

Nos. 23-5600, 23-5609

**IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH
CIRCUIT**

L.W., ET AL., PLAINTIFFS-APPELLEES,

v.

JONATHAN THOMAS SKRMETTI, ET AL., DEFENDANTS-APPELLANTS,
UNITED STATES OF AMERICA, INTERVENOR-APPELLEE.

APPEAL FROM THE U.S. DISTRICT COURT FOR THE MIDDLE DISTRICT
OF TENNESSEE, NO. 23-CV-376, HON. ELI J. RICHARDSON, PRESIDING

JANE DOE 1, ET AL., PLAINTIFFS-APPELLEES,

v.

WILLIAM C. THORNBURY, JR., ET AL., DEFENDANTS,
COMMONWEALTH OF KENTUCKY EX REL. ATTORNEY GENERAL
DANIEL CAMERON, INTERVENOR-APPELLANT.

APPEAL FROM THE U.S. DISTRICT COURT FOR THE WESTERN
DISTRICT OF KENTUCKY, NO. 23-CV-230, HON. DAVID J. HALE,
PRESIDING

**BRIEF OF *AMICI CURIAE* BIOMEDICAL ETHICS AND PUBLIC
HEALTH SCHOLARS IN SUPPORT OF PLAINTIFFS-APPELLEES**

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STATEMENT OF INTEREST¹

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. Vevarina et al., *Issues in biomedical ethics*, 39 *Disease-a-Month* 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 Tennessee Senate Bill 1 and Kentucky Senate Bill 150 are inconsistent with foundational principles of biomedical ethics.

INTRODUCTION

Tennessee Senate Bill 1 (“SB 1”), Tenn. Code Ann. § 68-33-101 and Kentucky Senate Bill 150 (“SB 150”), Ky. Rev. Stat. § 311.372 (collectively, the “Health Care Bans” or “Bans”) are extreme and unjustified intrusions into the medical profession. The laws categorically prohibit health care professionals from providing gender-affirming care to their transgender minor patients with gender dysphoria, even when the patient, the patient’s parent(s), and the patient’s medical

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. All parties on appeal in Nos. 23-5600 and 23-5609 consented to this brief.

providers all agree that the care is medically appropriate and in the patient's best interest. Although allegedly promoting medical ethics, the Health Care Bans in fact contravene fundamental and well-established principles of biomedical ethics and reflect a misunderstanding of how medical knowledge is generated. If allowed to take effect, the Bans will create serious, harmful consequences for individual patients and public health more generally.

Core principles of biomedical ethics include respect for autonomy, beneficence, and justice. The Health Care Bans eviscerate each of these principles. The Bans deprive minor patients of their ability to decide whether to receive medically necessary and appropriate treatment to which they and their parents have given informed consent (autonomy). The Bans 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 the Bans compel providers to deny care that only patients who are transgender need, thereby exacerbating stigma and inequity and damaging trust in the medical profession (justice).

Tennessee and Kentucky endeavor to rationalize these harms by suggesting that gender-affirming care is unsound or experimental, including by reference to arguments about randomized control trials and off-label use of prescription drugs. That position is unfounded and badly misunderstands how medical knowledge is credibly generated, particularly in the context of pediatric care. 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. And off-label use is legal, commonplace, and often necessary to serve a patient’s best interest. Far from being “experimental,” the gender-affirming care prohibited by the Health Care Bans was developed through rigorous and appropriate methods and is recommended by every major medical association in the United States.

In sum, by singling out and banning gender-affirming care for transgender minors, the Health Care Bans undermine biomedical ethics, science, and public health, without any regard for the grave harm that will come from denying vulnerable patients critical health care. This Court should affirm the preliminary injunctions granted below.

I. THE HEALTH CARE BANS REFLECT A FUNDAMENTAL MISUNDERSTANDING OF HOW SCIENTIFIC KNOWLEDGE AND MEDICAL STANDARDS ARE GENERATED.

The gender-affirming care prohibited by the Health Care Bans was developed through rigorous and appropriate methods and is recommended by every major medical association in the United States. *See* Jason Rafferty, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, *Am. Acad. of Pediatrics* 5–18 (2018), <https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for>; Br. of Am. Pediatric Ass’n et al. as *Amici*

Curiae Supporting Plaintiffs at 8-22, *Brandt v. Rutledge*, No. 21-2875 (8th Cir. Jan. 19, 2022) (“APA Br.”); *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.”). Nonetheless, Tennessee and Kentucky often wrongly characterize gender-affirming care as “experimental” and not evidence-based, pointing in support of that erroneous view to the lack of randomized control trials on hormone therapy and the fact that using puberty blockers and hormone therapy for gender-affirming care is not approved by the U.S. Food and Drug Administration. (*L. W., et al v. Jonathan Skrmetti, et al.*, Def.-Appellants’ Br. (“TN OB”) 11, 13, 26-28; *Jane Doe 1, et al v. William Thornbury, Jr., et al.*, Def.-Appellants’ Merit Br. 32.) These arguments reflect a fundamental misunderstanding of medical practice and the ways medical knowledge and treatment guidelines are generated, particularly in the context of pediatric care. Medical providers are not and have never been restricted to providing only those treatments that have been generated via randomized control trial and received FDA approval for the particular indication. Indeed, as explained herein, such restrictions would be impractical and unethical.

A. The Medical Care Targeted by the Health Care Bans Is Not “Experimental.”

Although Tennessee and Kentucky seek to justify their bans on gender-

affirming care for minors as preventing “experimental” treatment wrongly conflate clinical care with clinical research and fail to engage with the ethical standards attendant to each.

Medical care delivered by a clinician to a patient and clinical research have distinct purposes and processes. *See, e.g.,* Nat’l Comm’n for the Protection of Hum. Subjects of Biomedical Rsch., *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1978) (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 the provider is duty bound to act in that patient’s best interest. By contrast, the aim of a research study is to generate knowledge useful for *future* patients. *See* José A. Sacristán, *Clinical Research and Medical Care: Towards Effective and Complete Integration*, 15 BMC Med. Res. Methodol. (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4323129/>. A research study’s protocols must be ethically designed and administered, but there is no obligation to do what is in each participant’s best interest. Importantly, receiving gender-

affirming care does not automatically render a patient a subject of a research study (and certainly not an “experimental” one unmoored from ethical standards); gender-affirming care is known to advance the individual patient’s best interest and is provided as clinical care for that purpose.

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, opponents of gender-affirming care often misunderstand how medical knowledge is credibly and rigorously generated in suggesting that the lack of randomized control trials 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.

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 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 211–217 (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 J. Sex Med. 3002–3011 (2014), [https://www.jsm.jsexmed.org/article/S1743-6095\(15\)30626-3/fulltext](https://www.jsm.jsexmed.org/article/S1743-6095(15)30626-3/fulltext).

Study methods other than randomized control trials may be preferable in some circumstances, given that randomized control trials 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 PLoS One (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 and

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[0641-x](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* (2015),

<https://doi.org/10.1186/s13063-015-0918-4>. Randomized control trials also are only

ethical 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 *N. Engl. J. Med.* 141–145 (1987),

<https://www.nejm.org/doi/full/10.1056/NEJM198707163170304>. That is 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. See Rafferty at 10.

Likewise, any critique of the lack of “long-term studies” on the safety and efficacy of gender-affirming care, particularly for minors, is misplaced, as there are

many such studies.² And in any event, longitudinal studies need not last for some unspecified “long-term” period to be reliable, nor are such studies always the most ethically and legally appropriate. Often, other reliable and trustworthy methods are preferable. 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>.

Additionally, any argument that the Health Care Bans are justified because gender-affirming care for minors is supported only by “low-quality” evidence, is based on an erroneous understanding of what it means for evidence to be graded as “low-quality.” Generally, the level of quality ascribed to evidence is based on the type of research methodology used—evidence generated via a randomized control

² *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.”).

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”); 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 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 with gender-affirming care, 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 Meredith 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. *See* 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. *See id.* 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 Health Care Bans also cannot be justified because gender-affirming care involves off-label use of FDA-approved drugs. (TN OB11, 13, 26-28.) 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 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 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. 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* (Mar. 17, 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 (Feb. 23, 2021),

<https://sgp.fas.org/crs/misc/R45792.pdf>.

Thus, off-label use is legal, common, and often essential for delivering medically necessary care.

Off-label use is legal because FDA approval only limits 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 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 Food & Drug L.J. 251–252 (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 laws in recent years to promote and protect off-label prescriptions, as has the federal government. *See, e.g.*, Tenn. Code Ann. § 53-10-113 (2021) (permitting pharmaceutical manufacturers and representatives to engage in “truthful promotion” of off-label treatment); KY RS SB 150 (2020) (protecting healthcare workers against civil liability for administering off-label prescriptions to treat COVID-19); Am. Soc’y of Clinical Oncology, *Recent Developments in Medicare Coverage of Off-Label Cancer Therapies*, 5 J. Oncology Practice 18–20 (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 *Mayo Clinic Proc.* 982–990 (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 *J. Clinical Oncology* 3206–3208 (2006), <https://ascopubs.org/doi/10.1200/JCO.2006.06.8940>. Off-label use is especially common and important in treating minors, as they are often excluded from clinical drug studies, including for ethical reasons. *See* Wittich (citing study finding that nearly 80% of children discharged from pediatric hospitals were taking at least one off-label medication and discussing 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 *J. Okla. State Med. Assoc.* 776–783 (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 critically, 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 Food & Drug L.J. 71–104 (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. (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”).

In sum, the Health Care Bans do not prohibit treatment that is “experimental” or non-evidence based. Any arguments to the contrary 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 or on-label use to be safe and effective. Tennessee and Kentucky’s contrary position, if accepted, would undermine a significant portion of modern medical practice,

including almost all forms of pediatric health care and much of adult health care.

II. THE HEALTH CARE BANS CONTRAVENE KEY TENETS OF BIOMEDICAL ETHICS.

The Health Care Bans are 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). These universal principles, which are the cornerstones of modern-day healthcare standards, guide providers' treatment decisions regardless of the type of medical care they are providing, including care for gender dysphoria.

A. The Health Care Bans Force Providers to Disregard Patients' Autonomy.

As a general matter, the Bans repeatedly recognize 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, Tennessee and Kentucky have codified a definition of "informed consent"; have rendered the failure to adequately obtain informed consent tortious; and/or have created a statutory scheme governing how to evaluate such claims. *See, e.g.*, Tenn. Code Ann. § 29-26-118 (2021) (discussing burden of proof involving lack of informed consent); Ky. Rev. Stat. Ann. § 304.40-320 (2022) (defining "informed

consent”). Tennessee also has enacted a “Right to Try” law, which allows a terminally ill patient, with “a recommendation from [their] physician,” to “give[] written, informed consent” to use non-FDA approved drugs and medical products in order to treat their illness. Tenn. Code Ann. § 63-6-302 (2021); *see also* Ky. Rev. Stat. Ann. § 217.5404 (allowing the use of an “investigational drug, biological product, or device” where written consent is given).

In stark contrast to these laws reflecting the core principle of autonomy, the Health Care Bans attack autonomy by preventing individuals 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 (“ACP”) Ethics Manual* 170, *Annals of Internal Medicine* 86 (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 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 Parth Shah et al., *Informed Consent* (2021), <https://www.ncbi.nlm.nih.gov/books/NBK430827/>. After the patient makes their decision, the provider’s duty is to “protect and foster [the] patient’s free, uncoerced choices.” *ACP Ethics Manual* at 74.

Where, as here, 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 (which, for minors, also frequently includes their parents) 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 *Pediatric Perspectives* (2021), <https://pubmed.ncbi.nlm.nih.gov/33883246/> (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 *J. Bioethical Inquiry* 151–164 (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 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*, <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 J. of Fam. Psychotherapy 296, 287–303 (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.

From the perspective of biomedical ethics, a decision that is made jointly by a parent and child, aligns with a provider’s recommendation, and is discerned through a process of informed consent should be fully respected. 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* (Sept. 18, 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 parents all agree about the best course of action.³

³ The Health Care Bans expressly allow surgical inventions to be performed on minors with intersex conditions or for conditions outside of gender-affirming care, including infants too young to participate in the decision-making process, even though such procedures have irreversible, long-term consequences and raise serious

By prohibiting health care providers from offering medically necessary and appropriate treatment to adolescents with gender dysphoria and denying patients the ability to access such care when they and their parents have given informed consent, the Health Care Bans disrespect autonomy and undermines the provider-patient relationship.

B. The Health Care Bans Forces Providers to Violate Their Duty of Beneficence.

The 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.”).⁴ 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*

ethical concerns. *See* Ky. Rev. Stat. § 311.372 (2); Tenn. Code Ann. § 68-33-101(b)(1)(A); Human Rights Watch, “*I Want to Be Like Nature Made Me*”: *Medically Unnecessary Surgeries on Intersex Children in the US* (2017), https://www.hrw.org/sites/default/files/report_pdf/lgbtintersex0717_web_0.pdf.

⁴ A related principle, nonmaleficence, concerns avoiding the causation of harm. Nonmaleficence thus prohibits action while beneficence requires it. The Health Care Bans contravene both principles.

(1948). 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 70–78 (2001), <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice/duties-of-a-doctor>. And the AMA 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://www.ama-assn.org/system/files/code-of-medical-ethics-chapter-1.pdf>.

Applying the principle of beneficence to the treatment of a patient 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 *Pediatrics* (2012), <https://pubmed.ncbi.nlm.nih.gov/22351896>; Kristina R. Olson et al., *Mental health of transgender children who are supported in their identities*, *Pediatric Collections: LGBTQ+: Support and Care (Part 3: Caring for Transgender Children)* (2016) <https://publications.aap.org/pediatrics/articleabstract/137/3/e20153223/81409/Mental-Health-of-Transgender-Children-Who-Are>. By contrast, evidence from both

research and clinical experience makes clear that gender-affirming care improves patients' health and alleviates their suffering. *See* APA Br. at 19-21 (collecting evidence showing that gender-affirming care improves overall well-being; significantly lowers risk of depression, anxiety, and other negative mental health outcomes; and reduces rates of substance abuse and suicide attempts). Withholding care for gender dysphoria as the Health Care Bans require thus can result in serious harm to patients, contrary to the core principle of beneficence.

In order to practice beneficence, practitioners must act for the benefit of the patient and promote their welfare. The Bans disallow this, prohibiting providers from administering care that would relieve their patient's suffering.

C. The Health Care Bans Force 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. The Health Care Bans undermine this ethical duty of providers by creating a complete barrier to transgender adolescents receiving gender-affirming care.

The Health Care Bans deny care to minor patients based on their identity as transgender: care is banned only if it is for “gender transition procedures,” which is care that only transgender individuals seek. The Health Care Bans thus impose

medical strain and financial costs on only those patients. For example, as Plaintiffs-Appellees have explained, the Bans, 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 L. W., et al v. Jonathan Skrmetti, et al.*, Compl. at ¶¶ 102-103, 120-121, 132; *Jane Doe 1, et al v. William Thornbury, Jr., et al.*, Compl. at ¶¶ 51, 56, 62, 66, 70, 74, 77. These costs are on top of the many socioeconomic and geographic barriers to gender-affirming care that transgender youth often already face. *See Phillip E. Wagner et al.*, 39.1 *Health (Trans)gressions: Identity and Stigma Management in Trans* Healthcare Support Seeking* 51 (Oct. 2016) (noting “[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 Health Care Bans exacerbate and reinforce these already significant challenges by preventing transgender youth from accessing the gender-affirming healthcare 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. *L. W., et al v. Jonathan Skrmetti, et al.*, Compl. at ¶¶ 6, 119, 132; *see also* Kraschel at 5 (noting potential of legislative restrictions on gender-affirming care to disproportionately 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 Health Care Bans force health care providers to violate this principle by mandating discrimination against a vulnerable and stigmatized population.

* * *

The Health Care Bans are unsupported by biomedical ethics or any of its core principles. To the contrary, the Bans commands their violation, for no legitimate purpose, resulting in physical and emotional suffering.

CONCLUSION

The Health Care Bans are unwarranted restrictions on the provision of health care: they contravene multiple, fundamental principles of biomedical ethics and fail to rationally protect minors, instead mandating their harm. Permitting the Bans to take effect it would open the door to unprecedented state intrusion into medicine and patient rights. This Court should reject such a result and affirm the preliminary injunctions granted below.

Dated: August 10, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 10, 2023, this document was electronically filed with the clerk of the court for the U.S. Court of Appeals for the Sixth Circuit and served through CM/ECF upon all counsel of record in this case.

Dated: August 10, 2023

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CERTIFICATE OF COMPLIANCE

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Dated: August 10, 2023

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APPENDIX

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