Amv McGhee Missoula County District Court STATE OF MONTANA

By: Maria Cassidy DV-32-2023-0000541-CR Marks, Jason 77.00

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MONTANA FOURTH JUDICIAL DISTRICT COURT, MISSOULA COUNTY

SCARLET VAN GARDEREN, et al.

Cause No. DV 2023-0541 Hon. Jason Marks

Plaintiffs,

STATE OF MONTANA, et al.,

v.

Defendants.

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY **INJUNCTION**

INTRODUCTION

In their present Motion (Doc. 49) and supporting Brief (Doc. 50), Plaintiffs urge the Court to enjoin the enforcement of Senate Bill 99, also known as the Youth Health Protection Act, ("SB 99"/"the Act")—a duly enacted law prohibiting the use of experimental, irreversible, and often sterilizing medications and procedures on Montana children. Plaintiffs resort to euphemisms, faulty science, and emotional blackmail in an effort to block the protections the people of Montana have seen fit to provide children against a newfangled social contagion's potentially catastrophic consequences. Neither sound science nor the law even remotely justifies the relief Plaintiffs seek herein, and the Court should, accordingly, deny Plaintiffs' Motion.

BACKGROUND¹

I. Sex, Gender, and Gender Identity.

Plaintiffs premise their claims on the theory that gender identity is a "core sense of belonging to a particular gender" and that a person's sex is "assigned at birth" based on their observed external genitalia. (Doc. 60 ¶¶ 28–32). Their theories aside, according to the National Institutes of Health ("NIH"), sex is a distinct biological classification that is encoded in every person's DNA.² "Sex makes us male or female. *Every cell* in your body has a sex... Each cell is either male or female depending on whether you are a man or woman." Sex is much more than genitalia. (Decl. Michael Laidlaw, M.D., ¶¶ 13–16 (Aug. 31, 2023), attached as **Exhibit A**.) Because sex is encoded in every cell, surgery can only effect a superficial change. Sex cannot be changed. (*Id.* at ¶¶ 41–44).

¹ Against the strong objection of Defendants, the Court has disallowed expert testimony for the hearing on Plaintiffs' Motion for Preliminary Injunction. Defendants contend Plaintiffs cannot meet their burden of proof on the elements of a preliminary injunction based on hearsay declarations and inadmissible evidence. Defendants submit the following evidence largely in rebuttal to Plaintiffs' claims and to preserve their arguments in the face of the Court's denial of expert testimony.

² Nat'l Inst. of Health, Office of Research on Women's Health, How Sex and Gender Influence Health and Disease, available at https://perma.cc/9EP5-MXK8.

³ *Id.* (emphasis added).

"Gender is a social and cultural concept." "It refers to the roles, behaviors, and identities that society assigns to girls and boys, women and men, and gender-diverse people. Gender is determined by how we see ourselves and each other, and how we act and interact with others." Gender is distinct from sex.

"Sex and gender play a role in how health and disease affect individuals. There was a time when we studied men and applied those findings to women, but we've learned that there are distinct biological differences between women and men." Examples of these differences include heart attack symptoms, disease risk in addiction, addiction's influence on the brain, and autoimmune disorders, which disproportionately impact more women than men. The Endocrine Society acknowledges that "[s]ex is an essential part of vertebrate biology, but gender is a human phenomenon; sex often influences gender, but *gender cannot influence sex.*"

Gender identity "refers to subjective feelings that cannot be defined, measured, or verified by science." (Decl. James Cantor, ¶ 107 (Aug. 31, 2023), attached as **Exhibit B**; see also Ex. A at ¶¶ 17–26.) "In science, a valid construct must be both objectively measurable and falsifiable with objective testing. The concept of an 'inner sense' fits none of these requirements." (*Id.*) In many cases, gender discordance, or gender dysphoria, is a symptom of a greater issue. "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, and homelessness."

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⁴ Nat'l Inst. of Health, *How Being Male or Female Can Affect Your Health*, NIH News in Health, available at https://perma.cc/CJM3-ZZP4.

⁵ *Id*.

⁶ *Id*.

⁷ *Id*.

⁸ Aditi Bhargava et al., *Considering Sex as a Biological Variable in Basic and Clinical Studies: An Endocrine Society Scientific Statement*, 10 Endocrine Reviews (2021) (emphasis added).

⁹ Paul W Hruz, Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria, 87 The Linacre Quarterly 34-42 (2020) (citing M.D. Connolly, et al., Standards of Care for the Health of Transsexual, Transgender,

"Most concerning, nearly half of all affected individuals will contemplate suicide and a third will attempt suicide." Instead of addressing the underlying psychosocial comorbidities, the recent trend in medicine has been to fast-track affected individuals into lifelong medicalization.

The sudden rise in gender discordance in young individuals is cause for concern considering this was extremely rare just a generation ago. ¹¹ The American Psychiatric Association had estimated the number of adults at 2–14 per 100,000. ¹² Between 2006 and 2015, the number dramatically increased among youths. ¹³ "Currently, 2–9% of U.S. high school students identify as transgender, while in colleges, 3% of males and 5% of females identify as gender-diverse." ¹⁴ The United Kingdom ("UK") reported a similar increase. "[A]ccording to data reported by the Tavistock gender clinic in the UK, in 2009, there were 51 requests for services; in 2019–2020, 2,728 referrals were recorded—a 53-fold increase in just over a decade." ¹⁵ In 2018, the UK reported a 4,400 percent rise over the previous decade in teenage girls seeking gender treatments." ¹⁶ This sharp increase corresponded with increases in Canada, Germany, Finland, and Sweden over the same time period. ¹⁷

Gender discordance was initially an issue that primarily affected young girls, but the significant rise in many cases did not track with any childhood history. A

¹⁶ Gordon Rayner, "Minister Orders Inquiry into 4,000 Percent Rise in Children Wanting to Change Sex," The Telegraph, (Sept. 16, 2018), https://www.telegraph.co.uk/politics/2018/09/16/minister-orders-inquiry-4000-per-cent-rise-children-wanting/.

and Gender-Nonconforming People, Version 7, 13 International Journal of Transgenderism 165-232 (2012)), attached as Exhibit C.

¹⁰ *Id.* at 35 (citing N. Adams, et al., *Varied Reports of Adult Transgender Suicidality: Synthesizing and Describing the Peer-Reviewed and Gray Literature*, 2 Transgender Health 60-75 (2017)).

¹¹ Stephen B Levine et al., Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults, 48 Journal of Sex & Marital Therapy 706-727 (2022), attached as **Exhibit D**.

¹² Id. at 707.

¹³ *Id.* (citing M. Aitken, et al., Evidence for an Altered Sex Ratio in Clinic-Referred Adolescents with Gender Dysphoria., 12 The Journal of Sexual Medicine 756-763 (2015)).

¹⁴ *Id.*

¹⁵ *Id*

¹⁷ See N.M. de Graaf et al., Sex Ratio in Children and Adolescents Referred to the Gender Identity Development Service in the UK (2009–2016), 47 Archives of Sexual Behavior 1301–1304 (2018), attached as **Exhibit E**; L. Frisen, et al., Dramatic Increase of Gender Dysphoria in Youth, 114 Läkartidningen 1–6 (2017).

child with gender dysphoria would typically express discordance with their gender beginning in early childhood, but this expression was not documented in the recent upward spike of cases.¹⁸ "It is that feature which led to the term Rapid Onset Gender Dysphoria (ROGD). Cases commonly appear to occur within clusters of peers in association with increased social media use, and among people with autism or other mental health issues." (Ex. B at ¶ 135.) Based on 256 reports from parents, almost 65% of adolescent girls who discovered transgender identity in adolescence had done so after a period of prolonged social media/internet use.¹⁹ These children were not born in the wrong body—their discordance was the result of a social phenomenon.

II. Gender Dysphoria.

"Transgender" is not a medical or psychiatric diagnosis; "gender dysphoria" is. Individuals with gender dysphoria (1) "have a marked incongruence" between their biological sex "and their experienced/expressed gender," and (2) experience clinical levels of "distress about this incongruence." *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5") at 452. This is a mental health diagnosis. (Ex. B at ¶ 108.)

A. Child-Onset Gender Dysphoria.

"For many decades, small numbers of prepubescent children have been brought to mental health professionals for help with their unhappiness with their sex and in the belief they would be happier living as the other sex." (Id. at ¶ 112). A significant majority of cases involving children occur in biological males, "with

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¹⁸ See Kenneth J. Zucker et al., Demographics, Behavior Problems, and Psychosexual Characteristics of Adolescents with Gender Identity Disorder or Transvestic Fetishism, 38 Journal of Sex & Marital Therapy 151–189, 152 (2012), attached as Exhibit F.

¹⁹ L. Littman, Rapid-Onset Gender Dysphoria in Adolescents and Young Adults: A Study of Parental Reports, 14 PLOS ONE 1–41 (2018), attached as **Exhibit G**.

clinics reporting 2–6 biological male children to each female." *Id*.²⁰ More recently, however, despite the increased number of biological male children asserting transgender identities, "the dramatic increase [has been] driven primarily by the natal females requesting services."²¹ "Gender-dysphoric children and teens can intensely occupy the belief that their lives will be immensely improved by transition."²² But, despite these feelings, transitioning frequently misses the core issue. "Many suffer from significant comorbid mental health disorders, have neurocognitive difficulties such as ADHD or autism or have a history of trauma."²³

In fact, "[a] formal analysis of children (ages 4–11) undergoing assessment at the Dutch child gender clinic showed that 52% fulfilled criteria for a formal DSM diagnosis of a clinical mental health condition other than Gender Dysphoria." (Ex. B at ¶ 154.) This was not isolated to the Dutch. Comparing Dutch and Canadian clinic data showed "61.7% of the Canadian and 62.1% of the Dutch sample satisfied the diagnostic criteria for one or more mental health conditions other than gender dysphoria." (*Id.* at ¶ 155.) A recent systemic review of 22 studies examining the prevalence of Autism Spectrum Disorders ("ASD"), Attention-Deficit Hyperactivity Disorder ("ADHD"), and youth with gender dysphoria found that 6–26% of such children had a prior diagnosis of ASD. (*Id.*) The rate of ADHD among the children with gender dysphoria was 8.3–11%. (*Id.*) "Conversely, data from children (ages 6–18) with ASDs show they are more than seven times more likely to have parent-reported 'gender variance." (*Id.*)

²⁰ P.T. Cohen-Kettenis, et al., *Demographic characteristics, social competence, and behavior problems in children with gender identity disorder: A cross-national, cross-clinic comparative analysis,* 31 Journal of Abnormal Child Psychology 41–53 (2003); T.D. Steensma, et al., *Evidence for a change in the sex ratio of children referred for gender dysphoria: Data from the Center of Expertise on Gender Dysphoria in Amsterdam (1988–2016)*, 44 Journal of Sex & Marital Therapy 713–715 (2018); H. Wood, et al., *Patterns of referral to a gender identity service for children and adolescents (1976–2011): Age, sex ratio, and sexual orientation*, 39 Journal of Sex & Marital Therapy 1–6 (2013).

²¹ Ex. D at 708.

²² *Id*.

²³ *Id*.

The discontinuation of gender dysphoria ("desistance") often occurs as the child progresses into adulthood. The DSM-5 reports that persistence rates (the continuation of dysphoria) in biological males range "from 2.2% to 30%" and from 12% to 50% for biological females." DSM-5 at 455. This means that 70-97.2% of boys and 50–88% of girls will grow out of dysphoria by adulthood. Version 7 of the World Professional Association for Transgender Health ("WPATH") Standard of care concedes this point: "Gender dysphoria during childhood does not inevitably continue into adulthood." (WPATH v.7 at 11, attached as Exhibit H.) In boys, "dysphoria persisted into adulthood for only 6–23% of children." (*Id.*) In girls, there is "a 12-27% persistence rate of gender dysphoria into adulthood." (Id.) The Endocrine Society admitted as much in 2017: "the large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain [gender dysphoric]/gender incongruent in adolescence." (Endocrine Society Practice Guidelines at 3879, attached as **Exhibit I**.) Moreover, "[w]ith current knowledge, we cannot predict the psychosexual outcome for any specific child." (*Id.* at 3876.) Plaintiffs here make no mention of desistance or the impossibility of predicting whether any given child's gender dysphoria will persist or desist into adulthood. Their position appears to be treatment first, regardless of the high likelihood of desistance.

B. Adolescent-Onset Gender Dysphoria.

While the DSM-5 focuses specifically on child- and adult-onset gender dysphoria, dysphoria beginning in adolescence is a new clinical phenomenon. "Concurrent with the advent of social media, a third profile began appearing clinically and socially, characteristically distinct from the two previously identified profiles." (Ex B. at ¶ 135). "This group typically presents in adolescence, but lacks the history of cross-gender behavior in childhood like the childhood-onset cases have." (*Id.*) Moreover, this group is predominantly female. (*Id.*) This demographic

is associated with the phenomenon called Rapid-Onset Gender Dysphoria ("ROGD"), in which "the development of gender dysphoria is observed to begin suddenly during or after puberty in an adolescent or young adult who would not have met criteria for gender dysphoria in childhood."²⁴ "Cases commonly appear to occur within clusters of peers in association with increased social media use, and among people with autism or other mental health issues." (*Id.*)

The causes of this phenomenon are not yet fully understood. "A growing number of clinicians and researchers are noting that the dramatic rise of teens declaring a trans identity appears to be, at least in part, a result of peer influence."²⁵ Board-Certified Child and Adolescent Psychiatrist Geeta Nangia has found several contributing factors in her own patient population: (1) an increase in "pathologizing" a normal part of child development; (2) shifts in cultural norms of gender exploration in adolescence; (3) the advent of social media; (4) the heightened vulnerability in youth; and (5) the "social contagion" aspect. (Decl. Geeta Nangia, ¶ 20 (Sept. 1, 2023), attached as Exhibit J.) The "elevated number of friends per friendship group who became transgender-identified, the pattern of cluster outbreaks of transgenderidentification in these friendship groups, the substantial percentage of friendship groups where the majority of the members became transgender-identified, and the peer group dynamics observed[]" demonstrates the "plausibility of social and peer contagion for ROGD."26 Evidence from Sweden likewise shows that girls in this group also show high levels of comorbidities, including depression (28.9%), anxiety (32.4%), autism (15.2%), and ADHD (19.4%). (Decl. Sven Roman, ¶ 33 (Aug. 30, 2023), attached as Exhibit K.) Boys show similar numbers: 13.8%, 21%, 12.3%,

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²⁴ Ex. G at 2.

²⁵ Ex. D at 710.

²⁶ Ex. G at 42.

and 13%, respectively. (*Id.* at ¶ 34.) These percentages far exceed those in the general population. (*Id.* at ¶¶ 33–34.)

The causes aside, it is undeniable that the demographic seeking to transition has drastically increased. "In 2021, about 42,000 children and teens across the United States received a diagnosis of gender dysphoria, nearly triple the number in 2017." In 2012, there were fewer than 250 referrals to England's Gender Identity Service, and by 2021, "there were more than 5,000…twice the number in the previous year." "And the largest group, about two-thirds, now consisted of 'birth-registered females first presenting in adolescence with gender-related distress." In Sweden, the "Board of Health and Welfare [] confirmed a 1,500% rise between 2008 and 2018 in gender dysphoria diagnoses among 13- to 17-year-olds born as girls." (Ex K. at ¶ 16.)

C. Treating Gender Dysphoria.

1. Watchful Waiting.

As explained above, there is a high probability of desistance in youth struggling with gender dysphoria. A majority desists according to the DSM-5, WPATH, the Endocrine Society, and several long-term studies. This leaves therapy, or "watchful waiting," as the safest method of treatment for affected children. Watchful waiting is not a passive approach—rather, it provides time for the child to "undergo therapy, resolving other issues which may be exacerbating psychological stress or dysphoria." (Ex. B at ¶ 244.) Watchful waiting is a compassionate,

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²⁷ Robin Respaut, *Number of transgender children seeking treatment surges in U.S.*, (Oct. 6, 2022), https://www.reuters.com/investigates/special-report/usa-transyouth-data/.

²⁸ Amelia Gentleman, 'An explosion': what is behind the rise in girls questioning their gender identity?, The Guardian (Nov. 24, 2022), https://www.theguardian.com/society/2022/nov/24/an-explosion-what-is-behind-the-rise-in-girls-questioning-their-gender-identity.

³⁰ Richard Orange, *Teenage transgender row splits Sweden as dysphoria diagnoses soar by 1,500%*, The Guardian (Feb. 22, 2020), https://www.theguardian.com/society/2020/feb/22/ssweden-teenage-transgender-row-dysphoria-diagnoses-soar.

effective, and less risky approach that entails "a comprehensive assessment, individual and family therapy, and harnessing a support network for the patient." (Ex. J at ¶ 164.) The Dutch currently emphasize this is necessary at least until the age of 12. (*Id.*) "[A]dolescents in this study received extensive family or other social support [and they] were all regularly seen by one of the clinic's psychologists or psychiatrists."³¹

In a Canadian study of 139 boys clinic-referred for gender dysphoria, 87.8% of those who were assessed at a mean age of 7.49 years and reassessed at 20.58 years desisted.³² This study represented the largest sample to date and showed that the boys merely needed time and therapy. "Because only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, 'transition-on-demand' increases the probability of unnecessary transition and unnecessary medical risks." (Ex. B at ¶ 124.)

2. Gender-Affirming Care.

In stark contrast, so-called "gender-affirming care" is an experimental and far more risky treatment modality. This model represents a branch of medicine which, outside of cosmetic surgery, may be the only one in which the patient makes the diagnosis and prescribes the treatment. Gender-affirming care "aim[s] to directly and immediately validate the adolescent's feelings about becoming the opposite gender" and then sets the patient on a path toward puberty blockers, cross-sex hormone therapy, and eventually gender reassignment surgery. (Ex. J at ¶ 118.) "Social transition serves to convince the child or adolescent that they can be the opposite sex." (Ex. A at ¶ 285.) Early validation and encouragement of socially transitioning sets the child's course toward full gender transitioning. "[T]he highest rate of

³¹ A.L.C. de Vries, et al., *Puberty Suppression in Adolescents With Gender Identity Disorder: A Prospective Follow-Up Study*, 8 Journal of Sexual Medicine 2276–2283, 2281 (2011).

³² D. Singh, S.J. Bradley, & K. J. Zucker, *A Follow-Up Study of Boys With Gender Identity Disorder*, 12 Frontiers in Psychology 1–18 (2021), attached as **Exhibit L**.)

persistence, included some patients who had made a partial or complete gender social transition prior to puberty and *this variable proved to be a unique predictor* of persistence."³³

Validating a child's feelings of being of the opposite sex and encouraging social transition drastically reduces the opportunity for the child to desist. "A gender social transition in prepubertal children is a form of psychosocial treatment that aims to reduce gender dysphoria, but with the likely consequence of subsequent (lifelong) biomedical treatments as well (gender-affirming hormonal treatment and surgery)." It is, therefore, evident that affirmation likely causes persistence and disrupts the natural tendency for desistance as the affected child matures.

III. The Dutch Protocol.

Social transitioning encourages full medical transition, and in children and adolescents, this includes the suppression of puberty. The theory of puberty suppression originated with two Dutch endocrinologists who introduced the concept of using hormonal treatments to halt pubertal development in a 1996 article.³⁵ The authors boasted the therapy was "fully reversible; in other words, *no lasting undesired effects are to be expected.*"³⁶

This experiment was first attempted and published two years later when a 13-year-old girl identified as "B" began puberty blockers.³⁷ B was 18 when she fully transitioned with testosterone, a double mastectomy, the removal of her ovaries and uterus, and full genital reassignment surgery.³⁸ "B" reported being satisfied with the

³³ *Id.* at 14 (emphasis added).

³⁴ K.J. Zucker, *Debate: Different Strokes for Different Folks*, 25 Child and Adolescent Mental Health, 36-37 (2019), attached as **Exhibit M**.

³⁵ Louis Gooren & Henriette Delamarre-van de Waal, *The Feasibility of Endocrine Interventions in Juvenile Transsexuals*, 8 Journal of Psychology & Human Sexuality 69–74 (1996).

³⁶ *Id.* at 72 (emphasis added.)

³⁷ Peggy Cohen-Kettenis & S.H.M. van Goozen, *Pubertal Delay as an Aid in Diagnosis and Treatment of a Transsexual Adolescent*, 7 European Child & Adolescent Psychiatry 246–248 (1998).
³⁸ *Id.* at 247.

results.³⁹ Co-author Cohen-Kettenis postulated that, based on this one instance, lowering the age of hormonal treatments "may therefore result in a lower incidence. . . of postoperative regrets.⁴⁰ She further opined that the advantage of pubertal delay is that "no irreversible steps are taken," however, it risked being "a guarantee of sex reassignment, and it could make them therefore less rather than more inclined to engage in introspection."⁴¹

In 2006, Cohen-Kettenis published the "Dutch Protocol."⁴² Based on a study of 54 participants (sponsored by a manufacturer of puberty blockers),⁴³ the Dutch Protocol advocates puberty blockers at age 12, cross-sex hormones at 16, and reassignment surgery at 18.⁴⁴ An eligible candidate met "the Diagnostic and Statistical Manual of Mental Disorders-IV-RT criteria for gender disorder, [had] suffered lifelong extreme gender dysphoria, [was] psychologically stable and live[d] in a supportive environment."⁴⁵

But following the Dutch Protocol was not without its consequences. "After a short activation," the use of puberty suppressing hormones "bring[s] the patients into a hypogonadotropic state."⁴⁶ This "is a condition in which the male testes or the female ovaries produce little or no sex hormones," with potential complications including early menopause, infertility, low bone density and fractures later in life, low self-esteem, and sexual problems.⁴⁷ Due to the risk of infertility, Cohen-Kettenis recommended discussing "cryopreservation of semen" prior to the start of treatment

³⁹ *Id.* at 248.

⁴⁰ *Id*.

⁴¹ Id.

⁴² Peggy Cohen-Kettenis & Henriette A Delemarre-van de Waal, *Clinical Management of Gender Identity Disorder in Adolescents: A Protocol on Psychological and Paediatric Endocrinology Aspects*, 155 European Journal of Endocrinology S131–S137 (2006).

⁴³ *Id.* at S137.

⁴⁴ *Id.* at S135.

⁴⁵ *Id*.

⁴⁶ *Id.* at S134.

⁴⁷ Hypogonadotropic Hypogonadism, Penn Medicine (July 28, 2021), https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/hypogonadotropic-hypogonadism.

in boys.⁴⁸ This was a notable abandonment of the claim that that puberty suppression was effectively a harmless pause button,⁴⁹ which is further highlighted by the prevailing lack of research on the safety and effects of the experimental treatment.⁵⁰ The Dutch Protocol nevertheless emerged as the international standard for "treating" gender dysphoria,⁵¹ and Cohen-Kettenis even joined WPATH as one of its board of directors from 1995–1999, and 2003–2007.⁵²

IV. Desistance.

"Not all children with GID [gender identity disorder] will turn out to be transsexuals after puberty." "Prospective studies of GID boys show that this phenomenon is more closely related to later homosexuality than to later transsexualism." This conclusion was based in part on a number of prior studies, including one that followed 44 "pretransexual" boys over fifteen years. Of the 44 boys, only one was still considering transsexuality after 15 years. This was not an anomaly; it was a trend.

No fewer than eleven long-term studies paint a markedly different picture from that which Plaintiffs present. (Ex. B at ¶ 114.) Given enough time, and if social

⁴⁸ Peggy Cohen-Kettenis & Henriette A Delemarre-van de Waal, *Clinical Management of Gender Identity Disorder in Adolescents: A Protocol on Psychological and Paediatric Endocrinology Aspects*, 155 European Journal of Endocrinology S131–S137, S134 (2006) (further observing that "the growth spurt will be hampered and fusion of the growth plates delayed," raising the question of whether patients "may achieve a normal development of bone density," and acknowledging they "do not know what effects the [puberty suppressing treatments] alone, or in combination with cross-sex hormones, are on [carbohydrate and fat] metabolic aspects.").

⁴⁹ See also Peggy Cohen-Kettenis et al., *Treatment of Adolescents with Gender Dysphoria in the Netherlands*, 20 Child and Adolescent Psychiatric Clinics of North America 697 (2011) (equivocating in response to concerns regarding body height, brain development, and the purported benefits of puberty suppression and gender reassignment surgery.) ⁵⁰ *Id.* at 698 ("However, research on the effects of [gender reassignment], starting with [puberty suppressing hormone] analogues treatment, *is still scarce*, and understandable concerns about potential harm have to be taken seriously. The initial studies need to be expanded in scope and corroborated by results from other centers to ensure that the treatment is safe enough.") (emphasis added).

⁵¹ *Id.* at 690, 698.

⁵² History of the Association, WPATH.org https://wpath.org/about/history.

⁵³ P. T Cohen-Kettenis & L. J. G Gooren, *Transsexualism: A Review of Etiology, Diagnosis and Treatment*, 46 Journal of Psychosomatic Research 315–333 (1999).

⁵⁴ *Id*. at 319.

⁵⁵ *Id.* at 329.

⁵⁶ Richard Green, The Sissy Boy Syndrome: The Development of Homosexuality 12 (1987).

⁵⁷ *Id*.

transition is not encouraged, the vast majority of affected children (61-88%) choose not to change their gender. (Id. at ¶ 115.) "In sum, despite coming from a variety of countries, conducted by a variety of labs, using a variety of methods, at various times across four decades, every study without exception has come to the identical conclusion: among prepubescent children who feel gender dysphoric, the majority cease to want to be the other gender over the course of puberty." (Id.) It is all but certain that these children would have suffered irreparable and permanent damage to their bodies had they undergone social transition, puberty blockers, cross-sex hormones, and eventually surgery.

V. Affirmation's Consequences.

A. Puberty Blockers.

In 2019, a former patient at the Gender Identity Development Service ("GIDS") in England sued the GIDS, alleging that practices of prescribing puberty blockers for minors were unproven and potentially harmful and that minors were incapable of providing informed consent in this context. Bell v. Tavistock, [2020] EWHC 3274 (Admin), ¶ 7 (attached as **Exhibit N**.) The *Bell* court made numerous striking findings based on extensive expert testimony, concluding that "the clinical interventions involve significant, long-term and, in part, potentially irreversible long-term physical, and psychological consequences for young persons." *Id.* at ¶ 148 (emphasis added). "[I]t is right to call the treatment experimental or innovative in the sense that there are currently *limited studies/evidence* of the efficacy or longterm effects of the treatment." *Id.* (emphasis added). "[T]he vast majority of patients taking [puberty blockers] go on to [cross-sex hormones] and therefore [follow] a pathway to much greater medical interventions." *Id.* at ¶ 138 (emphasis added). The Bell court further concluded that a child under the age of 16 is not competent to have sufficient understanding to give informed consent and therefore requires a court to make the determination. Id. at ¶ 151. Although an appellate court ultimately reversed the lower court on the issue of informed consent and court involvement, it acknowledged that "[m]edical opinion is far from unanimous about the wisdom of embarking on treatment before adulthood." Bell v. Tavistock, [2021] EWCA Civ 1363, ¶ 3 (emphasis added).

Contrary to Plaintiffs' contentions that puberty blockers are safe and reversible (Doc. 50 at 3), experts continue to raise the exact concerns addressed in Bell v. Tavistock. "GnRH analogs are called puberty blockers. GnRH analogs are not [Food and Drug Administration, ("FDA")] approved for use in children with gender dysphoria. They are approved for use in children who have the relatively rare disorder called central precocious puberty." (Decl. Daniel Weiss, M.D., ¶ 125 (Aug. 31, 2023), attached as **Exhibit O**.) "There are no controlled trials that prove the safety of GnRH analogs in children with normal puberty." (*Id.* at ¶ 128.) "Children who fail to progress through puberty are infertile." (Id. at ¶ 135.) "If the testes or ovaries fail to mature, sperm and ova cannot be produced. Infertility will likely occur especially if followed by opposite sex hormones." (Id. at ¶ 136.) "[N]o studies at all have been done of when, whether, or with what probability either males or females can achieve healthy fertility if they later regret their transition decision and cease taking puberty blockers and/or cross-sex hormones." (Ex. B at ¶ 205). "The use of GnRH analogue medication for this purpose in adolescents is experimental as there have been no randomized controlled trials for this specific use case." (Ex. A at ¶ 79).

An internal review by National Health Service ("NHS") in England further found that "brain maturation may be temporarily or permanently disrupted by puberty blockers, which could have significant impact on the ability to make complex risk-laden decisions, as well as possible longer-term neuropsychological consequences." (Cass Review Letter, at 6, attached as **Exhibit P**.) "To date, there has been very limited research on the short-, medium- or longer-term impact of puberty blockers on neurocognitive development." (*Id.*) Regarding low bone density

issues, "[t]he systematic reviews by Sweden, Finland, and England all included bone health as an outcome." (Ex. B at ¶ 215.) Ultimately, "there is not sufficient evidence to conclude that the use of puberty blockers to block natural puberty is safe when administered as part of gender-affirming therapy, or that its effects are reversible." (Ex. A at ¶ 81.)

B. Cross-Sex Hormones.

"[T]he evidence that we have on this issue clearly shows that *practically all* children/young people who start [puberty blockers] progress on to [cross-sex hormones]." *Bell*, [2020] EWHC at ¶ 56 (emphasis added). Of adolescents that started puberty blockers, "only 1.9 per cent stopped the treatment and did not proceed to [cross-sex hormones]." *Id.* at ¶ 57. However, children lack the understanding that "[cross-sex hormones] may very well lead to a loss of fertility. . . and the impact . . . on sexual function." *Id.* at ¶ 138. "In fact, high dose opposite sex hormones may permanently damage the immature sex organs leading to sterilization." (Ex. A at ¶ 93). The impacts extend beyond infertility and sexual function, but "[m]ost of the data on the effects of opposite sex hormones come from follow up on adults." (Ex. O at ¶ 150). "There are very little data on minors." (*Id.*)

"Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers." (Ex. B at ¶ 91). "Short term effects of testosterone given to natal females include acne, baldness, facial hair, clitoral enlargement, and pelvic pain." (Ex. O at ¶ 153). "There may be deepening of the voice." (*Id.*) "Longer term adverse effects of testosterone given to females include: a greater than 3-fold increase in rate of heart attack and an almost doubling of the rate of stroke." (*Id.* at ¶¶ 161–62.) "Biologic males treated with estrogen have a 22-fold increase in the rate of breast cancer," an "increased risk

of prostate cancer," "a 36-fold higher risk of strokes," and "an increased risk of autoimmune disorders." (*Id.* at ¶¶ 163–64, 167, 169.)

C. Gender Reassignment Surgery.

Despite Plaintiffs' claims that "medical interventions beyond puberty blockers and hormone therapy are rare," gender-affirming surgeries tripled in the United States between 2016 and 2019. (Doc. 50 at 5.)⁵⁸ The most common surgery for gender dysphoric minors is a bilateral mastectomy, also known as "top surgery." (Ex. O at ¶ 170.) "Between 15-38% of children who undergo mastectomies require additional surgeries. Up to a third have post-operative complications. These complications include excessive scarring, pain and swelling from blood or fluid buildup, wound dehiscence (opening up where the surgical incisions were sewn together), and nipple necrosis (death of the nipple tissue)." (*Id.* at ¶ 173). "It is important to note that this operation cannot be reversed. The female will never regain healthy breasts capable of producing milk to feed a child." (Ex. A at ¶ 166).

Other surgeries for females include removal of the ovaries, uterus, fallopian tubes, cervix, and vagina, which results in sterilization. (Id. at ¶ 170.) For those who seek the surgical construction of a penis, "a roll of skin and subcutaneous tissue is removed from one area of the body, say the thigh or the forearm, and transplanted to the pelvis." (Id. at ¶ 172.) Because the transplanted structure lacks the ability to become erect, "erectile devices such as rods or inflatable devices are placed within the tube transplanted in order to simulate an erection." (Id.) "A recent systematic review and meta-analysis of 1731 patients who underwent phalloplasty found very high rates of complications (76.5%) including a urethral fistula rate of 34.1% and urethral stricture rate of 25.4%." (Id. ¶ 173.)

 58 Jason D. Wright, et al. National Estimates of Gender-Affirming Surgery in the US, 6(8) JAMA Network Open 1-11 (2023), attached as **Exhibit Q**.

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For males attempting to become female, the testicles must be removed to permanently lower testosterone levels, causing infertility. (Id. at ¶ 168.) If a vagina is desired, "the penis is surgically opened and the erectile tissue is removed. The skin is then closed and inverted into a newly created cavity in order to simulate a vagina. A dilator must be placed in the new cavity for some time so that it does not naturally close." (Id.) Complications include "urethral strictures, infection, prolapse, fistulas and injury to the sensory nerves with partial or complete loss of erotic sensation." (Id. at ¶ 169).

In 2016, the Centers for Medicare & Medicaid Services ("CMS") released a decision memorandum rejecting the establishment of a national coverage decision for gender reassignment surgery. In the memorandum, CMS considered whether data supported surgical intervention to treat gender dysphoria in the Medicare Population.⁵⁹ The report concluded that "there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively." ⁶⁰ In other words, CMS found insufficient evidence demonstrating that gender reassignment surgery improves health outcomes.

VI. Suicide Rates.

Plaintiffs assert that "[u]ntreated, gender dysphoria can result in...suicidality." (Doc. 50 at 2.) But the reality is that "[n]o studies have documented any reduction in suicide rates in minors (or any population) as a result of medical transition." (Ex. B at ¶ 146.) "No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality in minors." (Id.)

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⁵⁹ See Tamara Syrek Jensen, et al., Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (Aug. 30, 2016), available at https://perma.cc/9CQN-938N. ⁶⁰ Id.

According to a Swedish study, "[w]hen followed out beyond ten years, the sex-reassigned group had *nineteen times the rate of completed suicides* and *nearly three times* the rate of all-cause mortality and inpatient psychiatric care compared to the general population of Sweden." (Ex. A at ¶ 214) (emphasis added). "Among post-operative patients in the Netherlands, long-term suicide rates of six times to eight times that of the general population were observed depending on age group." (Ex. B. at ¶ 147/) "Also studying patients in the Netherlands, Wiepjes et al. (2020) reported the 'important finding' that 'suicide occurs similarly' before and after medical transition." (*Id.*) In other words, transitioning failed to resolve the children's core medical health issues.

"The notion that trans-identified youth are at alarmingly high risk of suicide usually stems from biased online samples that rely on self-report, and frequently conflates suicidal thoughts and non-suicidal self-harm with serious suicide attempts and completed suicides." In the UK, Tavistock found that the rate of completed transgender youth suicides to be "0.03% over a 10-year period," which is "far from the epidemic of trans suicides portrayed by the media." Plaintiffs may point to a correlation, but this does not amount to causation.

VII. The Ethical Dilemma of Informed Consent.

Plaintiffs also assert that gender-affirming care is only provided after discussing it with the child, the parents or legal guardians, "and obtaining informed consent." (Doc. 60 at ¶ 48.) But it remains unclear how informed consent can possibly be achieved in this context. The court struggled with this issue in *Bell v*. *Tavistock*:

It follows that to achieve *Gillick* competence the child or young person would have to understand not simply the implications of taking [puberty blockers] but those of progressing to cross-sex hormones. The

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⁶¹ Ex. D at 713.

⁶² *Id*

relevant information therefore that a child would have to understand, retain and weigh up in order to have the requisite competence in relation to [puberty blockers], would be as follows: (i) the immediate consequences of the treatment in physical and psychological terms; (ii) the fact that the vast majority of patients taking [puberty blockers] go on to [cross-sex hormones] and therefore that s/he is on a pathway to much greater medical interventions; (iii) the relationship between taking [cross-sex hormones] and subsequent surgery, with the implications of such surgery; (iv) the fact that [cross-sex hormones] may well lead to a loss of fertility; (v) the impact of [cross-sex hormones] on sexual function; (vi) the impact that taking this step on this treatment pathway may have on future and life-long relationships; (vii) the unknown physical consequences of taking [puberty blockers]; and (viii) the fact that the evidence base for this treatment is as yet highly uncertain.

[...]

The difficulty of achieving informed consent in these circumstances is further exacerbated by the lack of evidence as to the efficacy of [puberty blockers] in treating [gender dysphoria] and the long-term outcomes of taking it. We entirely accept that the fact that a treatment is experimental, or that the long-term outcomes are not yet known, does not of itself prevent informed consent being given. Otherwise no experimental treatment could ever be consented to. However, the combination here of lifelong and life changing treatment being given to children, with very limited knowledge of the degree to which it will or will not benefit them, is one that gives significant grounds for concern.

Bell, [2020] EWHC at ¶¶ 138, 143.

Children are impulsive by nature and are inclined to seek immediate gratification. "That adolescents find it difficult to contemplate or comprehend what their life will be like as adults and that they do not always consider the longer-term consequences of their actions is perhaps a statement of the obvious." *Id.* at ¶ 141. "There does not exist—indeed, there cannot exist—an age-appropriate way to equip a child who has not gone through puberty to make an informed decision about age-inappropriate issues, such as their future sex life, choices of sexual partners, sex-

bonded relationships including marriage, and sacrificing ever experiencing orgasm." (Ex. B at ¶ 234). A parent cannot make this drastic and consequential decision for a child, and a child is simply incapable of making such a decision. (*Id.* at ¶¶ 207, 212, 234; Ex. J at ¶¶ 61–112, 115–135.)

VIII. The Retreat by the International Community.

In the wake of *Bell v. Tavistock*, the UK's National Health Service ("NHS") moved to close its Tavistock clinic—its only child gender identity clinic.⁶³ The NHS also began a complete systematic review of its gender identity services, and in the interim report released this year,⁶⁴ it noted that the "gender-affirming care" model pervasive in the United States had been adopted by the Tavistock clinic.⁶⁵ It also found that "[e]vidence on the appropriate management" of gender dysphoric young people "is inconclusive both nationally and internationally."⁶⁶ The report noted a "lack of consensus" on the affirmative care model, but that "[p]rimary and secondary care staff … feel under pressure to adopt an unquestioning affirmative approach."⁶⁷ Further, doctors had told the authors they were "afraid of the consequences" if they did not bend to the "pressure to take a purely affirmative approach."⁶⁸ In June of this year, the NHS announced that puberty blockers would only be prescribed to gender dysphoric children in clinical trials.⁶⁹ The NHS also updated its website to reflect that "[l]ittle is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria…it is not known what the psychological

⁶³ BBC News, *NHS to close Tavistock child gender identity clinic*, BBC News (July 28, 2022), https://www.bbc.com/news/uk-62335665.

⁶⁴ The Cass Review: Independent Review of Gender Identity Services for Children and Young People: Interim Report (Feb. 2022), available at https://cass.independent-review.uk/publications/interim-report/ and attached as **Exhibit R**.) ⁶⁵ Id. at 14–15, 78.

⁶⁶ *Id*. at 19.

⁶⁷ *Id*. at 17.

⁶⁸ *Id*. at 48.

⁶⁹ Lauren Moss, *Puberty blockers to be given only in clinical research*, BBC News (June 9, 2023), https://www.bbc.com/news/uk-65860272.

effects may be. It's also not known whether hormone blockers affect the development of the teenage brain or children's bones." (Ex. B at ¶ 82).

In France, the National Academy of Medicine issued a statement on gender identity care in children and adolescents on February 22, 2022.⁷⁰ It expressed concerns about the "very strong increase in the demand" in France and other countries, urging "great medical caution" given the "vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause."⁷¹ It further explained "the greatest reserve is required for [puberty blocker and cross-sex hormone] use, given the side effects such as impact on growth, bone fragility, risk of sterility, emotional and intellectual consequences and, for girls, symptoms reminiscent of menopause."⁷² This is because "the risk of over-diagnosis⁷³ is real, as shown by the increasing number of transgender young adults wishing to 'detransition.' It is therefore advisable to extend as much as possible the psychological support phase."⁷⁴

That same month, Sweden's National Board of Health and Welfare ("NBHW") updated its recommendations on gender affirming care.⁷⁵ The NBHW found that between 2008 and 2018, the number of new cases "multiplied," with the largest increase among girls between 13–17 years old.⁷⁶ After a systemic literature

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⁷⁰ Medicine and gender transidentity in children and adolescents – Académie nationale de médecine, Une institution dans son temps (Feb. 25, 2022), https://www.academie-medecine fr/la-medecine-face-a-la-transidentite-de-genrechez-les-enfants-et-les-adolescents/?lang=en, attached as **Exhibit S**.)
⁷¹ Id.

⁷² *Id*.

⁷³ Defined as "the diagnosis of a medical condition that would never have caused any symptoms or problems. This kind of diagnosis can be harmful if it leads to psychological stress and unnecessary treatments." "What is overdiagnosis?, Informedhealth.Org *available at* https://www.informedhealth.org/what-is-overdiagnosis.html.

⁷⁵ *Uppdaterade rekommendationer för hormonbehandling vid könsdysfori hos unga*, Socialstyrelsen (Feb. 22, 2022), https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/, attached as **Exhibit T**.)
⁷⁶ *Id*.

review, the NBHW concluded that "it is not yet possible to draw any firm conclusions about the efficacy and safety of the treatments based on scientific evidence." Emerging results indicate "the risks of puberty-inhibiting and genderaffirming hormone therapy for those under the age of 18 currently outweigh the possible benefit for the group as a whole." The subsequently published conclusion of the review found that the use of puberty blockers in children "should be considered experimental treatment of individual cases rather than standard procedure."

This March, Norway followed course by formally deeming gender-affirming care to be "experimental treatment." Norway experienced "a large increase in enquiries" about such care in recent years with the largest increase coming from female adolescents. The report cited a "risk of under-, over- and incorrect treatment" of youth with gender dysphoria. Most importantly, "[t]he evidence base, especially research-based knowledge for gender confirmation treatment (hormonal and surgical), is inadequate, and the long-term effects are little known." 83

Finland has reached the same conclusion: "In light of available evidence, gender reassignment of minors is an experimental practice." The Finnish report noted, in adolescents, "psychiatric disorders and developmental difficulties may predispose a young person to the onset of gender dysphoria" and they "should"

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⁷⁷ *Id*.

⁷⁹ Jonas F. Ludvigsson, et. al., A Systematic Review of Hormone Treatment for Children With Gender Dysphoria And Recommendations for Research, 00 Acta Paediatr, 1–14 (2023).

⁸⁰ Sammendrag, Ukom (Mar. 9, 2023), https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag, attached as **Exhibit U**.)

⁸¹ *Id*.

⁸² *Id*.

⁸³ *Id*.

⁸⁴ Recommendation of the Council for Choices in Health Care in Finland (PALKO / COHERE Finland) (July 2, 2021), https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf, attached as **Exhibit V**.

receive treatment for their mental and behavioral health issues."⁸⁵ Clinical experience also revealed "that autistic spectrum disorders (ASD) are overrepresented among adolescents suffering from gender dysphoria..."⁸⁶ Ultimately, "[t]he initiation and monitoring of hormonal treatments must be centralized at research clinics on gender identity[.]"⁸⁷

Finally, the Royal Australian & New Zealand College of Psychiatrists issued a policy statement in August 2021 recognizing the "paucity of quality evidence on the outcomes of those presenting with Gender Dysphoria." The policy statement points to "evidence that people who experience incongruence with their gender identity and assigned gender have higher levels of mental illness than the general population." It also observes that "evidence and professional opinion is *divided* as to whether an affirmative approach should be taken in relation to treatment of transgender children or whether other approaches are more appropriate." The "need for better evidence in relation to outcomes for children and young people...and further research...into the long-term effects of medical and surgical affirming treatment" could not be more clear. Ontrary to Plaintiffs' claims, profound medical uncertainty exists in all aspects of gender-affirming care.

⁸⁵ *Id*. at 8.

⁸⁶ *Id*.

⁸⁷ *Id*. at 10.

⁸⁸ Mental health needs of people experiencing Gender Dysphoria/Gender, RANZCP https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/recognising-and-addressing-the-mental-health-needs-of-people-experiencing-gender-dysphoria, attached as **Exhibit W**.

⁹⁰ *Id.* (emphasis added)

⁹¹ *Id.*; *See also Topic Brief: Treatments for Gender Dysphoria in Transgender Youth*, AHRQ, Nom. No 0928, at 2. (Feb. 17, 2021), *available at* https://effectivehealthcare.ahrq.gov/system/files/docs/topic-brief-gender-dysphoria.pdf ("There is a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation."), attached as **Exhibit X**.

IX. Senate Bill 99.

On April 28, 2023, Governor Greg Gianforte signed Senate Bill 99 ("SB 99"/"the Act") into law. A true and correct copy of SB 99 is attached as **Exhibit Y**. Titled the "Youth Health Protection Act," SB 99 prohibits certain medical and surgical treatments to treat gender dysphoria in minors. (Ex. Y.) The Act further prohibits the use of public funds, programs, property, and employees in providing or promoting those treatments; it provides that violations by health care professionals constitute professional misconduct; it creates a new private cause of action; and it prohibits any discharge of professional liability through insurance, among other provisions. (*Id.*)

SB 99 "is designed to protect children from the administration of drugs and chemicals, from the imposition of surgical procedures, with the purpose of causing the child to [] cosmetically appear more like the person of the opposite sex and lesser like his or her own sex and to conform to an identity incongruent with the child's sex." Senator John Fuller, SB 99's primary sponsor, explained by analogy that "if a wounded and mentally ill veteran decided he identified with a legless amputee, no one would ever entertain his desire to cut off his legs. Instead, he would be treated differently, with compassion for the cause of his misguided wishes." This unfortunately fell on the deaf ears of SB 99's opponents, who only took issue with Senator Fuller's amputation analogy. But they miss the point. The surgical removal of breasts or genitalia is amputation that results in permanent disfigurement and genital mutilation, not a "life-saving benefit" as Plaintiffs claim. (Doc. 50 at 5.) It is

⁹² See 2/7/23 Senate Floor Session, at 13:14:08; available at

http://sg001-harmony.sliq net/00309/Harmony/en/PowerBrowser/PowerBrowserV2/20170221/-1/46207?agendaId=251307.

⁹³ *Id.* at 13:15:00.

⁹⁴ *Id.* at 13:17:24 (Senator Flowers requested a "point of order" because "[Senator Fuller] references amputation...there's no...there's no...there's no reality there and there's nothing in his bill that refers to amputation.").

not SB 99's purpose to "burden" anyone, rather it is to protect children from the likely devastating and permanent consequences of misguided wishes. (Ex. Y.)

ARGUMENT

In 2023, the Montana Legislature amended Mont. Code Ann. § 27-19-201, which governs the circumstances in which courts can grant injunctive relief. The Legislature mirrored the federal standard, which allows for a preliminary injunction to be granted only when the applicant establishes that: a) the applicant is likely to succeed on the merits; b) the applicant is likely to suffer irreparable harm in the absence of preliminary relief; c) the balance of equities tips in the applicant's favor; and d) an injunction is in the public interest. This test is conjunctive, meaning the applicant must satisfy not just one element, but *all* elements, of the test. *Winter v. Natl. Res. Def. Council, Inc.*, 555 U.S. 7 (2008) (applying identical test) (citations omitted).

Plaintiffs "bear[] the burden of demonstrating the need for an injunction order." Mont. Code Ann. § 27-19-201(4). A preliminary injunction is an extraordinary remedy that may only be awarded upon a clear showing that the movant is entitled to such relief; it is never awarded as of right. *Winter*, 555 U.S. at 22 (citation omitted). Lastly, if Plaintiffs establish that a preliminary injunction should issue, the injunctive relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). 95

Plaintiffs' Motion for Preliminary Injunction should be denied because they cannot meet any, no less *all*, of the four elements necessary to obtain a preliminary injunction. Plaintiffs cannot show a likelihood of success on the merits, a likelihood

⁹⁵ See also SB 99, Section 10 (setting forth SB 99's "Severability" clause); *United States v. Texas*, 2023 U.S. LEXIS 2639, 2023 WL 4139000, at *17 (U.S. June 23, 2023) (Gorsuch, J., concurring) (considering the systemic harms of overbroad injunctions as part of the abuse-of-discretion review).

of suffering irreparable harm, that the balance of the equities tips in their favor, or that a preliminary injunction is in the public interest. Because the test is conjunctive, any one of these deficiencies is sufficient to defeat Plaintiffs' Motion.

I. PLAINTIFFS ARE NOT LIKELY TO SUCCEED ON THE MERITS.

Montana courts presume that enacted laws are constitutional. *See Powder River Cnty. v. State*, 2002 MT 259, ¶ 73, 312 Mont. 198, 60 P.3d 357. This is not a toothless presumption: "[t]he constitutionality of a legislative enactment is prima facie presumed," and "[e]very possible presumption must be indulged in favor of the constitutionality of a legislative act." *Id.* at ¶¶ 73–74. The question for a reviewing court is not whether it is possible to condemn, but whether it is possible to uphold the statute. *Satterlee v. Lumberman's Mut. Cas. Co.*, 2009 MT 368, ¶ 10, 353 Mont. 265, 222 P.3d 566. Plaintiffs bear the burden to prove unconstitutionality beyond a reasonable doubt, and if any doubt exists, it must be resolved in favor of the constitutionality of SB 99. *Id.*; *Powell v. State Compensation Ins. Fund*, 2000 MT 321, ¶ 13, 302 Mont. 518, 15 P.3d 877.

A. THE ACT SURVIVES ANY LEVEL OF SCRUTINY.

The Act passes any level of scrutiny, particularly considering the stakes involved. He has "a compelling interest in protecting the physical and psychological well-being of minors." Sable Communications of Cal. v. FCC, 492 U.S. 115, 126 (1989). Perhaps the most salient example of Montana's compelling interest and SB 99's constitutional application here is the protection of Montana's children from experimental medical treatments and procedures that are unsupported by evidence-based medicine and have been shown as likely to cause permanent physical and psychological harm. No matter

⁹⁶ Defendants show that SB 99 satisfies strict scrutiny, although they dispute its application to Plaintiffs' claims because rational basis is the proper level of scrutiny here. *See, e.g., Mont. Cannabis Indus. Ass'n. v. State*, 2012 MT 201, ¶ 24 ("[R]egulation of [a particular] medication or treatment does not implicate a fundamental constitutional right.").

how often Plaintiffs repeat "safe and effective" or "medically necessary," the reality is that reliable evidence does not support either of these descriptors in relation to the treatments at issue.⁹⁷

Reliable evidence, on the other hand, exposes the likelihood of serious consequences that potentially include impaired physical development, bone fragility and density issues, loss of sexual function, infertility, impaired brain development, emotional and intellectual consequences, negative psychological consequences, increased risks of strokes and cancers, and a lifetime of dependence on the drugs, among others. Not to mention the numerous untreated comorbidities that often accompany and precede gender dysphoria. This, alongside the "very low quality" evidence undergirding the protocols adopted by WPATH and the Endocrine Society, but the protocols adopted by WPATH and the Endocrine Society, and the *irreversible* effects of such treatment, further demonstrates that Montana's regulation in this context falls well within its appropriate police

⁹⁷ See Ex. B at ¶ 69 ("This claim is unsupported by any substantial scientific evidence, depreciates widely recognized risks of serious harm to minors so medicalized, and ignores both the many unknowns and the growing international doubts about their use."); Ex. N at ¶¶ 56, 138, 143 148, 151. See also Background, Section VIII, above (describing the notable reversals in policy among the many countries that once widely supported the treatments Plaintiffs advocate).

⁹⁸ Ex. O at ¶ 119–169; Ex. B at ¶ 89–96; Ex. A at ¶ 28–52.

⁹⁹ Ex. At at ¶ 113; Ex. B at ¶¶ 154–160; Ex. O at ¶¶ 44; Ex. K at ¶¶ 29–37; Ex. J at ¶¶ 53, 126, 136–147.

^{100 &}quot;"[T]he majority of drugs prescribed [for gender-affirming care] have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence." (Ex. A at ¶ 80, quoting Expert Report of Johanna Olson-Kennedy ¶ 72 (Jul. 11, 2023). See also Id. ¶¶ 189–204; Ex. O at ¶¶ 64–72; Ex. B at ¶¶ 82, 88–102; Ex. O at ¶ 71 ("The most recent Endocrine Society guidelines were published in 2017. The authors of those guidelines judged their evidence to be of low or very low quality.").

101 Ex. A at ¶ 79, Ex. O at ¶ 125.

¹⁰² See Background, Section V.A., above, Ex. A at ¶ 79; Background VIII, Ex. B at ¶ 82. See also Ex. H at 8 ("Overall, the existing data should be considered a starting point, and health care would benefit from more rigorous epidemiologic study in different locations worldwide."); Ex. I at 3882 ("The primary risks of pubertal suppression in [gender dysphoric]/gender-incongruent adolescents may include adverse effects on bone mineralization," "compromised infertility," "and unknown effects on brain development.") (emphasis added).

power.¹⁰³ This is especially true considering that most children with gender dysphoria ultimately desist with maturity, rendering the provision of puberty blockers entirely unnecessary and unjustifiable in the vast majority of cases.¹⁰⁴

The same conclusion necessarily follows regarding cross-sex hormones and "gender reassignment" surgeries. Reliable evidence underscores the lack of support for the use of cross-sex hormones in this context¹⁰⁵ and instead indicates the substantial likelihood of harm caused by the same.¹⁰⁶ The surgical procedures at issue likewise commonly entail the prospect of horrific complications and appalling

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^{103 &}quot;At all events, the medical and regulatory authorities are not of one mind about using hormone therapy to treat gender dysphoria. Else, the FDA would by now have approved the use of these drugs for these purposes. That has not happened, however, giving us considerable pause about constitutionalizing an answer they have not given or, best we can tell, even finally studied." *Skrmetti*, 73 F.4th at 416; "Under a highly reticulated process that requires considerable long-range testing, the FDA determines when new drugs are safe for public use, including use by minors, and when new drugs are safe for certain purposes but not others. In making these decisions and in occasionally frustrating those who would like to have access to new drugs sooner, the Constitution rarely has a say over the FDA's work." *Id.* at 417 "It is well within a State's police power to ban off-label uses of certain drugs. At the same time, it is difficult to maintain that the medical community is of one mind about the use of hormone therapy for gender dysphoria when the FDA is not prepared to put its credibility and careful testing protocols behind the use." *Id.*

^{104 &}quot;Research has not yet identified any reliable procedure for discerning which children who present with gender dysphoria will persist—as against the vast majority who will desist—absent transition and 'affirmation.'" (Ex. B at ¶ 122; see also id. ¶¶ 112–134; Ex. O at ¶¶ 175–184, Ex. A at ¶¶ 237–240; Ex. K at ¶ 2; Ex. J at ¶¶ 46–56). Jumping to "affirmation" and putting a minor on puberty blockers, in a significant majority of cases, cuts off any chance that child may have had at desisting and sets them up for cross-sex hormones. 104 (Ex. B at ¶ 18; Ex. A at ¶ 115). "[T]he fact that the vast majority of patients taking [puberty blockers] go on to [cross-sex hormones] and therefore that s/he is on a pathway to much greater medical interventions." Bell, [2020] EWHC at ¶ 138 (emphasis added).

¹⁰⁵ "Despite Dr. Olson-Kennedy's belief, there are no studies on the safety of opposite sex hormones in children with 'gender dysphoria.'" (Ex. O at ¶ 150.) *See also*, Background Section V.B.

lood clots) and a "moderate risk" of "macroprolactinoma (pituitary gland tumors), breast cancer, coronary artery disease, cerebrovascular disease, cholelithiasis (gallbladder stones), and hypertriglyceridemia (elevated triglycerides that may lead to coronary heart disease)[;]" and In girls taking testosterone, there is a "very high risk" of "erythrocytosis" (higher than normal count of red blood cells) and a "moderate risk" of "severe liver dysfunction, coronary artery disease, hypertension, and breast or uterine cancer."). See also Ex. O at ¶ 154; Ex. B at ¶¶ 204–05; Ex. A at ¶ 156 (Cross-sex hormone therapy in both boys and girls leads to infertility.)

outcomes, ¹⁰⁷ all without the degree of reliable evidence one should reasonably demand accompany such assumption of risk. ¹⁰⁸

Plaintiffs nonetheless rely heavily on the standards as set forth in WPATH and the Endocrine Society, raising the simple but serious questions of how and why. 109 Whatever the answers to these questions, the evidence reveals the dubious nature of proponents' tactics, including the frequently invoked false choice of a "living son [or] dead daughter [or vice versa,]" as absolutely no reliable studies show the treatments at issue to alleviate any risk of suicide. 111 No wonder so many parents fall prey the emotional blackmail forcing them to "affirm" when presented with the specter of their child committing suicide. It further strains the bounds of credulity to suggest that a child or their parent could truly provide informed consent for the treatments at issue given these circumstances. 112

A prevailing theme emerges from the evidence: "[j]ust because an intervention is popular does not prove it to be safe or beneficial." Indeed, "[t]he neurosurgeon who pioneered the once popular brain surgery pre-frontal lobotomy

¹⁰⁷ Ex. O at ¶¶ 170–174; Ex. A at ¶¶ 157–173.

¹⁰⁸ See WPATH, v.8 at S102, attached as **Exhibit Z** ("Systematic long-term follow-up studies are *urgently needed* to compare individuals with the same intersex conditions who differ in the age at surgery or have had no surgery with regard to gender identity, mental health, and general quality of life.") (emphasis added); *Id.* at S257 ("At least 12 months of gender-affirming hormone therapy, or longer, *if required*," is necessary "to achieve the desired surgical result for gender-affirming procedures.") (emphasis added); Ex. I at 3882 (The Endocrine Society's recommendations mirror WPATH by advising "that clinicians approve genital gender-affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, *unless* hormone therapy is not desired or medically contraindicated.") (emphasis added).

¹⁰⁹ Both of Plaintiffs' experts are members of WPATH (Expert Report of Olson-Kennedy ¶ 14); (Decl. Danielle N. Moyer, ¶ 10 (Jul. 9, 2023), as well as Plaintiff Hodax (Decl. Juanita Hodax, ¶ 7 (07/07/23).) Plaintiff Mistretta provides care "in accordance" with WPATH's Standard of Care (Decl. Katherine Mistretta, ¶ 6 (Jun. 6, 2023).

¹¹⁰ Ex. B at ¶ 142.

[&]quot;No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality in minors. Instead, multiple studies show tragically high rates of suicide *after* medical transition, with that rate beginning to spike several years after medical transition." (Ex. B at ¶ 146; *see also id.* at ¶¶ 138–152; Ex. O at ¶¶ 109–116; Ex. A at ¶¶ 213–232) (emphasis added).

¹¹² See Ex. B at ¶¶ 207, 212, 234; Ex. J at ¶¶ 61–112, 115–135 (True informed consent is not possible because children simply cannot appreciate the significance of their decision); Ex. J at ¶ 135 ("[F]or a parent to provide consent to non-emergent treatments that stand to affect the rest of a minor's life in every arena, and to do so without the minor's full ability to appreciate the above debate and potential long-term ramifications, violates the minor's future right to autonomy.") See also Id. ¶¶ 114, 125, 152, 157–58.

¹¹³ Ex. O at ¶ 106.

for mental disorders [being] awarded the Nobel Prize" provides one salient example. 114 It seems a gross understatement to say Montana has a compelling interest in protecting its children in this context.

Moreover, SB 99 is "necessary to promote" this compelling state interest, Driscoll v. Stapleton, 2020 MT 247, ¶ 18, 401 Mont. 405, and the means it employs are "narrowly framed to accomplish that purpose." Wygant v. Jackson Bd. of Ed., 476 U.S. 267, 280 (1986). Defendants have not only demonstrated the high risk of life-altering negative outcomes associated with the treatments and procedures at issue, but they have also exposed the scientific invalidity of the studies and assertions forming the basis of Plaintiffs' entire lawsuit. (See Background, Sections I-VIII, above.) SB 99 prohibits only those specific treatments and procedures posing such risk (i.e. puberty blockers, cross-sex hormones, and "gender affirming" surgery), while permitting the treatment shown to be most effective and involving the least risk (i.e. mental health treatment/"watchful waiting"). SB 99 does not restrict these treatments for valid purposes such as "treatment for a person with a medically verifiable disorder of sex development[]" or the treatment of any condition "caused or exacerbated by" such treatment for gender dysphoria. (Ex. Y at §§ 4(1)(c)(i)— (ii).) Accordingly, it is clear that SB 99 is narrowly tailored to serve Montana's compelling interest in protecting its children. Plaintiffs also fail to identify any available less-restrictive alternative that would just as effectively advance Montana's compelling interest here. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 582 (2001).

SB 99 therefore survives strict scrutiny and by extension all lesser levels of scrutiny. It should be clear that Montana rightly joined other states and the growing international consensus in concluding that the "gender-affirming" treatment at issue

¹¹⁴ *Id*.

should be restricted¹¹⁵ and by putting an end to this experiment on Montana's children. All of Plaintiffs' claims, as well as their request for preliminary injunctive relief, fail as a matter of law.

B. PLAINTIFFS CANNOT SUSTAIN THEIR FACIAL CHALLENGE TO SB 99.

To satisfy their burden in their facial challenge in this case, Plaintiffs must demonstrate that "no set of circumstances exists under which [SB 99] would be valid." *Mont. Cannabis Indus. Ass'n v. State*, 2016 MT 44, ¶ 14, 382 Mont. 256, 262 (internal citations and quotations omitted). "The crux of a facial challenge is that the statute is unconstitutional in all its applications." *Advocates for Sch. Trust Lands v. State*, 2022 MT 46, ¶ 29, 408 Mont. 39, 505 P.3d 825. If Defendants show any constitutional applications, Plaintiffs' facial challenge fails. *Id.* at ¶ 29.

As established above, SB 99 survives any applicable level of scrutiny considering the compelling interest at issue and the narrow means by which it serves that interest. SB 99, therefore, survives all of Plaintiffs' as-applied challenges even under strict scrutiny (assuming that Plaintiffs' claims should be evaluated under a strict scrutiny standard, which Defendants deny). Plaintiffs' facial challenge must also fail by logical extension.

This is more than enough to defeat Plaintiffs' facial challenge as a matter of law, but even if it weren't, SB 99's other clearly constitutional applications are dispositive. For example, SB 99's prohibition of funding for the relevant treatments and procedures is undoubtedly valid. *See Rust v. Sullivan*, 500 U.S. 173, 193 (1991) (a "legislature's decision not to subsidize the exercise of a fundamental right does not infringe the right.") (citation omitted). SB 99's provisions barring certain state employees from promoting the treatments and procedures at issue are also perfectly constitutional. *See Garcetti v. Ceballos*, 547 U.S. 410 (2006) (finding no First

¹¹⁵ See, Background, Section VIII, above.

Amendment protection for the speech of government employees while on the job in the scope of their duties). Moreover, no Plaintiff challenges Section 4, subsections (3), (4), (5), (7), (8), (9), or (10), of SB 99, nor does any Plaintiff assert harm stemming from SB 99's prohibition of "gender affirming" surgeries on minors. These additional examples should leave no question that Plaintiffs' facial challenge cannot survive.

C. THE ACT DOES NOT VIOLATE EQUAL PROTECTION.

Court identifies the classes involved and determines if they are similarly situated. Second, the Court determines the appropriate level of scrutiny to apply to the challenged statute. Finally, the Court applies the appropriate level of scrutiny to the statute." *Snetsinger v. Mont. Univ. Sys.*, 2004 MT 390, ¶ 15, 325 Mont. 148, 104 P.3d 445. To identify similarly situated classes, the court isolates the factor allegedly subject to impermissible discrimination; if two or more groups are identical in all other aspects, they are similarly situated. *Id.* at ¶ 19. If the single distinguishing factor between the two classes, however, constitutes a "fundamental distinction" relative to statute's purpose, the classes are not similarly situated. *Id.* at ¶ 21. But the equal protection clause doesn't preclude different treatment of different groups "so long as all individuals within the group are treated the same." *Id.* at ¶ 18.

1. The Act Does Not Discriminate Based on Sex.

Plaintiffs' sex discrimination argument fails for the simple reason that SB 99's prohibitions apply equally to male and female children. No minor, regardless of sex, can obtain experimental treatments for the purpose of "gender transition." It applies evenly across the board. The mere fact that sex is implicated does not

¹¹⁶ At least one state court and two federal circuit courts in four separate cases have followed this logic. *See Doe v. Thornbury*, No. 23-5609, 2023 U.S. App. LEXIS 19657, at *1 (6th Cir. July 31, 2023); *L.W. v. Skrmetti*, 73 F.4th 408, 422 (6th Cir. 2023); *Eknes-Tucker v. Governor, of the State of Ala.*, No. 22-11707, 2023 U.S. App. LEXIS 21942, at *7 (11th Cir. Aug. 21, 2023); *Noe v. Parson*, 23-AC-CC04530 (Cole Cty. Cir. Ct. Aug 25, 2023).

automatically mean unlawful discrimination, and Plaintiffs cite no authority establishing transgender identifying individuals as a protected class.¹¹⁷

Indeed, the prevalence of various psychological comorbidities associated with gender dysphoria, coupled with the purely subjective nature of transgender identification, renders the isolation and comparison of classes of substantially similar individuals effectively impossible. Plaintiffs' equal protection claim therefore fails the first prong of the analysis. The fact remains that Montana's regulation of an experimental and dangerous course of treatment for gender dysphoria "is not a sex-based classification and is thus not subject to the heightened scrutiny that applies to such classifications" solely because it mentions sex. *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2245 (2022) (citing *Geduldig v. Aiello*, 417 U.S. 484, 496) (1974)). SB 99 survives all potential levels of scrutiny in any event.

2. The Act Does Not Discriminate Based on Transgender Status.

Gender dysphoric minors who seek experimental treatment to transition suffer from a *psychological* condition and are not similarly situated to minors who need hormonal treatments due a *physical* disorder in sexual development. SB 99 prohibits certain procedures for the former but not for the latter, but this does not offend equal protection principles because these classes are categorically dissimilar. The same

¹¹⁷ Bostock only protects transgender identification in the employment discrimination context under Title VII. Skrmetti, 73 F.4th at 420; see also Students for Fair Admissions, Inc. v. President & Fellows of Harv. Coll., 2023 U.S. LEXIS 2791, 2023 WL 4239254, at *59–60 (U.S. June 29, 2023) (Gorsuch, J., concurring) (noting the different language in Title VI and the Equal Protection Clause and explaining "[t]hat such differently worded provisions should mean the same thing is implausible on its face.").

¹¹⁸ See also Skrmetti, 73 F.4th at 419 ("The regulation of a medical procedure that only one sex can undergo does not trigger heightened constitutional scrutiny unless the regulation is a mere pretex[t] designed to effect an invidious discrimination against the members of one sex or the other. No such pretext has been shown here. If a law restricting a medical procedure that applies only to women does not trigger heightened scrutiny, as in *Dobbs*, a law equally applicable to all minors, no matter their sex at birth, does not require such scrutiny either.") (citations and quotations omitted); *Eknes-Tucker*, No. 22–11707, at *50 (rejecting a similar argument).

reasoning applies when considering a class of individuals seeking treatment for a medically verifiable disorder of sex development or a medical issue "caused or exacerbated by" the banned experimental treatments. (Ex. Y at § 4(1)(c).) Plaintiffs' equal protection argument fails for this reason as well.

3. Transgender Identifying Individuals Do Not Comprise a Suspect Class.

Individuals who identify as transgender are not a suspect class pursuant to the applicable authorities, and Plaintiffs cite no Montana case law holding otherwise. To the contrary, "neither federal jurisprudence nor this Court's case law recognizes gender or sexual orientation as an arbitrary classification or 'suspect class' for equal protection purposes." *Snetsinger*, ¶ 82 (Nelson, J., concurring). "[N]either the Supreme Court nor this court has recognized transgender status as a quasi-suspect class. Until that changes, rational basis review applies to transgender-based classifications." *Skrmetti*, 73 F.4th at 419.

Moreover, Plaintiffs attempt to make transgender individuals a suspect class by utilizing the test from *In re S.L.M.* falls short. (Doc. 50 at 23–24.) Plaintiffs miss that the test, adopted from the U.S. Supreme Court, requires showing that transgenderism is "an immutable characteristic determined solely by accident of birth." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973). "Develop[ing] a sense of their gender identity" at a young age or in adolescence is not an immutable characteristic. (Doc. 60 at ¶ 36.) This is further supported by the desistance rates—if transgender identity is an immutable characteristic, how can individuals later decide they are not transgender? As established above, SB 99 survives any level of scrutiny, no less the applicable rational basis review.

¹¹⁹ Plaintiffs invoke the term "cisgender" as if it were a well-established scientific term dating back a century when, apparently, it was coined by a graduate student in 1994. *See* Dana Defosse, I Coined The Term 'Cisgender' 29 Years Ago. Here's What This Controversial Word Really Means., Huffington Post (Feb. 18, 2023), https://www.huffpost.com/entry/what-cisgender-means-transgender n 63e13ee0e4b01e9288730415.

D. THE ACT DOES NOT VIOLATE THE RIGHT TO PARENTAL AUTONOMY.

Plaintiffs further argue that SB 99's prohibition of the treatment and procedures at issue violates the fundamental right to parental autonomy, but this misses the mark even assuming Mont. Code Ann. § 40-6-701 codifies a parent's general right to subject their child to experimental medical treatments. Although the Legislature has strengthened parents' rights to direct their children's medical care, it also clearly intended to specifically exempt the application of such rights, via SB 99, from the treatments at issue here, which have already been shown to be wildly unjustifiable. *See* Mont. Code Ann. § 1-2-102 (the Legislature's particular intent controls over its general intent). These facts are not mutually exclusive.

The reality is that Plaintiffs cannot and do not dispute that the State has the constitutionally valid authority to enact and enforce laws that limit a parent's rights when the exercise of those rights would subject a child to the likelihood of irreparable and potentially catastrophic physical and psychological injury. This falls squarely within the State's well established compelling interest in preventing such injury, as consistent with numerous other laws allowing the State to exercise this power under comparable circumstances. See, e.g., Mont. Code Ann. § 41-3-101(1)(a) (stating Montana's policy to "provide for the protection of children whose health and welfare are or may be adversely affected and further threatened by the conduct of those responsible for the children's care and protection" in the context of its laws protecting children from abuse and neglect); § 45-5-501(1)(b)(iv) (identifying persons under 16 years old as being among those categorically incapable of providing sexual consent); § 45-5-622 (prohibiting endangering the welfare of children); § 45-5-625 (prohibiting the sexual abuse of children). See also Prince v. Massachusetts, 321 U.S. 158, 167 (1944) ("the state has a wide range of power for limiting parental freedom and authority in things affecting the child's welfare."); Pickup v. Brown, 740 F.3d 1208 (9th Cir. 2014) (rejecting First Amendment, Due Process, Right to Parent, Vagueness, and Overbreadth challenges to law prohibiting therapists from engaging in any practices that "seek to change an individual's sexual orientation ... including efforts to change behaviors or gender expressions.") This claim, therefore, fails as a matter of law, and Plaintiffs cannot demonstrate any likelihood of success on its merits.

E. THE ACT DOES NOT VIOLATE THE RIGHT TO PRIVACY.

The right to privacy, as with other fundamental rights, is bounded by the State's police power, which it properly exercises for the protection of the health and welfare of children. SB 99 does exactly that by protecting Montana's children from the well-documented and significant risks of irreversible harm posed by the experimental treatment at issue here. "Public safety, public health, morality, peace and quiet, law and order—these are some of the more conspicuous examples of the traditional application of the police power to municipal affairs. Yet they merely illustrate the scope of the power and do not delimit it." *Billings Properties v. Yellowstone County*, 144 Mont. 25, 31, 394 P.2d 182 (1964). The "police power" of the State of Montana is contained in Article XV, § 9, of the Constitution, which states that "the police powers of the state shall never be abridged." *Billings Properties*, 144 Mont. at 30.

Fundamental rights are not immune from any state regulation. For example, while the Montana Constitution granted the fundamental right to pursue employment, it also circumscribed that right by subjecting it to the State's police power to protect the public's health and welfare. *Wiser v. State*, 2006 MT 20, ¶ 24, 331 Mont. 28, 129 P.3d 133. As the Montana Supreme Court acknowledged, "[l]iberty is necessarily subordinate to reasonable restraint and regulation by the state in the exercise of its sovereign prerogative-police power." *Id.* (quoting *State v. Safeway Stores*, 106 Mont. 182, 203, 76 P.2d 81, 86 (1938)). "Accordingly, while one does have the fundamental right to pursue employment, one does not have the

fundamental right to practice his or her profession free of state regulation promulgated to protect the public's welfare." *Id.* The State's police power was recognized by the United States Supreme Court as early as 1837 when it stated that "state and local governments possess an inherent power to enact reasonable legislation for the health, safety, welfare or morals of the public." *Id.* (citing *Charles River Bridge v. Warren Bridge Co.*, 11 Peters 496, 9 L. Ed. 773 (1837)); *State v. Skurdal*, 235 Mont. 291, 294, 767 P.2d 304, 306 (1988). "That the states currently possess that police power is unquestioned." *Skurdal*, 235 Mont. at 294, 767 P.2d at 306 (citing *Polk v. Okla. Alcoholic Bev. Control Bd.*, 1966 OK 224, 420 P.2d 520 (Okla. 1966)). Indeed, "Montana recognizes that such police power exists even when the regulations are an infringement of individual rights." *Id.*,767 P.2d at 306 (citing *State v. Rathbone*, 110 Mont. 225, 241, 100 P.2d 86, 92 (1940)).

Plaintiffs cite *Armstrong v. State*, 1999 MT 261, 296 Mont. 361, 989 P.2d 364, in support of their assertion that "[t]here is no State interest, let alone a compelling interest, in denying transgender Montanans the right to make medical decisions without state compulsion." (Doc. 50 at 36.) But "the right of choice in making personal health care decisions and in exercising personal autonomy is not without limits. In certain instances, the state may demonstrate a compelling interest in and obligation to legislate or regulate to preserve the safety, health and welfare of a particular class of patients or the general public from a medically-acknowledged, *bona fide* health risk." *Armstrong*, ¶ 59. So-called "gender-affirming care" poses that exact risk as set forth in detail above.

For the large new population of young people who are first being put on puberty blockers and/or cross-sex hormones at a somewhat later stage of puberty, no studies at all have been done of when, whether, or with what probability either males or females can achieve healthy fertility if they later regret their transition decision and cease taking puberty blockers and/or cross-sex hormones. Much less has this been studied as a function of the stage of development at which they began puberty blockers and/or cross-sex hormones, and how long their gonads were subjected to cross-sex hormones.

(Ex. B at ¶ 205). Even Plaintiffs acknowledge that state regulation is justified when a *bona fide* health risk is present. (*See generally*, Doc. 50 at 35.) "The decision to undergo medicalized transition also represents the decision never to have biological children of one's own." (Ex. B at \P 204). It is hard to imagine a more serious *bona fide* health risk than near certain sterilization.

The Montana Supreme Court concluded in *Armstrong* that the right to health care is a fundamental privacy right, but only to the extent that it protects an individual's right to obtain a particular *lawful* medical procedure. "In *Wiser*, ¶ 15, this Court circumscribed its holding in *Armstrong* when we stated that 'it does not necessarily follow from the existence of the right to privacy that every restriction on medical care impermissibly infringes that right." *Mont. Cannabis Indus. Assn.*, 2012 MT at ¶ 27 (internal citations omitted). The *Wiser* Court additionally determined that an individual does not have a fundamental right to obtain medical care, free of regulation. *Id.* Plaintiffs do not have a fundamental privacy right to puberty blockers and cross-sex hormones—unapproved, experimental drugs with no long-term safety data in this context. The same is certainly true for surgical procedures that entail such high risks of debilitating complications.

The Montana Supreme Court echoed the Ninth Circuit in its consideration of whether the right to privacy encompasses the right to use Laetrile (an unapproved cancer drug) free of government regulation, explaining that the rational basis test applied because "[c]onstitutional rights of *privacy* and personal liberty do not give individuals the right to obtain laetrile free of the lawful exercise of government police power." *Id.* at ¶ 31 (quoting *Carnohan v. United States*, 616 F.2d 1120, 1122 (9th Cir. 1980)). The Montana Supreme Court agreed with *Carnohan* in concluding

that the right to privacy does not encompass the affirmative right of access to medical marijuana. Id. at ¶ 32. A person is not entitled to experimental drugs in this context as a matter of constitutional right, especially when a child is at risk. This is a perfect example of a situation in which the State must intervene and use its police power to protect that child from harm.

SB 99 is therefore subject to and easily passes rational basis scrutiny. Regulations formulated within the State's police power are presumed reasonable absent a clear showing to the contrary. *State v. Deitchler*, 201 Mont. 70, 72, 651 P.2d 1020, 1021–22 (citing *Bettey v. City of Sidney*, 79 Mont. 314, 319, 257 P.1007, 1009 (1927)). Plaintiffs cannot honestly argue the State has no compelling, let alone legitimate, interest in protecting children from unknown and potentially devastating long-term effects of experimental drugs and procedures. Plaintiffs fail to demonstrate a likelihood of success on the merits of this claim.

F. THE ACT DOES NOT VIOLATE THE RIGHT TO SEEK HEALTH.

Plaintiffs cannot establish the existence of any fundamental right to puberty blockers, cross-sex hormones, or "gender affirming" surgery premised on their right to seek health under the Montana Constitution. The Montana Supreme Court has held that, "in pursuing health, an individual does not have a fundamental affirmative right of access to a particular drug. A patient's 'selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health," and the regulation of that medication or treatment does not implicate a fundamental constitutional right." *Mont. Cannabis Indus. Assn.*, ¶ 24 (citing *Rutherford v. U.S.*, 616 F.2d 455, 457 (10th Cir. 1980)). "Because the fundamental right to seek one's own health is not implicated," a strict scrutiny analysis is not appropriate in this context. *Id*.

Accordingly, while the Act passes strict scrutiny due to the State's compelling interest established above, the Court should apply rational basis scrutiny because

Plaintiffs do not have a fundamental right to a particular drug or treatment. The regulations contained in the Act are well within the State's police power to enact and clearly further the State's interest in protecting children's health. The Act neither implicates nor violates the fundamental right to seek health, and Plaintiffs are not likely to succeed on the merits of this claim.

G. THE ACT DOES NOT VIOLATE THE RIGHT TO DIGNITY.

Plaintiffs blithely compare *Walker v. State*—a postconviction relief petition appeal involving prison living conditions of cells covered in blood, feces, and vomit—to the Act and conclude that the Act violates the right to dignity. 2003 MT 134, 316 Mont. 103, 68 P.3d 872. However, far from deplorable prison conditions, the case at bar involves a commonsense use of the state police power to prevent children from being subjected to a course of treatment unsupported by evidence-based medicine. Plaintiffs also do not discuss any of the facts of the *Walker* case, presumably because they lend Plaintiffs no support.

Walker involved an appeal of a denial of a petition for postconviction relief by a defendant convicted of negligent arson and felony forgery. Walker argued that the trial court erred by denying the petition because the Montana State Prison's behavior management plans violated his right to be free from cruel and unusual punishment. The court agreed, holding that the correctional practices permitting prisons, in the name of behavior modification, to disregard the innate dignity of human beings was unconstitutional. Walker, ¶ 82. The Montana Supreme Court analyzed the right to dignity in that case within the context of the state's correctional facilities and the state's responsibility for individuals within residential correctional systems. In contrast, the present case involves a law placing age restrictions on dangerous treatments and procedures for the purpose of protecting children. There is no comparison. Plaintiffs cite no other cases to support their argument that the Act

somehow violates their right to dignity. The right to dignity is not implicated here, and Plaintiffs are not likely to succeed on the merits of this claim.

H. THE ACT DOES NOT VIOLATE THE RIGHT TO FREE SPEECH AND EXPRESSION.

The Act is a proper regulation within the State's power to regulate medicine and does not violate the right to free speech and expression. In *Planned Parenthood* v. Casey, 505 U.S. 833, 884 (1992), the United States Supreme Court denied a First Amendment challenge to the requirement that physicians inform patients of risks to the fetus:

All that is left of petitioners' argument is an asserted First Amendment right of a physician not to provide information about the risks of abortion, and childbirth, in a manner mandated by the State. To be sure, the physician's First Amendment rights not to speak are implicated, but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State. We see no constitutional infirmity in the requirement that the physician provide the information mandated by the State.

Id. (internal citations omitted). Such requirements govern conduct—medical treatment—not speech, and they fall within the state's ability to regulate the practice of medicine. *Accord Doe v. Christie*, 33 F. Supp. 3d 518, 525 (N.J. Dist. 2014) (applying *Casey*'s logic to a First Amendment challenge to New Jersey's ban on gay conversion therapy).

Here, the Act permissibly regulates the practice of medicine. Through the Act's age restrictions on puberty blockers, cross-sex hormones, and certain surgeries—and physician advocacy of the same—the State has properly exercised its police power by protecting children from likely devastating long-term effects of experimental treatments. Plaintiffs are not likely to succeed on the merits of this claim, either. *See also Garcetti v. Ceballos*, 547 U.S. 410 (2006) (there is no First Amendment protection for the speech of government employees while on the job in

the scope of their duties); *Rust*, 500 U.S. at 177, 198 (it is permissible to limit speech concerning abortion in a federally funded program, upholding a Title X regulation imposing a so-called "gag order.")

II. PLAINTIFFS WILL NOT SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION.

Plaintiffs must show more than a possibility of future harm; they are required "to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis in the original) (citing *Los Angeles v. Lyons*, 461 U.S. 95, 103 (1983); *Granny Goose Foods, Inc. v. Teamsters*, 415 U.S. 423, 441 (1974); *O'Shea v. Littleton*, 414 U.S. 488, 502 (1974); 11A Charles Alan Wright, Arthur R. Miller, & Mary Kay Kane, *Federal Practice and Procedure* § 2948.1, 139 (2d ed. 1995) ("*Wright & Miller*") (applicant must demonstrate that in the absence of a preliminary injunction, "the applicant is likely to suffer irreparable harm before a decision on the merits can be rendered"); *Wright & Miller* at 154–155 ("A preliminary injunction will not be issued simply to prevent the possibility of some remote future injury"). "Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1301 (2012) (Roberts, C.J., in chambers).

Plaintiffs argue that if a preliminary injunction is not granted, the minor Plaintiffs "will be stripped" of their care, the parent Plaintiffs "will have to contemplate drastic measures," and the provider Plaintiffs "will no longer be able to provide appropriate care and guidance." (Doc. 50 at 44–45.) Plaintiffs' entire argument is premised on the false assertion that the prohibited treatment and procedures are in fact medically appropriate and necessary rather than experimental and dangerous. As demonstrated in detail above, Plaintiffs cite no evidence in support of their argument that is not subject to significant legitimate criticism that completely undercuts its reliability and scientific validity. For example, "Dr. Olson

Kennedy admits that 'the majority of drugs prescribed [for gender-affirming care] have not been tested in children and safety and efficacy of children's medicines are frequently supported by low quality evidence." Dr. Olson-Kennedy is correct in this regard. Not only is there a glaring absence of safety testing on many such drugs in the context of minors' psychological treatment, but the growing body of evidence demonstrates the <u>likelihood</u> of significant harms associated with the experimental treatments and procedures at issue here. An injunction of SB 99 would therefore have the exact opposite effect—greatly *increasing* the likelihood of harm to the minor Plaintiffs and other Montana children.

None of the provider Plaintiffs nor their experts offer any medical opinion or evidence pertaining to any of the minor Plaintiffs. Plaintiffs nevertheless urge this Court to enjoin SB 99 solely based on the statements of minors expressing concern should they not be able to continue with their experimental treatment. The Court cannot find irreparable harm simply based upon the unhappiness of adolescents. Further, the parent Plaintiffs potentially having to find doctors outside the state or consider removing their children from the treatments altogether likewise fails to demonstrate irreparable harm. This is an inherent risk of embarking on experimental treatments—one day the treatment might no longer be available. The alleged harms by both minor and parent Plaintiffs fail to outweigh the countervailing harms to the minor Plaintiffs should they continue with the experimental treatment, and to the State and its children more broadly. 121

The provider Plaintiffs offer similarly unpersuasive arguments. Plaintiff Mistretta does not provide the Court the number of patients to whom she currently provides the experimental therapy. She states that over the course of her career, she has treated "several hundred transgender patients," but no current numbers. (Dec.

 $^{^{120}}$ Ex. A at \P 80, quoting Expert Report of Olson-Kennedy at \P 72.

¹²¹ Ex. A at ¶¶ 277–283.

Mistretta at \P 8.) The number of patients that would purportedly have to cease experimental treatment due to the Act is unknown. Plaintiffs also provide no figures substantiating any alleged economic harms. Plaintiff Mistretta does attest to providing a wide range of services beyond gender-affirming care, so it appears any reduction in earnings resulting from SB 99 would be mitigated by the other services provided. (*Id.* at \P 10.) The same applies to Plaintiff Hodax. (Hodax Decl. \P 11.)

Plaintiffs cannot show irreparable harm to justify a preliminary injunction here. This stands in stark contrast to the irreparable harm to the State and its children should the injunction issue as established by reliable evidence-based medical literature and Defendants' experts. Moreover, the Court cannot ignore the growing number of individuals who have witnessed or suffered and continue to suffer the significant harms of these experimental treatments. The damage is never isolated—the fallout extends well beyond the child that undergoes the experiment. The following are just a few of the many stories reflecting such irreparable harm, the number of which only continues to grow:

Jamie Reed, a former case manager at a transgender clinic, "personally witnessed children experience shocking injuries from puberty blockers and cross-sex hormones, which often were prescribed to them without complete informed parental consent or an accurate assessment of the child's needs." (Decl. Jamie Reed, ¶ 5 (Aug. 30, 2023), attached as **Exhibit AA**.) She was told to "stop raising [] concerns" and not allowed to track children she had "concerns" about. (*Id*. at ¶ 7.) She observed that "[n]early all children and adolescents who came to the Center presented with severe comorbidities" and "witnessed puberty blockers worsen patients' mental health." (*Id*. at ¶¶ 9–10.) "[P]arents routinely said they felt pressured to consent" and she witnessed doctors obtain consent by stating "[y]ou can either have a living son or dead daughter," or vice versa. (*Id*. at ¶ 14.) The parents and children were also not informed "of all known side effects before placing children

on cross-sex hormones or puberty blockers." (Id. at ¶ 15.) "In hundreds of cases," the doctors "regularly issued puberty blockers or cross-sex hormones despite concerns raised by the child's individual circumstances." (Id. at ¶ 21.) This was not unique to just this clinic, which "is like the vast majority of pediatric gender centers in the United States." (Id. at ¶¶ 23).

Camille Kiefel, who formerly identified as transgender, "suffered a series of traumatic events" as a child and had been "diagnosed with ADHD." (Decl. Camille Kiefel, ¶¶ 4–5 (Aug. 30, 2023), attached as **Exhibit BB**.) After seeing a gender therapist as an adolescent, she "came out as nonbinary[.]" (*Id*. ¶ 10.) Despite her "anxiety and depression," she had a double mastectomy after receiving "two letters recommending surgery from mental health professionals at gender clinics[.]" (*Id*. at ¶¶ 11–13.) She "developed complications," her "suicidal ideation worsened," and was "deeply distraught" over the surgery. (*Id*. at ¶¶ 14–15.) After seeking "holistic treatments," she came to "peace" with being a woman and "detransitioned." (*Id*. at ¶¶ 17–18.) She will "never breast feed" if she has children. (*Id*. at ¶ 19.)

Yaacov Sheinfeld lost his daughter to this experiment. At 15, his daughter began "counseling for depression," yet had never brought up gender dysphoria. (Decl. Yaacov Sheinfeld, ¶ 2 (Aug. 31, 2023), attached as **Exhibit CC**.) At 17, his daughter came out as transgender and by 18 began testosterone without him knowing. (Id. at ¶¶ 3–5.) Despite still being depressed, a social worker recommended a "double mastectomy" and called Mr. Scheinfeld an "an Israeli chauvinist" for objecting. (Id. at ¶¶ 6–7.) His daughter threatened suicide if she did not get surgery, and she underwent surgery at 19. (Id. at ¶ 9.) She was subsequently hospitalized for suicidal thoughts. (Id. at ¶ 10.) Even with a medical professional monitoring, she became more depressed, her pain intensified, and she began taking Fentanyl. (Id. at ¶¶ 10–12.) She was later found dead with Fentanyl and alcohol in her body. (Id. at ¶¶ 13.) Mr. Sheinfeld is only one of many other stories of parents who have suffered

such devastating consequences. (*See, e.g.*, Decl. Jeanne Crowley (Aug. 31, 2023), attached as **Exhibit DD**.)

Aether Dixon suffered from sexual abuse as a child, was bullied in school, and lacked good role models growing up. (Decl. Aether Dixon, ¶¶ 4–5 (Aug. 31, 2023), attached as Exhibit EE.) After binge-watching a Youtuber "come out as trans," she decided to do the same at 12 years old. (Id. at ¶ 5.) Due to family "backlash," she "fully socially transitioned to a male identity at 13." (*Id.* at \P 6.) She began wearing a chest binder and despite "begging," her mother refused to allow her to take puberty blockers. (*Id.* at \P 9–10.) At 16, a gender therapist affirmed her trans identity without a psychological evaluation or testing, and never asked about past abuse. (Id. at ¶ 12.) At 17, she was prescribed testosterone "on the first visit." (Id. at ¶ 13.) Her mother refused to allow Aether to take it, but relented when the therapist asked her "Do you want a dead daughter or living son?" (Id. at ¶ 14.) While on testosterone, Aether "was diagnosed with a cardiovascular disorder," she had painful "vaginal atrophy," and she "felt a lot of rage." (Id. at ¶¶ 18-20.) She began to "detransition" before age 20 and stopped testosterone. (Id. at \P 23–24.) The "cardiovascular effects" continue, as does the painful vaginal atrophy, and other physical issues. (Id. at \P 24.) She began "psychological therapy" and believes that had she had therapy earlier, she "would have been spared the pain and irreversible effects of medically transitioning." (*Id.* at \P ¶ 27–28.)

Should the State be prevented from enforcing SB 99, the irreparable harms to Montana's children and families, like those above, will continue unabated. Any child that suffers from gender dysphoria may be subject to the many irreversible, permanent consequences of puberty blockers, cross-sex hormones, and surgery. These consequences far outweigh any irreparable harm Plaintiffs assert here, and Plaintiffs cannot satisfy this requisite element of their preliminary injunction request.

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST FAVOR THE STATE.

The balance of the equities and the public interest factors merge when the government is a party. Nken v. Holder, 556 U.S. 418, 435 (2009). A preliminary injunction movant must show that "the balance of equities tips in his favor." Shell Offshore, Inc. v. Greenpeace, Inc., 709 F.3d 1281, 1291 (9th Cir. 2013) (citing Winter, 555 U.S. at 20). In assessing whether the plaintiffs have met this burden, courts have a "duty . . . to balance the interests of all parties and weigh the damage to each." See L.A. Memorial Coliseum Commn. v. Natl. Football League, 634 F.2d 1197, 1203 (9th Cir. 1980). "If, however, the impact of an injunction reaches beyond the parties, carrying with it a potential for public consequences, the public interest will be relevant to whether the district court grants the preliminary injunction." Stormans, Inc. v. Selecky, 586 F.3d 1109, 1139 (9th Cir. 2009). When an injunction is sought that will adversely affect a public interest, a court may in the public interest withhold relief until a final determination on the merits, even if the postponement is burdensome to the plaintiff. *Id.* (citing Weinberger v. Romero-Barcelo, 456 U.S. 305, 312-13 (1982)). In fact, courts "should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Id.* (quoting Weinberger, 456 U.S. at 312).

"The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007) (upholding a statutory ban on partial birth abortion). The Court cannot ignore the profound medical uncertainty in this context. Even Plaintiffs' expert and medical interest groups acknowledge as much. The lack of data demonstrating the purported benefits of these experimental treatments is palpable. A growing number of voices from both the United States and Europe have raised the alarm on so-called "gender-affirming care" and urge far greater restraint.

Both the public interest and the balance of equities weigh heavily against Plaintiffs here. If the Court denies a preliminary injunction, the worst that would happen is that those suffering from gender dysphoria would be limited to psychological therapy. Being prevented from undergoing experimental pharmacological and surgical treatment is not a harm that justifies the extraordinary relief Plaintiffs seek here. As the evidence demonstrates, many individuals with gender dysphoria also suffer from comorbidities, including anxiety and depression, which may be effectively addressed by counseling or other mental health treatment. Even WPATH supports this course of treatment. 122

Conversely, should the Court grant an injunction, the resulting harms are farreaching. It would subject even more Montana children to irreversible and permanent psychological, emotional, and physical consequences, all the while ignoring the medical and scientific uncertainty that becomes ever more glaring with the passage of time. Under these circumstances, the balance of equities and the public's interest in enforcing SB 99's prohibitions weigh heavily against Plaintiffs' request for a preliminary injunction.

CONCLUSION

There can be no reasonable dispute that the State of Montana has a compelling interest in protecting its children. The citizens of Montana, through their elected representatives in the Legislature, determine the policy of this state, not Plaintiffs or lobbyist groups like WPATH and the Endocrine Society. And against the backdrop of deeply flawed and disputed science, the Legislature's decision is paramount. By enacting SB 99, Montana has joined the growing number of other states and nations in curbing the dangerously experimental nature of "gender-affirming care" and

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¹²² "Counseling, gender exploration, mental health assessment and, when needed, treatment with [mental health professionals] trained in gender development may all be indicated with or without the implementation of medical-affirming care." (Ex. Z at S60.)

¹²³ See Background Section VIII, above.

denying its proponents the ability to experiment on Montana's children. SB 99 survives even the highest level of constitutional scrutiny under these circumstances and pursuant to the applicable authorities. For the reasons stated in this Brief, this Court should deny Plaintiffs' Motion for Preliminary Injunction.

DATED this 1st day of September, 2023.

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