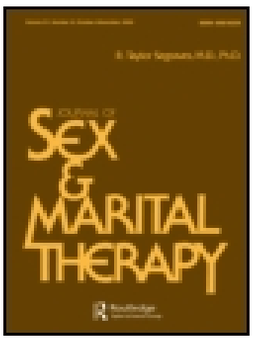

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COMMENTARY

What Are We Doing to These Children? Response to Drescher, Clayton, and Balon Commentaries on Levine et al., 2022

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Introduction

In our paper, "Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults" (Levine, Abbruzzese, & Mason, 2022), we asserted that the consent process for youth gender transition is so problematic in much of the Western world that it can no longer be considered "informed."

We reflected on how far the entire field of gender medicine has drifted from the principles of evidence-based medicine and the scientific method. Attempts to study the sharp rise of gender dysphoria in previously gender-normative teens (Bradley, 2022; Littman, 2018) are met with consternation by the gender-medicine establishment (World Professional Association for Transgender Health [WPATH], 2018). The significant rate of problematic adaptations, psychiatric symptoms, and self-harm in this youth cohort (Becerra-Culqui et al., 2018; de Graaf, Giovanardi, Zitz, & Carmichael, 2018; de Graaf et al., 2021; Kaltiala-Heino, Sumia, Työläjärvi, & Lindberg, 2015; Kozlowska, Chudleigh, McClure, Maguire, & Ambler, 2021; Strang et al., 2018; Thrower, Bretherton, Pang, Zajac, & Cheung, 2020) is explained away as merely manifestations of minority stress, with unsubstantiated claims that these mental health problems will resolve with gender transition—and *only* with gender transition. Efforts to help the distressed teens psychotherapeutically, which is the standard approach for all other types of psychiatric symptoms, are stigmatized as conversion therapy. The growing evidence of *detransition*, apparent in recent data (Boyd, Hackett, & Bewley, 2021; Hall, Mitchell, & Sachdeva, 2021; Roberts, Klein, Adirim, Schvey, & Hisle-Gorman, 2022), is either dismissed or recast as a benign gender journey (Turban, Loo, Almazan, & Keuroghlian, 2021), and the reports of regret by many of the detransitioners themselves are ignored (Littman, 2021; Vandenbussche, 2022). Perhaps most problematic, the information shared by gender clinicians with patients and families about "gender-affirming" interventions is markedly skewed: it overstates the demonstrated benefits of hormones and surgeries and trivializes their risks and the uncertainties of future outcomes.

Our critical ethical evaluation also included proposed solutions. We suggested that clinicians familiarize themselves with the difference between the classical early-onset of cross-sex identification, which typically spontaneously resolves before adulthood (Ristori & Steensma, 2016; Singh, Bradley, & Zucker, 2021), and the novel presentation of youth with postpubertal onset of gender dysphoria and a much wider range of gender identities, for whom the outcomes are unknown. We suggested that rather than merely deferring to their medical societies' wholesale adoption of "gender-affirmative" guidelines from the gender medicine establishment, clinicians

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would benefit from scrutinizing the unconvincing results from key studies. We implored clinicians to slow down and engage patients and families in thorough and thoughtful discussions not only of the possible benefits but also the significant risks and uncertainties inherent in a medically dependent lifetime.

The editor invited four respected academicians to write commentaries (Balon, 2022; Clayton, 2022; Drescher, 2022; de Vries, 2022). Two agreed that current trends are problematic and must be addressed to safeguard youth from harm (Balon, 2022; Clayton, 2022). Two disagreed, but in very different ways (Drescher, 2022; de Vries, 2022). Drescher took a decidedly civil rights-based perspective, arguing that while the evidence is low quality, ultimately, the principles of body autonomy should trump all other concerns. de Vries conceded that the evidence base for pediatric gender transition suffers from deficiencies but asserted that it is of sufficient quality to widely scale hormonal and surgical "gender-affirming" interventions.

Below, we provide our thoughts about the first three commentaries we received (Drescher, 2022; Clayton, 2022; Balon, 2022), starting with our response to Drescher. We have responded to de Vries (2022) in a separate forthcoming publication.

Response to Drescher

Drescher's commentary (Drescher, 2022) illuminated the mindset of clinicians who are aware of the limitations of the evidence base of youth gender transition, yet actively promote medicalization while eschewing any noninvasive treatment alternatives. Drescher ridiculed the title of our publication (Levine et al., 2022) by naming his own commentary "Informed Consent or Scare Tactics?" Having carefully examined his objections to our paper, we, in turn, suggest that Drescher's commentary would have been better titled "Risks, Schmisks"— as it succinctly summarizes his counterarguments.

Drescher mocked our suggestion for a slow and deliberate informed consent process for youth embarking on a medicalized lifetime with a skit in which a patient receives extensive disclosures of the risks of taking aspirin for a headache. While Drescher referred to his writing exercise as a "parody," it is a generous description, and not just because some might find it lacking in humor; the situations he compares are not even remotely equivalent. Even prolonged aspirin use increases the absolute risk of severe bleeding by just 0.47% (Zheng & Roddick, 2019). In contrast, 100% of children will be rendered sterile if puberty is blocked at Tanner Stage 2 and followed with cross-sex hormones, as currently suggested by the Endocrine Society (Hembree et al., 2017). While the risks of exogenous sex hormones have been well-documented and led to a black box warning from the FDA (Jeffrey, 2003; Togun, Sankar, & Karaca-Mandic, 2022), there is now mounting evidence of the detrimental effects of puberty blockers on a range of physiological parameters (Nokoff et al., 2021) including bone density (Biggs, 2021; Klink, Caris, Heijboer, van Trotsenburg, & Rotteveel, 2015; Nokoff, Ma, Moreau, & Rothman, 2022). We think a better example of using comedy to make a point is a skit by comedian Bill Maher, who recently noted that bone density is "kind of important if you like having a skeleton" (Maher, 2022).

The exuberant irreverence of Drescher's commentary extended to his discussion of the evidence base for youth gender reassignment, with the suggestion that the GRADE designation of *low-quality evidence* is merely a "a scary buzzword" (Drescher, 2022, p. 3). To clarify, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) is an international best practice in evidence evaluation, which provides a structured way to assess key factors that increase or decrease confidence of findings in a body of evidence (GRADE Working Group, 2013). The GRADE ratings of "very low" and "low" quality—the only two ratings that the body of evidence for youth gender reassignment has ever received—indicate that *the true effect* of hormones and surgeries is likely *markedly different* from the results reported by the studies (Balshem et al., 2011; Reed & Guyatt, n.d.). The problem is *not* that the field of youth gender reassignment has not yet produced "enough" studies, as Drescher's own phrasing of "low levels of evidence" suggests; the actual problem is that *none* of the numerous studies produced to date,

individually or collectively as a body of evidence, are reliable or trustworthy. This is because all the available studies are uncontrolled observational studies subject to bias, confounding, or chance (National Institute for Health and Care Excellence [NICE] 2020a, 2020b).

Drescher also incorrectly asserted that the reason the evidence base for gender transition has been graded as *very low/low quality* is due to the "absence of randomized clinical trials (RCTs)" (Drescher, 2022 p. 3). While it is true that data from a body of randomized *controlled* trials (whether the comparator is placebo or another active intervention) starts with the presumption of *high quality,* it can be downgraded to *low quality* if there are serious concerns arising from risk of bias, imprecision, inconsistency, indirectness, and publication bias. Conversely, non-randomized study of an intervention (e.g., an observational study) can be upgraded to *moderate* or *high quality* when there is a large magnitude of effect; a demonstrated dose-response relationship; and when the potential confounders are not expected to inflate the outcomes in a positive direction—in other words, when the research signals plausible, sizeable benefits (Reed & Guyatt, n.d.). The problem is *not* that quality research in the space of gender medicine is not feasible; it is that increasingly, gender clinicians who lead the studies view the matter as settled science, and as a result do not bother to design research capable of producing high or even moderate quality evidence. Even more troubling, when called out, such clinicians insist that using rigorous study designs in pediatric gender medicine is unethical (Turban, Almazan, Reisner, & Keuroghlian, 2022).

Nor is it correct to assume that randomization is unethical. According to the principle of research equipoise, "when there is uncertainty or conflicting expert opinion about the relative merits of diagnostic, prevention, or treatment options, allocating interventions to individuals in a manner that allows the generation of new knowledge (randomization)" is ethically permissible (London, 2017, p. 525). That "gender-affirming" interventions are administered to youth "based on very limited data" and that long-term outcomes are unknown has been acknowledged by even the most ardent proponents of pediatric gender transition (Olson-Kennedy et al., 2019, p. 2). Rigorous research has been conducted in other "high stakes" areas of medicine and has led to the development of highly effective treatments, as evidenced by the advances in pediatric oncology (Berg, 2007). Pediatric gender medicine cannot claim an exceptional status when it comes to the quality of research it must undertake.

Drescher is also incorrect in stating that "none of the surgical procedures … are performed on children with GD/GI [gender dysphoria/gender incongruence]" (Drescher, 2022, p. 4). We have seen the claim that "gender-affirming surgery is not performed on children" repeated with increasing frequency. We are not sure whether this assertion hinges on the definition of a "child" as someone who has not yet had their 13th birthday; or if it is a case of blissful ignorance by those inexperienced with this patient population. Patients as young as 12-13 have been obtaining "gender-affirming" mastectomies in the United States for several years, as evidenced by the data from the National Institutes of Health (NIH)-funded research (Olson-Kennedy, Warus, Okonta, Belzer, & Clark, 2018, Figure); research from a large U.S. healthcare system (Tang et al., 2022, Figure 2); and a recent publication in JAMA Pediatrics (Ascha et al., 2022). The latter asserted strong benefits of mastectomies for youth based on the finding that the young people were no longer "dysphoric" about their chest appearance a mere 3 months post-surgery. Version 8 of the WPATH "Standards of Care," published in September 2022, ratified the notion that surgeries should be available to youth when it removed previously stated minimum age limits for "gender-affirming" surgical procedures (Block, 2022; Coleman et al., 2022).

Setting Drescher's misunderstanding of the evidence aside, his fundamental problem with our paper appears to be that we did not outline treatment alternatives to "gender affirmation" for youth gender dysphoria—beyond psychotherapy. Yet, psychotherapy is *exactly* what Sweden—the first country in the world to legally recognize transgender people—and Finland recommend as the first (and typically only) line of treatment for gender dysphoric youth (COHERE, 2020; Socialstyrelsen, 2022a, 2022b). The UK is now moving in a similar direction, calling on clinicians to lean on their existing skills in mental health support of gender dysphoric youth, and to not

"exceptionalise gender identity issues" (Cass, 2022). With these recent changes, Europe is returning to the proven axiom taught to medical students early in their training: "when you hear hoofbeats, think of horses not zebras." In this context, the profound gender-related distress that has engulfed Western youth in recent years is much more likely to be a novel manifestation of the identity formation struggles of youth, rather than a rare intractable "mismatch" between the body and the brain that must be medically and surgically corrected.

We are puzzled about why Drescher, a psychoanalyst himself, dismissed the contribution of his own field to the management of gender dysphoria in youth by describing it as "just talk" (Drescher, 2022, p. 4). More disheartening, however, is that he chose to conflate psychotherapy for gender dysphoria with "conversion therapy." The notion that psychotherapy was a missing element in their care was endorsed by detransitioners, who say that a better understanding of the nature of their gender distress would have helped them avoid irreversible and deeply regrettable medical interventions (Littman, 2021; Vandenbussche, 2022).

While Drescher appeared comfortable with recommendations to change anatomy, physiology, and create the need for lifelong "gender-affirming" interventions based on low quality evidence, he was quick to disdain the alternative of psychotherapy because it "lack[s]… empirical evidence" (Drescher, 2022, p. 4). It is, of course, untrue that psychotherapy for gender dysphoria in youth lacks "empirical evidence"; what it lacks is *high quality* evidence. Rigorous comparative trials of psychotherapeutic approaches to gender dysphoria in youth are urgently needed. However, if Drescher undertakes a literature search, he will discover that beyond the article by Schwartz (2021), to which he dedicated a significant part of his response, there is a growing body of (low quality) evidence that psychotherapy *can* ameliorate gender distress in youth and can reduce or eliminate the need for invasive medical interventions (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Evans, 2022; Hakeem, 2012; Lemma, 2018; Spiliadis, 2019). Psychotherapy to "resolv[e] confusion [about gender feelings] and com[e] to self-acceptance" was also a key part of the Dutch protocol (de Vries et al., 2006, p. 87).

The concern that vulnerable adolescents and young adults do not get appropriate mental health evaluation and treatment and are effectively rushed into transition, has been voiced not only by the "critics," as Drescher asserts, but also by the supporters of "gender-affirmative" interventions such as Dr. Erika Anderson—a psychotherapist, transgender woman, and recent President of the US branch of WPATH, USPATH (Anderson, 2022). There is a convincing body of evidence that gender dysphoria frequently occurs in *lesbian and gay* youth (Bryant, 2006; Cantor, 2020, Appendix 1; Korte et al., 2008). It also disproportionately affects *autistic* youth (Bradley, 2022; Hisle-Gorman et al., 2019; Thrower et al., 2020), as well as vulnerable individuals who have experienced various forms of trauma (D'Angelo et al., 2021; Kozlowska et al., 2021). We would have expected Drescher to support the notion that young gay and autistic people suffering from gender dysphoria deserve access to noninvasive treatment alternatives that avoid life-long health risks and do not render them sterile.

A second reason for Drescher's objection to our publication is that he viewed our recommendation for delay in irreversible medical interventions as putting the interests of "cisgender" gender dysphoric youth above the interests of "transgender" youth. We remind Drescher that the predictive validity of the youth gender dysphoria (or gender incongruence) diagnoses is unknown (Davy & Toze, 2018; Paris, 2015; Zucker, 2010), and that no criteria exist for how to reliably differentiate youth who will desist from a transgender identity as adults, from those for whom this identity will be life-long. That the majority of trans-identified *children* will not be trans-identified adults is well established (Hembree et al., 2017; Ristori & Steensma, 2016; Singh et al., 2021). The notion that trans-identified *teens or young people* do not desist, which seems to have been uncritically adopted by gender clinicians, is patently untrue, as demonstrated by a growing number of studies of detransitioners, the majority of whom do not identify as transgender after they medically detransition (Littman, 2021; Vandenbussche, 2022). Recent data from gender clinics show that the rate of medical *detransition* is now reaching 10-30% within just a few years after the initiation of transition (Boyd et al., 2021; Hall et al., 2021; Roberts et al.,

2022); this percentage will likely grow as the patients reach the 10 + year mark when regret has been noted to typically emerge (Dhejne, Öberg, Arver, & Landén, 2014; Wiepjes et al., 2018).

Drescher chose to engage in ad hominem attacks on those involved in the publication of our paper. He referenced an anonymous libelous blog in his attempt to discredit the US registered nonprofit organization, the Society for Evidence-Based Gender Medicine (SEGM) and fanned the flames of baseless insinuations by inventing a non-existent association between SEGM and anti-homosexual groups. In questioning SEGM's goals, Drescher changed SEGM's name, substituting "evidence-based" with "empirical-based," and inadvertently revealed a lack of understanding of the difference between these two concepts. "Empirical-based" medicine relies on expert opinion backed by only minimal research. It is also known as "eminence-based." In contrast, the cornerstone of "evidence-based medicine" is a rigorous, impartial evaluation of the evidence to assess its certainty, which allows for truly informed decision-making (Drisko & Friedman, 2019). SEGM's stated goal is to help gender medicine move past its current "empirical-based" status and toward the rigorous principles of evidence-based medicine. While Drescher failed to identify any inaccuracies in the information disseminated by SEGM, he did find fault with the authors' disclosure of an association with SEGM. We remind him and other researchers that such disclosures are an ethical requirement for publications and are not optional. Unfortunately, disclosures of interest, including *conflicts of interest,* such as when pharmaceutical companies pay authors promoting the benefits of "gender-affirmative hormones," are often omitted, and only come to light months after the research conclusions have been widely publicized (Erratum for TURBAN 2019-1725., 2021). Another rarely disclosed conflict of interest in pediatric gender medicine is the fact that the investigators of the studies are commonly the same clinicians who are prescribing or administering "gender-affirming" interventions. This is perhaps the single most problematic source of bias in current research, since the investigators have a significant intellectual (and sometimes financial) stake in "demonstrating" that their work produced positive results (Boutron et al., 2022).

We invite Drescher to examine his own potential conflicts of interest and intellectual biases, including the possibility that his decade-long advocacy to de-pathologize gender dysphoria in the diagnostic categories of DSM and ICD (Drescher, Cohen-Kettenis, & Winter, 2012) may have created a confirmation bias. Had Drescher critically engaged with the fact that over 70% of gender dysphoric youth presenting for care had been diagnosed with a mental illness or neurocognitive disorder prior to the onset of gender dysphoria (Becerra-Culqui et al., 2018), perhaps he would see the reason behind the recommendation for psychotherapy as the first and even only line of treatment, pending reaching maturity.

We agree with Drescher's concerns about the politicization of transgender health care, as some states move to issue harsh penalties for those who provide gender transition services to minors. We agree that regulating treatments for gender dysphoria is best handled by the medical establishment self-correcting, rather than allowing politicians to make medical decisions. Drescher does not seem to realize, however, the extent to which his own attitude, shared by many gender clinicians, that youth gender transitions must continue without restraint before any reliable data are available, has contributed to this polarization. Drescher's concern for the wellbeing of gender dysphoric youth is palpable, and we share it, even if he finds that hard to believe. What the field needs now is more reliable outcome data, not more passion and political rhetoric.

Response to Clayton

In the process of comparing our informed consent recommendations to those authored by WPATH's affiliate AusPATH, Clayton revealed that the guidance widely used in Australia and New Zealand is not entirely data dependent. Given AusPATH's close links to WPATH, we agree with Clayton that her commentary "holds much relevance to the international context" (Clayton, 2022b p. 1).

Clayton juxtaposed two sets of opposing claims regarding the evidence for "gender affirmation" of youth: the claim by advocates of this practice who insist that data show significant benefits and low risks, and the assertions of critics that the benefits are highly uncertain, and the risks are significant. She suggested that this contradiction may be resolved by engaging in "close reading of the cited primary sources" (Clayton, 2022b p. 3). As Clayton's prior research demonstrated, there is a troubling "asymmetry" in how the results from gender clinics-based research are frequently reported: "[f]indings of positive outcomes of medical interventions are trumpeted in abstracts, while their profound limitations remain behind the paywall, thus, below the radar of busy clinicians" (Clayton et al., 2022, p. 3). Once the individual studies are scrubbed of uncertainty in the abstracts, the evidence enters a new cycle of laundering where "[n]ew publications reference prior ones with increasing and unwarranted confidence" (Clayton et al., 2022, p. 3).

Unfortunately, not only individual studies, but even systematic *reviews of evidence*, which generally reside on the highest rung of the evidence pyramid, can suffer from bias. Clayton's prior research focused on a problematic "systematic review" by Rew, Young, Monge, and Bogucka (2021), which exemplified a "concerning trend to overstate the evidence underpinning clinical practice recommendations for youth with GD [gender dysphoria]" (Clayton et al., 2022, p. 3).

We see similar problems in the review commissioned by WPATH as the basis for its "Standards of Care 8" (Baker et al., 2021). This review failed to examine any *physical health* risks of hormonal interventions and found only low-quality or insufficient evidence of *psychological* benefits due to high risk of bias in study designs, small sample sizes, and confounding with other interventions. This did not preclude the authors from endorsing "hormone therapy," including puberty blockers and cross-sex hormones for youth as an "essential component of care" (Baker et al., 2021, p. 13.). These conclusions, which cannot be substantiated by the review's actual findings, have since been used by WPATH to issue the recommendations to treat gender dysphoria medically, stating that "delay in transition" is rarely advisable and should only be used as a "last resort" (Coleman et al., 2022, p. S37).

It is worth noting that Baker, the lead author of the WPATH-comissioned systematic review, appears to have coauthored another highly flawed evidence review widely known by its pithy subtitle, "What We Know" (Frank & Baker, 2018). Baker's commitment to generating research that furthers a policy agenda to promote access to hormones is well-publicized (Health Policy Research Scholars, 2019). Had the goal been scientific accuracy, rather than political advocacy, the title of that review would have been "What We *Don't* Know."

It is notable that when led by researchers with no intellectual or financial conflicts of interest, evidence reviews universally find the benefits of pediatric gender reassignment unconvincing, and the unquantified risks of harm alarming. This includes recent evidence reviews commissioned by health authorities in the UK (NICE, 2020a, 2020b); Sweden (SBU, 2022); Finland (Pasternack, Söderström, Saijonkari, & Mäkelä, 2019), and most recently, the state of Florida in the United States (Brignardello-Peterson & Wiercioch, 2022).

Clayton reminded readers that advancing from the current lack of evidence requires rigorous study designs capable of generating high quality evidence. She illustrated the importance of rigorous research designs by invoking the *placebo effect*—the well-established powerful influence of "the whole therapeutic ritual, including medical marketing" that "affects the patient's neuro-psycho-biological state…" (Clayton, 2022b, p. 5). Clayton questioned the extent to which the observed short-term improvement reported by uncontrolled studies may be subject to the placebo effect, with clinicians themselves operating under a "therapeutic illusion" enabled in part by the widespread promotion of the expected benefits of gender transition in "social media, and celebrity culture" (p. 5). She noted that when "interventions have high risk of serious and irreversible adverse effects" (p. 5), rigorous study designs that control for these factors are essential.

Clayton also reflected on the blurred line that separates "innovative clinical practice," which can be offered widely by any willing provider, from "research," which is subject to a tightly

regulated process. She questioned whether "affirming" interventions for youth can only ethically be performed in research settings, in view of these interventions' irreversible effects and the risks involved to very young individuals. This is the direction that Sweden recently assumed (Socialstyrelsen, 2022a, 2022b). In the U.S., such a change is not likely to come from the Federal government, but it can take place at the state level, as U.S. laws delegate the responsibility to regulate the practice of medicine to individual states. If this were to happen, gender clinics in participating states might be more motivated to design research that generates useful data to answer the unanswered questions about outcomes.

Having interrogated the evidence, Clayton concluded, "[a]ny claims of certainty are premature and risk more harm than benefit" and observed that the gender medicine establishment's misguided insistence that the science is settled "hinder[s] the rigorous debate and research required to improve the state of knowledge in this area of medicine" (Clayton, 2022b, p. 6). Clayton's overview of medicine's misadventures detailed in her previous publication (Clayton, 2022a), and in the relevant examples in her present commentary (Clayton, 2022b), provide a powerful argument to all clinicians to reconsider their informed consent processes for youth gender transitions. We highly recommend her erudite commentary to all individuals in the field.

Response to Balon

Balon reinforced, elaborated, and provided historical perspective of the importance of a "serious, thorough, and careful" legal and ethical informed consent process (Balon, 2022, p. 3). His epigram, "*Whatever you do, do it deliberately and consider the end*" (Balon, 2022, p. 1) indicated his grasp of the central issue of our contribution—our concern about the proliferation of gender transitions undertaken in youth, despite the unknown long-term outcomes of these radical interventions. He sagely observed that in 2012, when the requirement for psychiatric evaluation was waived to enable patients to efficiently obtain hormones (Coleman et al., 2012), the protection of patients and their families was jeopardized.

Balon agreed that the process of medical gender transition of youth is often undertaken in a way that is not truly informed: "Similar to Levine et al. (2022), I am also not sure whether, with the increased incidence of gender identity variation, all parties involved in the informed consent process are well and appropriately informed and educated" (Balon, 2022, p. 1). He recognized the difficulty of obtaining informed consent from patients and families when the clinicians themselves do not have reliable information: "the word informed does not relate "just" to patients' (and their families) side of the informed consent equation, but also to the clinicians' side. It is obvious that our state of knowledge regarding appropriate and timely gender transition (whatever the intervention is) and its consequences is not where we would like it to be" (Balon, 2022, p. 1).

Balon emphasized how far the field of gender medicine is from a rational dispassionate heuristic embrace of the disagreements: "It seems that most of the time ideology, emotions and personal convictions beat knowledge and evidence in these debates" (Balon, 2022, p. 3). Balon's plain language summary of the current situation is apt: "Simply said, the ship has sailed, and we assume that its course is correct, and landing will be correct and the life after will be happy. Is that so, though?" (Balon, 2022, p. 1). Alarmed by the "possibility of underlying belief systems replacing scientific evidence," Balon encouraged all parties to continue the scientific debate, "agree to disagree and through our disagreement and continuous study of gender and transgender issues continue to improve the care of our patients." Balon reminded all those involved in the debate that there is "[u]ltimately, just one side to this debate…the patient side" (Balon, 2022, p. 3).

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