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* BIOMEDICAL ETHICS AND PUBLIC HEALTH SCHOLARS 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, none of the *amici curiae* is a corporate entity or has issued stock.

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STATEMENT OF INTEREST[1]

Amici curiae listed in the Appendix are professors of law, medicine, and public health who teach and write about biomedical ethics and health-related rights and discrimination. Biomedical ethics, sometimes referred to as bioethics, is "the discipline of ethics dealing with moral problems arising in the practice of medicine and the pursuit of biomedical research." J. R. Vevaina et al., *Issues in biomedical ethics*, 39(12) Disease-a-Month 869, 869 (1993), https://pubmed.ncbi.nlm.nih.gov/8243220. *Amici* have a strong interest in ensuring that principles of biomedical ethics are accurately described and properly applied. They submit this brief to explain how Florida Administrative Code 59G-1.050(7) is inconsistent with foundational principles of biomedical ethics.

INTRODUCTION

Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion") is an extreme and unjustified intrusion by the State into the medical profession. The law denies transgender Medicaid beneficiaries coverage for gender-affirming care, even when the patient's medical provider deems the care medically necessary for treating gender dysphoria and in the patient's best interest. Although the State claims

[1] *Amici* certify that no person or entity, other than *amici curiae*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief or authored this brief in whole or in part. The parties have consented to the filing of this brief.

that the law is necessary to promote the health, safety, and welfare of its citizens, the Challenged Exclusion in fact misapprehends how medical knowledge is generated and contravenes fundamental and well-established principles of biomedical ethics, creating serious, harmful consequences for individual patients and public health more generally.

The State endeavors to rationalize these harms by erroneously claiming that gender-affirming care is "experimental." Far from being "experimental," the gender-affirming care prohibited from coverage by the Challenged Exclusion was developed through rigorous and appropriate methods and is recommended by every major medical association in the United States. Randomized-control trials are not, and have never been, requisite for medical care to be considered appropriate, and in fact are ill-suited for many types of treatment. Nor must longitudinal studies always be of a particular duration to be reliable. And off-label use is legal, commonplace, and often necessary to serve a patient's best interest. In short, the State's arguments about efficacy and safety misunderstand how medical knowledge is credibly generated.

Moreover, the Challenged Exclusion eviscerates core principles of biomedical ethics, including respect for autonomy, beneficence, and justice. Because a denial of Medicaid coverage is effectively a denial of care for Medicaid beneficiaries, the Challenged Exclusion deprives economically disadvantaged transgender patients of their ability to receive medically necessary and appropriate treatment to which they

have given informed consent (autonomy). It forces providers to deny their patients care that is known to alleviate suffering, and thus to abandon their patients to serious physical and mental harm (beneficence). And it compels providers to deny care that only patients who are transgender need, thereby exacerbating stigma and inequity and damaging trust in the medical profession (justice).

In sum, the Challenged Exclusion singles out and effectively bans gender-affirming care for economically disadvantaged transgender patients based on false notions of science, public health, and biomedical ethics, without considering the grave harm that will come from denying vulnerable patients critical health care. This Court should grant the relief sought by Plaintiffs and deny Defendants' Motion for Summary Judgment.

I. THE CHALLENGED EXCLUSION RESTS ON A FUNDAMENTAL MISUNDERSTANDING OF HOW SCIENTIFIC KNOWLEDGE AND MEDICAL STANDARDS ARE GENERATED.

The State claims that the gender-affirming care prohibited by the Challenged Exclusion is "experimental." Dkt. 120, Defs' Mot. for Summ. J. and Mem. of Law ("MSJ") at 15–25. The State's pejorative characterization is contrary to reality: the gender-affirming care prohibited by the Challenged Exclusion is not "experimental," but was developed through rigorous and appropriate methods and is recommended by every major medical association in the United States. *See, e.g.*, Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-*

Diverse Children and Adolescents, 142(4) Am. Acad. of Pediatrics 1, 5 (2018) ("Rafferty"), https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for; Ayden I. Scheim et al., *Health and Health Care Among Transgender Adults in the United States*, 43 Annual Rev. of Pub. Health 503, 510 (2021) ("Scheim"); *see also* Gesine Meyer et al., *Safety and rapid efficacy of guideline-based gender-affirming hormone therapy: an analysis of 388 individuals diagnosed with gender dysphoria*, European J. of Endocrinology 155 (2020); Dkt. 120-28, Expert Rebuttal Report of Aron Janssen ¶¶ 23, 29, 56.

The State attempts to support its attack on gender-affirming care with putative expert reports that criticize the lack of randomized control trials, the duration of the longitudinal studies completed to date, and what they call "low quality" or "very low quality" evidence on gender affirming care. *See* MSJ at 22–23; Dkt. 120-15, Expert Report of Michael Laidlaw ("Laidlaw Report") ¶¶ 78, 210, 308; Dkt. 128-1, Expert Report of Michael Biggs ¶ 9. Likewise, the State's putative experts also emphasize that using puberty blockers and hormone therapy for gender-affirming care is not approved by the U.S. Food and Drug Administration ("FDA"). Dkt. 120-17, Expert Rebuttal Report of Quentin Van Meter ("Van Meter Reb. Report") ¶ 36. These arguments reflect a fundamental misunderstanding of medical practice and the ways medical knowledge and treatment guidelines are generated.

Medical providers are not, and have never been, restricted to providing only those treatments that have been generated via randomized control trial or longitudinal study of a specific length and that have received FDA approval for the particular indication. And the quality of evidence supporting treatment of gender dysphoria is of the same quality of evidentiary support relied upon for treatment in many other disciplines of medicine. Indeed, as explained below, limiting care according to the restrictions suggested by the State here would be impractical and unethical.

A. The Medical Care Targeted by the Challenged Exclusion Is Not "Experimental."

The State and its proffered experts seek to justify the Challenged Exclusion as preventing "experimental" treatment, including by invoking inapposite examples of unethical research on human subjects. This line of argument wrongly conflates clinical care (at issue here) with clinical research and fails to engage with the ethical standards attendant to each. Contrary to the State's suggestion, receiving gender-affirming care does not automatically render a patient a subject of a research study (and certainly not an "experimental" study unmoored from ethical standards).

Medical care delivered by a clinician to a patient and clinical research have distinct purposes and processes. *See, e.g.*, Nat'l Commission for the Protection of Hum. Subjects of Biomedical Rsch., *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) (discussing the

importance of distinguishing between research and clinical practice); U.S. Food & Drug Admin., *Clinical Research Versus Medical Treatment* (Mar. 22, 2018), https://www.fda.gov/patients/clinical-trials-what-patients-need-know/clinical-research-versus-medical-treatment (describing differences between clinical research and medical treatment in terms of intent, intended benefit, funding, timeframe, and other factors). In the clinical care setting, the provider's aim is to improve a patient's health and well-being, and the provider is duty bound to act in that patient's best interest. By contrast, the aim of a research study is to create generalizable knowledge useful for *future* patients. *See* José A. Sacristán, *Clinical Research and Medical Care: Towards Effective and Complete Integration*, 15(4) BMC Med. Res. Methodol. 1 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323129/. A research study's protocols must be ethically designed and administered to ensure participant safety, but there is no obligation to do what is in each participant's best interest. In contrast, gender-affirming care is known to advance the individual patient's best interest and is provided as clinical care for that purpose.

One of the State's proffered experts, Dr. Paul W. Hruz, suggests in his report that providing gender-affirming care to advance an individual patient's best interest is comparable to the Tuskegee study and Nazi experiments. Dkt. 120-13, Expert Report of Paul W. Hruz ¶ 109. That claim is both offensive and wrong, for myriad reasons. For one thing, neither the Black men in the Tuskegee study nor the victims

of the Nazis' wartime research were willing participants. For another, those efforts were carried out without any person's informed consent and involved an extremely disproportionate risk of harm to the people involved with no known or expected benefits.

Specifically, the government-sponsored Tuskegee study withheld effective treatment from Black men with syphilis, resulting in the deaths of up to 100 study participants and enduring and devastating harms to Black men's health. *See* Allan M. Brandt, *Racism and Research: The Case of the Tuskegee Syphilis Study*, 8(6) The Hastings Center Report 21 (1978), https://dash.harvard.edu/bitstream/handle/1/3372911/Brandt_Racism.pdf; Vann R. Newkirk II, *A Generation of Bad Blood*, The Atlantic (June 17, 2016), https://www.theatlantic.com/politics/archive/2016/06/tuskegee-study-medical-distrust-research/487439/ (reviewing research finding that the Tuskegee study undermined Black men's trust in the medical system and "was responsible for over a third of the life-expectancy gap between older black and white men in 1980"). The Tuskegee researchers sought to justify depriving the study participants of the contemporary standard of care for syphilis based on their racist beliefs about Black men. This case, by contrast, concerns providers who are working to ensure that economically disadvantaged individuals with gender dysphoria can access treatment known to be safe and effective and are thus endeavoring to *improve* their patients'

health and well-being. If anything, it is the Challenged Exclusion that echoes the Tuskegee study because it prevents access to treatment known to be effective, thereby harming individuals and undermining trust in the medical system.[2]

B. Medical Knowledge Is Credibly Generated Through Multiple Methods, Not Just Randomized Control Trials and "Long-Term" Studies.

In addition to conflating research and treatment, the State's attempted defense of the Challenged Exclusion misunderstands how medical knowledge is credibly and rigorously generated by suggesting that the lack of randomized control trials or longitudinal studies of a certain length is dispositive. There is no one method used to generate medical knowledge, and no one method is considered requisite to a treatment being deemed medically appropriate. Rather, medical knowledge and practice are informed by a range of research and clinical inputs. That is so in part because the appropriateness of a given research method can turn on the contemplated intervention and context.

A randomized control trial—where some participants are randomly assigned to a treatment group and others are randomly assigned to a control group—is one of many types of credible research designs used to evaluate a medical intervention. Medical interventions also can be and often are evaluated through observational

[2] It should go without saying that gender-affirming care is wholly unlike the ghastly experiments the Nazis performed on unwilling Jewish people, racial and ethnic minorities, people with disabilities, and others during the Holocaust.

studies, which include cross-sectional studies (based on data collected from a single point in time) and longitudinal studies (based on data collected from particular individuals over time). *See, e.g.*, Edward L. Hannan, *Randomized Clinical Trials and Observational Studies: Guidelines for Assessing Respective Strengths and Limitations*, 1(3) JACC: Cardiovascular Interventions 211 (2008), https://www.sciencedirect.com/science/article/pii/S1936879808001702. In addition, randomized clinical trials, which compare different established interventions to one another, may be used to inform medical treatment. For example, a randomized clinical trial has been used to evaluate sex hormone treatment for gender dysphoria, comparing different, established pharmacological treatments to one another. *See* Carla Pelusi et al., *Effects of Three Different Testosterone Formulations in Female-to-Male Transsexual Persons*, 11(12) J. Sex Med. 3002 (2014), https://doi.org/10.1111/jsm.12698.

Study methods other than randomized control trials and extended longitudinal studies may be preferable in some circumstances, given that these methods are not always feasible, appropriate, or the most reliable way to evaluate a medical intervention. For instance, randomized control trials are rarely used for interventions focused on children or pregnant people, or for surgical interventions. *See, e.g.*, Denise Thomson et al., *Controlled Trials in Children: Quantity, methodological quality and descriptive characteristics of Pediatric Controlled Trials published*

1948–2006, 5(9) PLoS One 1 (2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2948021/; Katrien Oude Rengerink et al., *Pregnant women's concerns when invited to a randomized trial: A qualitative case control study*, 15 BMC Pregnancy & Childbirth 1 (2015), https://bmcpregnancychildbirth.biomedcentral.com/articles/10.1186/s12884-015-0641-x; Natalie S. Blencowe et al., *Interventions in randomized controlled trials in surgery: issues to consider during trial design*, 16 Trials 7 (2015), https://doi.org/10.1186/s13063-015-0918-4.

Importantly, randomized control trials are ethical only when there is clinical "equipoise," which means they are only appropriate when there is genuine uncertainty about whether the intervention will be more effective than the control. *See* Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 New Eng. J. Med. 141 (1987), https://www.nejm.org/doi/full/10.1056/NEJM198707163170304. This is so because it is unethical to knowingly expose participants to an inferior intervention or control. This principle plainly applies to hormone therapy for gender dysphoria. Performing randomized, placebo-controlled trials on the efficacy of that treatment would be unethical, because the prevailing view among the medical community is that for patients who need it, hormone therapy is superior to a lack of pharmacological

treatment.[3] *See* Rafferty at 10; Scheim at 507-12. As such, it is unsurprising and not at all troubling that randomized control trials for gender-affirming care are limited.

Likewise, the State and its proffered experts critique the lack of "long-term studies" on the safety and efficacy of gender-affirming care, particularly for minors, despite the existence of many such studies.[4] The State's suggestion that longitudinal studies are only reliable when they last for some unspecified "long-term" period is wrong. And in championing such studies as essential, the State disregards the ethical and legal issues that may be avoided by other equally reliable and trustworthy

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[3] A randomized control trial of hormone therapy for gender dysphoria would also likely have feasibility problems. Given the efficacy of the treatment, many of the participants assigned to the control group would be expected to drop out of the study to be able to obtain the care.

[4] Contrary to Defendants' assertions, there have been a number of long-term studies on gender-affirming care and its benefits. *See, e.g.*, Jack L. Turban et al., *Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults*, 17(1) PLoS ONE 2 (2022), https://doi.org/10.1371/journal.pone.0261039 (collecting studies); Katherine L. Kraschel et al., *Legislation restricting gender-affirming care for transgender youth: Politics eclipse healthcare*, 3(8) Cell Reports Medicine 4 (2022) ("Kraschel") https://doi.org/10.1016/j.xcrm.2022.100719 ("Over a dozen studies have collectively linked [gender affirming care] to improvements in depression, anxiety, and suicidality."); *see also Brandt v. Rutledge*, 47 F.4th 661, 671 (8th Cir. 2022) ("According to surveys of the research on hormone treatment for adolescents done by the British National Institute for Health & Care Excellence, several studies have shown statistically significant positive effects of hormone treatment on the mental health, suicidality, and quality of life of adolescents with gender dysphoria. None has shown negative effects."); *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1146 (M.D. Ala. 2022) ("[A]t least twenty-two major medical associations in the United States endorse transitioning medications as well-established, evidence-based treatments for gender dysphoria in minors.").

methods. For example, before conducting longitudinal studies involving children, researchers must consider a child's privacy and autonomy all while maintaining data integrity—a sometimes difficult balancing act that can be avoided by using an alternative study design. *See, e.g.*, Gert Helgesson, *Children, Longitudinal Studies, and Informed Consent*, 8 Med., Health Care & Philos. 307 (2005), https://doi.org/10.1007/s11019-005-0978-4.

The State also betrays its erroneous understanding of what it means for evidence to be graded as "low-quality." MSJ at 31. Generally, the level of quality ascribed to evidence is based on the type of research methodology used—evidence generated via a randomized control trial is typically labeled "high quality" and evidence generated via an observational study is typically labeled "low quality." Howard Balshem, et al., *GRADE guidelines: 3. Rating the quality of evidence*, 64(4) J. Clinical Epidemiol. 401 (2011) ("Balshem"); Dkt. 120-30, Holger Schünemann et al. (eds.), *Grading of Recommend., Assess., Dev. & Eval. Handbook* 14 (2013) ("GRADE Handbook"). Randomized trials with limitations such as inconsistent results or publication bias will go down in quality, and observational studies with a dose-response gradient (relationship between a stimulus and a response) or large magnitude of effect will go up in quality. GRADE Handbook at 13.

These "high quality" and "low quality" labels on which the State fixates thus are descriptive of the underlying method, but they do not necessarily reflect the

reliability of the evidence generated. As noted, observational evidence is sometimes favored for both ethical and practical reasons. And here, randomized control trials are not appropriate for the reasons described above. Because randomized control trials are often inappropriate or infeasible, research that falls in the technical category of "low quality" can still be reliable and valuable when it comes to clinical practice. *See* Dkt. 169, Br. of Amici Curiae Hussein Abdul-Latif et al. at 6 (citing Meredithe McNamara, et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria*, Yale Sch. of Med. 1, 15 (2022) ("McNamara")). Indeed, low-quality evidence may be sufficient to justify a strong recommendation for clinical care. GRADE Handbook at 5; Balshem at 402-04 ("A particular level of quality does not imply a particular strength of recommendation. Sometimes, low or very low quality evidence can lead to a strong recommendation."). Were it otherwise, whole swaths of modern care for which randomized control trials are inappropriate for ethical and/or practical reasons would be called into question. *See* Robert J. Ligthelm et al., *Importance of observational studies in clinical practice*, 29(6) Clinical Therapeutics 1284 (2007), https://pubmed.ncbi.nlm.nih.gov/18036390/ (noting that observational evidence is sometimes favored for both ethical and practical reasons). For example, despite their "low quality" technical category, observational studies have been used in forming the Cholesterol Guidelines of the American College of Cardiology and the American

Heart Association. Br. of Amici Curiae Hussein Abdul-Latif et al. at 6 (citing McNamara at 16). The same is true for a range of other treatments, from gall bladder surgery to the determination that aspirin is not appropriate to treat fevers in children. McNamara at 14, 16.

C. Off-Label Drug Use Is Legal, Common, and, When Medically Indicated, Safe and In Service of a Patient's Best Interest.

The State's proffered experts also emphasize that gender-affirming care involves off-label use of FDA-approved drugs. MSJ at 17; Van Meter Reb. Report ¶ 36; Dkt. 120-12, Expert Report of Stephen B. Levine ¶ 179; Laidlaw Report ¶ 78. But off-label use is "a widely employed practice," *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006), that is legal, accepted, and—when, as here, medically indicated—safe and in service of a patient's best interest.

An understanding of the FDA approval process makes clear why there is nothing inherently unsafe or inappropriate about off-label use. Garnering the FDA's approval of a drug requires showing that it is both safe—*i.e.*, the benefits outweigh the potential risks—and effective for its intended use. *See* U.S. Food & Drug Admin., *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective. It is well-established practice that once a drug has been approved by the FDA, health care providers may then prescribe it for other medically appropriate uses and in other

dosages. *See Taft*, 444 F.3d at 505; Dkt. 120-25, Expert Report of Dan H. Karasic ¶ 66. Such off-label use occurs because medical knowledge about how a drug might be beneficial in a different context or a different dosage continues to develop after FDA approval, but it is often too costly and impractical for drug makers to put each possible use of a drug through the FDA's "formal, lengthy, and expensive" approval process. Am. Cancer Soc'y, *Off-Label Drug Use* (2015), https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/off-label-drug-use.html (noting that off-label drug use is "well-documented and very common in" oncology, "pediatrics and HIV/AIDS care"). In addition, providers often prefer that drug makers *not* seek approval for every off-label use, given that it could increase the cost of the drug and limit the scope of its clinical application, all of which would make it less available to their patients. *See* Cong. Rsch. Serv., *Off-Label Use of Prescription Drugs* 4 (2021), https://sgp.fas.org/crs/misc/R45792.pdf.

Off-label use is legal because FDA approval limits only how a drug can be marketed—*i.e.*, a drug cannot be marketed for a use different from its FDA-approved use—but not how or why a physician can prescribe it. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 351 & n.5 (2001); John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, & Cosmetic Act*, 55(2) Food & Drug L.J. 251, 251-52 (2000) (discussing off-label use and noting that "regulatory efforts are directed

primarily at device marketing by manufacturers, not device use by physicians"). In fact, multiple federal and state laws have been enacted in recent years to promote and protect off-label prescriptions. *See, e.g.*, Okla. Rev. Stat. § 63-1-2604 (prohibiting health insurers from excluding coverage of off-label cancer treatments); Am. Soc'y of Clinical Oncology, *Recent Developments in Medicare Coverage of Off-Label Cancer Therapies*, 5(1) J. Oncology Prac. 18 (2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2790627/ (discussing 1993 legislation requiring Medicare to cover off-label uses of anti-cancer drugs and an expansion of Medicare's off-label coverage in 2008).

Off-label use also is common and "generally accepted." *Buckman*, 531 U.S. at 351; Christopher M. Wittich et al., *Ten common questions (and their answers) about off-label drug use*, 87(10) Mayo Clinic Proc. 982 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/ (discussing off-label drug uses that have "become widely entrenched in clinical practice and become predominant treatments for a given clinical condition" and citing studies showing that in a group of commonly used medications, 21% of prescriptions were for off-label use). For example, about half of drugs used to treat cancer are prescribed off label. *See* Am. Soc'y of Clinical Oncology, *Reimbursement for cancer treatment: Coverage of off-label drug indications*, 24(19) J. Clinical Oncology 3206 (2006), https://ascopubs.org/doi/10.1200/JCO.2006.06.8940. Prohibiting off-label

treatments would thus foreclose a significant amount of modern cancer care, causing immense harm. Off-label use is also especially common and important in treating minors, as they are often excluded from clinical drug studies, including for ethical reasons. *See* Wittich (citing a study finding that nearly 80% of children discharged from pediatric hospitals were taking at least one off-label medication and discussing a range of widely practiced off-label drug uses in pediatric population); H. Christine Allen et al., *Off-Label Medication Use in Children, More Common Than We Think: A Systematic Review of the Literature*, 111(8) J. Okla. State Med. Assoc. 776 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6677268 (surveying ten years of literature and finding that "[t]he use of off-label medications in children remains a common practice for pediatric providers").

Finally, and importantly, off-label use is often essential for delivering the best care. James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53(1) Food & Drug L.J. 71, 72 (1998), https://pubmed.ncbi.nlm.nih.gov/11795338/ ("Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize."); William Janssen, *A Historical Perspective on Off-Label Medicine: From Regulation, Promotion, and the First Amendment to the Next Frontiers*, SSRN Elec. J. 1 (2014), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2519223 (explaining that in

some circumstances, "a physician's *failure* to prescribe the medical product for such an unapproved use can constitute medical malpractice"). Thus, and contrary to the State's ill-informed argument, off-label use is legal, common, and often essential for delivering medically necessary care.

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In sum, none of the State's proclaimed "justifications" for the Challenged Exclusion hold up to scrutiny. Contrary to the State's claims, the Challenged Exclusion does not prohibit treatment that is "experimental." The State's arguments are based on a fundamental misunderstanding of both how scientific knowledge is generated and the FDA approval process. Treatment methods do not require a randomized control trial, observational studies of a specific length, exclusively "high quality" evidence, or on-label use to be safe and effective. The State's contrary position, if accepted, would undermine a significant portion of modern medical practice, including almost all forms of pediatric health care, much of adult health care, and a significant portion of cancer care, and would inflict unjustifiable harm on transgender Medicaid beneficiaries.

II. THE CHALLENGED EXCLUSION CONTRAVENES KEY TENETS OF BIOMEDICAL ETHICS.

Although the State attempts to justify the Challenged Exclusion by reference to concerns about the health, safety, and welfare of its citizens, the Challenged Exclusion is directly at odds with key tenets of biomedical ethics: respect for

autonomy, beneficence, and justice. Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 13 (8th ed. 2019) ("Beauchamp & Childress"). These universal principles are the cornerstones of modern-day health care standards and guide providers' treatment decisions regardless of the type of medical care they are providing—including care for gender dysphoria.

A. The Challenged Exclusion Forces Providers to Disregard Patients' Autonomy.

Florida law repeatedly recognizes the importance of obtaining informed consent and respecting patient decision making, reflecting the core biomedical ethical principle of respect for autonomy. That principle requires that patients have the ability to decide whether to receive appropriate medical care within the framework of informed consent. Beauchamp & Childress at 105. For example, Florida has rendered the failure to adequately obtain informed consent tortious and has created a standard jury instruction on how to evaluate the negligent failure to obtain informed consent. Fla. Stat. § 766.103 (discussing medical malpractice claim involving lack of informed consent); Fla. Standard Jury Instruction No. 402.7. Florida also has enacted a "Right to Try" law, which allows a terminally ill patient, in consultation with their physician, to give "informed consent" to use non-FDA

approved drugs and medical products in order to treat their illness. Fla. Stat. § 499.0295.[5]

In stark contrast to these manifold laws reflecting the core principle of autonomy, the Challenged Exclusion attacks autonomy by preventing Medicaid beneficiaries from pursuing, and health care professionals from providing, beneficial medical treatment with due regard for a patient's interests.

Empowering a patient's autonomy is essential to the integrity of the provider-patient relationship, as well as the patient's individual liberty and ability to determine the course of their life. In keeping with that bioethical principle, "the physician's professional role [is] to make recommendations on the basis of the best available medical evidence and to pursue options that comport with the patient's unique health needs, values, and preferences." Lois Snyder Sulmasy & Thomas A. Bledsoe, *American College of Physicians Ethics Manual* ("Ethics Manual"), 170 Annals of Internal Med. S16 (7th ed. 2019), https://www.acpjournals.org/doi/10.7326/m18-2160; *see also* Beauchamp & Childress at 105 (respect for autonomy requires health care professionals "to disclose information, to probe for and ensure understanding and voluntariness, and to foster adequate decision making"). Informed consent is a crucial mechanism for

[5] Florida's "Right to Try" law also undermines the State's argument that off-label usage is problematic and therefore a sufficient justification to prohibit care. *See supra* Section I(C).

ensuring respect for autonomy. In all non-emergency encounters, the provider is obligated to offer the patient material information and guidance, but the patient must be trusted and empowered to make the informed and voluntary decision that best advances their interests. *See, e.g.*, Parth Shah et al., *Informed Consent*, StatPearls [Internet] (2022), https://www.ncbi.nlm.nih.gov/books/NBK430827/; *Cobbs v. Grant*, 8 Cal. 3d 229, 242-43 (1972) (noting that "it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie" and holding that "as an integral part of the physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each"). After the patient makes their decision, the provider's duty is to "protect and foster [the] patient's free, uncoerced choices." *Ethics Manual* at S1.

Where the patients at issue are minors, the informed consent process usually involves the provider, the minor patient, and the minor's parents. When that is so, each actor has an important role to play: the provider offers medical instruction, the parents provide stewardship and consent, and the minor—assisted by that medical instruction and parental stewardship—provides assent. *See* Am. Med. Ass'n ("AMA"), Code of Medical Ethics Opinion 2.2.1, *Pediatric Decision Making*, https://www.ama-assn.org/delivering-care/ethics/pediatric-decision-making

(discussing the importance of "[r]espect and shared decision making" between parents and minors "in the context of decisions for minors"); Beth A. Clark, *Ethics in Child & Youth Care Practice with Transgender Youth*, 8 Int'l J. of Child, Youth & Fam. Studies 74 (2017), http://dx.doi.org/10.18357/ijcyfs82201716754 (discussing relational ethics).

The process of informed consent involves five core elements: 1) patient competence, 2) disclosure, 3) comprehension, 4) voluntariness, and 5) consent. Beauchamp & Childress at 122. As to the first element, parents generally have competence to participate in the informed consent process on behalf of their minor children, and many adolescent patients also have the competence to participate in the informed consent process, including in the context of gender-affirming care. *See* Jessica Kremen et al., *Addressing Legislation That Restrict Access to Care for Transgender Youth*, 147(5) Pediatrics 3 (2021), https://pubmed.ncbi.nlm.nih.gov/33883246/ (finding minor patients who are transgender "possess decisional capacity, and with guardian consent and the support of a multidisciplinary team, [] are able to contribute to decisions in their own best interests about [Gonadotropin Releasing Hormones] and gender-affirming hormones"); Beth A. Clark & Alice Virani, *This Wasn't a Split-Second Decision: An Empirical Ethical Analysis of Transgender Youth Capacity, Rights, and Authority to Consent to Hormone Therapy*, 18(1) J. Bioethical Inquiry 151 (2021),

https://pubmed.ncbi.nlm.nih.gov/33502682/ (concluding, based on qualitative empirical analysis, that "trans[gender] youth demonstrated the understandings and abilities characteristic of the capacity to consent to hormone therapy and that they did consent to hormone therapy with positive outcomes"); Richard E. Redding, *Children's Competence to Provide Informed Consent for Mental Health Treatment*, 50(2) Wash. & Lee L. Rev. 695, 707 (1993), https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1759&context=wlulr ("Research . . . indicates that children often are capable of making important life decisions in a rational manner, including decisions about medical and psychological treatment.").

Once competence has been established, the elements of disclosure and comprehension require the provider to accurately and sensitively present relevant information about any diagnosis; the nature and purpose of recommended interventions; the burdens, risks, and expected benefits of all options, including forgoing treatment; and any limitations to the medical community's knowledge regarding burdens, risks, and expected benefits. AMA, Code of Medical Ethics Opinion 2.1.1, *Informed Consent* ("AMA *Informed Consent*"), https://www.ama-assn.org/delivering-care/ethics/informed-consent; Aníbal Torres Bernal & Deborah Coolhart, *Treatment and Ethical Considerations with Transgender Children and Youth in Family Therapy*, 23(4) J. of Fam. Psychotherapy 287, 296 (2012),

http://dx.doi.org/10.1080/08975353.2012.735594.

For the fourth element, voluntariness, the provider must then assess the patient's (and, if not a mature minor, the parents') ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision. AMA *Informed Consent*. Fifth, and finally, the patient—and, where the patient is a minor, usually the parents as well—decides how to proceed.

The State's proffered expert, Dr. Michael Laidlaw, lacks a foundational understanding of pediatric care, which is evident in his opinion that informed consent is not possible for minors. Dr. Laidlaw argues that the lack of evidence as to the benefits and risks of harm of gender affirming care prevents their "true informed consent." Laidlaw Report ¶ 181. From the perspective of biomedical ethics, a decision should be fully respected if it is made by a patient or patient and a parent/guardian, aligns with a provider's recommendation, and is discerned through a process of informed consent. Indeed, medical professionals, parents, and adolescents are regularly entrusted to together decide the best course of treatment, including when the treatment has significant risks or permanent consequences. Pediatric chemotherapy or radiation, for example, are subject to principles of informed consent, despite the potential lasting effects on growth development and reproductive capabilities. *See, e.g.*, Am. Cancer Soc'y, *Late Effects of Childhood*

Cancer Treatment (2017), https://www.cancer.org/treatment/children-and-cancer/when-your-child-has-cancer/late-effects-of-cancer-treatment.html. Pediatric breast reduction performed to address excess breast tissue, back pain, or social anxiety; pediatric rhinoplasty; and orthopedic surgery on minors following sports injuries likewise can have enduring impacts. There is nothing unique about gender-affirming care that demands a different scheme than allowing care when the provider, patient, and if the patient is a minor, parents all agree about the best course of action.

By prohibiting health care providers from offering medically necessary and appropriate treatment to economically disadvantaged patients with gender dysphoria and denying patients the ability to access such care when they have given informed consent, the Challenged Exclusion disrespects autonomy and undermines the provider-patient relationship.

B. The Challenged Exclusion Forces Providers to Violate Their Duty of Beneficence.

The provider's duty to act in the best interest of the patient is called beneficence, and is best understood as "a group of norms pertaining to relieving, lessening, or preventing harm and providing benefits and balancing benefits against risks and costs." Beauchamp & Childress at 13; *see also id.* at 217 ("[M]orality requires that we treat persons autonomously and refrain from harming them, but

morality also requires that we contribute to their welfare.").[6] Medical professionals all over the world take oaths and are held to duties that encompass beneficence. For example, the World Medical Association's "Modern Hippocratic Oath" requires physicians to attest upon admission to the medical profession that the "health of [their] patient[s] will be [their] first consideration." World Medical Association, *Declaration of Geneva* (1948), https://www.wma.net/policies-post/wma-declaration-of-geneva/. Likewise, the United Kingdom's General Medical Council requires physicians to "make the care of your patient your first concern." *Good medical practice: Duties of a doctor registered with the General Medical Council*, Gen. Med. Council (2001), https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/duties-of-a-doctor. And the American Medical Association recognizes that "[t]he practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering." AMA, Code of Medical Ethics Opinion 1.1.1, *Patient-Physician Relationships*, https://code-medical-ethics.ama-assn.org/ethics-opinions/patient-physician-relationships.

[6] A related principle, nonmaleficence, concerns avoiding the causation of harm. Nonmaleficence thus prohibits action while beneficence requires it. The Challenged Exclusion contravenes both principles.

Medicaid embodies the principal of beneficence by ensuring the welfare of economically disadvantaged individuals. The program provides individuals with increased access to and better quality of health care. The government thus prevents harm by providing patients with safe and beneficial health care. Conversely, the denial of such care results in serious harm to individuals and negatively impacts the health, safety, and well-being of a community.

Applying the principle of beneficence to the treatment of Medicaid beneficiaries with gender dysphoria is straightforward. When untreated, gender dysphoria has serious mental and physical consequences, including anxiety, depression, self-harm, and suicidality. *See, e.g.*, Norman P. Spack et al., *Children and adolescents with gender identity disorder referred to a pediatric medical center*, 129(3) Pediatrics 418 (2012), https://pubmed.ncbi.nlm.nih.gov/22351896; Kristina R. Olson et al., *Mental health of transgender children who are supported in their identities*, 137(3) Pediatrics 1 (2016), https://publications.aap.org/pediatrics/article-abstract/137/3/e20153223/81409/Mental-Health-of-Transgender-Children-Who-Are; Nicolle K. Strand & Nora L. Jones, *Invisibility of "Gender Dysphoria*", 23(7) AMA J. of Ethics 557 (2021) ("Strand"), https://journalofethics.ama-assn.org/article/invisibility-gender-dysphoria/2021-07. By contrast, evidence from both research and clinical experience makes clear that gender-affirming care

improves patients' health and alleviates their suffering. *See, e.g.*, *Brandt*, 47 F.4th at 671; *Brandt v. Rutledge*, 551 F. Supp. 3d 882, 891 (E.D. Ark. 2021); Kraschel at 4.

In order to practice beneficence, practitioners must act for the benefit of the patient and promote their welfare. This is not possible when the State denies Medicaid coverage to transgender beneficiaries. The Challenged Exclusion prohibits providers from administering care that would relieve their patient's suffering.

Withholding care for gender dysphoria as the Challenged Exclusion requires thus can result in serious harm to patients, contrary to the core principle of beneficence.

C. The Challenged Exclusion Forces Providers to Violate Their Duty of Justice.

A third core principle of bioethics—justice—requires providers to acknowledge inequalities in the delivery of medical care and to work toward fair, equitable, and appropriate treatment for all. Beauchamp & Childress at 267–68; Clark, *Ethics in Child & Youth Care Practice with Transgender Youth* at 79; Strand at 559.

The Challenged Exclusion undermines this ethical duty of providers by barring transgender Medicaid beneficiaries from receiving gender-affirming care. Specifically, the Challenged Exclusion denies care to a certain class of economically disadvantaged patients based on their identity as transgender: coverage for care is

banned only if it is for treatment of gender dysphoria, which is care that only transgender individuals seek.

Moreover, by limiting access to care for only Medicaid beneficiaries, the Challenged Exclusion requires providers to differentiate between their economically disadvantaged transgender patients and all other patients seeking the same care. The Challenged Exclusion thus imposes medical strain and financial costs on only those patients who rely on Medicaid. For example, as Plaintiffs have explained, the Challenged Exclusion, if allowed to go into effect, will force them to consider moving out of state or to endure the negative health effects from stopping hormone therapy and to fear for their ability to survive without treatment. *See* Dkt. 1 ("Compl.") ¶¶ 213, 248. These costs are on top of the many socioeconomic and geographic barriers to gender-affirming care that transgender individuals often already face. *See, e.g.*, Phillip E. Wagner et al., *Health (Trans)gressions: Identity and Stigma Management in Trans* Healthcare Support Seeking*, 39.1 Women & Language 49, 56 (2016) (noting that "[t]he difficult decisions trans* individuals make in regard to their healthcare have been well documented" and include "[f]inancial barriers, insurance issues, and access to services"). The Challenged Exclusion exacerbates and reinforces these already significant challenges by preventing transgender Medicaid beneficiaries from accessing the gender-affirming health care they require.

Also, being denied coverage for gender-affirming care may lead transgender people to avoid seeking medical care altogether, or to choose between their health care, their food, their safety, or their housing. Compl. ¶¶ 145, 148, 150, 152, 243-244; *see also* Kraschel at 5 (noting potential of legislative restrictions on gender-affirming care to disproportionally affect marginalized communities). Avoiding or delaying care leads "to poorer physical and mental health outcomes." Luisa Kcomt et al., *Healthcare avoidance due to anticipated discrimination among transgender*, 11–(100608) SSM - Population Health 1 (2020), https://www.sciencedirect.com/science/article/pii/S2352827320302457.

As a matter of biomedical ethics and its core principle of justice, medical practitioners must not cause patients to fear seeking care, nor deny them care that, by definition, only people who are transgender need. The Challenged Exclusion, however, forces health care providers to violate this principle by mandating discrimination against a vulnerable, economically disadvantaged, and stigmatized population. By prohibiting transgender Medicaid beneficiaries from accessing treatment for gender dysphoria simply because they are transgender and economically disadvantaged, the Challenged Exclusion deprives them of their autonomy and signals that they are not worthy of beneficence. Without autonomy and beneficence, only injustice can occur.

* * *

The State claims the Challenged Exclusion advances the health, safety, and well-being of its citizens, MSJ at 31, but it does not. It is doing the opposite. The Challenged Exclusion is unsupported by biomedical ethics or any of its core principles; to the contrary, it commands their violation, for no legitimate purpose, resulting in physical and emotional suffering.

CONCLUSION

Unwarranted restrictions on the provision of health care by the State are unethical and detrimental to public health. The Challenged Exclusion contravenes multiple, fundamental principles of biomedical ethics and requires providers to harm their transgender patients who are Medicaid beneficiaries. Were the State permitted to enforce the Challenged Exclusion, it would open the door to unprecedented State intrusion into medicine and patient rights. This Court should grant the relief sought by Plaintiffs and deny Defendants' Motion for Summary Judgment.

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Respectfully submitted,

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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 curiae* conferred with counsel for the parties on April 19, 2023. Plaintiffs and Defendants consent to the filing of *amici*'s brief.

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