UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants.*	Case No. 4:22-cv-325-RH-MAF

BRIEF OF DO NO HARM AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS

TABLE OF CONTENTS

Page

TABLE OF AUTORITIES ii

INTRODUCTION AND INTEREST OF AMICUS 1

ARGUMENT 2

I. Florida's Determination that The Treatments Were Experimental Is Reasonable. 2

A. Experimental Gender Medicine Poses Significant Health Risks. 3

B. Experimental Gender Medicine Invites Significant, Currently Unknown Health Risks. 8

C. The Treatments at Issue are Experimental Because There are No Benefits That Outweigh Those Harms and Risks. 12

CONCLUSION 18

TABLE OF AUTHORITIES

Cases **Page**

Rush v. Parham, 625 F.2d 1150 (5th Cir. 1980).....2, 18

Statutes, Rules, and Regulations

Fla. Admin R. 59G-1.035(2).....1

Other Authorities

Abbruzzese, et al., *The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies—and research that has followed*, J. OF SEX & MARITAL THERAPY (Jan. 2, 2023), https://tinyurl.com/2urmzh7r.....10, 16

AGENCY FOR HEALTH CARE ADMINISTRATION, FLORIDA MEDICAID DEFINITIONS POLICY, Section 2.46 (Aug. 2017), https://bit.ly/3KG6VvT.....2

Emily Bazelon, *The Battle over Gender Therapy,* N.Y. TIMES (June 15, 2022), https://tinyurl.com/ydtzkrhb.....1

Michael Biggs, *Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom*, 51 ARCHIVES OF SEXUAL BEHAVIOR (Jan. 18, 2022), https://tinyurl.com/2p8799zf.....15

Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, J. OF SEX & MARITAL THERAPY (Sept. 19, 2022), https://bit.ly/3Kgax6p.....3, 7, 16

Jennifer Block, *Gender dysphoria in young people is rising—and so is professional disagreement*, BMJ (Feb. 23, 2023), https://tinyurl.com/2vfdjzc6.....15

Jennifer Block, *Norway's guidance on paediatric gender treatment is unsafe, says review,* BMJ (Mar. 23, 2023), https://tinyurl.com/54x88u82.....5

Board of Directors: The Tavistock and Portman, NHS ENGLAND (June 23, 2015), https://bit.ly/3UdrNh3.....10

Care of Children and Adolescents with Gender Dysphoria, Summary, SOCIALSTYRELSEN (2022), https://bit.ly/3KIEiOO.....4, 11

Hillary Cass, *Independent review of gender identity services for children and young people: Interim report*, NAT'L HEALTH SERV. (Feb. 2022), https://tinyurl.com/2mcmc452.....10

Diane Chen, et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 TRANSGENDER HEALTH 246 (2020), https://tinyurl.com/m6vzyru7 9

Philip J. Cheng, et al., *Fertility concerns of the transgender patient*, 8 TRANSLATIONAL ANDROLOGY AND UROLOGY 209 (June 2019), https://bit.ly/3nW2K6p 4

Alison Clayton, *Gender-Affirming Treatment of Gender Dysphoria in Youth: A Perfect Storm Environment for the Placebo Effect—The Implications for Research and Clinical Practice*, 52 ARCHIVES OF SEXUAL BEHAVIOR (2022), https://tinyurl.com/2p87mmen 14

Eli Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, 23 INT'L J. OF TRANSGENDER HEALTH S1 (Sept. 6, 2022), https://bit.ly/41c6sHl 5, 6

Nastasja M. de Graaf, et al., *Suicidality in clinic-referred transgender adolescents*, 31 EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 67 (2022), https://tinyurl.com/3d9886cw 15

Annelou de Vries & Peggy T. Cohen-Kettenis, *Clinical Management of Gender Dysphoria in Children and Adolescents: The Dutch Approach*, 59 J. OF HOMOSEXUALITY 301 (Mar. 28, 2012), https://tinyurl.com/2s37hba5 9

Annelou de Vries, et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. OF SEX MED. 2286 (Aug. 8, 2011), https://tinyurl.com/5427t9tb 16

Annelou de Vries, et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS 696 (Oct. 2014), https://tinyurl.com/457z7pzr 16

Suzzanna Diaz & J. Michael Bailey, *Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases*, ARCHIVES OF SEXUAL BEHAVIOR (Mar. 29, 2023), https://tinyurl.com/mrxa7shn 11

Sarah C.J. Jorgensen, et al., *Puberty blockers for gender dysphoric youth: A lack of sound science,* 5 J. OF THE AM. COLLEGE OF CLINICAL PHARMACY 1005 (Sept. 15, 2022), https://bit.ly/3Mkz253 .....3, 4

Riittakerttu Kaltiala-Heino, et al., *Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development*, 9 CHILD & ADOLESCENT PSYCH. & MENTAL HEALTH 1 (Apr. 9, 2015), https://tinyurl.com/y3ve9t37 .....10, 11

David Larson, *Duke Health Emerges as Southern Hub for Youth Gender Transition*, THE CAROLINA J. (Aug. 31, 2022), https://tinyurl.com/44rd939t 4, 13

Stephen B. Levine, et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults,* 48 J. OF SEX & MARITAL THERAPY 706 (Mar. 17, 2022), https://tinyurl.com/2a4xjdtc 15

Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition who Subsequently Detransitioned: A Survey of 100 Detransitioners,* 50 ARCHIVES OF SEXUAL BEHAVIOR 3353 (Oct. 19, 2021), https://tinyurl.com/2p97uks5 12

Lisa Littman, *Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria,* 13 PLoS ONE (Aug. 16, 2018), https://bit.ly/40P6zbY 17

Valentin Maurer, et al., *Penile Flap Inversion Vaginoplasty in Transgender Women: Contemporary Morbidity and Learning-Curve Analysis from a High-Volume Reconstructive Center*, FRONTIERS IN SURGERY (Feb. 23, 2022), https://bit.ly/3KDJ135 6

Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors, PALVELUVALIKOIMA (2020), https://tinyurl.com/24pp8edj 4

Robin Respaut & Chad Terhune, *Putting Numbers on the Rise in Children Seeking Gender Care*, REUTERS (Oct. 6, 2022), https://tinyurl.com/yvd23mhb 8

Leor Sapir, *The Distortions in Jack Turban's Psychology Today Article on 'Gender Affirming Care,'* REALITY'S LAST STAND (Oct. 7, 2022), https://tinyurl.com/2s4dd3yy 14

Leor Sapir, *The School-to-Clinic Pipeline*, CITY J. (2022), https://tinyurl.com/y2hakf4z 7

Leor Sapir, *Trust the Experts' Is Not Enough: U.S. Medical Groups Get the Science Wrong on Pediatric 'Gender Affirming' Care*, MANHATTAN INST. (2022), https://tinyurl.com/4eyp7mna 13, 17

Leor Sapir, *Yes, Europe is Restricting "Gender-Affirming Care,"* CITY J. (Feb. 13, 2023), https://tinyurl.com/2duhpsmm.....16

Chad Terhune, et al., *As More Transgender Children Seek Medical Care, Families Confront Many Unknowns*, REUTERS (Oct. 6, 2022), https://tinyurl.com/3kk39auk.....3, 8

The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak, THE ECONOMIST (Apr. 5, 2023), https://econ.st/3GnvET8 1

Jack Turban, *The Evidence for Trans Youth Gender-Affirming Medical Care*, PSYCH. TODAY (Jan. 24, 2022), https://tinyurl.com/mry7kbcu 14

Wouter B. van der Sluis, et al., *Clinical Characteristics and Management of Neovaginal Fistulas After Vaginoplasty in Transgender Women*, 127 OBSTETRICS AND GYNECOLOGY 1118 (June 2016), https://tinyurl.com/mw3z63m5.....6

Jing J. Zhao, et al., *Surgical Site Infections in Genital Reconstruction Surgery for Gender Reassignment, Detroit: 1984-2008*, 15 SURGICAL INFECTIONS 99 (2014), https://bit.ly/3Uklubu 6

INTRODUCTION AND INTEREST OF AMICUS

No reliable scientific evidence justifies the use of puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria in minors. To the contrary, such treatments carry harmful lifelong consequences, including infertility, total loss of adult sexual function, and increased risk of several other serious medical conditions. Despite activists' efforts to stifle dissent, even otherwise sympathetic audiences have begun to raise the alarm over the use of these treatments. In recent exposés, writers for *The Economist* and *The New York Times* have warned that the evidence supporting such treatments is "worryingly weak" and that "it is impossible to justify the current recommendations about gender-affirming care based on the existing data." *The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak*, THE ECONOMIST (Apr. 5, 2023), https://econ.st/3GnvET8; *see* Emily Bazelon, *The Battle over Gender Therapy*, N.Y. TIMES (June 15, 2022), https://tinyurl.com/ydtzkrhb.

While public discourse over the appropriate treatments for gender dysphoria in minors has become tragically politicized, a fair-minded reading of the existing medical literature leads to the inescapable conclusion that the Florida Agency for Health Care Administration (the "Agency") was correct to conclude that the treatments for minors at issue in this case are "experimental or investigational." Fla. Admin R. 59G-1.035(2).

Amicus Do No Harm is a diverse group of physicians, healthcare professionals, medical students, patients, and policymakers whose goal is to protect healthcare from a radical, divisive, and discriminatory ideology. Basing its name in the ethical underpinnings of the Hippocratic Oath, Amicus believes healthcare should be free from experimental procedures that place political agendas ahead of patient well-being. Amicus submits this brief in support of Defendants' motion for summary judgment, and respectfully submits that the Agency's determination was reasonable in light of the irreversible harms inherent in these treatments for minors.

ARGUMENT

I. Florida's Determination that The Treatments Were Experimental Is Reasonable.

The evidence overwhelmingly shows the Agency's "determination that" these treatments for minors are "experimental is reasonable." *See Rush v. Parham*, 625 F.2d 1150, 1157 (5th Cir. 1980). Under Florida's Medicaid rules, treatment is "experimental" when "[r]eliable evidence shows the consensus among experts regarding the drug, . . . medical treatment, or procedure is that further studies or clinical trials are necessary to determine its . . . safety, or efficacy as compared with the standard means of treatment or diagnosis." AGENCY FOR HEALTH CARE ADMINISTRATION, FLORIDA MEDICAID DEFINITIONS POLICY, Section 2.46 (Aug. 2017), https://bit.ly/3KG6VvT. Thus, a treatment is experimental where there is no

consensus of its efficacy and safety based on reliable or authoritative evidence. And here, the medical evidence strongly supports the Agency's determination that certain gender-dysphoria treatments are experimental and are properly excluded from Medicaid coverage.

A. Experimental Gender Medicine Poses Significant Health Risks

All of the treatments at issue—puberty blockers, cross-sex hormones, and gender-transition surgeries—pose significant health risks to patients. Take first puberty blockers, technically labeled GnRH agonists. For minors suffering from gender dysphoria, pharmaceutical interventions commonly begin with the prescription of these drugs to halt the normal course puberty. *See* Chad Terhune, et al., *As More Transgender Children Seek Medical Care, Families Confront Many Unknowns*, REUTERS (Oct. 6, 2022), https://tinyurl.com/3kk39auk. Though advocates suggest puberty blockers merely "pause" puberty and are "fully reversible," the use of puberty blockers has been linked to serious side-effects, including decreased bone density, cognitive impairment, polycystic ovarian syndrome, metabolic syndrome, and greater risk of infertility. *See* Michael Biggs, *The Dutch Protocol for Juvenile Transsexuals: Origins and Evidence*, J. OF SEX & MARITAL THERAPY 1, 11-12 (Sept. 19, 2022), https://bit.ly/3Kgax6p; Sarah C.J. Jorgensen, et al., *Puberty blockers for gender dysphoric youth: A lack of sound science,* 5 J. OF THE AM. COLLEGE OF CLINICAL PHARM. 1005 (Sept. 15, 2022),

https://bit.ly/3Mkz253; Philip J. Cheng, et al., *Fertility concerns of the transgender patient*, 8 TRANSLATIONAL ANDROLOGY AND UROLOGY 209 (June 2019), https://bit.ly/3nW2K6p. Moreover, it is well documented that the prescription of these drugs could permanently diminish adult sexual function in patients. Even the president of the World Professional Association for Transgender Health (WPATH), has acknowledged that individuals who are prescribed puberty blockers by age 11 would likely never have the capacity to attain an orgasm in their lifetime. *See* David Larson, *Duke Health Emerges as Southern Hub for Youth Gender Transition*, THE CAROLINA J. (Aug. 31, 2022), https://tinyurl.com/44rd939t.

Florida is not alone in concluding that puberty blockers are an "experimental" treatment. Just last year, Sweden's public-health body barred puberty blockers for adolescents in all but "exceptional cases" because "the efficacy and safety, benefits and risks of treatments are not proven." *Care of Children and Adolescents with Gender Dysphoria, Summary*, SOCIALSTYRELSEN, 3 (2022), https://bit.ly/3KIEiOO. Likewise, health authorities in Finland have implemented almost identical restrictions, labeling gender transitions for youth as "an experimental practice." *Recommendation of the Council for Choices in Health Care in Finland (PALKO/COHERE Finland): Medical Treatment Methods for Dysphoria Related to Gender Variance in Minors*, PALVELUVALIKOIMA, 8 (2020), https://tinyurl.com/24pp8edj. The same is true for the United Kingdom. And

Norway looks poised to join these countries given the recent statement by one of its preeminent health officials that puberty blockers and cross-sex hormones to treat gender dysphoria are "treatments under trial." *See* Jennifer Block, *Norway's guidance on paediatric gender treatment is unsafe, says review,* BMJ, 1 (Mar. 23, 2023), https://tinyurl.com/54x88u82. Given the serious, and often long-term, side effects associated with puberty blockers, their use in the treatment of gender dysphoria is patently experimental.

After blocking a child's normal puberty, doctors may prescribe cross-sex hormones to artificially induce some of the effects of the puberty of the opposite sex. For males, the use of cross-sex hormones is associated with numerous health risks, such as thromboembolic disease, including blood clots; cholelithiasis, including gallstones; coronary artery disease, including heart attacks; macroprolactinoma, which is a tumor of the pituitary gland; cerebrovascular disease, including strokes; hypertriglyceridemia, which is an elevated level of triglycerides in the blood; breast cancer; and irreversible infertility. Eli Coleman, et al., *Standards of Care for the Health of Transgender and Gender Diverse People*, 23 INT'L J. OF TRANSGENDER HEALTH S1, S43 (Sept. 6, 2022), https://bit.ly/41c6sHl ("WPATH Standards of Care 8"). For females, the use of cross-sex hormones is associated with risks of erythrocytosis, which is an increase in red blood cells; severe liver dysfunction; coronary artery disease, including heart attacks; depression; hypertension; infertility;

and increased risk of breast, cervical, and uterine cancers. *Id.* S254. The serious and potentially life-threatening side effects associated with cross-sex hormones clearly shows the use of these drugs to treat gender dysphoria is experimental.

The treatment of gender dysphoria may culminate in sex reassignment surgeries, which replicate primary and/or secondary sex characteristics of the opposite sex. Such procedures may involve bilateral mastectomy to remove the breasts, penectomy to remove the penis, vaginoplasty to create a vagina, or scrotoplasty to create a penis and scrotum, as well as non-genital procedures like facial feminization or chest masculinization. *See* Jing J. Zhao, et al., *Surgical Site Infections in Genital Reconstruction Surgery for Gender Reassignment, Detroit: 1984-2008*, 15 SURGICAL INFECTIONS 99 (2014), https://bit.ly/3Uklubu. The known risks of these surgeries include fistulas, chronic infection, atrophy, need for colostomy, and complete loss of sexual sensation. *See* Wouter B. van der Sluis, et al., *Clinical Characteristics and Management of Neovaginal Fistulas After Vaginoplasty in Transgender Women*, 127 OBSTETRICS AND GYNECOLOGY 1118 (June 2016), https://tinyurl.com/mw3z63m5; Valentin Maurer, et al., *Penile Flap Inversion Vaginoplasty in Transgender Women: Contemporary Morbidity and Learning-Curve Analysis from a High-Volume Reconstructive Center*, FRONTIERS IN SURGERY (Feb. 23, 2022), https://bit.ly/3KDJ135; Zhao, *supra*. In addition, when minors are prescribed puberty blockers, the drugs inhibit the growth of the minor's

genital tissue, which reduces the tissue needed to construct artificial genitalia and thus requires surgeons to borrow tissue from other areas of the body, such as the colon. The need for a second surgical site increases the risk of infection, which has even led to death after a sex-reassignment surgery. *See* Biggs, *supra,* at 8. Sex-reassignment surgeries are manifestly experimental given the harmful, and potentially life-threatening, side effects associated with them.

Although the transitioning process generally entails three sequential steps that each present their own risks—puberty blockers, cross-sex hormones, and surgery—the harms for all three steps must be considered together because the use of puberty blockers may *increase the likelihood* of seeking cross-sex hormones and surgery. In medicine, interventions sometimes create or worsen the problems they are supposed to alleviate, a process known as iatrogenesis. *See* Leor Sapir, *The School-to-Clinic Pipeline*, CITY J. (2022), https://tinyurl.com/y2hakf4z. Here, delaying a child's natural puberty while his or her peers continue to develop the characteristics that come from puberty may actually *worsen* a minor's gender dysphoria. *Id.* The prescription of puberty blockers could thus increase the likelihood of *additional* medical intervention with cross-sex hormones and surgery. Indeed, research shows that the vast majority of children (96%-98%) who start puberty blockers continue on to use cross-sex hormones. Biggs, *supra*, at 5. This high conversion rate underscores the risks of promoting these treatments. Until the attendant risks can be properly

studied, understood, and mitigated, these treatments and procedures are undoubtedly experimental.

B. Experimental Gender Medicine Invites Significant, Currently Unknown Health Risks

Beyond the *known* harms and risks of the treatments at issue in this case, the *unknown* risks equally warrant concluding that these treatments for minors are experimental. These unknown risks include (1) harms that may be associated with these treatments but have not been sufficiently or reliably studied; and (2) harms that are wholly unknown given the relatively novel applications of these treatments for gender dysphoria. These unknown risks amply justify Florida's reasonable determination that these treatments are experimental.

Recent data reveal a sharp uptick in the number of children and adolescents who are being treated for gender dysphoria. *See generally* Robin Respaut & Chad Terhune, *Putting Numbers on the Rise in Children Seeking Gender Care*, REUTERS (Oct. 6, 2022), https://tinyurl.com/yvd23mhb. As this number increases, so too will the number of patients who suffer adverse medical outcomes due to unknown long-term risks of these treatments.

For example, the use of puberty blockers for gender dysphoria has never been approved by the U.S. Food and Drug Administration, and no clinical trial has ever established the safety of using them for this purpose. *See* Terhune, *supra.* To obscure this fact, activists argue the off-label use of puberty blockers is safe because they are

also used to treat youth suffering from precocious puberty, meaning puberty that begins too early. *See* Annelou de Vries & Peggy T. Cohen-Kettenis, *Clinical Management of Gender Dysphoria in Children and Adolescents: The Dutch Approach*, 59 J. OF HOMOSEXUALITY 301 (Mar. 28, 2012), https://tinyurl.com/2s37hba5. But unlike the treatment of gender dysphoria in young people, the treatment of precocious puberty involves *the resumption of normal puberty* at an appropriate age—making it an entirely separate condition and course of treatment from using puberty blockers for gender dysphoria. As this Court noted in its Order on Plaintiffs' preliminary injunction, "a treatment that is well established in one circumstance may be experimental in another." Doc. 64 at 5 (Oct. 24, 2022). The use of puberty blockers here provides a perfect example.

The unknowns regarding puberty blockers are startling. Specifically, it remains unknown the extent to which puberty blockers impact brain development and cognition. *See* Diane Chen, et al., *Consensus Parameter: Research Methodologies to Evaluate Neurodevelopmental Effects of Pubertal Suppression in Transgender Youth*, 5 TRANSGENDER HEALTH 246 (2020), https://tinyurl.com/m6vzyru7. In one study, authors were concerned that puberty blockers "may prevent key aspects of development during a sensitive period of brain organization," and did not know whether a patient would "catch-up" to otherwise normal brain functioning. *Id.* at 249. Even more worrying, some have raised

concerns that the use of puberty blockers may *contribute* to suicidal ideation and behavior. *See Board of Directors: The Tavistock and Portman*, NHS ENGLAND 53 (June 23, 2015), https://bit.ly/3UdrNh3 (noting a statistically significant increase in self-harm after a year of puberty suppression). No treatment could be deemed safe and effective when it remains unknown whether its application could permanently stunt patients' cognitive development or may lead them to suicide.

There are also unanswered questions concerning the correlation between gender dysphoria and other comorbid psychiatric diagnoses. Many of the children and adolescents seeking experimental gender medicine today concurrently suffer from depression, anxiety, autism spectrum disorder, or attention deficit hyperactivity disorder. Abbruzzese, et al., *The Myth of "Reliable Research" in Pediatric Gender Medicine: A critical evaluation of the Dutch Studies—and research that has followed*, J. OF SEX & MARITAL THERAPY 1, 12 (Jan. 2, 2023), https://tinyurl.com/2urmzh7r. Moreover, evidence suggests these comorbidities both afflict a *substantial* portion of minors treated for gender dysphoria and often *precede* the onset of gender dysphoria. Of minors referred to the United Kingdom's gender service, up to one-third were either autistic or otherwise neurodivergent. Hillary Cass, *Independent review of gender identity services for children and young people: Interim report*, NAT'L HEALTH SERV. (Feb. 2022), 32, https://tinyurl.com/2mcmc452. In a review of patient medical records, Finnish

experts found that comorbid mental health diagnoses preceded gender dysphoria in 75% of reviewed cases. Riittakerttu Kaltiala-Heino, et al., *Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development*, 9 CHILD & ADOLESCENT PSYCH. & MENTAL HEALTH 1, 5 (Apr. 9, 2015), https://tinyurl.com/y3ve9t37. And a recent survey of parents found that mental health issues preceded a diagnosis of gender dysphoria by an average of almost 4 years. Suzzanna Diaz & J. Michael Bailey, *Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases*, ARCHIVES OF SEXUAL BEHAVIOR, 5 (Mar. 29, 2023), https://tinyurl.com/mrxa7shn. Without properly understanding the relationship between gender dysphoria and other comorbid psychiatric diagnoses, minor patients are put at risk of receiving experimental and risky treatments in place of those that may effectively and safely mitigate their underlying mental-health problems.

That risk is especially acute given the lack of adequate explanation for the precipitous rise in minors presenting with gender dysphoria and the disproportionate number of young females now suffering from gender dysphoria. That recent change in the profile of the typical patient led experts in Sweden to greatly curtail the use of puberty blockers and hormonal treatments in their country. *See* SOCIALSTYRELSEN, *supra* 4.

Lastly, a growing body of evidence points to individuals who have come to regret irreversible physical changes made to their bodies to treat gender dysphoria. These individuals are commonly referred to as "detransitioners." *See* Lisa Littman, *Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition who Subsequently Detransitioned: A Survey of 100 Detransitioners,* 50 ARCHIVES OF SEXUAL BEHAVIOR 3353 (Oct. 19, 2021), https://tinyurl.com/2p97uks5. Currently, there are zero reliable, long-term studies on rates of regret and detransition among the new cohort of children and adolescents who were treated under the "gender affirming" model. Therefore, the extent to which these children and adolescents may come to regret their gender transition, or will otherwise face adverse effects, is completely unknown.

C. The Treatments at Issue are Experimental Because There are No Benefits That Outweigh Those Harms and Risks

Any potential benefits of experimental gender medicine, to the extent they exist, are vastly outweighed by the known harms and risks associated with these treatments for minors. Health authorities in Sweden, Finland, and the United Kingdom have conducted systematic reviews of evidence and, having found that the evidence of benefits is too uncertain to outweigh the risks, have decided to place severe restrictions on medical transition procedures. Florida has now reached the same reasonable conclusion. At least three facts support that determination.

First, there is no reliable evidence to support the conclusion that these treatments result in long-term improvement of minors with gender dysphoria. Currently, there are simply no studies long enough to provide such a finding. This lack of evidence is unsurprising given the fact that more than 90% of the research on gender dysphoria has occurred in the last ten years. *See* Larson, *supra* 4.

Even though some studies purport to show *short*-term benefits, the effects are so minimal as to be immaterial, and the studies do not control for the confounding effects of psychotherapy or the placebo effect. For example, researchers consistently fail to control for the effects of psychotherapy—non-pharmaceutical and non-surgical interventions designed to guide a child through his or her gender-related distress. Due to this methodological shortcoming, to the extent a study reports benefits of experimental gender medicine, those benefits could be attributed to counseling instead of drugs. Leor Sapir, *Trust the Experts' Is Not Enough: U.S. Medical Groups Get the Science Wrong on Pediatric 'Gender Affirming' Care*, MANHATTAN INST., 5 (2022), https://tinyurl.com/4eyp7mna. Moreover, there is a strong possibility that any short-term improvement reported in conjunction with experimental gender medicine is the result of a placebo effect. Specifically, the mere fact that an adolescent receives these treatments may lead to a self-reported improvement in his or her psychological outlook—even if the physical effects caused by the treatments are not themselves the cause of that improvement.

Conversely, unsupported suggestions of increased risk of depression, anxiety, and suicide if these treatments are denied may create a "nocebo" effect—whereby a patient develops negative side effects that he or she *believes* will occur absent treatment. *See* Alison Clayton, *Gender-Affirming Treatment of Gender Dysphoria in Youth: A Perfect Storm Environment for the Placebo Effect—The Implications for Research and Clinical Practice*, 52 ARCHIVES OF SEXUAL BEHAVIOR (2022), https://tinyurl.com/2p87mmen.

Second, advocates of these treatments push the sensational, and unfounded, claim that minors who cannot access the treatments are at imminent risk of suicide. For example, a popular article by one of the most vocal proponents of experimental gender medicine cited six studies related to suicidality and the treatment of gender dysphoria. *See* Jack Turban, *The Evidence for Trans Youth Gender-Affirming Medical Care*, PSYCH. TODAY (Jan. 24, 2022), https://tinyurl.com/mry7kbcu. But these studies are riddled with methodological weaknesses. Indeed, the lead author of one of the studies stated that the article overstated her research and that she "cannot claim that [her] research would have shown that gender affirming hormonal treatment reduces suicidality." *See* Leor Sapir, *The Distortions in Jack Turban's Psychology Today Article on 'Gender Affirming Care,'* REALITY'S LAST STAND (Oct. 7, 2022), https://tinyurl.com/2s4dd3yy. Because gender-dysphoric children also suffer from high rates of other mental health conditions that are associated with

suicidality, a simple comparison between gender-dysphoric and non-dysphoric children cannot show whether a child's gender dysphoria, as opposed to other mental health conditions, increases the risk of suicidality. Michael Biggs, *Suicide by Clinic-Referred Transgender Adolescents in the United Kingdom*, 51 ARCHIVES OF SEXUAL BEHAVIOR 685, 687–88 (Jan. 18, 2022), https://bit.ly/3Kk3ARL. In fact, when a recent study controlled for mental health comorbidities, the differences in suicidality rates between gender-dysphoric and non-dysphoric children were either miniscule or non-existent. *See* Nastasja M. de Graaf, et al., *Suicidality in clinic-referred transgender adolescents*, 31 EUROPEAN CHILD & ADOLESCENT PSYCHIATRY 67 (2022), https://tinyurl.com/3d9886cw.

Even in the context of heightened suicide risk, however, assertions regarding the alleged benefits of experimental gender medicine generally rely on low-quality evidence. Stephen B. Levine, et al., *Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults,* 48 J. OF SEX & MARITAL THERAPY 706, 712–13 (Mar. 17, 2022), https://tinyurl.com/2a4xjdtc. In a recent interview, an expert in the field identified "serious problems" with the current Endocrine Society treatment guidelines, which he criticized for failing to "look at the effect of the interventions on gender dysphoria itself." *See* Jennifer Block, *Gender dysphoria in young people is rising—and so is professional disagreement*, BMJ (Feb. 23, 2023), https://tinyurl.com/2vfdjzc6. As discussed above, experts in

Sweden, Finland, and the UK, have all found that the evidence supporting the benefits of these treatments is poor. *See* Leor Sapir, *Yes, Europe is Restricting "Gender-Affirming Care,"* CITY J. (Feb. 13, 2023), https://tinyurl.com/2duhpsmm.

Lastly, proponents try to use the so-called Dutch Protocol as a cudgel against any opposing opinion, arguing that Dutch clinicians have established the safety and efficacy of these treatments for minors. This protocol is the foundation for the "gender affirming model" for treating gender dysphoria and was one of the earliest experiments in using puberty blockers and cross-sex hormones as treatments for pediatric gender-related confusion. *See* Annelou de Vries, et al., *Puberty Suppression in Adolescents with Gender Identity Disorder: A Prospective Follow-Up Study*, 8 J. OF SEX MED. 2286 (Aug. 8, 2011), https://tinyurl.com/5427t9tb; Annelou de Vries, et al., *Young Adult Psychological Outcome After Puberty Suppression and Gender Reassignment*, 134 PEDIATRICS 696 (Oct. 2014), https://tinyurl.com/457z7pzr. The protocol, however, has been subjected to intense methodological criticism due to the researchers' selection of only the most successful cases, inappropriate use of a scoring mechanism that guaranteed the results would show an improvement in patient gender dysphoria, conflation of the effects of drugs with the effects of counseling, and omission of a patient who died during surgery from the already small sample (n=55). *See* Abbruzzese, *supra* at 5-15 (2023); Biggs, *The Dutch Protocol for Juvenile Transsexuals, supra*, at 2, 8-11.

Beyond these serious flaws, the Dutch research is weaker yet for its inapplicability to the present context. To be eligible for inclusion in the Dutch research, participants were required to meet five requirements: (1) they suffered from early-onset gender dysphoria, (2) the condition persisted or intensified into adolescence, (3) they were psychologically and emotionally stable with no comorbid psychiatric diagnoses, (4) they had parental approval, and (5) informed consent was obtained as a continuous process, often over the course of months. Sapir, *Trust the Experts*, *supra* at 5-6. Because many of the children presently receiving transition drugs and surgeries do not meet those criteria, the findings of the Dutch Protocol cannot be generalized to patients in the United States. Specifically, the majority of minors now seeking treatment are adolescent girls with no prior history of dysphoria and with high rates of mental health comorbidities. *Id.* This new presentation—also referred to as rapid onset gender dysphoria, or ROGD—has led researchers to develop a theory of "social contagion," which posits that peer or online influence could be a significant cause of the recent uptick in gender dysphoria. *See* Lisa Littman, *Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria,* 13 PLOS ONE 1, 4 (Aug. 16, 2018), https://bit.ly/40P6zbY. Under the affirmative model, gender *identity*, not gender dysphoria, appears to drive treatment decisions. So long as this remains the case, these treatments are properly deemed experimental.

In sum, any suggestion that the benefits of these treatments for gender dysphoria in minors outweigh the harms is belied by the attendant risks and lack of reliable and authoritative evidence supporting the alleged benefits. Thus, Florida's determination that the treatments for minors at issue here are "experimental" is eminently "reasonable." *See Rush*, 625 F.2d at 1157.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion for summary judgment.

Date: April 7, 2023

Respectfully submitted,

/s/ David H. Thompson
David H. Thompson
Brian W. Barnes*
John D. Ramer*
Cooper & Kirk PLLC
1523 New Hampshire Ave, N.W.
Washington, D.C. 20036
(202) 220-9600
dthompson@cooperkirk.com

Counsel for Amicus Curiae Do No Harm
**Pro Hac Vice* application pending

LOCAL RULE 7.1(F) CERTIFICATION

As required by Local Rule 7.1(F), the undersigned counsel certifies that this brief contains 3,794 words.

/s/ David H. Thompson
David H. Thompson

Counsel for Amicus Curiae Do No Harm