- individual's general identifying characteristics
- the initial and evolving gender, sexual and psychiatric diagnoses
- details regarding the type and duration of psychotherapy or evaluation the individual received
- the mental health professional's rationale for hormone therapy or surgery
- the degree to which the individual has followed recommended medical management and likelihood of continued compliance
- whether or not the mental health professional is a part of a gender team

Psychiatric care may need to continue for several years after gender reassignment surgery, as major psychological adjustments may continue to be necessary. Other providers of care may include a family physician or internist, endocrinologist, urologist, plastic surgeon, general surgeon and gynecologist. The overall success of the surgery is highly dependent on psychological adjustment and continued support.

After diagnosis, the therapeutic approach is individualized but generally includes three elements: sex hormone therapy of the identified gender, real life experience in the desired role, and surgery to change the genitalia and other sex characteristics.

Hormonal Therapy

For both adults and adolescents, hormonal treatment for gender dysphoria must be administered and monitored by a qualified healthcare practitioner as therapy requires ongoing medical management, including physical

examination and laboratory evaluation studies to manage dosage, side effects, etc. Lifelong maintenance is usually required.

Adults: Prior to and following gender reassignment surgery, individuals undergo hormone replacement therapy, unless medically contraindicated. Biological males are treated with estrogens and anti-androgens to increase breast size, redistribute body fat, soften skin, decrease body hair, and decrease testicular size and erections. Biological females are treated with androgens such as testosterone to deepen voice, increase muscle and bone mass, decrease breast size, increase clitoris size, and increase facial and body hair. In both sexes hormone replacement therapy (HRT) may be effective in reducing the adverse psychologic impact of gender dysphoria. Hormone therapy is usually initiated upon referral from a qualified mental health professional or a health professional competent in behavioral health and gender dysphoria treatment specifically. Twelve months of continuous hormone therapy (gender appropriate) is required prior to hysterectomy and salpingo-oophorectomy and orchiectomy.

Adolescents: For some adolescents the onset of puberty may worsen gender dysphoria. For these individuals puberty-suppressing hormones (e.g., GnRH analogues) may be provided to individuals who have reached at least Tanner stage 2 of sexual development (Hembree, et al., 2009; World Professional Association for Transgender health [WPATH], 2012). Consistent with adult hormone therapy, treatment of adolescents involves a multidisciplinary team, however when treating an adolescent a pediatric endocrinologist should be included as a part of the team. Pre-pubertal hormone suppression differs from hormone therapy used in adults and may not be without consequence; some pharmaceutical agents may cause negative physical side effects (e.g., height, bone growth).

Gender Reassignment Surgery

The term "gender reassignment surgery," also known as sexual reassignment surgery, gender confirming surgery or gender affirmation surgery, may be part of a treatment plan for gender dysphoria. The terms may be used to refer to either the reconstruction of male or female genitalia specifically, or the reshaping by any surgical procedure of a male body into a body with female appearance, or vice versa in order for an individual to function socially in the role to which they identify. Such procedures that tend to display outward appearance generally include facial procedures, chest reconstructive procedures as well as some genital reconstructive procedures (e.g.,phalloplasty).

Gender identity disorder does not persist into adolescence in most children (Hembree, et al., 2009). Evidence suggests that 75-80% of prepubertal children do not turn out to be transgender in adolescence (Hembree, et al., 2009). According to WPATH (2007) persistence of gender dysphoria from adolescence into adulthood is much higher. Performing gender reassignment surgery prior to age 18, or the legal age to give consent, is not recommended by professional societies (American College of Obstetricians and Gynecology [ACOG], 2017; WPATH, 2012; American Psychiatric Association (APA), 2012, Endocrine Society, 2009). Gender reassignment surgery is intended to be a permanent change (non-reversible), establishing congruency between an individual's gender identity and physical appearance. Therefore, a careful and accurate diagnosis is essential for treatment and can be made only as part of a long-term diagnostic process involving a multidisciplinary specialty approach that includes an extensive case history; gynecological, endocrine and urological examination; and a clinical psychiatric/psychological examination. Individuals who choose to undergo gender reassignment surgery must be fully informed regarding treatment options with confirmation from the mental health professional that the individual is considered a candidate for surgical treatment.

Twelve months of continuous hormone therapy is required prior to irreversible genital surgery unless medically contraindicated. Contraindications to hormonal therapy include but are not limited to hypercoagulability conditions, known coronary artery disease, liver disease, and venous thromboembolism.

In addition, prior to surgery the individual identified with gender dysphoria must undergo a "real life experience". During this time the individual adopts the new or evolving gender role and lives in that role for at least 12 continuous months as part of the transition pathway. This process assists in confirming the person's desire for gender role change, ability to function in this role long-term, as well as the adequacy of his/her support system. During the real life experience a person would be expected to maintain their baseline functional lifestyle, participate in community activities, and provide an indication that others are aware of the change in gender role. Some individuals may not be able to continuously live in the gender role for which they identify, for example, concerns surrounding one's employment environment may preclude an individual from meeting this requirement.

In such instances the clinician must confirm the individual has had a satisfactory social role change prior to surgery.

Other Associated Surgical Procedures

Services Otherwise Medically Necessary: Age appropriate gender-specific services that would otherwise be considered medically necessary remain medically necessary services for transgender individuals, as appropriate to their biological anatomy. Examples include (but are not limited to):

- for female to male transgender individuals (e.g., who have not undergone a mastectomy, breast cancer screening)
- for male to female transgender individuals who have retained their prostate cancer screening or treatment of a prostate condition.

Reversal of Gender Reassignment: Gender reassignment surgery is considered an irreversible intervention. Although infrequent, surgery to reverse a partially or fully completed gender reassignment (reversal of surgery to revise secondary sex characteristics), may be necessary as a result of a complication (i.e., infection) or other medical condition necessitating surgical intervention.

Masculinization/Feminization Procedures: Various other surgical procedures may be performed as part of gender reassignment surgery, for example masculinization or feminization procedures. When performed as part of gender reassignment surgery some procedures are performed to assist with improving culturally appropriate male or female appearance characteristics and may be considered not medically necessary. Please refer to the applicable benefit plan document for terms, conditions, and limitations of coverage in addition to the applicable Cigna Medical Coverage Policy for conditions of coverage.

Professional Society/Organization

American College of Obstetricians and Gynecologists (ACOG): ACOG published a Committee Opinion in 2017 for the care of transgender adolescents. Within this document regarding surgical management ACOG notes transgender male patients may undergo phalloplasty when one reaches the age of majority, and a transgender female patient may undergo vaginoplasty when one reaches the age of majority. In addition the authors acknowledge the Endocrine Society guidelines (Hembree, et al., 2009) which state that an individual is at least age 18 years for genital reconstructive surgery (ACOG, 2017).

American Psychiatric Association (APA): In 2012 the APA published a task force report on treatment of gender identity disorder. Within this document, regarding adolescents specifically, the authors state the evidence is inadequate to develop a guideline regarding the timing of sex reassignment surgery. However the task force acknowledges the Endocrine Society guidelines (Hembree, et al., 2009) and that given the irreversible nature of surgery, for adolescents most clinicians advise waiting until the individual has attained the age of legal consent and a degree of independence (APA, 2012).

WPATH Standards of Care: The World Professional Association for Transgender Health (WPATH) promotes standards of health care for individuals through the articulation of "Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People" (WPATH, 2012, Version 7). Although there is no recent update, WPATH standards of care are based on scientific evidence and expert consensus and are commonly utilized as a clinical guide for individuals seeking treatment of gender disorders.

Endocrine Society: In 2009 the Endocrine Society published a clinical practice guideline for endocrine treatment of transsexual persons (Hembree, et al., 2009). As part of this guideline, the endocrine society recommends that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable; that surgery be recommended only after completion of at least one year of consistent and compliant hormone treatment; and that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery.

Use Outside of the US: Several other countries including the United Kingdom offer treatment options for individuals with gender dysphoria. Treatments are similar to those offered in the United States.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	No National Coverage Determinatin	
LCD		No Local Coverage Determination	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Table 1: Gender Reassignment Surgery: Covered Under Standard Benefit Plan Language

Intersex Surgery: Female to Male

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55980	Intersex surgery, female to male
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent implant
11971	Removal of tissue expander without insertion of implant
17380†	Electrolysis epilation, each 30 minutes
17999††	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19318	Breast reduction
19350†††	Nipple/areola reconstruction
53430	Urethroplasty, reconstruction of female urethra
53450	Urethromeatoplasty, with mucosal advancement
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54660	Insertion of testicular prosthesis (separate procedure)
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
56625	Vulvectomy simple; complete
57110	Vaginectomy, complete removal of vaginal wall
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58999††††	Unlisted procedure, female genital system (nonobstetrical)

†**Note: Considered medically necessary when performed as electrolysis of donor site tissue to be used for phalloplasty.**

††**Note: Considered medically necessary when used to represent pectoral implants.**

†††**Note: Considered medically necessary when performed as part of a mastectomy or breast reconstruction procedure following a mastectomy. Considered integral and/or not covered when performed with reduction mammoplasty.**

††††**Note: Considered medically necessary when used to report metoidioplasty with phalloplasty.**

HCPCS Codes	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
L8600	Implantable breast prosthesis, silicone or equal

Intersex Surgery: Male to Female

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
55970	Intersex surgery; male to female
15771†	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772†	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
17380††	Electrolysis epilation, each 30 minutes
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
44145	Colectomy, partial; with coloproctostomy (low pelvic anastomosis)
54125	Amputation of penis; complete
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54690	Laparoscopy, surgical; orchiectomy
55899†††	Unlisted procedure, male genital system
56620	Vulvectomy simple; partial
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57335	Vaginoplasty for intersex state

HCPCS Codes	Description
C1789	Prosthesis, breast (implantable)

†**Note: Considered medically necessary when used to report liposuction techniques specific to breast augmentation.**

††**Note: Considered medically necessary when performed as electrolysis of donor site tissue to be used to line the vaginal canal for vaginoplasty.**

†††**Note: Considered medically necessary when used to report coloproctostomy.**

ICD-10-CM Diagnosis Codes	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Table 2: Gender Reassignment Surgery: Other Procedures

Generally considered not medically necessary when performed as a component of gender reassignment even when coverage for gender reassignment surgery exists, unless subject to a coverage mandate or specifically listed as available in the applicable benefit plan document.

Note: For New York regulated benefit plans (e.g., insured): Subject to case by case review by a medical director.

CPT®* Codes	Description
11950	Subcutaneous injection of filling material (eg, collagen); 1 cc or less
11951	Subcutaneous injection of filling material (eg, collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (eg, collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (eg, collagen); over 10.0 cc
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (eg, tattoo removal)
15786	Abrasion; single lesion (eg, keratosis, scar)
15787	Abrasion; each additional 4 lesions or less (List separately in addition to code for primary procedure)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy, forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand

CPT®* Codes	Description
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999†	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19324	Mammaplasty, augmentation; without prosthetic implant (Code deleted 12/31/2020)
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (eg, wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599††	Unlisted procedure, larynx
31750	Tracheoplasty; cervical
31899†††	Unlisted procedure, trachea, bronchi
40799††††	Unlisted procedure, lips
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual

†**Note: Generally not medically necessary when used to report cheek and malar implants or fat transfers performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††**Note: Generally not medically necessary when used to report laryngoplasty and/or voice modification surgery performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

†††**Note: Generally not medically necessary when used to report voice modification surgery performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

††††**Note: Generally not medically necessary when used to report lip reduction/enhancement performed in conjunction with gender reassignment surgery, even when coverage for gender reassignment surgery exists.**

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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EXHIBIT 12

Gender Dysphoria Treatment

Policy Number: 2021T0580J
Effective Date: April 1, 2021

Instructions for Use

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Related Commercial Policies

- Blepharoplasty, Blepharoptosis and Brow Ptosis Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Habilitative Services and Outpatient Rehabilitation Therapy
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries

Community Plan Policy

- Gender Dysphoria Treatment

Coverage Rationale

See Benefit Considerations

Notes:

- This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.
- This Medical Policy does not apply to self-funded and fully insured group policies in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
  - Complete at least 12 months of successful continuous full-time real-life experience in the desired gender

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    - Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)
- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria:

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

Note: For fully insured group policies in New York, refer to the Benefit Considerations section for more information.

- Abdominoplasty (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Blepharoplasty (also refer to the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis and Brow Ptosis Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Laser or electrolysis hair removal not related to genital reconstruction
- Hair transplantation
- Lip augmentation
- Lip reduction

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- Liposuction (suction-assisted lipectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	

14000, 14000, 14001, 14041, 15734, 15738, 15750, 15757, 15758, 15820, 15821, 15822, 15823, 15830, 15847, 15877, 17999, 19303, 19316, 19318, 19325, 19340, 19342, 19350, 21121, 21123, 21125, 21127, 21137, 21138, 21139, 21172, 21175, 21179, 21180, 21208, 21209, 21210, 30400, 30410, 30420, 30430, 30435, 30450, 53410, 53430, 54125, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 57110, 57335, 58150, 58180, 58260, 58262, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 58940, 64856, 64892, 64896, 67900	Medical notes documenting the following:
	• The history of medical conditions requiring treatment or surgical intervention
	• A well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment
	• Recurrent or persistent functional deficit caused by the abnormality
	• Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment
	• Color photos, where applicable, of the physical and/or physiological abnormality
	• Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function
	• For CPT codes 58260, 58262, 58290 and 58291, provide the additional information:
	  ○ The history of medical conditions requiring treatment or surgical intervention
	  ○ Physician plan of care with proposed procedures and whether this request is part of a staged procedure
	  ○ A written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual. The assessment should include all of the following:
	  ▪ The member is capable to make a fully informed decision and to consent for treatment
	  ▪ The member must be at least 18 years of age (age of majority)
	  ▪ If significant medical or mental health concerns are present, they must be reasonably well controlled
	  ▪ The member has completed at least 12 months of successful continuous full-time real-life experience in the desired gender
	  ▪ The member has completed 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)
	  ○ A treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria

**For code descriptions, see the Applicable Codes section.*

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Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics [(or in young adolescents, the anticipated secondary sex characteristics)].
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender [or in young adolescents, a desire to prevent the development of the anticipated 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 different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of ones' sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012):
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.

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- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal

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CPT Code	Description
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material

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CPT Code	Description
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

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CPT Code	Description
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

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CPT Code	Description
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed /alternative gender and assigned gender (DSM-5). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for Gender Dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for Gender Dysphoria include sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service.

This medical policy does not apply to self-funded and fully insured group policies in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Drug Policy titled Gonadotropin Releasing Hormone Analogs.

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Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the Reproduction exclusion in the member specific benefit plan document)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Coverage Determination Guideline titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). See below for additional information on New York fully insured group policies.
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For Fully Insured Group Policies in New York Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n=2447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming cross-sex hormone (CSH) and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming CSHs and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all

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tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of follow-up were 54 patients and 4.6 years, respectively (1 study did not report [NR]). Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients

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underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ± 2.1 years. The mean operative duration was 210 ± 44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ± 1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ± 1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital gender affirming surgery (GAS) involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016 Zhang et al conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

A Hayes report concluded that, overall, the quality of the evidence on gender reassignment surgery for gender dysphoria was very low (Hayes, 2014; updated 2020). The evidence suggests positive benefits, but because of serious limitations, permits only weak conclusions. Limitations include small sample sizes, retrospective data, lack of randomization and control and a lack of objective and validated outcome measures.

- Patients who underwent chest/breast or genital surgery were generally pleased with the aesthetic results.
- Following gender reassignment surgery, patients reported decreased gender dysphoria, depression and anxiety and increased quality of life.
- The majority of gender reassignment surgery patients were sexually active, but the ability to orgasm varied across studies.
- Complications of surgery following gender reassignment surgery were common and could be serious.

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- Rates of regret of surgery and suicide were very low following gender reassignment surgery.
- Data were too sparse to draw conclusions regarding whether gender reassignment surgery conferred additional benefits to hormone therapy alone.
- Data were too sparse to draw conclusions regarding whether outcomes vary according to which surgeries were performed.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n=894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported. The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n=49) (group 1) and labia minora flap (n=158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n=191; FtM n=133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1833 participants with gender dysphoria (1093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity

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- The use of cross-sex hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender- Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2017; reaffirmed 2020) provides guidance on health care for transgender adolescents. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should understand gender identity and be able to treat transgender patients or refer them appropriately for medical and surgical therapeutic options.
- Surgical management for transgender male patients is typically reserved for patients 18 years and older.
- For transgender male patients, phalloplasty may be performed when the patient reaches the age of majority.
- Transgender female patients who choose to undergo surgery for a neovagina may have vaginoplasty after the age of majority.
- Transgender patients should be counseled about fertility and fertility preservation prior to surgical treatment.

A separate ACOG committee opinion (2011; reaffirmed 2019) provides guidance on health care for transgender individuals. The document makes the following recommendations regarding surgery:

- Obstetrician-gynecologists should assist or refer transgender individuals for routine treatment and screening as well as hormonal and surgical therapies.
- Hormonal and surgical therapies should be managed in consultation with health care providers with expertise in specialized care and treatment of transgender persons.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation. See the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 12, 2020)

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Policy History/Revision Information

Date	Summary of Changes
04/26/2021	Template Update • Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in *Clinical Evidence* section • Removed *CMS* section • Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in *Instructions for Use*
04/01/2021	Coverage Rationale • Added notation to indicate this Medical Policy does not apply to self-funded and fully insured group policies in California; refer to the California-specific Benefit Interpretation Policy titled *Gender Dysphoria (Gender Identity Disorder) Treatment* Supporting Information

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Date	Summary of Changes
	• Archived previous policy version 2021T0580i

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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EXHIBIT 13

TRANSGENDER "TRANSITION" PROCEDURES PERFORMED ON MINORS
ANSWERS TO QUESTIONS AND INFORMATION FOR JOINT INTERIM COMMITTEE

Submitted by Rep. Rex P. Shipp

June 10, 2021

Part I - Evaluating the scope of the challenge

1. What is biological sex dysphoria?

Biological sex dysphoria is the feeling of discomfort or distress that might occur in people whose gender identity differs from their biological sex or sex-related physical characteristics.

"The medical diagnosis is gender dysphoria. A biological male feeling and believing himself to be a girl and the distress that accompanies these feelings and beliefs is an example of gender dysphoria (previously known as gender identity disorder).

There are billions of neurons that make the brain. Neurons are very specialized cells that transmit and store information. The control center, if you will, of every cell in the body is the nucleus, which contains DNA. The DNA is wound up into specialized units called chromosomes. There are 46 chromosomes in every human cell. Two of these are specialized chromosomes called sex chromosomes. Assuming normal development, females have two X chromosomes, and males have one X and one Y chromosome. These sex chromosomes are present in every cell in the body. They remain in the cells from conception until death and do not change." Michael K. Laidlaw, M.D.

Historically, biological sex dysphoria primarily affected a very small percentage of biologically male children who were first diagnosed at a very young age (generally, under the age of five). More recently, however, a growing number of pre-teen and early teen females (primarily) are experiencing what has come to be called Rapid Onset Gender Dysphoria (ROGD).

"In my clinical practice I find that social media, internet exposure to pornography, and childhood sexual abuse are often contributing factors to ROGD in my clients ages 10-13. For my client base, the "coming out" is linked to access to the internet or getting their own cell phone where when they google "feeling uncomfortable about your body" google will tell you all about gender dysphoria and being transgender. Other factors can include undiagnosed autistic spectrum and other learning disabilities causing social anxiety." Sheri Golden, Ph.D.

A distraction frequently raised in the context of this issue is the tiny percentage of people who suffer from disorders of sexual development (DSD), sometimes referred to as an intersex condition. Those in whom sexual anatomy is ambiguous or clearly conflicts with their chromosomal make-up are rare, estimated by one expert as "occurring in fewer than 2 out of every 10,000 live births." The vast majority of "transgender" individuals are not "intersexed."

Exhibit
0005
9/30/2021
Dr. Lappert

Any proposed legislation would be carefully written and should not inhibit the normal and traditional treatment of these chromosomal birth defects.

2. How many Utah children experience biological sex dysphoria or Utah adolescents experience rapid onset gender dysphoria?

There are no medical records available that would show how many children see pediatricians because their parents express concerns about any gender confusion their child might be experiencing. Nor are there records that would show how many who do so are advised that that ambiguity in gender expression or feelings is fairly common in children, and that the wisest course is "watchful waiting" because the feelings will resolve themselves in most cases. Nor are there records that would show how many parents have concerns but never report those concerns to anyone. Even if records were available, it still would be particularly difficult to establish or estimate a number because a child's gender expression or emotional feelings about his or her biological gender are not fixed and can change over time.

Rapid onset gender dysphoria in teens is unquestionably a social phenomenon. Often driven by social media and the need to be noticed or to be "trendy," teens sometimes identify as a sexual or gender minority for a season. However, we have no research studies to follow how this changes over time. This very fluidity in identity is a fundamental feature of adolescence and illustrates the dangers of making life decisions based on what could well be a temporary enthrallment.

Reliable research on sexual or gender issues in children and adolescents – particularly in individual states like Utah – is essentially nonexistent. Further, identifying randomly selected subjects, employing reliable and reasonably accurate survey methodology, and following the research subjects over time would be extraordinarily difficult. In addition, for a number of reasons, an attempted survey of even a large sample of school-age children and adolescents could easily yield inaccurate or misleading results in either direction. Voluntary response rates would vary and likely would be considerably less than 100 percent even among the survey sample population, for reasons ranging from individual reluctance to parental objection.

We do know from other evidence (e.g. *Examining Health Outcomes for People Who Are Transgender*, 2019) that there has been an increase in adolescents reporting gender dysphoria of over 1,000 percent in the United States and 4,000 percent in Great Britain over the last decade. Another primary indicator is the number of gender clinics that have begun operation within the last five years. In Utah there has been a five-fold increase in the number of prescriptions for testosterone to girls under the age of 18 in the last five reporting years according to information in the Utah Controlled Substances Database. (As discussed further below, there is no medical reason to administer testosterone to girls; the only possible reason is for gender "transition.")

Evidently, an increasing number of physicians and mental health professionals believe there is money to be made by specializing in this area. New gender clinics are springing up almost overnight. For example, Planned Parenthood is now offering transgender services in the vast majority of its facilities, and has expanding its advertising from its traditional focus on abortion services to include "transgender" pharmaceutical and medical conversion therapies. This indicates that the problem affects a significant number of youth and is increasing.

3. How many Utah children and adolescents are undergoing various forms of "gender affirming" pharmaceutical or medical (surgical) conversion therapies?

Transgender "affirming" processes begin with social transition (changes in name, clothing, public presentation, etc.) and then progress to early pharmaceutical interventions – puberty blocking drugs – to stop normal adolescent development. The next transition phase is administering what are popularly called cross-sex hormones (boys receiving abnormally large doses of estrogen, or girls being injected with large doses of testosterone). The final phase is "sex reassignment" surgeries, in which healthy breasts are removed from females and healthy genitals from males, along with a variety of additional surgical procedures to construct artificial male or female genitalia to "reshape" the body to artificially resemble the body of an opposite-sex individual.

The unregulated nature of these experimental processes and the growing number of unregulated venues where these procedures are available make it impossible to know at what age, in what number, or to what degree gender conversion therapies are taking place in Utah.

a. Puberty blockers:

"Puberty blockers are gonadotropin releasing hormone agonists (GnRHa) which basically chemically castrate either sex at the level of the brain, thus suppressing ("blocking") the formation of either testosterone or estrogen. They are FDA approved for use in precocious (premature) puberty and for treatment of prostate cancer, both being disease states. They are not FDA approved for treatment of gender dysphoria, where their use in otherwise physically healthy minors is experimental, not proven safe, not proven effective, not proven to reduce suicides, and is something to which a minor does not have the competence to consent." Andre Van Mol, M.D.

There are proper medical and FDA-approved uses for puberty blockers with children in certain rare cases such as precocious puberty, idiopathic short stature, endometriosis, or sex hormone-stimulated cancers. (The most common puberty blockers are gonadotropin-releasing hormone agonists (GnRHa) such as Lupron.) The legislation being suggested includes express exceptions for all of the known medical conditions for which these drugs are proper FDA-approved treatment.

"By current protocol, children with gender dysphoria are given these powerful hormones at around age eleven. This is too young for them to understand the implications of what will happen to their minds and bodies. Time is required for maturity of the developing adolescent mind, and hormones play an important role in this development." Michael K. Laidlaw, M.D.

For children experiencing biological sex dysphoria (transgender feelings), there is nothing under current law restricting or limiting physicians, psychiatrists, licensed physician assistants, and even nurse practitioners from prescribing puberty blockers to stop the normal developmental process. Under current law, GnRHa and similar drugs are not controlled substances. There is no mandatory reporting system for prescriptions filled for these drugs.

b. Cross-sex hormones ("masculinizing" or "feminizing" drugs)

By "masculinizing" drugs, we understand the question to refer to administration of testosterone or other androgens to minor females. By "feminizing" drugs, we understand the question to refer to administration of estrogen or compounds with estrogenic effect to minor males.

The next step in "affirming" gender transition of minors for those who first took puberty blockers is the administration of cross-sex hormones. The male hormone testosterone is given to biological females who wish to present themselves as male, in order to give them more masculine physical characteristics (such as facial and body hair and deepening of the voice). The female hormone estrogen is given to biological males who wish to present themselves as female, in order to give them more feminine characteristics such as enlarged breasts. In effect, the cross-sex hormones are used to initiate an artificial partial puberty corresponding to the desired gender identity. In this situation, there may be pressure to start cross-sex hormones at even younger ages, so that the child does not remain in an artificial pre-pubescent state while his or her peers are continuing to develop more adult sexual characteristics.

"*There is no such thing as 'trans puberty.' What happens is that [an] abnormal, pathologic state . . . is induced*." Michael K. Laidlaw, M.D.

Testosterone is a Schedule III controlled substance. (Utah Code Ann. § 58-37-4(2)(c)(vi)(Z).) Consequently, every retail, institutional, and outpatient hospital pharmacy, and every in-state and out-of-state mail order pharmacy, is legally required to report every dispensing of this substance to the Utah Controlled Substance Database (CSD). (Utah Code Ann. § 58-37f-203(3).) The CSD is not accessible by the public. However, we understand from a former legislator who obtained the information from the CSD that more than 550 prescriptions for testosterone issued to minor females were filled in 2019, and that this number is more than a five-fold increase over 5 years before. There is no medical reason to prescribe testosterone to a female other than to facilitate gender "transition."

Estrogen is not a controlled substance, and there is no mandatory reporting system for prescriptions filled for estrogen. Therefore, the number of minor males for whom estrogen was prescribed to facilitate gender "transition" is unknown.

c. Sex reassignment surgeries

"Sex reassignment surgery" is a massive misrepresentation of what these operations actually do. You can't change a person's sex. All that is happening is that the patient is undergoing an intentional mutilation in order to create a counterfeit appearance of the other sex. Nearly 100% of children who are enrolled in "gender clinics" are pushed along from puberty blockers, to wrong sex hormones, to top surgery, and then to bottom surgery, because at each step, the hoped for resolution of their anxiety only finds temporary effect, so the next step is encouraged." Patrick Lappert, M.D.

There are a variety of medical procedures and surgeries that are undertaken in an attempt to make female bodies appear more male, and male bodies to appear more female. Healthy bodies are declared to be "wrong" and are treated as mere material to be mastered and reshaped. These range from the actual removal of healthy breasts and genitals to plastic surgery to construct a more masculine or feminine sounding or appearing body.

"Typically, surgery turning a male into a trans-female involves dissecting the penis, turning the skin inside out, and placing it into a surgically created cavity to create a false vagina. After surgery, a dilator has to be placed in this artificial vagina to keep it from collapsing. Since he still has a small child-sized penis (because of puberty blockers), he does not have enough skin to line the false vagina. Potential remedies include sewing in a section of intestine along with the penis skin to make the false vagina. Once he has surgery to remove his testicles he will be forever infertile, with no chance to produce biological offspring." Michael K. Laidlaw, M.D.

While we have no reporting requirements that would show how many of these various procedures are taking place in Utah, or the age of the patients on whom they are performed, the Internet is replete with the pictures and stories of minor children who have undergone these procedures.

4. How many Utah minors who begin treatment for biological sex dysphoria with puberty blocking drugs subsequently move on to cross-sex hormones and sex reassignment surgeries?

Transgender "affirming" advocates and clinics outline in their publications and websites a step-by-step process that begins with social transitioning, moves to drug and hormone treatment, and concludes with surgical procedures. If one accepts the worldview that an individual can be born as a male with a female brain or as a female with a male brain (*i.e.*, transgender is something you are and not just a dysphoria about biological sex that you experience), then advancing toward becoming your authentic self is the logical goal. Current research from Great

Britain and Sweden suggests that individuals who are socially affirmed in a new transgender identity and begin puberty blockers almost always proceed to cross-sex hormones and surgical transition.

The entire transgender affirming process is so new, so medically experimental, so irreversible in its effects, and so lacking in longitudinal (long term) research that much of the eventual consequences of this socially-driven phenomenon are completely unknown. That is precisely why it is so potentially harmful. Regardless of the number of Utah children affected, be it 5 or 50 or 500, every child and adolescent should be protected from these "adults only" procedures.

5. How are social awareness, population growth, and the evolving understanding of appropriate treatment for gender dysphoria likely to affect the estimates above?

Different parties have vastly different views on what constitutes "appropriate treatment for gender dysphoria." As a nation-wide (and world-wide) social phenomenon, public and even professional awareness is changing rapidly.

We believe the appropriate treatment for children and adolescents is competent and caring counseling by an adept mental health professional. Medical professionals in the United Kingdom, Finland, and most recently Sweden have declared that the permanent, irreversible chemical or surgical damage to the healthy bodies of minors cannot be justified as a wise or sensible approach to what is scientifically a mental health issue. We hope that this growing awareness and Utah's willingness to protect vulnerable children and adolescents will be the foundation for an "evolving understanding of appropriate treatment."

"As a family therapist for over 25 years, as well as educating on gender identity development for nearly 20 years, I have found that when children are confused about their gender, there are usually underlying factors that need to be addressed. Offering to change a child's body, instead of addressing his or her mind, completely ignores the underlying issues. Hormones and amputation of body parts are neither safe, nor effective solutions. However, individual and family therapy (talk therapy) have been shown to be effective with many of these children. Not only is this a safer option, but it addresses the deeper issues." Julie Hamilton, Ph.D., LMFT

Professional perception of what constitutes appropriate treatment for biological sex dysphoria depends primarily on the professional's "worldview" of the issue. Transgenderism is based on the idea that a person can be born into the "wrong body" (*i.e.*, that someone born male can have a "female brain," and vice versa). "Affirming" mental health professionals and physicians accept and advocate that position. Consequently, they favor drug, hormonal, and surgical interventions to try to re-fashion the body to align with internally-perceived gender. However, there is no scientific evidence for this underlying proposition. There is no evidence that there is anything different about a transgender female's brain or body from that of any other male. There is no evidence that there is anything different about a transgender male's brain or body from that of any other female. Persons experiencing biological sex dysphoria are having a

mental or emotional experience—albeit a very painful and difficult and often persistent one—which may arise from any of a number of causes or contributing factors particular to the individual.

It is for this reason that medical professionals are becoming more reluctant to undertake medical procedures on people whose bodies do not present medical issues. Mental health and medical professionals who do not accept transgenderism's underlying assumption—which is an ideological proposition, not a scientific fact or evidence-based scientific hypothesis—believe that these emotional challenges should be addressed through therapeutic counseling procedures.

Part II – Assessing the treatment options

1. **What are the short- and long-term potential benefits and harms of addressing gender dysphoria in minors with medical intervention?**

    a. Puberty blockers:

"Puberty blockers (GnRHa or PB) cause infertility (blocking sperm and egg development) as long as they are used, and their reversibility after discontinuation is not assured. If puberty blockers are followed by cross-sex hormones, sterility is assured. Puberty blockers inhibit and compromise bone density development precisely during life's greatest period of increase for such. This may lead to early osteoporosis. Genitalia are arrested in an underdeveloped stage and sexual dysfunction is also noted (for males: erectile, orgasmic and ejaculatory impairment; for females: a menopausal-like state is induced).

The Lupron package insert warns of mood swings, depression, suicidal ideation and attempts. Brain development milestones are hindered with unknown long-term effects, and the puberty time frame shared with peers is forever sacrificed. Numerous studies show that initiation of puberty blockers selects persistence of gender dysphoria over its natural desistance. Therefore, puberty blockers are not "buying time" or "pause buttons" to "wait and see," but are gateway drugs to cross sex hormones and possible gender reassignment surgery, along with all of their shortcomings.

Their use in otherwise physically healthy minors is experimental, not proven safe, and not proven effective. Thus ruled the United Kingdom's High Court in Bell v Tavistock (Dec 2020), which led to the NHS amending service specifications for Gender Identity Development Services for children and adolescents. Likewise, Sweden's famed Karolinska Hospital issued a similar policy change effective April 1, 2021. Puberty blockade will no longer be allowed for minors under 16, and only under court order (UK) or in a closely monitored clinical trial (Sweden) for those under 18." Andre Van Mol, M.D.

The legislation being suggested includes express exceptions for all of the known medical conditions for which these drugs are the proper FDA-approved treatment. The FDA has not approved use of puberty blockers for treatment of biological sex dysphoria. Use of GnRHa for this purpose is still highly experimental.

Current Utah law does nothing to protect children from physicians, physician assistants, or even nurse practitioners from prescribing these drugs, even though the medical practitioner may have little or no experience or specialty training in the physical or psychological consequences of prescribing these drugs, or knowledge of the current medical research.

Delaying puberty in a child who has confused or dysphoric feelings about his or her biological sex may bring a very temporary perception of relieved stress in delaying physical development that the child thinks he or she does not want, and with which the child is, in the immediate moment, uncomfortable. However, if the confused feelings don't actually represent reality—in other words, if a child with confused feelings has not actually been "born into the wrong body"—prescribing medications can only "mask" or distract from the exploration of underlying problems or sources of the confused feelings.

Transgender activists argue that use of puberty blockers is harmless. They say that their effects are fully reversible if a minor stops taking them. Making any such claims for experimental treatments about which there is little longitudinal medical research is speculative at best and irresponsible at worst. Notably, last year the United Kingdom's National Health Service (NHS) backed away from previous categorical statements that effects of puberty blockers are fully reversible; new NHS statements are much more cautious.

The biggest concern, however, is that in the overwhelming majority of cases, children who are socially transitioned and placed on puberty blockers progress to the next phase of "transition," that is, the administration of cross-sex hormones.

b. Cross-sex hormones

Cross-sex hormones – large doses of feminizing hormones (estrogen) given to biological boys places them at increased risk for blood clots, high triglycerides, cardiovascular disease, high blood pressure, and diabetes. Large doses of masculinizing hormones (testosterone) given to biological girls places them at increased risk for high red blood cells, high cholesterol, cardiovascular disease, high blood pressure, diabetes, and destabilization of certain psychiatric disorders.

The effect of administering cross-sex hormones after puberty blockers is permanent sterilization. A young person who has taken puberty blockers will have already prevented the development of the reproductive system to the point where viable sperm or eggs would be produced in the first place. Indeed, the medical disclosure forms patients or their parents are required to sign before these treatments can proceed emphasize this.

Individuals who have already undergone natural puberty will generally be rendered infertile, at least temporarily, by the administration of cross-sex hormones, which inhibit ovulation in biological females and the production of sperm in biological males. While claims that either puberty blockers or cross-sex hormones alone are "fully reversible" are questionable, the use of both amounts to what some have called "chemical castration."

c. Sex reassignment surgery

It is very important to understand the reality of attempted sex-change surgical procedures. For females, this involves mastectomies, hysterectomies, removal of the ovaries, chest and facial masculinization procedures, and construction of artificial male genitalia from other tissues. For males, attempted sex-change surgery involves orchiectomy (removal of the testes); reduction and reconstruction of the penis to form an artificial clitoris; construction of an artificial vagina and artificial vulva; breast augmentation surgery, and facial feminization procedures. These procedures are irreversible and cause permanent sterilization.

Life-long pharmaceutical treatment and very often repeated medical interventions will be necessary because of the extreme nature of these hormonal and surgical procedures.

"Elective mastectomy to masculinize a young woman's chest (sometimes as young as 13-year-old girls) is the intentional removal of normal tissue in hopes of satisfying a disordered subjective feeling. It cannot be equated to the removal of normal breast tissue in a girl with abnormally large breasts because this latter case is based upon the diagnosis of an orthopedic problem (neck, back, and shoulder pain limiting physical activity). There is an objective medical condition, and 3rd party payment requires reporting of the weights of the specimens in order to confirm the mechanical effects of the weight of the breast, and to distinguish this operation from a cosmetic procedure to make the girl look better. In the case of boys having breast tissue removed, here again we have an objective medical diagnosis of gynecomastia (breast glandular tissue in a boy is not normal).

In the case of transgender masculinization, the diagnosis is subjective, the diagnosis is made by the child, and the doctor has no way of confirming or refuting the diagnosis, and has no way of predicting if the child will benefit. There are no peer reviewed publications to support the procedure, only small studies, typically single center, with massive self-selection bias, and no long term follow up to show benefit. The best studies, which are longitudinal population based studies show that persons who have completed transition surgeries, when followed long term, have a 19-fold higher incidence of completed suicide.

Mastectomy is irreversible. All that can be offered to the ever growing population of females with transition regret is the construction of breast mounds. They will never be able to breast feed (so they have lost a human capacity) and in most cases will have lost erotic sensibility. They will always have large chest scars in most cases." Patrick Lappert, M.D.

Again, there is no medically defensible reason to cut off or mutilate healthy body parts or destroy healthy body functions in response to what is actually an emotional or mental health issue. None of these procedures address the underlying causes of the confused feelings for the individual involved. As with administration of cross-sex hormones, performing these procedures on a minor who does not have the maturity or judgment to make such life-long irreversible decisions for himself or herself is not justifiable.

In short, from a medical perspective, all of these procedures are only harmful and damaging.

The only arguable benefit from this damage is a perception of continued partial relief from distressed and conflicted feelings. How long such perceived relief lasts will vary according to the individual case because the underlying causes of the confused feelings will go unaddressed.

This is especially true for minors, who are at an age at which conflicted emotions on any number of issues are common, and for whom the emotional maturation and developmental processes are not complete. To permanently sterilize a minor at this stage of life, when the minor does not have the maturity and judgment to make the decision for himself or herself, is unjustifiable.

2. What are the short- and long-term potential benefits and harms of addressing gender dysphoria in minors with non-medical (counseling and support) interventions?

Children and adolescents experiencing either biological sex dysphoria or later-occurring rapid onset gender dysphoria are experiencing authentic confusion and distress. Ignoring these genuine symptoms of angst is risky and potentially dangerous. A process of acknowledgement, counseling, evaluation, and support directed by competent mental health professionals is the appropriate approach.

"In young children, for example, parents can be taught how to genuinely "affirm," i.e., learn to recognize their child's innate goodness and communicate their delight in his or her being. In time affirmation by others helps one to affirm oneself as one is, and as one has the potential to be(come). Family and parental therapy may be a tremendous help for enabling parents to affirm their child as s/he is now, even if s/he is discordant about his/her biological sex and how s/he would like to live as a gendered being. Fundamentally, parents can learn to unconditionally love their child." Philip Sutton, Ph.D.

Experiences of biological sex dysphoria in teens are taking place in a developmental season where incidents of childhood trauma, normal identity exploration, peer influence and various emotional conflicts or intellectual misunderstandings (to cite just a few examples) can effect an evolving sense of self. Understanding and evaluating these potential developmental factors requires both time and professional competence. There should be no rush to reach hypothetical and premature psychological conclusions, or to move toward experimental and

dangerous medical interventions which are clearly life-changing and irreversible.

"The research indicates that approximately 90% of dysphoric patients resolve dysphoria by their late 20s. Past peer reviewed research has shown that dysphoria in children can be resolved via psychotherapy, which indicates dysphoria is environmentally based. And yet…many medical doctors and therapists approve of and perform permanent removal of healthy body parts in order to supposedly relieve dysphoria. The research is already showing increased transgender treatment regret in some areas of the world. But the damage to their bodies is permanent in operative cases. Authentic and compassionate psychotherapy treatments must be adopted by our professions." David Pickup, LMFT

Since research clearly demonstrates that a very high percentage of children experiencing biological sex dysphoria will resolve their confusion in favor of their biological sex by the time they reach adulthood, surely a counseling approach makes more sense and does not foreclose "transition" opportunities for adults who eventually pursue a medical option.

3. How should potential harms and benefits be weighed in treatment decisions?

As a matter of general principle, of course, potential harms and benefits should be weighed in any treatment decision. But inherent in that is the imperative necessity of an accurate and truthful understanding, and honest and logical analysis, of the factors involved. In addition, we must consider the ability of children and adolescents to understand these potential harms and benefits and offer truly "informed consent".

"During the past decade, research on neurological maturity shows that the human brain is not finally "mature" until the mid-20's (25 is often given as the average.) It is simply not possible for pre-pubescent and pubescent girls and boys to truly understand the serious short and long-term (life-long) consequences of taking puberty blockers and cross-sex hormones. These boys and girls are simply humanly unable to understand the gravity of such decisions. This is even more true for the amputation of primary and secondary sexual organs. " Philip Sutton, Ph.D.

We must keep the following in mind:

There is no scientific or medical evidence to clearly establish any biological explanation for biological sex dysphoria. We are left to conclude that this is a very real emotional and psychological condition. This is a mental health, not a medical, condition.

Experimental, life-altering pharmaceutical and surgical procedures are a decision to artificially alter the body to meet a mental image the individual may have of himself or herself and to regulate challenging emotions. This process will require life-long medical treatments to force the natural body to accept these synthetically-imposed alterations.

Both a decision to go forward with or to postpone medical "transition" may have emotional consequences. The difference is that children and adolescents who postpone medical interventions and pursue the family and mental health counseling route can always pursue medical interventions as adults should they choose to do so for themselves. Children and adolescents who are permitted by adults to pursue medical transition can never "un-ring the bell." They can never really undo the damage to their body that these procedures will do.

Sadly, parents are sometimes misinformed about the long-term consequences to their children of medical interventions, or receive inadequate support from mental health professionals to assist their children while they pursue a "supportive counseling" approach.

Sometimes parents are misled into believing that a failure to support childhood biological sex transition processes will lead to an increased suicide risk for those they love. They need to know that there is no reliable research to support the idea that these medical transition procedures prevent suicide. While there may be some evidence that biological sex dysphoria increases distress in certain individuals, there is absolutely no research that demonstrates that children who follow a counseling process for their dysphoria are any more suicidal than those who follow a medical transition process. Experts agree that suicide is most likely to be associated with some form of ongoing mental illness.

"Ninety percent of suicides are associated with a psychiatric condition. The risk of suicide coincides of course with the high prevalence of mental illness in this group of people. Depression, for example, is present in at least 50 percent of those who commit suicides." Michael K. Laidlaw, MD

In fact

"Using quotes from the following studies done through NIH/NCBI to answer these concerns.

*'Approximately 58% of transgender patients had at least one DSM-5 diagnosis, most frequently Major Depressive Disorder. (13.6% cisgender) * NIH/NCBI November 2020.' Clearly this is a population at risk and in need of therapeutic counseling and perhaps medication to address these illnesses. Any type of medical transitioning will complicate diagnostic evaluation and treatment. Therefore, rather than reducing suicide risk, medical procedures involving hormone therapy and surgery have the potential to increase the risk because of missed diagnosis and complications of medications.*

*It seems that transitioning in and of itself is does not remove the risk of suicide in this population. As found in the study from *NIH/NCBI June 2020, "Suicide risk in transgender people is higher than in the general population and seems to occur during every stage of transitioning." Therefore the act of transitioning does not prevent the risk of suicide."* Steven Johnson, Ph.D. and Dale Johnson, M.S.

4. **To what extent have long-term outcomes, including physical health, mental health, satisfaction, and regret, been tracked in individuals receiving various treatments for gender dysphoria? What do those studies indicate?**

Again, the entire transgender "affirming" process is so new, so medically experimental, so irreversible in its effects, and lacking in longitudinal (long term) research that much of the eventual consequences of this socially driven phenomenon are completely unknown. That is precisely why it is so potentially harmful and exactly why we should not be preforming these irreversible pharmaceutical and medical conversion therapies on minors.

Part III – Clinical Guidelines

1. **Are the guidelines published by the World Professional Association for Transgender Health and the Endocrine Society and other published information adequate to guide professionals in their care of minors experiencing biological sex dysphoria?**

Twelve years ago a review of more than 100 international medical studies of post-operative transgender patients by the University of Birmingham Aggressive Research Intelligence Facility found "no robust scientific evidence that gender reassignment surgery is clinically effective . . . Research from the US and Holland suggests that up to a fifth of patients regret changing sex."

In regards to children and adolescents there are almost no scientific outcome studies whatsoever.

We must again return to the concern that there has been too little longitudinal research for scientifically-minded organizations to offer authoritative guidelines for either medical or mental health professionals. For example, even when small studies have been conducted, the results are often based on a minority of the participants because, as *The Guardian* newspaper in Great Britain reported, "The results of many gender reassignment studies are unsound because researchers lost track of more than half of the participants. For example, in a five-year study of 727 post-operative transsexuals published, 495 people dropped out for unknown reasons."

Additionally, how do you set medical guidelines without understanding the many psychological conditions that may be affecting the emotional stability of the client? According to one study (*Psychiatric Axis I Comorbidities among Patients with Gender Dysphoria*, 2014) Fifty-seven (62.7%) patients had at least one psychiatric comorbidity. Major depressive disorder (33.7%), specific phobia (20.5%), and adjustment disorder (15.7%) were the three most prevalent disorders. Consistent with most of earlier research, the majority of patients with gender dysphoria had psychiatric Axis I comorbidity.

The Endocrine Society Guidelines published in 2017 advocated for "watchful waiting" as the standard of care for gender dysphoria. The Society noted, "In some forms of Gender dysphoria/ gender incongruence, psychological interventions may be useful and sufficient."

Taking a conservative approach to treatment is justified because, as Professor Kenneth Zucker (of the Toronto Gender Clinic) notes, ". . . the field suffers from a vexing problem: There are no randomized controlled trials of different approaches, so the front-line clinician has to rely on lower-order levels of evidence in deciding on what optimal approach to treatment might be."

The so called "World Professional Association for Transgender Health," or WPATH, is simply a self-selected group individuals who are a political advocacy organization for "affirming" transgender procedures. WPATH is not a scientific or medical organization, and its membership is not restricted to medical or mental health professionals and scientists. No national government or international legal body officially appointed or recognizes WPATH. Nor is it accountable to any recognized body of scientists or medical researchers.

WPATH's views are by no means accepted objective standards, as demonstrated by the policies of the national medical associations in the United Kingdom, Sweden and Norway who oppose pharmaceutical and surgical procedures for children or young adolescents.

In simple terms, organizations who refuse to acknowledge the following concept have a divergent "worldview" that cannot be reconciled with those of us who do:

"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." Stephen B. Levine, M.D.

Part IV – Utah policy

1. **Should any particular treatments for gender dysphoria be limited to adults and emancipated minors? Why or why not?**

For reasons discussed above, cross-sex hormone treatments and surgical interventions for purposes of "transition" or attempted sex change should be limited to adults who have the maturity and judgment (and legal capacity) to make these decisions for themselves. As Stephen B. Levine, M.D. noted in his article published in the Journal of Sex & Marital Therapy, *Informed Consent for Transgendered Patients:*

> All of these patients should be helped by their clinicians to grapple with four relevant questions. Their answers provide the professional with a judgment about how realistic the patient is being:
> 1. What benefits do you expect that the consolidation of this identity, gender transition, hormones, or surgery will provide?

2. What do you understand of the social, educational, vocational, and psychological risks of this identity consolidation and gender role transition?
3. What do you understand about the common and rare, short- and long-term medical and health risks of hormone and surgical interventions?
4. What have you considered the nature of your life will be in 10 to 20 years?

Clearly children and adolescents cannot provide informed consent. The suggested legislation would apply only to procedures performed on minors. Adults are free to choose to undertake these procedures on their own bodies, regardless of whether other individuals personally would agree with that choice.

2. is there statutory, regulatory, or case law you believe the committee should be particularly mindful of?

Yes. In 2019, the Legislature enacted a law prohibiting female genital mutilation on minors (HB 430, Chapter 398 of the 2019 General Session). It was aimed at the practice of genital mutilation of young girls followed in some African Muslim cultures that has found its way to the United States.

Utah Code Ann. § 76-5-701(1) defines "female genital mutilation" comprehensively and with great specificity. Under paragraph (f), it includes "any other actions intended to alter the structure or function of the female genitalia for non-medical reasons." Female-to-male "bottom surgery" certainly alters the structure and function of female genitalia, in addition to involving specific procedures identified in some of the preceding paragraphs of that subsection. Subsection (2) provides that female genital mutilation is child abuse for mandatory reporting purposes under § 62A-4a-403.

Section 76-5-702(1) then makes performing a female genital mutilation on a minor female, giving permission for such a procedure on a minor female, or removing or facilitating the removal of a minor female from the state for the purpose of facilitating such a procedure a second degree felony. Subsection (2) provides that it is not a defense that the practice is required as a matter of religion or custom or that the girl's parent or guardian consented to it. Subsection (3) then provides that a surgical procedure is not a violation of the section defining female genital mutilation if it is necessary for medical reasons or if it is "requested for sex reassignment surgery by the person on whom it is performed."

Under subsection (4), a medical professional who is convicted of a violation will have his or her license revoked. Additionally, section 76-5-704 creates a civil right of action by the victim of female genital mutilation for damages.

Given that these sections apply only to procedures performed on minors, it appears that mutilating a minor girl's genitals as part of surgical "transition" (or consenting to or facilitating

such a procedure for that purpose) is exempt from the criminal sanctions as long as the minor girl requests the procedure.

The exception for sex reassignment surgery was in the bill as originally introduced. We have not been able to find any relevant legislative history regarding that exception. Given the apparent absence of discussion on the issue, it may be that the sponsors were looking at the "sex reassignment surgery" exception as a way to address the rare true "intersex" birth situation for which surgery may be medically appropriate. Or (without any offense to the sponsors or drafters intended) it could be that the provision was not well thought-through in the context of the bill's exclusive application to minors.

As a matter of public policy, it is difficult to understand why performing these procedures, or a parent's consenting to these procedures, is criminalized if it is for reasons of religious conviction, but it's OK if the minor girl is emotionally confused or delusional at the moment.

The version of the suggested legislation considered in the general session earlier this year would not have criminalized performing attempted sex-change surgery on a minor female (assuming the parents consented), but would have defined performing such procedures on a minor as unprofessional conduct that could lead to revoking the medical license of the surgeon performing the procedure. If a measure such as the suggested legislation is enacted, the exemption from criminal prosecution in section 76-5-702(3) could remain unchanged. However, to avoid ambiguity, the legislation should provide specifically for the possibility of professional discipline notwithstanding the exemption from criminal sanction. It should also provide that the private right of action in section 76-5-704 applies and that parental consent is not a defense to a private right of action.

We express appreciation to these noted professionals who contributed to this report:

Chauncey Adams, Ph.D. - Dr. Adams is a Clinical Psychologist with more than thirty years' experience in private practice, served as a psychology consultant in the Washington County school district, and as a the Behavioral Medicine Clinical Director, and former Chair of the Psychiatry Department at the IHC St. George Regional Medical Center. He is a graduate of Brigham Young University, a Member of the American Psychological Association, and a past Board Member of the Utah Psychological Association

Shirley E. Cox, D.S.W. – Dr. Cox has spent many years in private practice and 27 years as a social work educator at Weber State, University of Nevada, Las Vegas, and Brigham Young University. She has received numerous awards for her teaching and community practice including: the Liberal Arts

Outstanding Faculty Award, the Morris Committee on Excellence in Teaching Award, the NASW Nevada Chapter Social Worker of the Year. Her individual and jointly authored publications appear in outlets such as: The Journal of International Social Work and the Journal of Social Work Education.

Michelle Cretella, M.D. - Dr. Cretella received her medical degree from the University of Connecticut School of Medicine and she completed her internship and residency in pediatrics at the Connecticut Children's Medical Center. She practiced pediatrics with a special interest in behavioral health for 15 years and now serves as the Executive Director of the American College of Pediatricians (ACPeds). Dr. Cretella is a peer reviewer for the Journal of American Physicians and Surgeons, Issues in Law and Medicine, and the International Journal of Behavioural and Healthcare Research.

Sheri L. Golden, Ph.D. – Dr. Golden holds a PhD in Counselor Education and Supervision, and an MS in Human Services and Mental Health Counseling, with a specialization in Human Sexuality, from Capella University. Dr. Golden practices as a licensed professional counselor at Steeple Counseling LLC, and is the Director of Counselor Education at The Steeple Institute.

Julie Harren Hamilton, Ph.D. - Dr. Hamilton is a licensed marriage and family therapist with a private practice in south Florida. A graduate of Nova Southeastern University, she is a former Assistant Professor of Psychology in the Graduate Counseling Psychology Department of Palm Beach Atlantic University. She is a former president of the Palm Beach Association for Marriage and Family Therapy.

Geoffrey Heath, J.D., LL.M. – Mr. Heath graduated from the University of Utah, the University of Michigan Law School, and received an LL.M. degree from George Washington University. He is a former supervisory attorney and administrative judge of an Executive department of the Federal government.

Paul W. Hruz, M.D., Ph.D. – Dr. Hruz is an associate professor of pediatrics, endocrinology, and diabetes and an associate professor of cell biology and physiology at Washington University School of Medicine in St. Louis. A graduate of Marquette University, he received both his Ph.D. and his M.D. from the Medical College of Wisconsin.

Dale Johnson, M.S. - Received her undergraduate degree at Salisbury University and received a Master's degree in counseling from Johns Hopkins University. She worked for many years as a school counselor and served as the Department Chair for a staff of 15 where they served over 2000 "high risk" high schools students annually. Dale now acts as a Court Appointed Special Advocate.

Steve Johnson, Ph.D. – Dr. Johnson received his M.A. from the University of Nebraska at Omaha and his Ph.D. at the University of Illinois (dissertation on cognitive dissonance). He is a member of the National Register of Health Service Providers in Psychology and was in private practice in clinical psychology for almost 40 years. During those same years he served as a school psychologist specializing in emotionally and behaviorally disrupted adolescents, conducted cognitive and personality testing, parent and staff training and therapeutic groups. He has taught at George Mason and Western Maryland Universities.

Patrick Lappert, M.D. – Dr. Lappert has been practicing in the field of Plastic Surgery for over 25 years. He completed his undergraduate studies in Biology at the University of California, Santa Barbara, his medical degree at the Uniformed Services University School of Medicine and his general surgery residency at the Naval Hospital Oakland, and is Board Certified in General Surgery. Dr. Lappert completed his Plastic Surgery Residency at the University of Tennessee-Memphis and is Board Certified

by the American Board of Plastic Surgery. He was the former Chief of Plastic Surgery at the largest military hospital in the world (Naval Hospital Portsmouth, VA).

Michael K. Laidlaw, M.D. – Dr. Laidlaw is a board-certified physician in private practice for almost two decades specializing in Endocrinology, Diabetes, and Metabolism. He is a graduate of the University of Southern California School of Medicine, and is a member of the Endocrine Society and the National Board of Physicians and Surgeons.

Stephen B. Levine, M.D. – Dr. Levine earned his M.D. from Case Western Reserve University School of Medicine in and serves as a Clinical Professor of Psychiatry there. His clinical practice is with the University Hospitals of Cleveland Sexual Dysfunction Clinic (presently called The Center for Marital and Sexual Health). He received 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.

Paul McHugh, M.D. – Dr. McHugh is a psychiatrist, researcher, educator and currently the University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine and the author, co-author, or editor of seven books in his field. He graduated from Harvard College and Harvard Medical School. He served as the Chairman of the Department of Psychiatry at the University of Oregon and as the Henry Phipps Professor of Psychiatry and the director of the Department of Psychiatry and Behavioral Science at the Johns Hopkins University. At the same time, he was psychiatrist-in-chief at the Johns Hopkins Hospital.

David H. Pickup, L.M.F.T. – Mr. Pickup holds a Master's Degree in Psychology and is a Doctoral Candidate in Psychology at California Southern University. He is a member of the American Psychological Association and the California Association of Marriage and Family Therapists and is in private practice with offices in California and Texas. He regularly speaks at regional, national, and international conferences on subjects related to human sexuality.

David Clarke Pruden, Sr., M.S. – Mr. Pruden graduated from the University of Utah and Utah State University in Family and Human Development. He is currently the Managing Editor of the Journal of Human Sexuality and an author and speaker on adolescent resilience and sexuality. He was a former adjunct faculty member at USU and Provo College and in his long career served as the Executive Director of the Utah Republican Party and the Director of the Utah Newspaper Association.

Philip M. Sutton, Ph.D. – Dr. Sutton is a licensed psychologist in Michigan, and a licensed marriage and family therapist and clinical social worker in Indiana. He earned his Master of Science in the clinical psychology program and Ph.D. in the marriage and family therapy program at Purdue University and earned a BA in philosophy at the University of Notre Dame. He has been in practice as a clinical psychologist for more than thirty years.

Andre Van Mol, M.D. – Dr. Van Mol is a board-certified family physician with more than 20 years in private practice and is the co-chair of the American College of Pediatrician's Committee on Adolescent Sexuality. His education included the University of Southern California, the Medical College of Wisconsin, Charleston Naval Hospital, and the Naval Aerospace Medical Institute. He is a diplomate of the American Board of Family Practice.

Quentin Van Meter, M.D. – Dr. Van Meter graduated from the College of William and Mary, the Medical College of Virginia and completed his pediatric endocrinology fellowship at Johns Hopkins Hospital. After a 20-year career in the Navy Medical Corps he developed his own full-time private practice. He is an adjunct associate professor of Pediatrics at Emory University School of Medicine and an Associate Clinical Professor of Pediatrics at Morehouse Schools of Medicine.

Addendum A – Detransition Statements

Below is just a small sampling of stories among hundreds of examples you will find on the Internet. For example, go to YouTube and search "detransition" to listen to the many individuals speaking very candidly about their transition stories. To understand the scope of this growing problem, then consider the many more individuals who are too humiliated or traumatized to share their stories, or who just want to move on.

No matter where you are, there are aspects that are dangerous and terrifying about being a woman. And if we don't change that now, then we are just going to continue on this path of changing women and losing women to wanting to be a man because they cannot possibly survive in this society.

Pushing a person like myself in that direction and encouraging that person to take medical steps, I think was a very dangerous thing. Um, I was not told about much of the long-term effects from my therapist. After almost five years on testosterone, I started to experience liver and kidney failure. However, I was not prepared or told even that kidney and liver damage could be related to cross-sex hormones.

I felt like all these success stories were out there this whole time and why was I not doing it right? Why was everything out of control? Why was I not fixed? And when I was reading the stories of these detransition women, I realized it's because transitioning can't fix you.

Rachel Foster - See full interview at: https://youtu.be/w8taOdnXD6o

---

I was about 17 when I had the word for transgender. I felt different before that but I didn't have like a particular word for it and I took intro to psych in high school and, you know, during that time, as a teenager, obviously, everybody goes through like changes and doesn't quite understand themselves. And I happened to be also autistic… A thing about autism is that, um, at least for high functioning, autism will tend to have like obsessions. So when they get into something it's like really into something, um, and they'll do all sorts of like research and, and it can like really, and they convince themselves also. And so I convinced myself that, uh, that I was absolutely trans, like that's what I needed to do…

I started seeing a gender therapist specifically because I'm really, um, resourceful with the internet. And so all I did was like Google gender therapist in Calgary and that was how that happened. After like three sessions I got my, um, permission slip or whatever for transitioning, medically for hormones. And so I started in 2013 on testosterone and it wasn't until 2015 or 2016, actually that I had any surgery. I had a top surgery and unfortunately I had a hysterectomy and oophorectomy, so, uh, I can't have babies. Top surgery I did in May of 2016 and the hysterectomy and oophorectomy I did in 2017. I ended up going through with it and, you know, really regretting it.

I think that up until recently there, haven't been like a lot of detransitoners speaking out, and I think it's important for the trans community, for people considering transitioning and for people who have like doubts in their minds who have already transitioned to hear our stories…

Ashira – See full Interview at: https://youtu.be/i0EFPv1_jdI

My first feelings of doubt. I can't really pinpoint the first thought that I ever had, but it was after my transition had finished. And that was when I changed all of my legal documents. And I felt like I could breathe after that, like I was done, let's live my life the way it was supposed to for the first time. And it was, there was a strong sense of relief in the, in the immediate, you know, and after four years of effort. I started having real doubts was in April of 2019 around my 21st birthday…

I've already done everything that I set out to do. And yet I still feel this dissonance and the dissonance was actually more apparent than the dissonance that I felt before my initial transition. And that was deeply, deeply concerning to me because transition is supposed to correct that initial dissonance. I hated my body now…

And when my voice started to change, I was elated when I got top surgery, I was elated. And so naturally because I was elated after each step, I thought, you know, this meant that I was going in the right direction. But when it was finished, I was left, incomplete, broken. I was suicidal. I couldn't even say the words. I regret my transition. I couldn't bear to hear myself say it. It was the, it was the unthinkable. It was my greatest nightmare.

Daisy – See full video at: https://youtu.be/R_KD46_Ophg

When I was 16 in high school, I thought that I might be a trans man so socially I transitioned about a year. And then when I was 17, I went on to a hormone replacement therapy and I was on that until I was 19. And then I got off of it and I detransitioned fully.

The therapist and the medical staff without being presented enough risks… like if they're not aware of a lot of detransitioners out there and the possibility of detransitioning, then they're going to just be like, oh, well, this person just has gender dysphoria so it's just allowed them to go and fully transitioned. If you've been on hormone replacement therapy you're going through your third puberty and that's kind of traumatic. It's very intense.

Willow – See full video at: https://youtu.be/d-z4H4NvGjw

Billy Burleigh took cross-sex hormones and getting surgeries to change his outward appearance after a difficult childhood and being sexually assaulted by his swim coach. He did his best to live as a woman but ultimately the truth of his biology won out. Billy hopes that by sharing his story, he will help others avoid the damaging and expensive procedures he endured.
https://youtu.be/55IR8taw2Ig

Sydney Wright started cross-sex hormones shortly after she turned 18 and almost died from the effects of testosterone. As she matured she realized she wanted to transition as a result of childhood trauma and internalized homophobia.
https://vimeo.com/481533780

Hacsi Horvath had a traumatic childhood and in a deep depression grabbed hold of the idea that he was actually a woman as a way to start a new life. After years on cross-sex hormones and genital mutilating surgery, he realized it was a mistake.
https://youtu.be/qbCX8XgvBMI

Laura Perry detransitioned after being on cross-sex hormones and having her breasts removed. She has spoken out widely about the harms of the gender industry.
https://www.youtube.com/watch?v=ucdLlJi8j50

EXHIBIT 14

LOCAL NEWS

Alabama bill that would criminalize treatment for transgender minors headed to full Alabama Senate

A Gadsden police officer testified about getting care for his transgender daughter, which would be outlawed by the proposed legislation.

Author: **Micah Danney (alreporter.com)**
Published: **3:02 PM CST February 14, 2021**
Updated: **3:05 PM CST February 14, 2021**

MONTGOMERY, Alabama — The Alabama Senate Health Committee on Wednesday approved a bill that would outlaw puberty-blocking medications and gender-affirming care for minors, giving it a favorable report in an 11-2 vote. An Alabama House committee heard testimony in a public hearing on a companion bill, but the committee did not vote on the measure.

The legislation would also prevent school faculty from encouraging minors to not tell their parents or legal guardians that they do not identify as their biological sex, and would require that faculty divulge that information to parents and guardians.

During the House hearing, some members questioned why the bill was assigned to them instead of the House Health Committee.

They heard from four speakers who supported the bill and four who opposed it. There were medical professionals on both sides, with those in favor saying the bill would protect children from reckless medical procedures and those against saying it would deny life-saving health care to minors at high risk for self-harm and suicide.

Others have had personal experience.

Speaking against the bill was David Fuller, a sergeant with the Gadsden Police Department. He spoke about raising his transgender daughter, who was assigned male gender at birth but seemed different from a young age and struggled with depression and other emotional issues. She revealed her gender dysphoria to him when she was 16.

“I mean, I was probably like you guys — I didn’t like this. I didn’t understand this,” he said. “I was ignorant to it.”

As he began to learn about it, he discovered the statistic that half of transgender teens try to kill themselves, he said. It terrified him. Then he learned that the suicide risk returns almost to normal for teens who are supported by their families and communities — and who have access to health care. Studies have shown that gender-affirming care, such as puberty blockers, is linked with lower suicide risk for transgender people.

After his daughter shared her suicidal thoughts, Fuller took her to specialists at the University of Alabama at Birmingham. He said they were keen to slow down any talk of medical treatment like puberty-blockers or hormone therapy. Most importantly, he said, they provided support and information about options that could be pursued overtime at a delicate and critical time for his family, which he credited with saving his daughter’s life.

“They made us feel like we weren’t alone, that we were normal in an abnormal situation, and that they could help us,” Fuller said.

One voice in favor was Walt Heyer, an author and traveling speaker who has become known in some Christian circles for his story of living as a woman for eight years before transitioning back to a man. He regrets that decision and period of his life, he said. Heyer said that confusion in minors about gender identity can start early and lead to medical decisions that have lasting consequences, so he supports the bill’s blanket ban on medical treatments.

Another speaker opposed to the bill was Dr. Morissa Ladinsky, a Birmingham pediatrician who has experience working with transgender youth. She said that they may assert their gender identity anywhere from preschool to puberty or later, and any treatment that affirms that identity is long-term and involves “lengthy informed consent” with all parents.

No irreversible treatments are allowed on minors, she said. Puberty-blocking medications can be reversed and surgeries are not performed on children.

“Folks, there are not pediatricians traveling around Alabama just writing hormone prescriptions for minors,” she said.

Ladinsky accused the bill of unfairly criminalizing pharmacists for filling the prescriptions that it would outlaw. Pharmacists rarely, if ever, know the reason a drug is prescribed, she said.

“This bill tells truly vulnerable youth, those facing gender dysphoria, that you are going to make their health care a crime,” she said. “It invades the sacred domain of parenting, reaches into the practice of medicine and shuts down the parent voice in medical decision-making.”

Dr. Patrick Lappert, a Decatur plastic surgeon, spoke in favor of the bill. He cited a Swedish study that found an increase in suicide rates and other mental health issues among transgender people in adulthood, apparently contrary to the notion that early medical treatment had saved them.

Mental Health Monday: LGB…

Sweden has a universal database for medical records, which Lappert said makes its data most reliable in tracking the health of transgender people longterm. A 30-year study in Sweden

published in 2011 found that participants who had sex-reassignment surgery went on to have significantly higher rates of mortality, suicidal behavior and psychiatric morbidity than the general population. The researchers concluded that "sex reassignment, although alleviating gender dysphoria, may not suffice as treatment for transsexualism, and should inspire improved psychiatric and somatic care after sex reassignment for this patient group."

But a 50-year survey published in 2010 found that out of 767 respondents, just 2 percent expressed regret about their reassignment surgery. Among participants who underwent non-surgical treatments like puberty-blockers, less than 2 percent expressed regret. More recent research has found that mental health gets better and continues later in life the earlier that medical treatment addresses gender dysmorphia.

Lappert, who has spoken against the use of medicine and surgery for transgender people as a Catholic deacon in his local diocese, said that the vast majority of teens who present themselves as being in the wrong body "have gotten over the idea" once they reach early adulthood. When a committee member questioned Lappert's medical expertise on the issue, Lappert said that he would not treat a person seeking guidance for their gender dysphoria but would refer them to a qualified mental health professional.

Responding to further questions from the committee, Fuller took issue with what he said was implied by Lappert's mentioning of the Swedish study.

"I'll tell you why that happens: It is terribly hard to be a transgender person in this world, on this planet, anywhere. And God forbid in Alabama — here we are legislating against the health care these kids need," Fuller said.

The Human Rights Campaign, a national group that advocates for LGBTQ rights, issued a statement on Wednesday saying that the bill is part of a seven-state, coordinated push for legislation by a national campaign.

"These bills are not addressing any real problem, and they're not being requested by constituents," the group said. "Rather, this effort is being driven by national far-right organizations attempting to sow fear and hate."

Dillon Nettles, director of policy and advocacy at the ACLU of Alabama, issued a statement on the Senate Health Committee's passage of the bill:

"Alabama lawmakers are once again threatening the healthcare choice of everyday Alabamians. By passing SB10 out of the Senate Health committee today, children across Alabama are at risk of losing life-preserving care due to their identity and the government.

"This legislation also puts Alabama's doctors at risk of being charged with a Class C felony simply for performing their duties by supporting the health and well-being of transgender children.

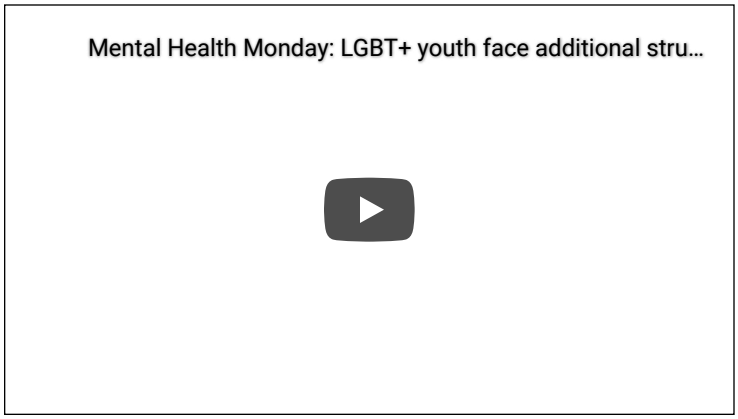
"This legislation is wholly dangerous and irresponsible, particularly at a time when the importance of qualified and non-exclusionary medical professionals is more evident than ever, and children are already struggling under the circumstances of this pandemic."

The bill is expected to go to a full vote in the Senate. It will be on the House Judiciary Committee's agenda again in two weeks.

This story originally appeared in the Alabama Political Reporter.

IN OTHER NEWS: Mental Health Monday: LGBT+ youth face additional struggles during pandemic

Mental Health Monday: LGB…



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In LGBTQ-friendly fashion, Biden White House website now allows choice of pronouns

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Mental Health Monday: LGB…

EXHIBIT 15

Exhibit
0033
9/30/2021
Dr. Lappert

Transgender Surgery
&
Christian Anthropology

COURAGE
A Roman Catholic Apostolate

Deacon Patrick W. Lappert, MD
Birmingham in Alabama
256-303-8509

The Challenge

- "Male and female He created them" has been replaced by a confusion of exceptional cases.
- Aggressive re-characterization of the nature of the human person.
  - Academia, entertainment, law, and even at church.

Finally and above all, man has made stupendous progress in the domination and rational organization of the forces of nature, such that *he* ***tends to extend this domination*** *to his own total being;* ***to his body***, to psychical life, to social life, and even to the laws which regulate the transmission of life. ~ Humanae vitae 2

The Challenge

- Understand the subject.
- Fluent in the language.
- No shocking surprises.
  - Patient, but insisting upon the truth

Human Nature

- The human person: body and spirit together comprising a single nature.
  - By our nature we are made for *the other*.
  - Possessed of an intellect by which we can know the good, the true, and the beautiful.
  - Possessed of a will by which we can choose the good, the true, and the beautiful; *the moral life*.

Human nature

- The moral life: built upon foundational truths.
- Not arbitrary.
- Not repressive, but rather affirming of the intrinsic dignity of the person.

What is a human being?

Human Nature

- The human body
  - The "reproductive system", and the fulness of humanity.
- Dimorphism and complementarity.
- The human family is in our nature.

The Image and Likeness of God

Human Nature

- Why must we consider first the *nature* of the human person?
  - Defines the "end" of medical and surgical care.
  - Human nature is that which is perfected by the life of grace.
  - That which is perfectly realized in the Incarnation of Jesus Christ.

Modern "Gender"

- A confusion of biology, psychology, and political science.
  - Use of biology to explain psychology
  - Political terms to explain the emotional life.
- Shifting from biological determinism, to freedom of expression.
- Language of "science" counterpoised with rejection of scientific evidence as "tool of oppression".

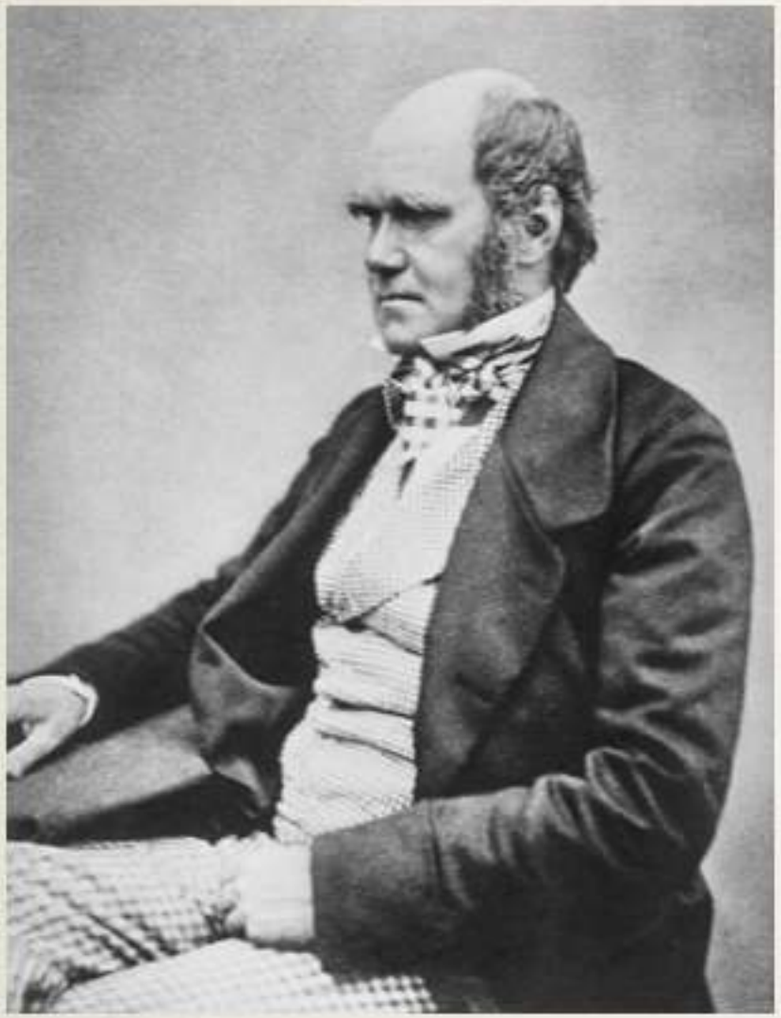
"Great Expectations"

- Science (separate from faith): A "pure" thing.
  - Deeper, "more evolved"
- Technology: domination of nature
  - Capability to modify the person in any way that "choice" demands.
- *Progress*: irresistible power of history leading to liberation from the oppression of the past. Transgenders no longer *"outcasts"*!

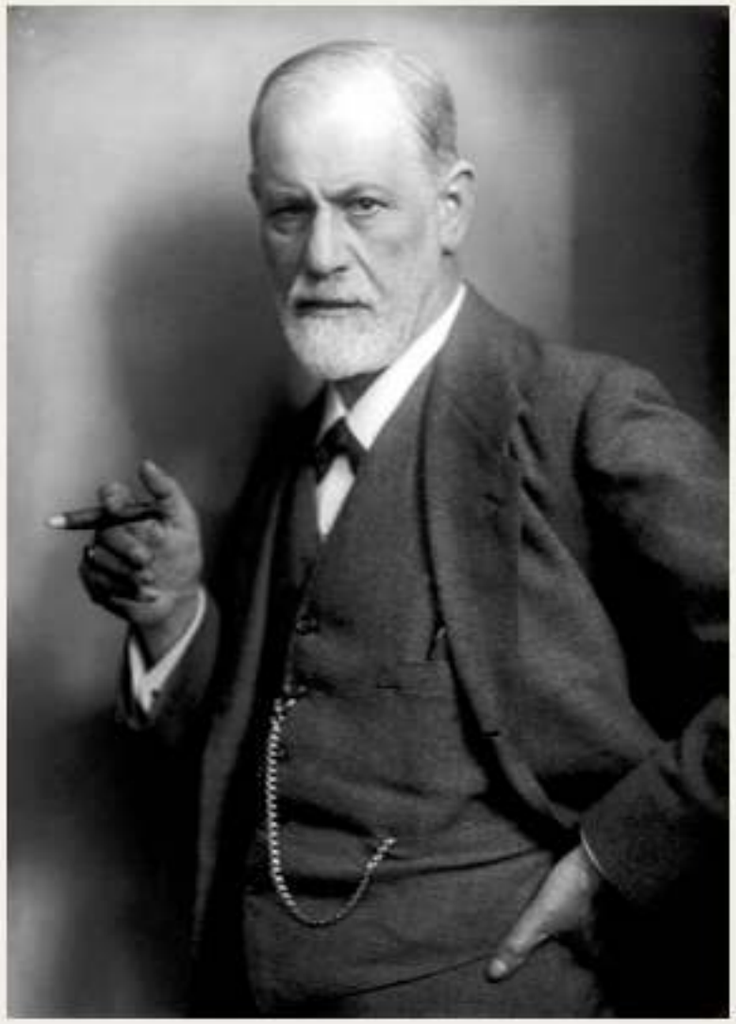
Transgender Language

- Outgrowth of "gender identity" principles.
- Relationship to the "sexual revolution".
- The divorce of the two aspects of human sexual union.
- Catholic anthropology vs. materialistic anthropology.

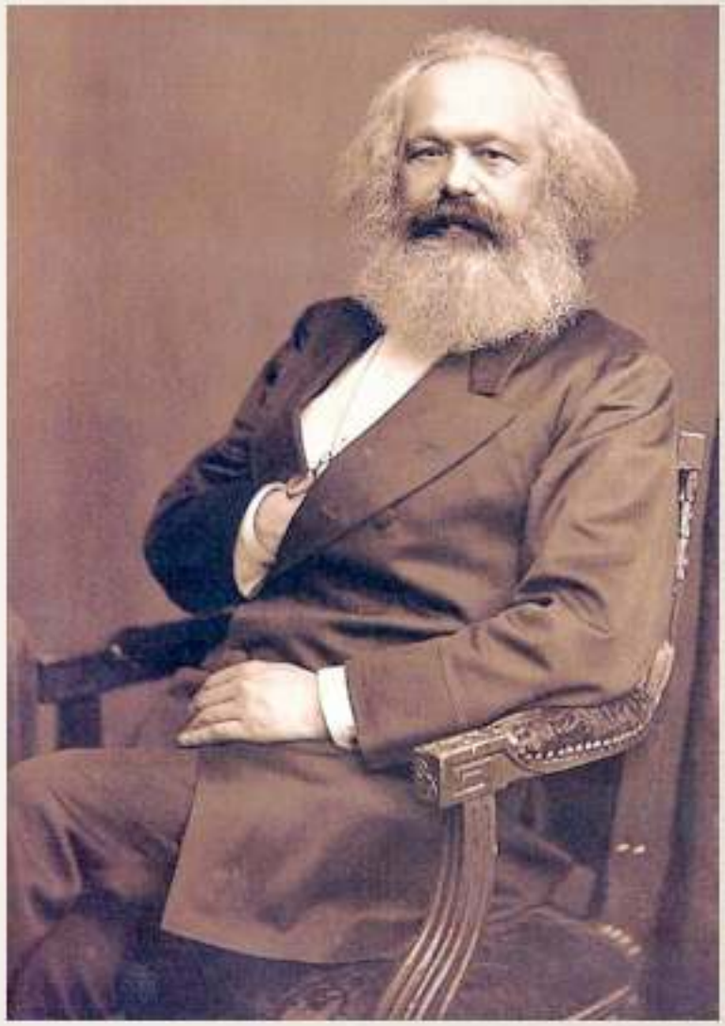
The 3 Stranded Rope



Charles Darwin



Sigmund Freud



Karl Marx

The human person is materially caused, materially driven, and his highest aim and happiness is materially defined.

Psychological Language

- Seeking to give a complete explanation of human behavior, without recourse to theology.
- Man as merely a particularly complicated animal.
  - Inherent drives common to animal life.
    - Assorted coping mechanisms to deal with the frustration of those drives. Some are pathological = neurosis / psychosis
  - "The Pleasure Principle" ~ Freud

Psychological Language

- The search for "pleasure" is the central instinct:
- Sexual pleasure seen as the zenith.
- The central element in character development:
- Sexual drive, and sexual experiences are seen as the prime movers in the development of personality and social capacities.
- Good (pleasurable) experiences = good personality development.

Psychological Language

- Human sexuality is viewed from the standpoint of the *one person, their needs*, and the satisfaction of those needs.
- Any moral perspective on human sexuality seen as an arbitrary social restriction, or *"taboo"*, without foundational truth.
- Belief that much psychopathology can be avoided by changing society, and ignoring moral questions.

Modern Sexuality Sumarized

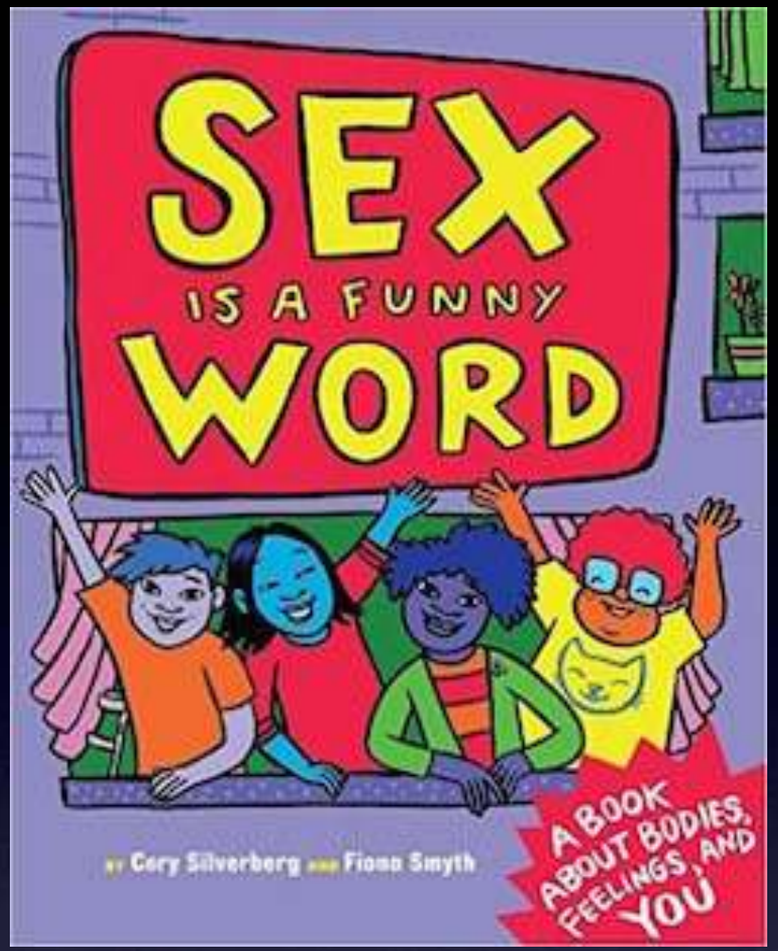
(Lappert's Axioms)

"Adult sexuality" is an endlessly variable, *personal* expression of *individuality,* the purpose of which is to produce joy for that person. It sometimes involves other people, and with alarming frequency, is known to produce other people.

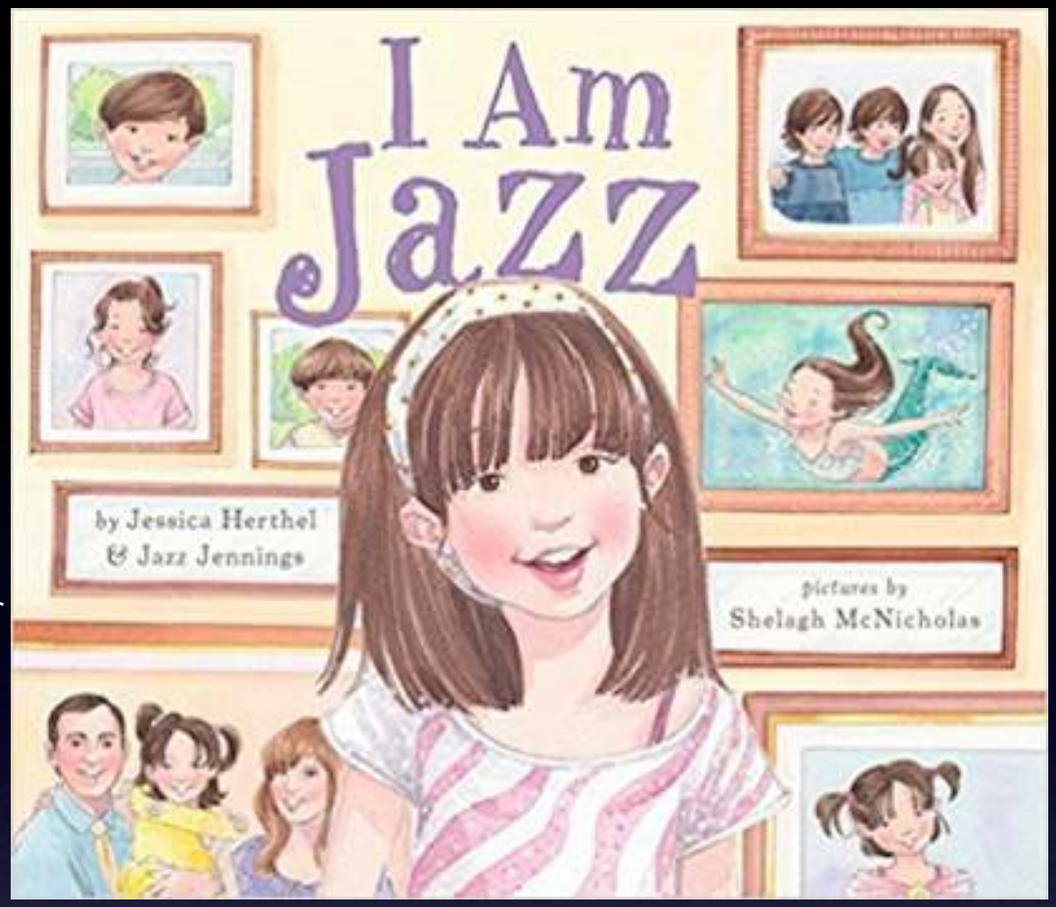
Modern Sexuality Sumarized

(Lappert's Axioms)

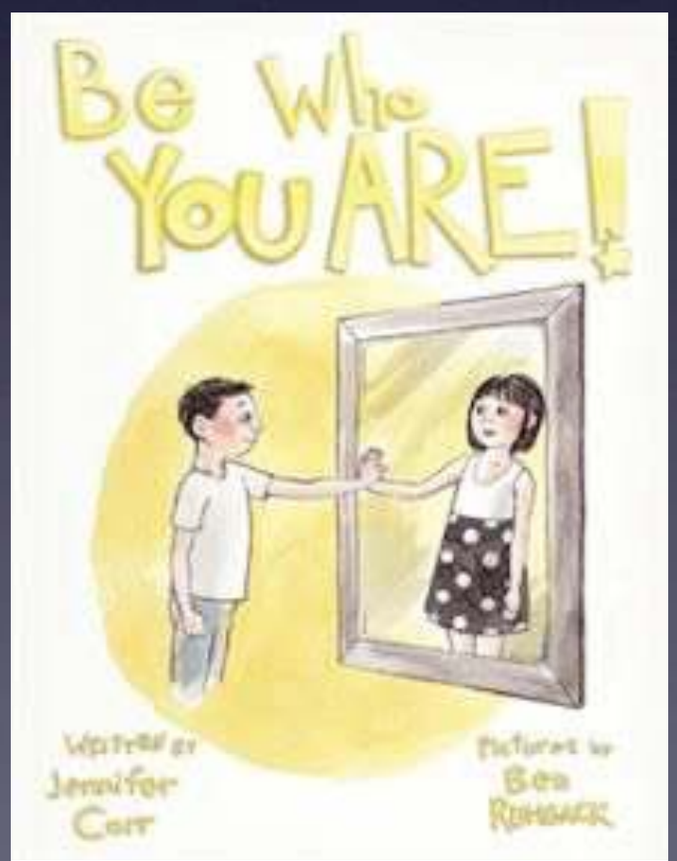
"Adult sexuality", is the developmental result of "childhood sexuality", just as adult language is the developmental result of childhood language. For this reason, it has become the habit of psychologists, and teachers to talk to children about "adult" sexual activity.

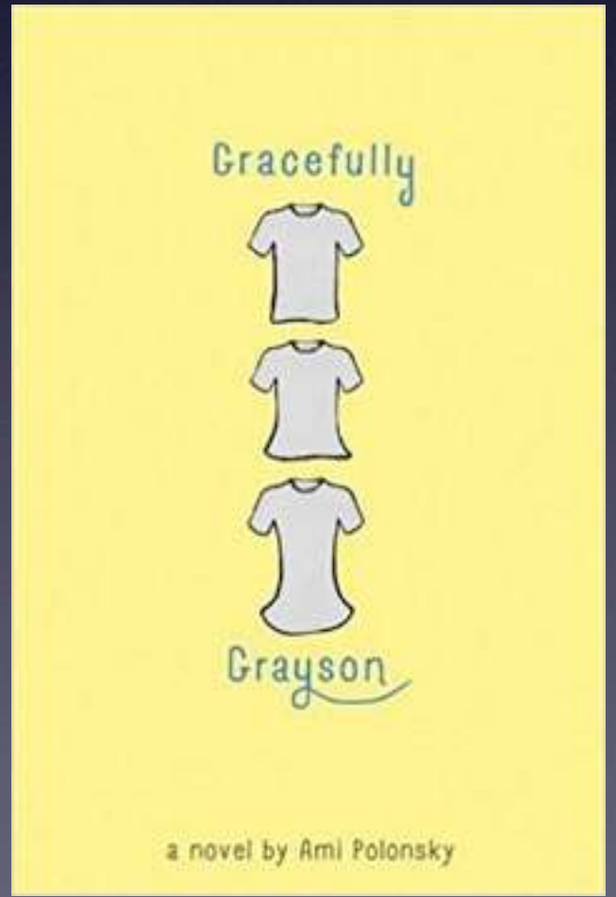


Recommended for
4- 8 y.o. children



Recommended for
7- 10 y.o. children





Recommended fo
9 y.o. children

"I like to say that I'm a girl stuck in a boy's body."
Lia, age 9
#GrowingUpTrans
pbs.org/frontline
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Making Life Better with Plastic Surgery

- When you "don't feel right, because something "doesn't look right".
  - Aesthetics or Reconstruction

Managing the Unseen Wound

- Profound sorrow, anger, anxiety.
- Seeking a material (aesthetic) explanation and remedy.

Body Dysmorphic Disorders

- Broad category of disorders of misperception about physical appearance
- Anorexia
- BDD/ Aesthetic surgery patients
- Seeking limb amputations etc.

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SEARCH INVE

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Science
Neurophilosophy

The science and ethics of voluntary amputation

Should amputation be offered as a treatment to people suffering from Body Integrity Identity Disorder?

Mo Costandi

Wednesday 30 May 2012
13.07 EDT

Shares 107 Comments 74

Body Dysmorphic Disorder

- Type of Obsessive- Compulsive Disorder
  - Depressive presentation
  - Social isolation. "Outcast"
- Treatment
  - SSRIs, Cognitive-Behavioral Therapy

Gender Dysphoria

- The unhappiness associated with the condition because:
  - "I don't look the way I know I should"
  - "The world does not accept me as I know I really am"
  - Social isolation due to:
    - Incongruous behavior
    - Secret life with associated shame.

Transgender

- Obsessive thinking with varying degrees of "dysphoria"
- Perceiving something that is not objectively there:
- Delusional thinking
- Errors of assumption

Criteria For Delusion

- Karl Jaspers in *General Psychopathology* (1913) The criteria are:
  - certainty (held with absolute conviction)
  - incorrigibility (not changeable by compelling counterargument or proof to the contrary)
  - impossibility or falsity of content (implausible, bizarre or patently untrue)

Co-morbidities:

- Alcohol and drug abuse, depression, incarceration, homelessness, high rate of suicidal ideation.
- Variable in Expression:
  - Private stress management by cross-dressing
  - Public, anonymous cross-sex persona, including sexual contact (sometimes prostitution).
- Transitioning in stages.

Biological Language

- Seeks to establish the material causation for the psychological instincts/ drives
  - Genetic, neuroanatomic, endocrine, etc.
- Seeks to understand the biological basis for "gender"
  - Sexual dimorphism/ polymorphism vs. social construct and learned behaviors

Biological Language

- "Evolution" words applied to human sexual functioning.
  - Searching for the "adaptive advantage" of fruitless sexual activity.
    - The problem of reconciling a Darwinian view of the human person, and a putative inherited behavior that is annoyingly maladaptive.
- The hope: genetic trait of animal life would silence moral arguments.

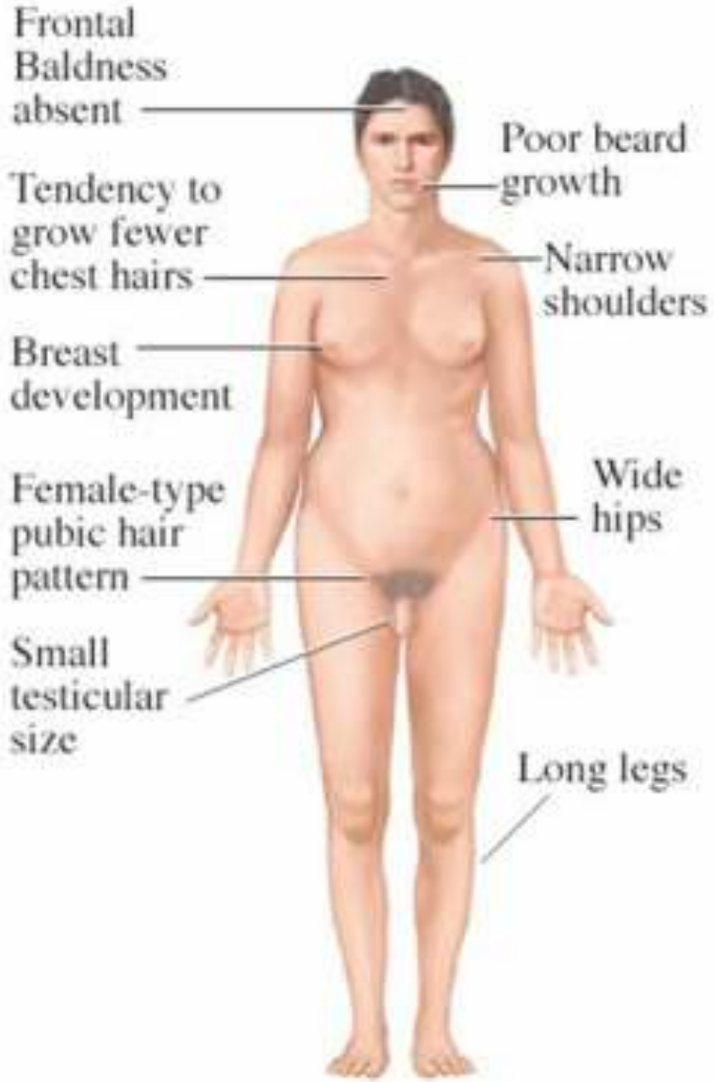
Biological Determinism
vs.
The Moral Life

Biological Language

- "Isn't there a genetic explanation for "transgender?"
- "We learned in school that there are many genetically caused examples of people who are somewhere in between "man" and "woman".
  - Klinefelter's Syndrome
  - Androgen Insensitivity Syndrome (AIS)
- "That is what I have. I am "intersex", and I choose to be....."

Biological "Intersex"
(Hermaphroditism)

Klinefelter syndrome



- **Lower IQ than sibs**
- **Tall stature**
- **Poor muscle tone**
- **Reduced secondary sexual characteristics**
- **Gynaecomastia (male breasts)**
- **Small testes/infertility**

Clinical Support for Intersex Persons

- Multidisciplinary: Pediatrics, Geneticists, Pediatric Surgery, Urology, Psychology.
- Assessment: Including genital ambiguity, problems with voiding etc.
- Planning based upon “sexual assignment”.

Gender Assignment Surgery
(ambiguous genitalia)

- Seeks to remedy structural problems that interfere with voiding.
- Seeks to establish an arrangement of tissue that would make sexual intercourse possible.
- Make reproduction possible only in cases of structural problems of shape, size, and patency.

So…is it biological?

- Genetic, like Klinefelter or AIS?
  - No genetic marker, no mutation.
    - Normal male or female karyotype
- Hormonal?
  - Hormone levels entirely normal for age/sex matched controls
- Anatomical?
  - Brain scans: MRI, PET Scan etc.
    - No structure/ activity that mimics opposite sex.

Nature v. Nurture

- Speculation among "sexologists" working in Intersex Clinics.
  - "Gender Identity" is:
    - Malleable, or "fluid"
    - Socially determined
    - Typically produced by "repressive" processes

The "Science" of Gender

Dr. Harry Benjamin

Dr. Alfred Kinsey

Dr. John Money

Nature v. Nurture

- Difficulty in separating the vague and as yet not demonstrated genetic influences from social/ cultural influences.
- Database skewed by selection bias among genetically/ developmentally abnormal patients.

The Twin Study

- The "gold standard" for exclusion of biological determinism (genetic).
- Monozygotic twins raised in different social circumstances.

The Index Case

John Money, PhD

Sexologist in the Intersex Clinic
Johns Hopkins

-Convinces parents to raise their son as a girl.

-"Socialize" strenuously as a girl

-Castrate, and administer estrogen

-Ultimately use reconstructive surgery to produce a neo-vagina.

Published Results in "Peer Reviewed Journals"

- Papers and presentations based upon "long term follow up".
- "Successful" in every way.
- Torrent of "scientific literature" re: gender roles/ identity etc.
- Political dimension

John Money, PhD

The Reimer Twins

“Brenda” Reimer

"Scientific" Basis of Gender Politics

- Gender "assignment" is a process of repression.
- Forces persons into "binary" model of sexual expression.
- Sexual expression is a form of political expression.
- "Dr. Money's twin study proves this conclusively!"

Annual Visits to John Money, PhD

- Expected result further drives the intervention.
- Photographs them as he "instructs" them in "sex-play".
- Fear and anxiety

Truth

- Was eventually given the truth at age 15.
- Enthusiastically embraces boyhood.

The Experiment is Ended

- Hormone replacement due to castration.
- Surgical efforts
- The silence of John Money, PhD

David the Man

Husband, and adoptive father of three children

David the Man

- Battle with depression.
- Financial difficulties
- Wife leaves him after 14 years.
- Brother dies of drug overdose.

David Reimer 1965- 2004

The Nexus

- Catholic Anthropology

&

- Plastic/ Reconstructive Surgery

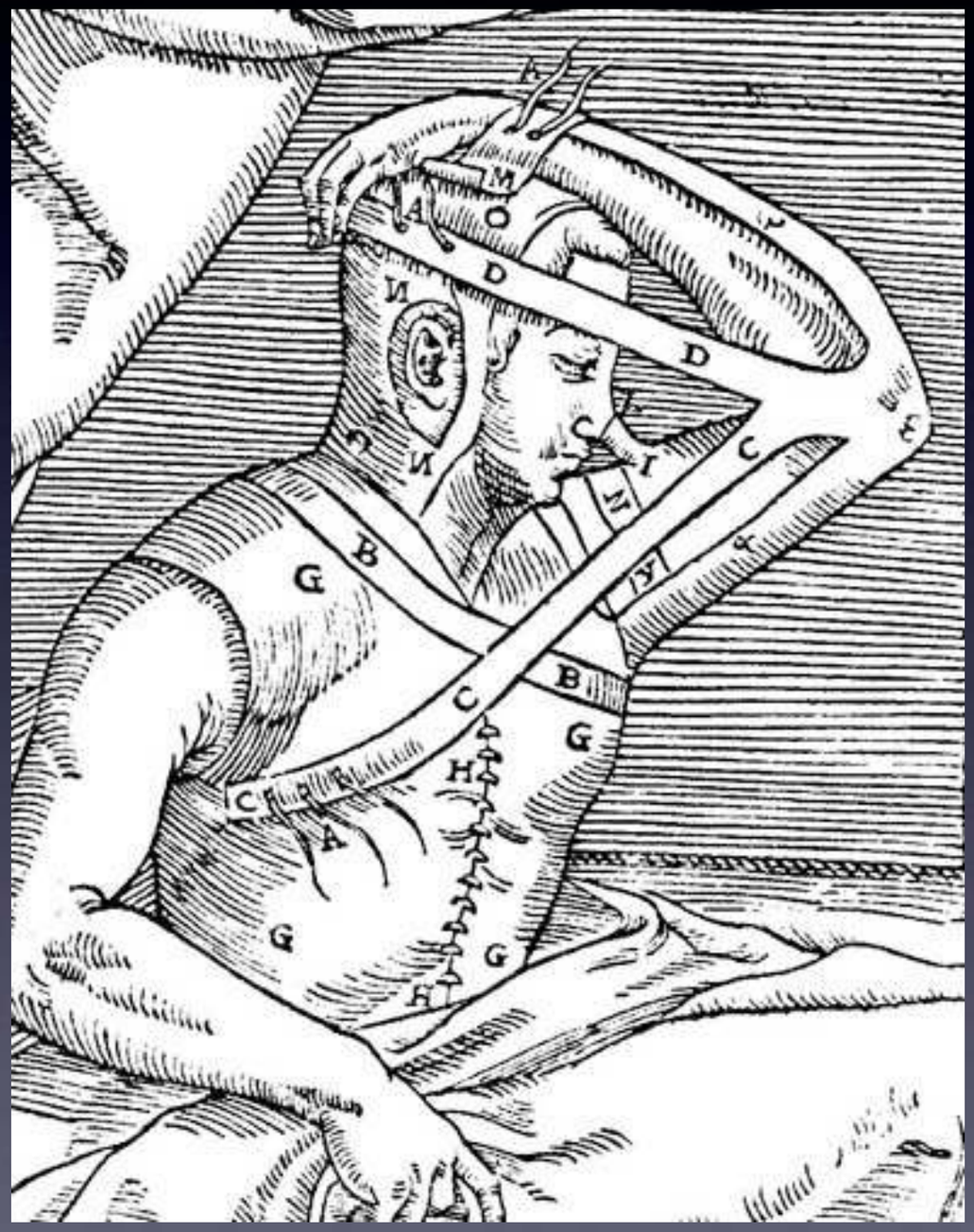
A Quick Review of Plastic Surgery

- The oldest form of surgery
- Ear reconstruction- India
- Nasal reconstruction- Italy
  - Restoration of the social outcast.

Sushruta- 7th Century BC India

The Mutillation of Emperor Justinian II *"Rhinotmetos"* 695 AD

History-



Plastic & Reconstructive Surgery

- Basic Principles:
  - Establishment or Restoration
    - Form and Function
  - Based upon a thorough understanding of the nature of the missing or injured part, and its relationship to the person.
  - Directed at the "perfection" of the nature of the human person.

Restoration

- Lost due to trauma, or surgical management of malignancy, infection, etc.
- Missing at birth, due to developmental anomalies, or in-utero events.

Missing from trauma

- Adult male: traumatic amputation of non-dominant thumb
- Needs prehensile, helping hand with good grip and fine "key pinch" functions.

Restoration

- Degree of functional restoration is dictated by the intrinsic natural function of the lost part
  - Hand:
    - Grasping, pinching, stabilizing, pushing, dominant vs. helping.
- Goals are tailored to the life of the patient

Congenital Cleft Palate

- Congenital malformation of the face with varying degrees of palatal integrity
- Feeding difficulty
- Speech problems
- Hearing problems
- Dental problems

The Cost of Reconstruction

- What will be lost, or compromised in the course of reconstruction?
- "Donor defect".
- Risk vs. benefit

"Transitioning"
(Progressive Expression of Condition)

- Obsessive thoughts leading to compulsive behaviors.
- Interferes with living in the present moment.
- Managing anxiety by unhealthy means.
- Withdrawal, cross-sex dressing / acting in secret.

Transitioning

- Secretive, dysfunctional life leads to conflicts with family, and peers. Causes “dysphoria”.
  - Psychological counseling: the broad and the narrow.
  - APA: Presumes that “gender non-conforming” is the essential and true nature of the person, therefore health is to be found in giving full expression to the subjectively perceived persona.

Transitioning

- Psychological Testing of "maleness and femaleness" (objective standard).
- Cross-sex identity development: clothing, name, persona.
- Endocrine management
  - Puberty blocking in pre-pubertal children; cross-sex hormones.
- Voice training, hair management.

Children's Hospital of Philadelphia

FIND A DOCTOR DEPARTMENTS CONDITIONS LOCATIONS YOUR VISIT Search...

Endocrinologist

Wilma C. Rossi, MD, MBE

Gender and Sexuality Development Clinic

CONTACT US

"Providers, patient and parents were ready to start hormone therapy with testosterone to help him align his body with who he had always known he was on the inside."

"While gender-related healthcare can be expensive in the short term, it is recognized to lead directly to improved health outcomes and long-term cost savings." ~CHOP

The Washington University

Transgender Center

at St. Louis Children's Hospital

E-m

314.454.KIDS (54

800.678.KIDS (

Resources About Us What to Expect

cs.wustl.edu/transgender-center/#

"Your first visit to the Washington University Transgender Center at St. Louis Children's Hospital will take about 60-90 minutes. You'll meet with one of our physicians for an informational discussion about age-appropriate therapies (depending on if the patient has started puberty.) You may be referred to a mental health provider for ongoing psychosocial support and assessment, if indicated.
Records from patient's primary care physicians should be sent prior to the first visit, so our doctors can review them for pre-existing conditions that may be affected by hormone therapy."

Karen Hamon, BSN, RN, CDE

Pronouns: She, Her, Hers

Karen is a Clinical Nurse Coordinator in outpatient care at Washington University School of Me
of Endocrinology and Diabetes. She received her Bachelor's of Science in Nursing from Goldfar
Science in Justice Systems with a minor in Sociology from Truman State University. Karen's prio
pediatric general medicine floor and as an inpatient diabetes educator at St. Louis Children's H
Diabetes in 2013 and has won two division awards since then. She is also currently a finalist fo
Karen is very passionate about social justice issues and jumped at the chance to be part of the

Casey E. Lofquest, MSN, RN, CPNP

Pronouns: She, Her, Hers

Casey is a Pediatric Nurse Practitioner (PNP) in outpatient care at Washington University Schoo
Division of Endocrinology and Diabetes. She received both her Bachelor's of Science in Nursing
specialty), from Saint Louis University. Casey's prior experience includes staff nursing care in p
intensive care nursing. She practiced as a PNP in primary care in Arnold, MO, prior to joining th

PHOTOGRAPHY BY GARA DYSON

Jessica, one of the center's patients, with Dr. Christopher Lewis

-Education regarding gender dysphoria and its possible treatments. Gender dysphoria refers to the distress that may accompany the incongruence between one's gender identity and one's assigned sex at birth.

-Administering pubertal blockers, which delay puberty and suppress unwanted and irreversible secondary sexual characteristics; for example, deepening of the voice and facial hair for transgender females and breast development for transgender males.

-Administering cross sex (gender-affirming) hormones that make a person's physical body match their gender identity. These may begin between the ages of 14 and 16 after patients meet readiness and eligibility criteria.

Puberty blocking drugs
Cross-sex hormones

Absence of medical evidence

Human experimentation

Irreversible effects on:

- Fertility
- Neuropsychiatric/ musculoskeletal development

Desistance data. 9% vs. 100%

Transitioning

- Surgery
  - Secondary surgeries: hair, forehead, nose, jaw, neck, breast. Euphemism: “Top Surgery”.
  - Definitive and final: castration and vaginoplasty, or hysterectomy / oophorectomy and phalloplasty. “Bottom Surgery”.

PSEN University: Gender Affirming Surgeries 101 - Webinar (Includes Gender Affirming 101 Series)

Member Price $250.00

Non-Member Price $325.00

Members Save $75.00

In Stock

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Product Description

Presented by: Loren Schechter, MD

About this Course :

This course is a live webinar CME course to be held on **April 18th 2018 at 7pm cst.** This course also includes the 2017 ***PSEN University: Gender Affirming 101 for Surgeons - Video Series*** which features ten webinar recordings from a

The Surgery

- Top surgery is largely reversible.
- Bottom surgery is irreversible. Fully functioning genital organs are mutilated in order to produce a counterfeit form.
  - Form has primacy
  - Function is destroyed (donor morbidity)

Grave Matter

- Willful sterilization destroys the procreative aspect.
- Simultaneous degradation of the unitive aspect.
  - major loss of sensory apparatus, and persistence of the native neural "map" in the brain.

Grave Matter

- "Banking" of ova and sperm for future in vitro and proxy pregnancies.
- Objectification of children; the "right to a child".
- Link between "reproductive technology", & "gender affirmation medicine".

Plea For Mercy

- Because self-identified transgender persons suffer greatly
  - High rate of substance abuse.
  - High rate of homelessness.
  - High rate of suicide attempt:
    - 18yo - 55yo steady at approx. 40% risk.

"The only way I will rest in peace is if one day transgender people aren't treated the way I was, they're treated like humans, with valid feelings and human rights. Gender needs to be taught about in schools, the earlier the better. My death needs to mean something" - Leelah Alcorn

UK: 48% of trans people under 26 attempt suicide (2014)
US: 41% of trans people attempt suicide (2014)
Canada: 43% of trans people attempt suicide (2012)

The Appeal From Sentiment

Compulsion To "Mercy"

- "Everything must be done to help these persons live their new identity"
  - Home, school, work
  - Names, pronouns, bathrooms, etc.
  - Health insurance directed toward transitioning, not treatment of OCD.
  - Attempts to diagnose and treat are labeled "hate speech".

So...it is working, right?

Evidence Based Medicine

- Over the years, many small retrospective studies.
- Inconsistent criteria for inclusion of patients and the selection of controls
- Much self-selection bias; high drop out rate.
- Small samples and short follow-up
- Varying degrees of “success”. Ranging from “improved in gender dysphoria” to continued elevated psychiatric hospitalization and suicide attempts and death.

The Swedish Study

- Population cohort study over 30 year period.
- Age and sex matched cohort.
- Data from consistent national database.
- Standardized reporting for identity change, hospitalization, psychiatric diagnosis and co-morbidities, and mortality.

The Swedish Study

Long-Term Follow-Up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden

Cecilia Dhejne,[1] Paul Lichtenstein,[2] Marcus Boman,[2] Anna L. V. Johansson,[2] Niklas Långström,[2,3] and Mikael Landén[1,2,4,*]

James Scott, Editor

Author information ▶ Article notes ▶ Copyright and License information ▶

This article has been cited by other articles in PMC.

Abstract

Go to: Go to:

Context

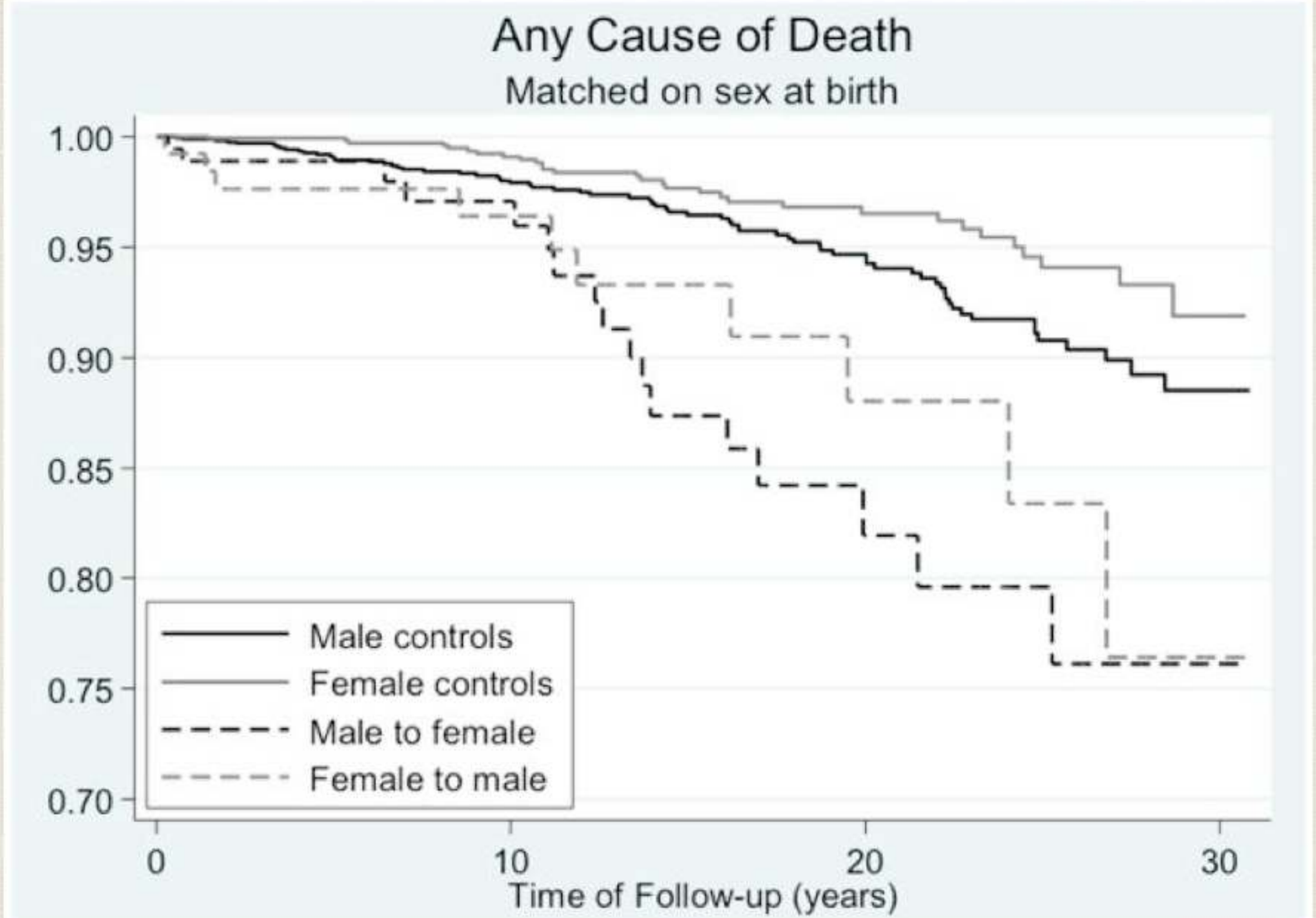
The treatment for transsexualism is sex reassignment, including hormonal treatment and surgery aimed at making the person's body as congruent with the opposite sex as possible. There is a dearth of long term, follow-up studies after sex reassignment.

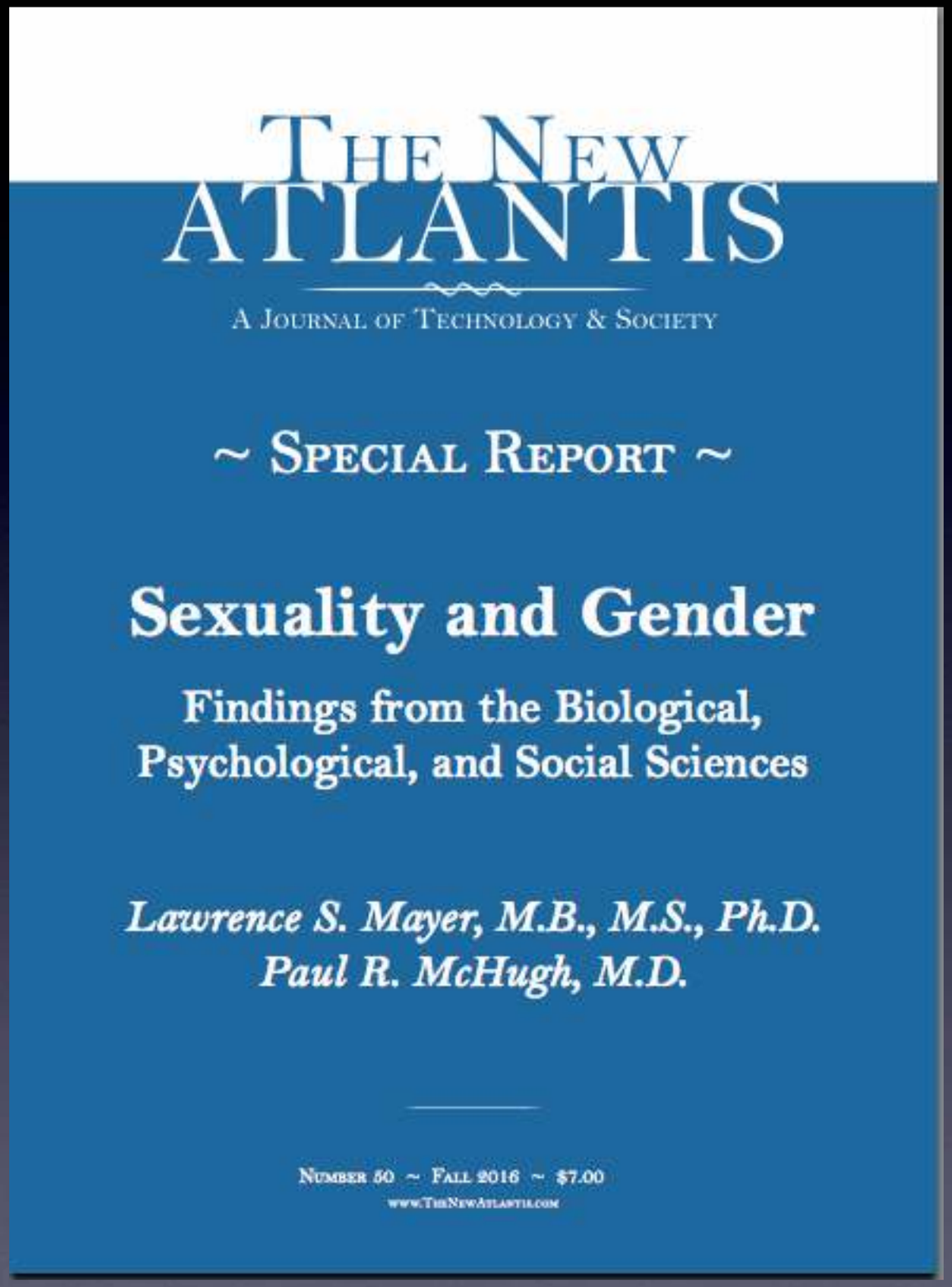
Swedish Study

Table S1. Risk of various outcomes in sex-reassigned subjects in Sweden compared to population controls matched for birth year and *birth sex*.

		Crude hazard ratio (95% CI)			Adjusted* hazard ratio (95% CI)		
Outcome	**No. of events (male-to-female/ female-to-male)**	**All sex-reassignment persons (N=324)**	**Male-to-female only (N=191)**	**Female-to-male only (N=133)**	**All sex-reassignment persons (N=324)**	**Male-to-female only (N=191)**	**Female-to-male only (N=133)**
Any death	27 (17/10)	2.9 (1.9-4.5)	2.6 (1.5-4.5)	3.7 (1.8-7.7)	2.8 (1.8-4.3)	2.4 (1.4-4.1)	3.8 (1.8-7.9)
Death by suicide	10 (6/4)	19.1 (6.5-55.9)	13.9 (3.9-49.6)	40.0 (4.5-357.9)	N/A	N/A	N/A
Death by cardiovascular disease	9 (6/3)	2.6 (1.2-5.4)	2.3 (0.9-5.7)	3.2 (0.9-11.9)	N/A	N/A	N/A
Death by neoplasm	8 (4/4)	2.1 (1.0-4.6)	1.7 (0.6-4.9)	2.8 (0.9-8.5)	N/A	N/A	N/A
Any psychiatric hospitalisation‡	64 (43/21)	4.2 (3.1-5.6)	4.7 (3.2-6.7)	3.4 (2.1-5.6)	2.8 (2.0-3.9)	3.2 (2.1-4.9)	2.2 (1.3-4.0)
Substance misuse	22 (14/8)	3.0 (1.9-4.9)	2.8 (1.6-5.1)	3.5 (1.6-7.8)	1.7 (1.0-3.1)	1.5 (0.7-3.1)	2.3 (0.9-5.8)
Suicide attempt	29 (22/7)	7.6 (4.7-12.4)	15.4 (7.9-30.2)	2.9 (1.3-6.8)	4.9 (2.9-8.5)	10.4 (4.9-22.1)	1.9 (0.7-4.8)
Any accident	32 (19/13)	1.6 (1.1-2.3)	1.4 (0.9-2.2)	1.9 (1.0-3.4)	1.4 (1.0-2.1)	1.2 (0.7-2.0)	1.8 (1.0-3.3)
Any crime	60 (33/27)	1.9 (1.4-2.5)	1.2 (0.8-1.7)	5.6 (3.5-9.1)	1.3 (1.0-1.8)	0.8 (0.5-1.2)	4.1 (2.5-6.9)
Violent crime	14 (8/6)	2.7 (1.5-4.9)	1.8 (0.8-3.7)	9.9 (3.2-30.7)	1.5 (0.8-3.0)	0.8 (0.3-2.1)	7.2 (2.1-24.4)

Notes: N/A Not applicable due to sparse data. *Adjusted for immigrant status and psychiatric morbidity up to baseline. ‡ Hospitalisations for gender identity disorder were excluded.


Any Cause of Death
Matched on sex at birth
1.00
0.95
0.90
0.85
0.80
0.75
0.70
Male controls
Female controls
Male to female
Female to male
0
10
20
30
Time of Follow-up (years)



A study of the studies.

-Examination of 500 papers in: epidemiology, genetics, endocrinology, psychiatry, neuro-science, embryology, and pediatrics

"The scientific definition of biological sex is, for almost all human beings, clear, binary, and stable, reflecting an underlying biological reality that is not contradicted by exceptions to sex-typical behavior, and cannot be altered by surgery or social conditioning."

~ Lawrence S. Mayer, M.B.,M.S., Ph.D.

"The notion that a two-year-old, having expressed thoughts or behaviors identified with the opposite sex, can be labeled for life as transgender has absolutely no support in science.

Indeed, it is iniquitous to believe that all children who have gender-atypical thoughts or behavior at some point in their development, particularly before puberty, should be encouraged to become transgender."

~Lawrence S. Mayer, M.B.,M.S., Ph.D.

OPEN ACCESS PEER-REVIEWED

RESEARCH ARTICLE

Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports

Lisa Littman

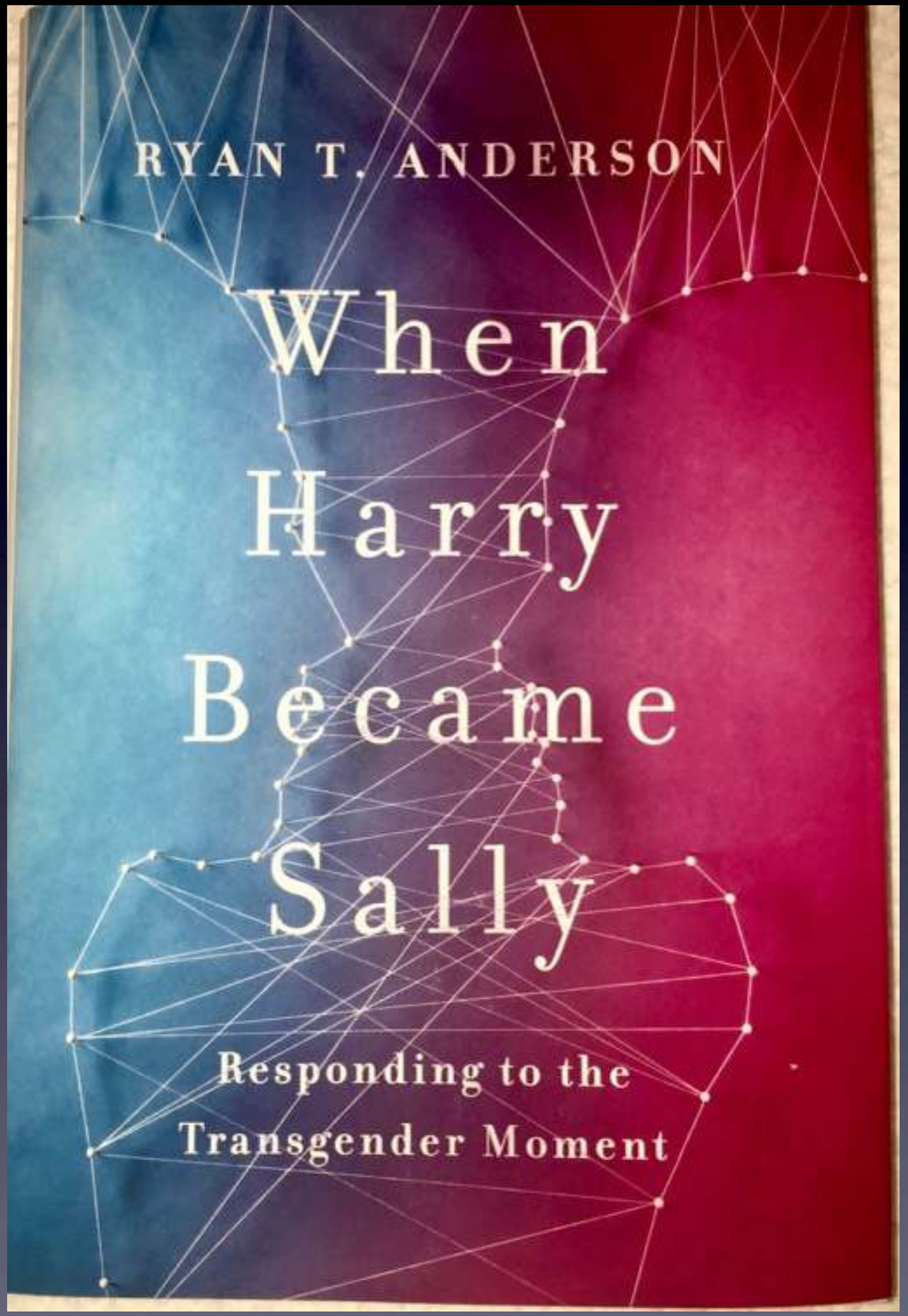
Published: August 16, 2018 • https://doi.org/10.1371/journal.pone.0202330

Instructions on lying	• "TL;DR find out what they want to hear if they're gonna give you T and then tell them just that. It's about getting treatment, not about being true to those around you. It's not their business and a lot of time doctors will screw stuff up for you."[a] • "…Get a story ready in your head, and as suggested keep the lie to a minimum. And only for stuff that can't be verified. Like how you were feeling, but was too afraid to tell anyone including your family."[b] • "I'd also look up the DSM for the diagnostic criteria for transgender and make sure your story fits it, assuming your psych follows it."[c]
Urgency to transition	• "…If you don't do it when you are young. You'll be miserable and unhappy with your body for the rest of your life."[d]
Vague and nonspecific symptoms called signs of GD	• "Signs of indirect gender dysphoria: 1. Continual difficulty with simply getting through the day. 2. A sense of misalignment, disconnect, or estrangement from your own emotions. 3. A feeling of just going through the motions in everyday life, as if you're always reading from a script. 4. A seeming pointlessness to your life, and no sense of any real meaning or ultimate purpose. 5. Knowing you're somehow different from everyone else, and wishing you could be normal like them…"[e]

a. https://www.reddit.com/r/asktransgender/comments/2nt8gi/having_a_psych_eval_soon/#bottom-comments
b. https://www.reddit.com/r/asktransgender/comments/4agf76/is_it_best_to_be_completely_honest_or_lie_a/
c. https://www.reddit.com/r/asktransgender/comments/4ihwar/what_things_should_i_never_tell_my_psychologist/
d. https://www.reddit.com/r/asktransgender/comments/3gpb94/at_the_final_stage_of_questioning_need_some/#bottom-comments
e. https://transgenderteensurvivalguide.tumblr.com/post/62036014416/that-was-dysphoria-8-signs-and-symptoms-of

Britain's Youngest Patient

Although Ms Cooper underwent a thorough psychological assessment and counseling at Hull Royal Infirmary prior to starting her sex change therapy she has suffered such torment living as a woman that she has tried to commit suicide twice.


RYAN T. ANDERSON
When Harry Became Sally
Responding to the Transgender Moment

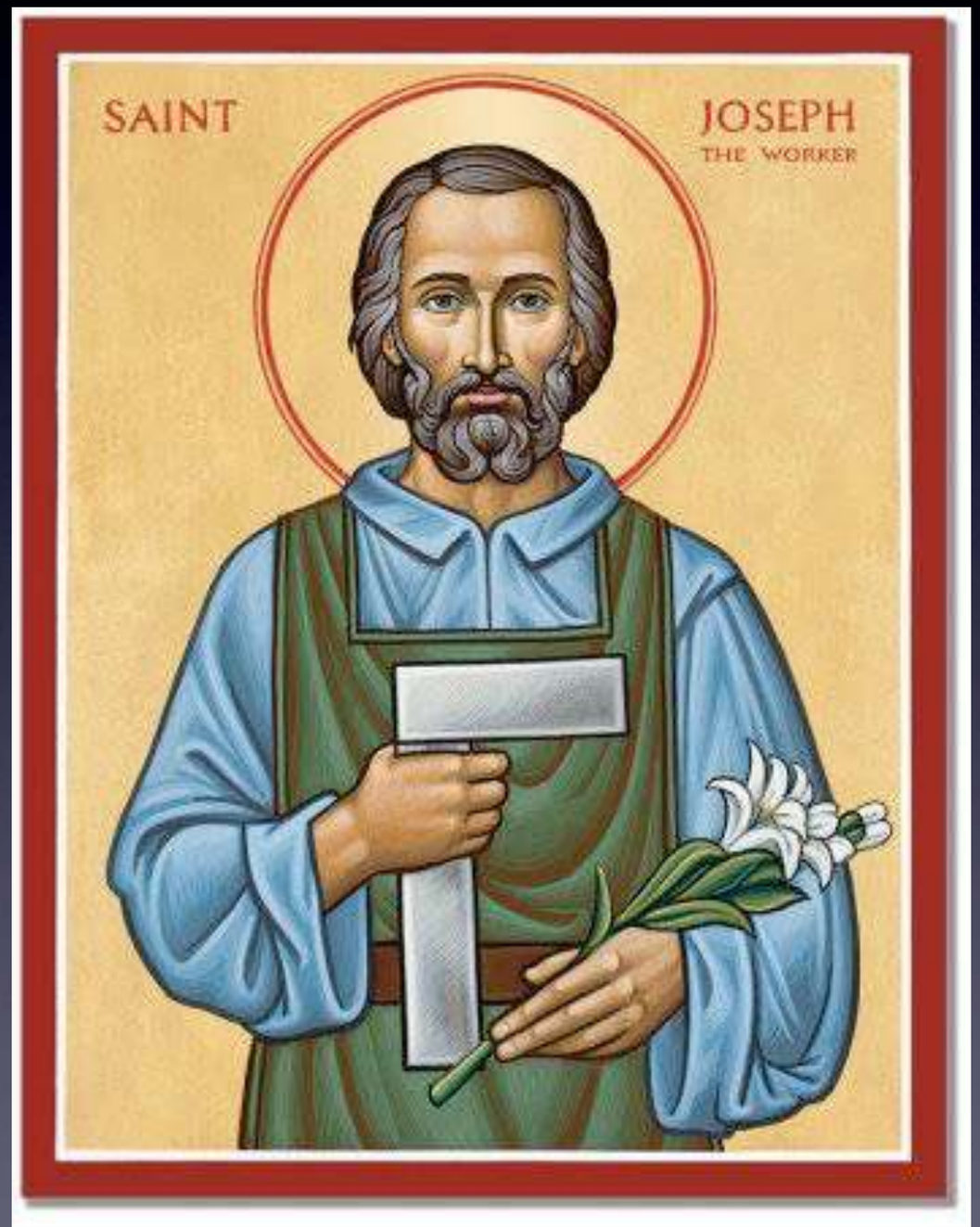
Summary

- Not a new condition. OCD w/ BDD.
- Psychological/ Spiritual wound.
- Ordinary childhood role playing being sexualized / treated with puberty blockers!
- In many cases, permanently mutilating surgeries.
- A huge engine of public opinion, policy, and enforcement aimed at the family, and the church.

- Transgender persons are at high risk for abuse and self harm.
- Care must be based in a true human anthropology.
- Missteps must be anticipated
- Protection from “blind guides”.
- Fluency in the language, and knowledge about the erroneous science will permit witnessing with patience and fraternal love.

Let Us Pray

God our Father,
creator and ruler of the universe, in every age you call man to develop and use his gifts for the good of others.
With Saint Joseph as our example and guide, help us to do the work you have asked and come to the rewards you have promised.
We ask this through our Lord Jesus Christ, your Son, who lives and reigns with you and the Holy Spirit, one God, for ever and ever.
Amen



VM
5859
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MARINES

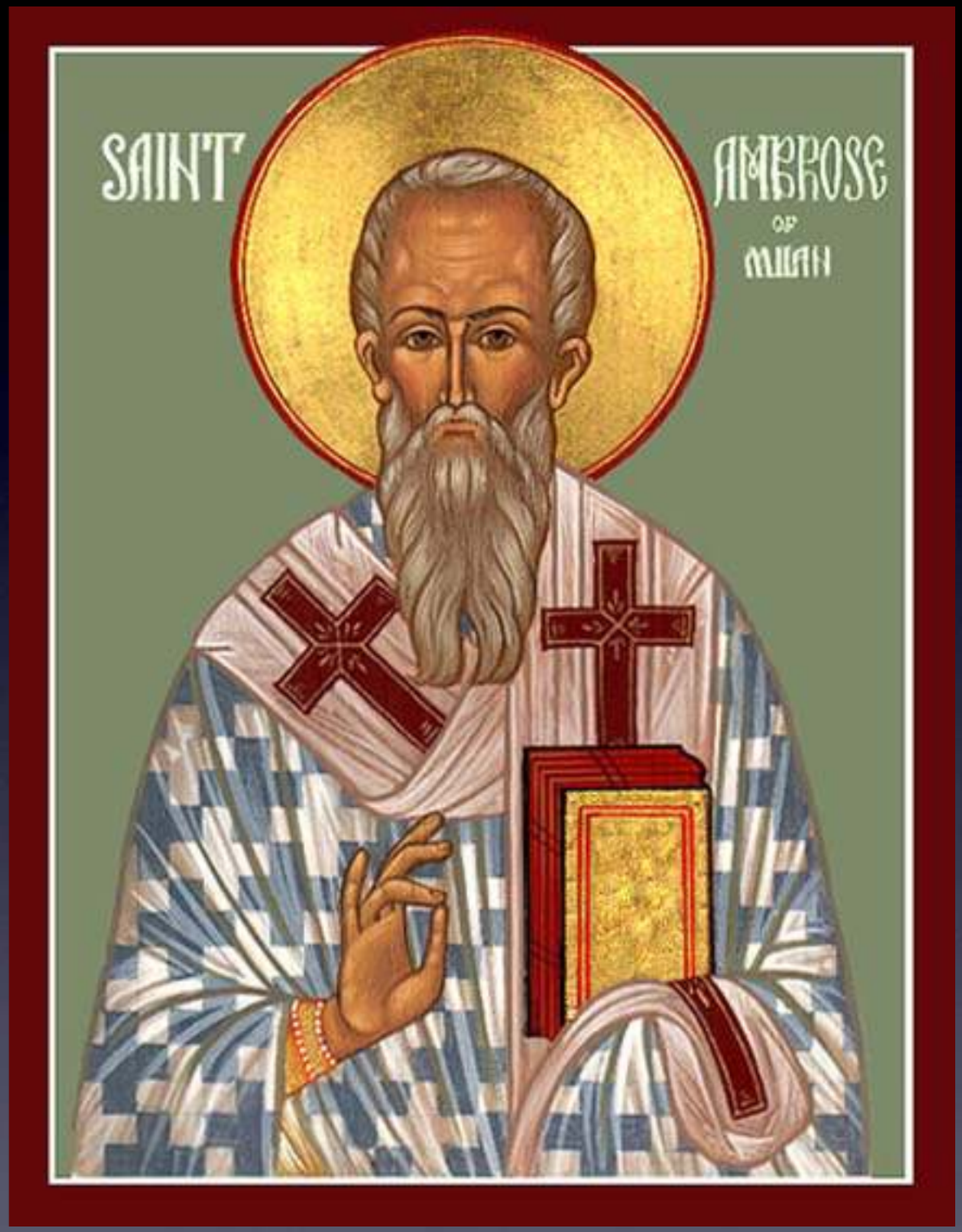
Let Us Pray

Oh glorious martyrs of Christ, Saints Cosmas and Damian, you gave your lives for the love of God, benefiting your fellow man, and crowning your martyrdom with an open and loyal profession of your faith. You taught us to love God above all things, and to love our fellow man as ourselves, professing always, and without fear, the religion of Jesus.Augmenting amongst the faithful populace many miracles, you are glorious indeed. Through your intercession, which brings about deliverance of these miracles, we pray to you for your aid in all things. May your patronage never be far from us in the illness of our body and soul.

Oh great protectors, Saints Cosmas and Damian, assist us with your love and free us from all evils. Amen

Let Us Pray

Lord,
you made Saint Ambrose
an outstanding teacher of
the Catholic faith and gave
him the courage of an
apostle.
Raise up in your Church
more leaders after your
own heart, to guide us with
courage and wisdom.
We ask this through our
Lord Jesus Christ, your Son,
who lives nad reigns with
you and the Holy Spirit,
one God, for ever and ever.
Amen.



Let us Pray

Almighty God, whose deacon Vincent, upheld by you, was not terrified by threats nor overcome by torments: Strengthen us to endure all adversity with invincible and steadfast faith; through Jesus Christ our Lord, who lives and reigns with you and the Holy Spirit, one God, for ever and ever.
Amen

St. Vincent of Saragossa

Let Us
Pray

□□

殉教

God our Father,
source of strength for all your saints; you led Paul Miki and his companions
through the suffering of the cross to the joy of eternal life.
May their prayers give us courage to be loyal until death in professing our faith.
Through Jesus Christ, your Son,who lives and reigns with you
in the unity of the Holy Spirit, one God, for ever and ever.
Amen.

Let Us Pray

O God, almighty Father, you have consecrated us to the work of bringing our brothers and sisters to the life of grace; there to grow in that perfection of our nature which leads to eternal life.
Grant unto us ,O Lord, an unswerving devotion to the service of those suffering from wounds that keep them from that fullness of life which you intend for all of us.
Do not allow us to be mislead by the deceptions of a world that has lost sight of you, and help us to follow in the obedience of your Son, Jesus Christ, who lives and reigns with you in the unity of the Holy Spirit, One God, for ever, and ever.
Amen

Axios
@axios

Follow

In a first, the Pentagon plans to pay for a transgender soldier's gender transition surgery

transition surgery for first time

www.sexchangeregret.com

1947 From Male to Female and Back Again 2013

Sex Change REGRET

Home | Things I've learned | Research I've found | Examples | Other Web Sites | Italiano | Bookstore

Walt's Welcome

Reaching Out to Those with Sex Change Regret

This is the book you need in your hands

The Challenge

- Evangelizing people who are being relentlessly mislead concerning human sexuality.
- In need of catechesis at all levels.
- In need of pastoral sensitivity to particular wounds.
- In need of the sacraments.

Bl. John Henry Cardinal Newman

Plea For Mercy

- For The Children!
- To prevent suicide!

Let Us Pray

O Mary, Powerful Virgin; thou art the mighty and glorious protector of the Church; Thou art the marvelous **Help of Christians**; Thou art terrible as an army in battle array; Thou alone hast destroyed every heresy in the whole world. In the midst of our struggles, our anguish, and our distress, defend us from the power of the enemy, and at the hour of death, receive our souls into Paradise.
Amen

Transgender Surgery and Christian Anthropology

COURAGE
A Roman Catholic Apostolate

Deacon Patrick W. Lappert, MD
Birmingham in Alabama
256-303-8509

EXHIBIT 16

NEWS

Plastic surgeon: Sex-change operation ‘utterly unacceptable’ and a form of ‘child abuse’

Dr. Patrick Lappert, a Catholic deacon in Alabama, says changing a person's sex is a lie and also a moral violation for a physician.

Exhibit
0034
9/30/2021
Dr. Lappert

Lisa Bourne

Mon Sep 9, 2019 - 6:42 pm EDT

EDITOR'S NOTE: This story contains explicit content.

September 9, 2019 (LifeSiteNews) – The idea that you can change someone's sex is a lie, an Alabama-based plastic surgeon said, and pursuing this avenue with children amounts to child abuse.

"It's a form of tyranny, exercising a form of tyranny over our own bodies," Dr. Patrick Lappert said. "And in the case of children, it's child abuse."

Appearing on a recent broadcast of Relevant Radio's Trending with Timmerie, Lappert said the view that the human body is something that someone owns, that they can do things in order to provoke happiness in themselves, is a self-reverential view divorced from the objective reality of the human person.

Lappert briefly touched on the negative physical effects of same-sex sexual activity, and he also explained in detail the disturbing reality of what happens when a person undergoes so-called sex-change surgery.

He called it "utterly unacceptable" on moral grounds for a plastic surgeon, because it disregards the surgeon's call to balance respect for both form and function of the body in his or her work.

Regarding children, Lappert said, sexualizing them at a young age with these ideas is grooming them for later abuse.

"It's atrocious," he said. "And no one even knows how that's going to play out. There's no body of scientific evidence to even support the safety of doing that to children. But it's being done."

"Children do not have the capacity to consent to those sorts of treatments," Lappert said of sex-change procedures. "You cannot tell a pre-adolescent child anything about their adult life and expect that they're going to understand what you're telling them."

"Their concept of themselves is in the formative years," he continued. "And to ask a child to think of their sexuality when they're pre-adolescent is utterly insane. And it's in fact another great evil that's being inflicted upon children because it's the sexualization of normal chaste friendships of childhood."

'They will never be the other sex'

Asked "What is a sex change?" Lappert responded, "Well, to begin with, the idea that you can change someone's sex is a lie."

"Many people have been led to believe by a lot of very clever programs and advertising from plastic surgeons and whatnot that you can actually change a man into a woman or a girl into a boy or anything like that," he said. "You cannot. Essentially all you can do is you can modify people's bodies both with medicines as well as with surgery to make them appear to be the other sex, but they will never be the other sex."

Lappert, a board certified general surgeon and plastic and reconstructive surgeon, is a Navy and Marine veteran, as well as a permanent deacon for the Diocese of Birmingham, Alabama. He is also chaplain for the Courage apostolate in the Birmingham diocese.

Experts have said for years that surgery or hormone treatment for gender-confused individuals, and certainly encouraging transgender ideas in children, is not the solution, and can result in exacerbating their condition.

Nonetheless, sex change surgeries have been on the rise, transgender ideology continues to be pushed in schools, civil government, and healthcare associations and institutions, while gender confused-individuals are also appearing more and more in pop culture, sports, media, and advertising.

The beginning stages

Lappert said gender confused individuals will typically begin by adopting a lifestyle and persona, change their name, hair and other aspects of their looks, and then move onto other identity components such as changing their driver's license and so on. Then hormonal medications are often introduced, and while sometimes these may initially make someone feel better about their gender confusion, this gives the false impression that surgical intervention will result in success, and taking hormones of the opposite sex over time can have a negative physical impact.

Irreversible

Most of the chemical interventions and cosmetic procedures done to alter a person's face or neck are to a degree reversible. However, Lappert warned, more invasive surgeries, such as mastectomy and procedures involving genitalia, are not.

A counterfeit vagina

In the case of men seeking to present as women, after they've had the other initial interventions performed, a definitive genital surgery includes castration, removal of the testicles, and the opening of the penis and removal of the erectile tissue, which is a procedure called penile inversion. This is where the penis is turned inside out and suspended up in the pelvis, turning it into "a receptive structure," Lappert explained.

The tissues of the scrotum are then turned into labia, meaning the external genitalia portions of the phallus itself are used to create the labia minora. In creating the receptive structure, the surgeon is trying to preserve the nerves, so that those parts of the genitalia that provoke erotic sensation can do so.

"Which is a very challenging thing to try to do when you're essentially mutilating the penis," he said, "to try to preserve the neurological support for it, so that the person can have erotic sensation from this counterfeit vagina that you've created."

"The problem is that this counterfeit vagina doesn't want to keep its dimensions," said Lappert. "And so you're constantly having to attend to the dilation of it to try to preserve its dimensions and so on. You also are taking the urethra that was in the penis and shortening it down so that it essentially is just an opening at the top of this counterfeit vaginal orifice that you've created."

This is the most commonly performed operation for males trying to present as female, he said.

A counterfeit penis

In the case of women trying to present as men, it begins with the removal of the ovaries and the uterus, removal of the vagina and the creation of a neo phallus, or a counterfeit penis.

This can be done a couple of different ways, he said, one being a high dose of testosterone, which will produce an enlargement of the clitoris, and then when you have exhausted those very high levels of testosterone, and they've had this effect on the clitoris, an operation is done to lengthen the urethra so that the urethra is extended along the underside of this enlarged clitoris, so that the urine empties at the tip of this structure.

That operation is called a metoidioplasty.

"And essentially what you get there is a small phallus," said Lappert, "and that's usually supplemented by creating a neo scrotum into which are placed two prosthetic testicles."

For women seeking a more developed physique, Lappert continued, a neo phallus is produced by what's called a flap operation.

This is where an area of tissue, typically from the leg, is raised up and surgically turned into a cylindrical structure inside of which is a urethral tube. That urethra tube is then connected to the native urethra, which appears at the base of the clitoris. The clitoris tissue itself is draped over the base of this neo phallus and then, again, a counterfeit scrotum with prosthetic testicles.

“And then in that whole apparatus you can also implant malleable or inflatable prosthetics that can produce the appearance of an erection,” explained Lappert. “So that's called a phalloplasty by flap operation.”

The most common flap operation done today is to harvest the skin for the neo phallus from the forearm, said Lappert.

“It's called a radial forearm flap and it's a tremendously disfiguring surgery on the forearm,” he said. “And so these women who are presenting as men will tattoo their forearms to conceal the disfigurement.”

“And then so (ultimately) what you wind up with is a counterfeit phallus or a counterfeit vagina,” stated Lappert.

Why are these counterfeit?

“Because they don't function the way those structures function,” said Lappert. “It’s obviously the case with the reproductive organ that what you're doing is you're robbing the person of an essential human capacity of the reproductive faculty. And that's not reversible or retrievable.”

“You cannot preserve the procreative function when you do these operations,” stated Lappert.

A sterile act

The doctor then touched on the spiritual component with these procedures.

“As Catholics, we recognize the human sexual embrace that's having two aspects, its unity and its procreative,” said Lappert. “It unites the two persons in an emotional-spiritual bond. But it's also a fruitful union.”

“Well, (with sex change procedures) you've robbed it of its fruitfulness,” he said. “It's now become a sterile act.”

The erotic sensation is never fully preserved

"The other thing that people don't understand is that because of the surgeries I've just described the desire to preserve erotic sensation from these structures that you're mutilating is never fully met," said Lappert.

In the nature of our nervous system there is a thing called neural mapping, he continued, meaning even though the physician works to preserve those nerves, the nerves continue to recognize sensations from their original form and function.

"The brain is still thinking that, even though you've turned your penis into a counterfeit vagina, whenever it is stimulated the brain is still thinking that there is a penis down there," said Lappert. "So here's a person trying to live as a woman hoping that they're going to be able to conduct their lives as women, who enters into a relationship with a man, and then in a sexual act is constantly being reminded by their own bodies that they are in fact still men, and that's a hard one to get over."

The malpractice of medicine

Lappert also warned that a whole generation of children is being raised whose psychosexual, physical, and neurological development are being stunted in hopes of supporting this cross-sex idea of themselves – pushed by the transgender industry.

He pointed out that if you took 100 children with cross-sex idea of themselves, 91 percent of them will desist.

"Ninety-one percent of them will stop thinking of themselves as the other sex," said Lappert. "But if you take the same hundred children to a transgender clinic at your local urban center, 100 percent of them will persist in it, which on the face of it tells you that this is this is the malpractice of medicine."

"If 91 percent of them would have gotten over the disease and 100 percent of them persistent and obviously you're doing something wrong here," he added. "But nonetheless that's how it's being presented."

"People are being led to believe that if you have the surgery your sorrows will go away," said Lappert. "But what's called gender dysphoria, this interior sense of sadness that the persons who suffer with transgender feel, they're being told that if they have all of this medical and surgical therapy, that those bad feelings will go away. And the best study looking into that tells us that that is not the case."

After a period of observation beyond some eight to 10 years, the suicide rate goes right back to where it was if nothing had been done for these people.

"If you didn't offer them any care at all, you'd have the same suicide rate that people have now after all of the surgical interventions," said Lappert. "And after the excitement dies down, and eight, 10 years later, they're right back to a 40 to 42 percent suicide rate. So that's a huge misrepresentation of benefit that is just not true."

Advocates for gender-confused individuals continually say these individuals need authentic psychological help that focuses upon the source of the confusion.

This kind of surgery is utterly unacceptable

Lappert called sex change surgery "an intentional destruction of a human faculty," and "so on moral grounds from the perspective of a plastic surgeon this kind of surgery is utterly unacceptable."

The language of slavery

Because these procedures result in sterilization, they are tied to assisted reproductive technology, Lappert explained, with patients asked how they want to "preserve their fertility," donating either sperm or ova, should they want children later.

"Those things will be put aside and for future assisted reproductive technology, essentially turning human persons into commodities," Lappert said.

A huge evil

"Because they will be told, you have a right to have a child even though you're having this transgender surgery," he said. "You have a right to have a child. So we're going to do these things for you. Well, that's the language of slavery, to speak of a person that's having a right to another person is the language of slavery."

"It's leading us to seeing the human person as a commodity that is regulated by the government, by government institutions, universities, and by laboratories," Lappert continued. "And that is a huge evil. It's a huge evil and never forget, that transgender surgery is right at the heart of that evil."

"First of all because it utterly perverts our sense of human sexuality," he said. "It internally divides the human person from their very own bodies. And now it's separating the human community from their reproductive faculties, in the era of assisted reproductive technology. So this is diabolical in every sense of the word. Diabolical."

Rejecting objective truth

Encouraging people to pursue sex-change surgery rejects understanding of who the human person is, said Lappert.

“One of the mistakes that people are making in contemporary life is viewing themselves as sort of a spirit creature and their bodies as something that they own or something that they possess,” he said. “They view their own bodies as something that they can do things to in order to provoke happiness in themselves. It's a very self-referential view of the human person and it has at its heart this division of the nature of the human person.”

Plastic surgery can never divorce itself from objective reality just as no form of medical care can separate itself from the objective truth of who the human person is, he said.

“So if I aim to be a good surgeon, then the very first thing I have to understand is the subject upon whom I am working,” Lappert stated. “If I have met grave misunderstandings about the objective reality of that of the person, I'm going to be making some serious mistakes when I embark on medical or surgical care.”

“To view the body as a thing, but somebody that a person owns, to view themselves, their personhood is something separate from their own bodies, is a very grave mistake,” he said. “And then to set about modifying the body in ways that you hope will bring about a lasting happiness can't possibly succeed, because it begins with a lie, it begins with an error about the objective truth of who the human person is.”

The full interview with Dr. Patrick Lappert is available HERE.

Two positive resources for gender-confused and same-sex attracted individuals featured in the discussion were the Roman Catholic Courage apostolate and Walt Heyer’s outreach titled Sex Change Regret. Heyer had transitioned to living as a woman and then returned to living as a man, and now performs outreach for gender-confused people.

Information on Courage is available HERE and HERE.

The Sex Change Regret website can be accessed HERE.

James Shupe, formerly Jamie Shupe, ex-transgender and former non-binary person, writes about his experience and chronicles transgender issues HERE.

The National Suicide Prevention Hotline provides free and confidential help and resources to individuals in distress 24/7. The number is 800-273-8255.

Additional resources are available here, here and here.

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Abstract

Body dysmorphic disorder (BDD) is primarily characterized by an excessive preoccupation with a perceived defect or flaw in appearance that others would be unable to observe, or would consider slight in appearance. BDD is accompanied by repetitive behaviors intended to hide, fix or check on the perceived appearance flaw. This article provides an overview of the current understanding of the factors influencing the onset and maintenance of BDD symptoms, as well as prevalence rates. The assessment and treatment of this common and severe disorder are also discussed.

Keywords

Assessment; BDD; BDD by proxy; Body dysmorphic disorder; Body image; Clinical features; Epidemiology; Etiology; Muscle dysmorphia; Treatment

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Dr. Wilhelm has been the principal investigator or site principal investigator of 7 NIMH-funded research grants. She is the vice chair of the Scientific Advisory Board of the International OCD Foundation, and she serves on the Scientific Council for the Anxiety and Depression Association of America as well as on the Tourette Syndrome Association Behavioral Science Consortium. Dr. Wilhelm serves on several editorial boards and is a Representative-at-Large for the Association for Behavioral and Cognitive Therapies (ABCT).

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