IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., Plaintiffs, v. JASON WEIDA, et al., Defendants.	Case No. 4:22-cv-00325-RH-MAF

BRIEF OF AMICI CURIAE HUSSEIN ABDUL-LATIF, SUSAN D. BOULWARE, REBECCA KAMODY, LAURA KUPER, MEREDITHE MCNAMARA, CHRISTY OLEZESKI, NATHALIE SZILAGYI, AND ANNE ALSTOTT IN SUPPORT OF PLAINTIFFS' CHALLENGE TO RULE 59G-1.050(7) OF THE FLORIDA ADMINISTRATIVE CODE AND IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Civil Procedure 7.1, the undersigned counsel for *amici curiae* Hussein Abdul-Latif, Susan D. Boulware, Rebecca Kamody, Laura Kuper, Meredithe McNamara, Christy Olezeski, Nathalie Szilagyi, and Anne Alstott represent that none of the above-referenced individuals is a corporate entity or has issued stock.

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STATEMENT OF INTEREST

The amici submitting this brief are a group of seven scientists and a law professor (collectively, "Amici"). The seven scientists on whose behalf this brief is submitted hold academic appointments at the University of Alabama at Birmingham, the University of Texas Southwestern, and Yale University. The law professor holds a tenured position at the Yale Law School. Amici include three Ph.D. child and adolescent psychologists and four M.D. physicians with specialties in pediatric endocrinology, child and adolescent psychiatry, and adolescent medicine.

All seven scientists are also clinicians who treat transgender youth daily. Collectively, Amici have over 57 years of clinical practice and have treated more than 2,100 transgender youth.

All Amici share an interest in the integrity of medicine and science, and all are concerned that the newly adopted Rule 59G-1.050(7) of the Florida Administrative Code sets a harmful, national precedent for denying standard medical care to transgender people. As scientists and clinicians, Amici have a strong interest in ensuring that this Court has sound scientific information at hand regarding the medical treatment of gender dysphoria. We submit this brief to support the Plaintiffs' challenge to the adoption of the Rule 59G-1.050(7), to support the Plaintiffs' request for declaratory and injunctive relief, and to oppose Defendants' motion for summary judgment.

We are deeply concerned that Defendants have mischaracterized the scientific evidence on medical treatment for gender dysphoria. The Defendants claim that such care is "experimental," but it is, in fact, well-grounded in solid scientific evidence that guides our clinical practice and that of other responsible medical providers.

Consistent with our expertise, Amici focus on medical care for gender dysphoria for adolescents. For reasons of brevity, we do not address the science of surgery used to treat gender dysphoria, but the safety and effectiveness of surgical treatments is amply confirmed in other materials available to the Court, including declarations submitted by Plaintiffs' experts.

Amici received no funding for this work and have no conflicts of interest to declare. This brief reflects our views and not necessarily those of the University of Alabama, the University of Texas, or Yale University.

SUMMARY OF ARGUMENT

Adopted in August 2022, new Section 59G-1.050(7) of the Florida Administrative Code (the "2022 Exclusion") denies Medicaid coverage for standard medical care for individuals with gender dysphoria. Specifically, the 2022 Exclusion denies Florida Medicaid coverage for medical services for the treatment of gender dysphoria, including puberty blockers, hormones and hormone agonists, "sex reassignment surgeries," and "any other procedures that alter primary or secondary

sexual characteristics" (collectively, "medical care for gender dysphoria"). Significantly, the 2022 Exclusion does not bar Medicaid coverage of the same medical treatments when offered to people with conditions other than gender dysphoria.

Amici are a group of seven scientists and a law professor who are deeply dismayed by the 2022 Exclusion, which denies long-established, effective, and evidence-based medical care to thousands of Florida Medicaid patients. We believe that the 2022 Exclusion is based on a misrepresentation of the scientific evidence for medical treatment for gender dysphoria.

Amici urge this Court to grant the declaratory and injunctive relief sought by Plaintiffs in order to avoid the irreparable harm that the 2022 Exclusion will impose on thousands of transgender Floridians. We also urge this Court to deny the Defendants' motion for summary judgment, which is based on Defendants' inaccurate claim that "there isn't enough [evidence] to create a genuine issue of material fact concerning the controlling question in this case: the reasonableness of the State's determination. Defendants' Motion for Summary Judgment at 4. We strongly contest the Defendants' claim that Plaintiffs' experts are merely "present[ing] their preferred approach to treating gender dysphoria, which includes the use of experimental treatments." In fact, medical care for gender dysphoria is long-established, provided safely to thousands of patients across the United States,

including in Florida, and is grounded in a solid body of peer-reviewed scientific evidence.

Among the key issues confronting this court are whether it was reasonable for the Florida AHCA to conclude that medical care for gender dysphoria is "experimental" and does not meet "generally accepted professional medical standards. Indeed, this Court directed the parties to pursue the standard enunciated in *Rush v. Parham*, 625 F. 2d 1150 (5th Cir. 1980), which remanded a Medicaid decision to a lower court, directing the fact-finder to consult "current medical opinion" to determine the reasonableness of the State of Georgia's determination that certain treatments were "experimental." Order Denying Preliminary Injunction (ECF No. 64), at 4; *Rush v. Parham*, 625 F. 2d at 1157.

In this brief, Amici demonstrate that the 2022 Exclusion is thoroughly unreasonable, because it rests on a misrepresentation of the scientific evidence on medical treatment for gender dysphoria . The exclusion was based on a fatally flawed document issued by Defendant Florida Agency for Health Care Administration ("Florida AHCA") on June 2, 2022. Division of Florida Medicaid, AGENCY FOR HEALTH CARE ADMINISTRATION, *Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria*, https://www.ahca.myflorida.com/letkidsbekids/docs/AHCA_GAPMS_June_2022_Report.pdf ["AHCA Report"] (last visited September 30, 2022).

The AHCA Report claimed that medical care for gender dysphoria fails to meet professional medical standards and is "experimental." In fact, the AHCA Report is thoroughly unscientific. Riddled with scientific errors, bias, and unfounded speculation, the AHCA Report provides no justification for the 2022 Exclusion and violates Florida's own administrative standards for determining Medicaid coverage. *See* Fl. Admin. Code Section 59G-1.035(4) (requiring that the AHCA consult "evidence-based clinical practice guidelines" and peer-reviewed scientific publications).

Contrary to the assertions of the Defendants, medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational.

By denying transgender patients access to standard medical care, the 2022 Exclusion harms Floridians who experience gender dysphoria and who could benefit from medical treatment. Indeed, a well-established body of science research documents the psychological and physical damage that results when patients with gender dysphoria are denied medical treatment: these include depressed mood, suicidal ideation and attempts, and disordered eating. The devastating truth is that 40% of transgender individuals who do not receive appropriate care will attempt or complete suicide in their lifetime. *See infra*.

As scientists, Amici are appalled that Florida's health care agency adopted the

2022 Exclusion and justified it with a report that so blatantly violates the basic tenets of scientific inquiry. We submitted timely comments opposing the 2022 Exclusion when it was proposed in June 2022. *See Letter from Anne Alstott, et al., to Simone Marstiller and Tom Wallace* (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/alstott%20et%20al%20full%20comment%20proposed%20rule%20re%20gender%20dysphoria_443049_284_55174_v3.pdf. Our comments were grounded in a lengthy analysis of the AHCA Report, to which we refer throughout this brief. Meredithe McNamara, et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, YALE SCHOOL OF MEDICINE (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida-medicaid/ ["McNamara (2022)"]. Our report cites and summarizes the peer-reviewed scientific literature to refute the misleading and often baseless claims made in the AHCA Report.

We strongly support the Plaintiffs' challenge and oppose Defendants' motion for summary judgment. The 2022 Exclusion lacks any scientific foundation, and its implementation has and will continue to inflict serious harm on the many transgender Floridians who rely on Medicaid for access to standard medical care for gender dysphoria.

ARGUMENT

I. THE 2022 EXCLUSION WRONGLY DENIES MEDICAID COVERAGE FOR STANDARD MEDICAL CARE FOR GENDER DYSPHORIA, WHICH IS SUPPORTED BY A ROBUST SCIENTIFIC CONSENSUS, MEETS GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS, AND IS NEITHER EXPERIMENTAL NOR INVESTIGATIONAL.

Medical care for the treatment of gender dysphoria, which for youth under the age of majority can include gonadotropin-releasing hormone agonists ("GnRHa" or puberty blockers) and hormone therapy (collectively, "transitioning medications,") has been vetted and approved by every relevant medical association in the United States based on the scientific evidence.

Two authoritative bodies of scientists, the World Professional Association for Transgender Health (WPATH) and The Endocrine Society, have published extensive clinical practice guidelines for treating gender dysphoria. *See* "Standards of Care for the Health of Transgender and Gender Diverse People," WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH 23, (8th ed. 2022) ["WPATH Standards of Care"]; Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*, 102 J. CLIN. ENDOCRINOL. METAB. 3869 (2017) ["Endocrine Society Guidelines"].

These clinical guidelines are based on rigorous, structured processes. Each involves the work of a committee of scientific experts and peer review by additional

experts. For example, the authors of the new WPATH guidelines include more than 90 leading researchers in the field of transgender medicine. *See* WPATH Standards of Care. The WPATH Standards of Care and Endocrine Society Guidelines are based on careful reviews of the scientific literature and are revised periodically to reflect scientific developments. These longstanding clinical practice guidelines have been used by clinicians for decades. McNamara (2022), at 5.

A. Standard medical care for gender dysphoria has been endorsed, based on careful reviews of the scientific evidence, by every relevant medical organization in the United States.

The scientific and medical consensus supporting medical treatment for gender dysphoria extends well beyond WPATH and the Endocrine Society. Medical care for gender dysphoria has been confirmed as standard care by every relevant medical organization in the United States, including the American Academy of Pediatrics (the "AAP"), the American Psychological Association (the "APA") and the American Academy of Child and Adolescent Psychiatry ("AACAP"). *See* Jason Rafferty, COMMITTEE ON PSYCHOSOCIAL ASPECTS OF CHILD AND FAMILY HEALTH, COMMITTEE ON ADOLESCENCE, SECTION ON LESBIAN, GAY, BISEXUAL, AND TRANSGENDER HEALTH AND WELLNESS, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, 142(4) PEDIATRICS e20182162 (2018); American Psychological Association, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People*, 70

Am. Psych. 832 (2015); Stewart L. Adelson, *Practice Parameter on Gay, Lesbian, or Bisexual Sexual Orientation, Gender Nonconformity, and Gender Discordance in Children and Adolescents*, 51 J. AM. ACAD. CHILD & ADOLESC. PSYCH. 957 (2012).

The confirmation of the WPATH Standards of Care, in all relevant respects, by these professional associations shows that WPATH should not be dismissed, as Defendant AHCA attempts to do, as an "advocacy group." AHCA Report, at 7, n. 3. WPATH is the leading medical society for transgender health, a fact recognized by the experts in the AAP, the APA, and AACAP. These are not shorthand endorsements of WPATH: they are lengthy and careful reviews of the scientific evidence from the perspective of each medical specialty. Thus, every relevant medical discipline has independently validated the scientific evidence supporting standard medical care for gender dysphoria. *Id.*

The degree of consensus across specialties is notable: each of these clinical guidelines approves the use of transitioning medications based on an individualized assessment of each patient. Each set of guidelines recommends the involvement of a mental health provider along with physicians, authorizes the use of transitioning medications only after the onset of puberty, and each prescribes a careful process designed to ensure the informed consent of parents or guardians along with the informed assent of the minor. *Id*.

As physicians and psychologists, Amici and others rely on the clinical practice guidelines published by WPATH, the Endocrine Society, the AAP, the APA, and AACAP because these organizations – comprised of Amici's national and international colleagues – have done their research and due diligence.

These consensus endorsements, based on scientific evidence spanning diverse medical specialties, sharply refute the AHCA Report's claim (repeated in substance by the Defendants in their motion for summary judgment) that medical treatments for gender dysphoria "do not conform to [generally accepted professional medical standards] and are experimental and investigational." AHCA Report, at 2.

B. The 2022 Exclusion denies Florida Medicaid coverage for transitioning medications only for transgender patients, ignoring the fact that the same treatments are used commonly and safely by cisgender patients and remain fully covered by Florida's Medicaid program.

The medications used to treat gender dysphoria are used commonly and safely in cisgender patients. Puberty blockers are the primary treatment for central precocious puberty. Estrogen is prescribed for patients of all ages to manage fertility and reduce heavy menstrual bleeding (to give just two examples of its many uses). Testosterone is prescribed to treat hypogonadism and is routinely prescribed to cisgender men with testosterone deficiency. *See* McNamara (2022), at 22, 24.

The Florida Medicaid program covers all these uses without question. The program authorizes physicians to tailor treatments to cisgender patients' needs and

trusts cisgender patients (and, in the case of children, their parents) to make informed decisions with their physicians' advice. The 2022 Exclusion denies standard medical care only for gender dysphoria, discriminating against transgender patients.

C. The denial of evidence-based medical care for gender dysphoria will irreparably harm thousands of transgender Floridians.

The best scientific evidence shows that gender dysphoria is real, that untreated gender dysphoria leads predictably to serious, negative medical consequences, and that medical care for gender dysphoria significantly improves mental health outcomes, including reducing rates of suicide.

The American Psychiatric Association explicitly recognizes gender dysphoria in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders ("DSM-5"), the standard reference for the diagnosis of mental health conditions. The DSM-5 sets forth criteria for diagnosis, including "a marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics" and "a strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender)." To meet diagnostic criteria, an individual must exhibit "clinically significant distress or impairment in social, occupational, or other important areas of functioning." American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders* (5th ed., 2013).

In other words, individuals who live in a manner that is physically and socially

incongruent to their gender identity can experience gender dysphoria – a clinically significant psychological distress that can lead to depressed mood, suicidal ideation and attempts, and disordered eating. *See* Susan D. Boulware, et al., *Biased Science: The Texas and Alabama Measures Criminalizing Medical Treatment for Transgender Children and Adolescents Rely on Inaccurate and Misleading Scientific Claims*, YALE SCHOOL OF MEDICINE (April 28, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/biased-science/ ["Boulware (2022)"], at 12-13. Suicidal ideation and attempts have been found to be significantly higher among transgender adolescents who cannot obtain or do not receive gender-affirming care than among their cisgender peers: 40% of trans individuals who do not receive hormones will attempt or complete suicide in their lifetime. *Id*.

Reliable research has shown that transitioning medications, when appropriate for individual patients, have major medical benefits, including improvements in anxiety and depression, social functioning, body image, and reductions in suicidal ideation. These findings have been well documented in numerous peer-reviewed studies published in authoritative journals. For the sake of brevity, Amici offer just a few recent examples, but the literature spans a decade or more, and there are careful summaries in the WPATH Standards of Care, the Endocrine Society Guidelines, and the clinical practice guidelines published by the AAP, the APA, and AACAP. *See*

also Boulware (2022), at 11-17 (summarizing the scientific evidence supporting medical care for gender dysphoria).

For instance, a 2020 meta-analysis of nine studies found positive outcomes from transitioning medications, including "decreased suicidality in adulthood, improved affect and psychological functioning, and improved social life." *See* Lynn Rew, et al., *Review*: *Puberty Blockers for Transgender and Gender Diverse Youth-A Critical Review of the Literature*, 26 CHILD. ADOLESC. MENT. HEALTH 3, 3 (2021). A 2022 study found that transitioning medications were "associated with 60% lower odds of moderate to severe depressive symptoms and 73% lower odds of self-harm or suicidal thoughts over a 12-month follow-up." *See* Diana M. Tordoff, et al., *Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care*, 5(2) JAMA NETWORK OPEN e220978 (2022) ["Tordoff (2022)"]. A 2020 study found that transitioning medications were associated with "important improvements in body dissatisfaction over the first year of treatment." *See* Laura E. Kuper, et al., *Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy*, 145(4) PEDIATRICS e20193006 (2020) ["Kuper (2020)"].

The scientific consensus is clear: peer reviewed scientific research has amply documented that medical treatment for gender dysphoria is effective. Since the publication of the AHCA Report, additional scientific studies have demonstrated the

benefits of such treatment. See Anna L. Olsavsky, et al., *Associations Among Gender-Affirming Hormonal Interventions, Social Support, and Transgender Adolescents' Mental Health*, J. ADOLESC. HEALTH, April 6, 2023, https://doi.org/10.1016/j.jadohealth.2023.01.031 (last visited April 8, 2023); Diane Chen, et al., *Psychosocial Functioning in Transgender Youth After Two Years of Hormones*, 388 N.E.J. MED. 240 (2023).

II. THE 2022 EXCLUSION RESTS ON A FLORIDA AHCA REPORT THAT IGNORES SOLID MEDICAL EVIDENCE AND CITES UNRELIABLE SOURCES AND FLAWED "EXPERT" ASSESSMENTS.

A. The purported "expert" assessments attached to the AHCA Report carry no scientific weight. They are unpublished, not peer-reviewed, and are written by authors whose expertise has been successfully challenged in legal proceedings and whose backgrounds raise red flags for bias.

The AHCA Report dismisses or ignores the WPATH Standards of Care and the Endocrine Society Guidelines, as well as the solid body of scientific evidence summarized above. Instead, the report relies on five attached documents that, the report claims, constitute "clinical and technical expert assessments." AHCA Report, at 2.

Despite their billing as "expert" reports, the attachments to the AHCA Report are thoroughly unreliable. They violate the standards of scientific inquiry in several ways and raise red flags for bias.

First, none of the documents attached to the AHCA Report meet standard

criteria for expert scientific investigations, because none is published or peer reviewed. Publication and peer review are fundamental to science, as they ensure that a scientist's data and conclusions are open to scrutiny from scientific experts. Contrary to these accepted standards, the attachments to the AHCA Report contain analysis and interpretations of pre-existing clinical research that have not been peer-reviewed or published in the scientific literature.

Florida's own standards for Medicaid coverage determinations recognize the importance of relying on published, peer-reviewed literature to guide public health decisions. Florida's standards state that determinations of Medicaid coverage must consult "*published* reports and articles in the authoritative medical and scientific literature related to the health service (*published in peer-reviewed scientific literature* generally recognized by the relevant medical community or practitioner specialty associations)."` (emphasis added) Fl. Admin. Code Section 59G-1.035(4). It is both unscientific and a violation of Florida's own regulations for the AHCA Report to rely on unpublished analysis as its principal evidence base.

Second, the AHCA Report does not disclose how its "experts" were identified or by what criteria their expertise was assessed. This is troubling because the qualifications and credibility of several of the experts have been successfully challenged in litigation.

For example, although the AHCA Report characterizes Quentin van Meter as

an expert in medical treatment for gender dysphoria, at least one court barred him from providing expert testimony on the issue. *See* Stephen Caruso, *A Texas Judge Ruled That This Doctor Was Not an Expert*, PENNSYLVANIA CAPITAL-STAR (Sept. 15, 2020) (reporting that van Meter was disqualified as an expert in a Texas divorce case, now sealed, involving medical treatment for an adolescent with gender dysphoria).

To take another example, an Alabama federal district court in 2022 took a skeptical view of testimony offered by another AHCA Report "expert," James Cantor. The court gave Cantor's testimony "very little weight" because Cantor had no clinical experience in diagnosing or treating gender dysphoria in minors. Opinion and Order, *Eknes-Tucker v. Marshall*, 2:22-CV-184-LCB, 2022 WL 1521889, (M.D. Ala. May 13, 2022), at 11. And testimony by another AHCA Report "expert," Patrick Lappert, was disqualified in 2022 by a North Carolina federal judge, who found that the evidence "calls Lappert's bias and reliability into serious question." *Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022), at 26.

Third, the AHCA Report's purported "experts" have strong indications of bias. Van Meter is the past president of the American College of Pediatricians (the "ACP"), a political group that opposes LGBTQ rights and has incorrectly asserted that gender dysphoria is simply "confusion." *See Michelle Cretella, Gender*

Dysphoria in Children, AMERICAN COLLEGE OF PEDIATRICIANS (2018), https://acpeds.org/position-statements/gender-dysphoria-in-children (last visited September 30, 2022). Lappert has worked closely with anti-LGBTQ religious groups and has actively lobbied for legal bans on medical care for transgender youth. *Kadel v. Folwell, supra*, at 26.

B. The AHCA Report incorrectly claims that there is little or no evidence to support the benefits of medical care for gender dysphoria. The report ignores robust, peer-reviewed research and instead relies on sources with no scientific credibility.

In its opening sentences, the AHCA Report makes a glaring error that is repeated throughout the document: "Studies presenting the benefits [of medical treatment for gender dysphoria for] mental health, including those claiming that the services prevent suicide, are *either low or very low quality and rely on unreliable methods such as surveys and retrospective analyses, both of which are cross-sectional and highly biased*." (emphasis added) AHCA Report, at 2.

The AHCA Report's claim is false. The analysis ignores the evidence-based medical consensus and solid research documented in Part I of this brief. Instead, the AHCA Report relies on unreliable assumptions and deceptive statements.

1. The AHCA Report relies on a purported "expert" analysis that makes highly misleading claims about the quality of the scientific evidence supporting medical treatment for gender dysphoria

The linchpin of the AHCA Report is one of the unpublished, non-peer-

reviewed "expert" reports commissioned by the AHCA, this one written by Romina Brignardello-Petersen and Wojtek Wiercioch. *See* AHCA Report, Attachment C [the "BPW Document"]. The BPW Document purports to be a comprehensive review of the scientific literature but, in fact, is extremely narrow in scope and so flawed in its analysis that it deserves no scientific weight.

Neither of the BPW authors are experts in medical care for gender dysphoria, either as researchers or clinicians. Brignardello-Petersen's only clinical experience appears to be in dentistry, and Wiercioch is a junior researcher with no prior research or clinical experience in this field. McNamara (2022), at 9-10. The authors' lack of expertise violates scientific standards for systematic reviews. *Id.* By analogy, one would not rely on, say, a dermatologist and a statistician to evaluate the scientific literature and make clinical recommendations for the practice of neurosurgery.

The result is that the BPW Document is full of scientific errors. For instance, the authors reviewed only a small sample of the relevant scientific literature and, without justification, included biased, non-peer-reviewed literature. McNamara (2022), at 12.

Most troubling, the BPW analysis deceptively dismisses nearly all existing studies of medical treatment for gender dysphoria as "low quality." The authors fail to explain that "low quality" in this context is a technical term and not a judgment about the medical reliability of the evidence. They also, misleadingly, fail to mention

that so-called "low quality" studies regularly guide important aspects of clinical practice. McNamara (2022), at 11-15.

As background, only randomized controlled trials (RCTs) are generally coded as "high quality" evidence in this technical sense. An RCT divides patients randomly into a control group (no treatment) and a treatment group. In contrast, an observational study records information about patients in a real-world setting, e.g., a cohort of patients treated at a clinic. The rating system used in the BPW document thus codes observational studies as "low quality."

The takeaway is that "low quality" in this context is a technical term and not a condemnation of the evidence. In fact, the drafters of the rating system used in the BPW document emphasize that technically "low quality" evidence can support a strong clinical treatment recommendation. Howard Balshem, et al., *GRADE Guideline: 3. Rating the Quality*, 64 J. CLIN. EPIDEM. 401, 402-404 (2011).

Technically "low quality" evidence is commonly used in medicine to support strong clinical recommendations. For example, pediatricians now agree – and parents have been told – that children should not be given aspirin for fevers. This recommendation is based on observational studies (not RCTs) that showed an association between aspirin treatment during viral illnesses and the development of Reyes syndrome (a rapid and progressive disease of neurological dysfunction that can be fatal). *Id.*

The BPW document fails to acknowledge that RCTs are not, and cannot be, the gold standard for medical research on gender dysphoria, due to strong ethical constraints. Medical care has long been shown, by reliable scientific methods, to address gender dysphoria and improve mental health. As we have repeatedly noted, these treatments have been recommended by rigorous clinical practice guidelines and endorsed by every relevant major medical organization.

Given this medical consensus and its solid evidence base, it would be unethical to conduct an RCT that predictably will harm the control group by denying them standard medical care for gender dysphoria. By analogy, it would be equally unethical to conduct an RCT on the treatment of juvenile diabetes by randomizing some participants to receive insulin and others to receive no medication at all.

Similar ethical issues, along with practical barriers, leave many areas of consensus medicine supported by observational studies (and not RCTs), and yet the Florida Medicaid program continues to cover these treatments. If the Florida Medicaid program consistently denied coverage to all procedures supported only by observational studies, the result would be a massive disruption in medical care.

For example, if the Florida Medicaid program excluded all medical care supported by technically "low quality" evidence, the program could not cover statins (drugs to lower cholesterol) for many patients, which are prescribed to 28% of adults over the age of 40 to prevent cardiovascular death. Other common practices that

would have to be reconsidered include post-menopausal hormone replacement therapy and mammography screening for breast cancer. Many common surgical procedures also rest on a technically "low quality" evidence base, including minimally invasive gall bladder surgery. McNamara (2022), at 16.

At its root, then, the AHCA Report is utterly misleading in its claim that the scientific evidence supporting medical treatment for gender dysphoria is "low quality." In fact, the evidence base for such care is comparably strong to the evidence that supports many other consensus medical treatments covered without objection by the Florida Medicaid program.

2. The AHCA Report mischaracterizes the scientific evidence, citing journalism and other unreliable sources while launching baseless criticisms at solid research studies.

The AHCA Report repeatedly cites unreliable sources, including journalism, a student blog, a website, and letters to the editor – rather than peer-reviewed empirical research. McNamara (2022), at 16-17. At the same time, the report makes baseless or exaggerated criticisms of authoritative studies.

For example, the AHCA Report attacks one 2015 study by claiming that the study design did not include a control group of adolescents without gender dysphoria. AHCA Report, at 15. This point is incorrect: the cited study included an appropriate control group. McNamara (2022), at 17, discussing Rosalia Costa, et al., *Psychological Support, Puberty Suppression, and Psychosocial Functioning in*

Adolescents with Gender Dysphoria, 12 J. SEX. MED. 2206 (2015) ["Costa (2015)"].

The June 2 Report also criticizes the Costa study for "rel[ying] heavily on self-assessments." *Id.* But this too is wildly off base. The study measures psychosocial functioning with a widely used and accepted instrument. Psychological research typically relies on such assessments, which are carefully constructed and psychometrically validated. This specious criticism provides another example of the June 2 Report's scant understanding of research in psychology and medicine. The AHCA Report also grossly misleads the reader in its discussion of other studies. McNamara (2022), at 17-19.

Most concerningly, the AHCA Report makes cherry-picked criticisms of a few studies without acknowledging that the weight of the literature as a whole strongly supports medical treatment for gender dysphoria. Scientific knowledge is, importantly, cumulative. It is thus unscientific to dismiss the effectiveness of transitioning medications by cherry-picking studies in isolation.

For instance, the AHCA Report fails to acknowledge that at least 16 studies show that transitioning medications benefit patients with gender dysphoria. These studies have demonstrated the benefits of medical treatment for gender dysphoria as measured by a variety of outcomes (body satisfaction, mental health, and suicidality, among others). They evaluate a series of diverse study populations, ensuring generalizability of results, and they use a diverse array of methods (including

retrospective report, cross-sectional, longitudinal, and qualitative). Further, the studies carefully control for confounding factors that could artificially distort the relationship between an intervention and outcome. McNamara (2022), at 18; Chen, et al. (2023) and Olsavsky, et al. (2023).

III. THE 2022 EXCLUSION IS BASED ON FALSE AND MISLEADING CLAIMS ABOUT MEDICAL REGULATION AND GENDER DYSPHORIA.

The AHCA Report contains numerous additional errors about medical regulation and gender dysphoria. We provide brief examples here, with a more detailed discussion in McNamara (2022), at 15-20.

A. The AHCA Report mistakenly claims that transitioning medications are experimental because they are used "off-label" and not approved by the FDA. In fact, off-label use, when supported by scientific evidence, as here, is common in medical practice and especially in pediatrics.

The AHCA Report repeatedly notes that the FDA has not approved the use of transitioning medications for the treatment of gender dysphoria in minors. AHCA Report, at 8, 14, 15, 19. The report infers that lack of FDA approval renders a treatment unauthorized and experimental, but this is false.

The term "off-label" has a very specific meaning: a drug is off-label if the FDA has not approved a particular medication for a particular use in a specific population. The off-label use of medications for children is common, because an "overwhelming number of drugs" have no FDA-approved instructions for use in

pediatric patients. Kathleen A. Neville, et al., American Academy of Pediatrics Committee on Drugs, *Off-label use of drugs in children*, 133 PEDIATRICS 563, 563 (2014) ["AAP Committee on Drugs"].

The lack of FDA approval does not imply that the use of medications should be restricted. There is a consensus in the medical community that off-label use is necessary because of limits imposed by burdensome and expensive regulatory processes. The American Academy of Pediatrics, recognizing these facts, specifically authorizes the off-label use of drugs, noting that

> [T]he term "off-label" does not imply an improper, illegal, contraindicated, or investigational use. Therapeutic decision-making must always rely on the best available evidence and the importance of the benefit for the individual patient. *Id.*

Off-label use is so common in pediatrics that off-label drugs are prescribed in nearly 20% of patient visits. Diya Hoon, et al., *Trends in Off-Label Drug Use in Ambulatory Settings: 2006-2015*, 144 PEDIATRICS 1, 5 (2019). Familiar examples include steroids administered to toddlers with croup (a severe, potentially airway-obstructing illness) and ondansetron (Zofran) used to treat nausea and vomiting to prevent dehydration.

The AHCA Report also asserts that testosterone is a controlled substance and is subject to risk of abuse, but this statement is highly misleading. Testosterone appears on the schedule of controlled substances due to the misuse of the drug by

some individuals and communities (e.g., athletes who may use the drug to build muscle). The classification does not imply that physicians should not dispense the drug if medically necessary. In fact, it is commonly prescribed to cisgender men with testosterone deficiency.

B. The AHCA Report falsely claims that medical care for gender dysphoria is provided to a large percentage of children who will come to regret their treatment. In fact, patients with gender dysphoria have vanishingly low rates of regret regarding their medical treatment.

The AHCA Report attempts to cast doubt on medical treatment for gender dysphoria by repeating the debunked claim that most teens with gender dysphoria ultimately reject their transgender identity. *See* AHCA Report, at 14 (claiming that "the majority of young adolescents who exhibit signs of gender dysphoria eventually desist and conform to their natal sex.")

This claim is demonstrably false, because it conflates the course of gender dysphoria in pre-pubertal children with the course in adolescents. Although some young children with gender dysphoria will ultimately not be transgender, the evidence shows a very different outcome for adolescents. The key point is that *adolescents* with gender dysphoria rarely find that their dysphoria resolves without treatment. Boulware (2022), at 17-19.

The distinction between pre-pubertal children and adolescents is important, because medical treatment for gender dysphoria begins only in adolescence, and

only if medically necessary. Thus, transitioning medications are provided only to a group known to be quite stable in their gender identity.

The AHCA Report also claims that many transgender people regret medical treatment for gender dysphoria. This, too, is false. The scientific evidence is clear: solid studies show very low percentages of regret (typically under 1%) among transgender people who receive medical treatment for gender dysphoria. Further, the overwhelming majority of transgender people (98%) continue treatments begun in adolescence. *See* Maria A.T.C. van der Loos, et al., *Continuation of Gender-Affirming Hormones in Transgender People Starting Puberty Suppression in Adolescence: a Cohort Study in the Netherlands*, 6 LANCET CHILD ADOLESC HEALTH 869 (2022); Andrea L. Nos, et al., *Association of Gonadotropin-Releasing Hormone Analogue Use with Subsequent Use of Gender-Affirming Hormones Among Transgender Adolescents*, 5 JAMA NETW OPEN e2239758 (2022); McNamara (2022), at 21-23.

C. The AHCA Report repeats discredited claims that "social contagion" leads teens to become transgender. Scientific evidence refutes this claim.

The AHCA Report claims that "social factors (e.g., peer influences and media) may be contributing factors to gender dysphoria," citing as evidence a single, discredited study. AHCA Report, at 12. The cited study by Lisa Littman claimed adolescents were experiencing "rapid-onset" gender dysphoria motivated by peer

pressure. But the study incorporated such serious methodological errors that the journal of publication required an extensive correction because of the article's misstatements. Boulware (2022), at 20-21.

Although the "social contagion" hypothesis has been widely repeated in the popular press and on social media, no clinical studies have confirmed it. Indeed, a careful 2022 study found no evidence that social contagion influenced teenagers to become transgender. *See* Greta R. Bauer, et al., *Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid-Onset Gender Dysphoria"?*, 243 J. PEDIATRICS 224 (2022).

Further, no professional organization recognizes so-called "rapid onset" gender dysphoria as a distinct clinical condition or diagnosis. Indeed, in 2021 a coalition of major psychological and psychiatric organizations issued a joint statement calling for responsible mental health practitioners to eliminate any use of "rapid-onset" gender dysphoria "given the lack of rigorous empirical support for its existence." *See* Coalition for the Advancement & Application of Psychological Science, *CAAPS Position Statement on Rapid Onset Gender Dysphoria (ROGD)*, 2021, https://www.caaps.co/rogd-statement.

Data substantiate that younger people today are more likely to identify as transgender than are older people, but this does not provide solid evidence of social contagion. The difference may be due to increasing social acceptance of gender

diversity (i.e., older people grew up in a much more restrictive and transphobic social environment). Furthermore, there is nothing new about adolescent presentation of transgender identity. *See* Sandy E. James, et al., *The Report of the 2015 U.S. Transgender Survey, National Center for Transgender Equality* (2015) (reporting results of the largest U.S. sample of transgender adults and finding that over half reported first realizing they were transgender in adolescence).

What the data does not show is a massive wave of transgender identity even among teens. Even using an expansive definition of "transgender," only about 0.5% of adults now identify as transgender, while 1.4% of youth aged 13-17 do, or about 300,000 young people. Jody L. Herman, et al., *How Many Adults and Youth Identify as Transgender in the United States?*, U.C.L.A. SCHOOL OF LAW, WILLIAMS INSTITUTE (2022).

Finally, the social contagion hypothesis is irrelevant to the validity and effectiveness of medical care for gender dysphoria. Importantly, medical treatments are not offered to all gender-questioning youth, and there is no rush to treatment. The WPATH Standards of Care and Endocrine Society Guidelines recommend transitioning medications for transgender adolescents only when an interdisciplinary medical team has determined that treatment is medically necessary.

D. The AHCA Report claims that inappropriate medical care is provided to adolescents with gender dysphoria who also have anxiety, depression, and other mental health conditions. These assertions are unsupported by evidence and disregard evidence-

based clinical practice guidelines that provide guidance for treating complex cases.

The AHCA Report speculates that because "a high proportion" of youth receiving medical care for gender dysphoria also have a behavioral health disorder, "available research raises questions as to whether the [individuals'] distress is secondary to pre-existing behavioral health disorders and not gender dysphoria." AHCA Report, at 6. In simpler terms, the AHCA Report speculates that gender dysphoria is not real but is, rather, an imagined by-product of underlying mental illness.

This speculation has no foundation in science and contradicts medical knowledge about the causes of and appropriate treatments for mental distress in transgender youth. While some youth with gender dysphoria also have anxiety, depression, and other mental health conditions, it is well-documented that these conditions often reflect the social stress and discrimination of being transgender. Put simply, being transgender in our society causes anxiety and depression. McNamara (2022), at 25-27. These effects, sometimes called "gender minority stress," are well-documented, but the AHCA Report makes no mention of the literature.

Further, psychological distress among individuals with gender dysphoria provides no reason for denying medical care. Any population of individuals – cisgender or transgender – will include some with mental health concerns. In response, the WPATH Standards of Care and Endocrine Society Guidelines include

a careful psychological assessment of each adolescent as part of the process for determining whether medical treatment for gender dysphoria is appropriate.

Importantly, experts in child and adolescent psychiatry, psychology, and medicine have established that youth — including youth with mental health conditions — can make complex medical decisions when well-supported by parents and professionals. Indeed, the scientific literature demonstrates that transgender youth with co-occurring mental health conditions can competently participate in medical decision-making. *See* Lieke J. Vrouenraets, et al., *Assessing Medical Decision-Making Competence in Transgender Youth*, 148 PEDIATRICS 6 (2021).

E. The AHCA Report speculates, without evidence, that psychotherapy alone is as effective as medical treatment for gender dysphoria. This claim contradicts the findings of solid scientific studies.

The AHCA Report claims, without scientific evidence, that youth with gender dysphoria should not be offered medical treatment but instead should only receive psychotherapy. AHCA Report, at 12, 20. This hypothesis is not grounded in any scientific evidence and, in fact, stands at odds with the findings of solid, peer-reviewed studies. Here we provide an overview of the science, with more detail in McNamara (2022), at 27-28.

At least three recent studies show that medical care for gender dysphoria has positive effects on mental health that are not associated with psychotherapy alone. A 2015 study documents that transitioning medications improve psychosocial

functioning in teens with gender dysphoria, compared to teens who receive psychotherapy but not transitioning medications. Costa (2015), at 2212-13. A 2022 study similarly found that youth with gender dysphoria reported better outcomes if they received transitioning medications, even after controlling for the effects of psychotherapy. Tordoff (2022), at 4-6. And a 2020 study also showed that transitioning medications are effective above and beyond the benefits of psychotherapy and psychiatric medications. Kuper (2020), at 5-7.

CONCLUSION

The 2022 Exclusion is based on a deeply flawed scientific report. The AHCA Report disregards the evidence-based consensus of medical experts and mischaracterizes the large body of solid, peer-reviewed scientific literature that supports medical treatment for gender dysphoria. Riddled with scientific errors, deceptive language, and outright falsehoods, the AHCA Report provides no scientific justification for the 2022 Exclusion or for the Defendants' claim that medical treatment for gender dysphoria is experimental. We strongly urge the Court to grant the relief sought by Plaintiffs and to deny the Defendants' motion for summary judgment.

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CERTIFICATE OF WORD COUNT

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CERTIFICATE OF SATISFACTION OF ATTORNEY-CONFERENCE REQUIREMENT

Pursuant to Local Rule 7.1(B), counsel for *amici* conferred with counsel for the parties on April 20, 2023. Plaintiffs and Defendants consent to the filing of *amici*'s brief.

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