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No. 23-0697

In the Supreme Court of Texas

THE STATE OF TEXAS, ET AL.,
APPELLANTS,

v.

LAZARO LOE, ET AL.,
APPELLEES,

APPEAL FROM THE 201ST JUDICIAL DISTRICT COURT, TRAVIS COUNTY

BRIEF OF *AMICI CURIAE* BIOMEDICAL ETHICS AND PUBLIC HEALTH SCHOLARS SUPPORTING APPELLEES

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STATEMENT OF INTEREST OF *AMICI CURIAE*[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 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 Act of May 17, 2023, 88th R.S., ch. 335, 2023 Tex. Sess. Law Serv. 733 ("Texas Senate Bill 14," the "Healthcare Ban," or the "Ban") is inconsistent with foundational principles of biomedical ethics.

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

INTRODUCTION

From flu shots to cancer treatments, medical providers regularly support patients (and their parents, when the patients are minors) in deciding whether a given medical treatment is necessary and appropriate for them, without any undue interference from the State.

Texas Senate Bill 14, upends that normal operation of medical practice for a specific, targeted group of patients: transgender minors seeking gender-affirming medical care for gender dysphoria. The Ban outlaws the normal course of medical decision-making for these individuals, under which a patient, their parents, and their medical providers carefully deliberate to make an informed, individualized decision about whether gender-affirming care is medically appropriate and in the best interest of the particular patient. The State imposed this sweeping Ban even though every major medical organization in the United States has concluded that gender-affirming care, including for minors, is not only safe and effective, but is the *only* evidence-based treatment for gender dysphoria.

Categorically barring patients from accessing evidence-based treatment is irreconcilable with foundational precepts of biomedical ethics, particularly where, as here, that treatment is the *only* evidence-based treatment available for a given medical need and the prohibition applies *only* to a group of patients singled out because of their identity.

As explained further below, core principles of biomedical ethics include respect for autonomy, beneficence, and justice. The Healthcare Ban deprives 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).

Texas tries to justify these harms by suggesting that gender-affirming care lacks a sound evidentiary base. That position is unfounded and badly misunderstands how medical knowledge is credibly generated. 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. The gender-affirming care prohibited by the Healthcare Ban has been developed through rigorous and appropriate methods and rests on a strong evidentiary basis.

In sum, the Healthcare Ban singles out and effectively bans gender-affirming care for 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 affirm the trial court's order.

ARGUMENT

I. GENDER-AFFIRMING CARE TO TREAT GENDER DYSPHORIA IS SUPPORTED BY A SUBSTANTIAL BODY OF EVIDENCE THAT DOES NOT JUSTIFY SINGLING IT OUT FOR DIFFERENTIAL TREATMENT.

The gender-affirming care prohibited by the Healthcare Ban was developed through rigorous and appropriate methods and is recommended by every major medical association in the United States. Kellan Baker, *The Future of Transgender Coverage*, 376 New Eng. J. Med. 19, 1801-04 (May 2017); 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); *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). Nonetheless, the State characterizes gender-affirming care as "experimental" and questionable treatment that has not been sufficiently vetted and is thus "unproven." *See* Appellants' Br. 32, 35. Likewise, the State's purported experts emphasize that using puberty blockers and hormone therapy to treat gender dysphoria lacks scientific support for safety and effectiveness and is not approved by the U.S. Food and Drug Administration ("FDA"), suggesting that the FDA's

silence on this particular use implies that the care is experimental or harmful. *Id.* at 12, 13.

These claims about gender affirming care are wrong. As the District Court found, the Ban "requires Texas medical providers . . . to disregard well-established, evidence-based clinical practice guidelines." 7CR 1253. The targeted medical care is supported by a strong evidentiary base, both in and of itself and compared to the evidentiary basis underlying many other forms of commonly provided care. The State's attempts to justify the Ban 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, for example. Indeed, as explained herein, such restrictions would be impractical and unethical. The medical care targeted by the Ban is based on appropriate, ethical study and medical knowledge—it is not "experimental."

To start, clinical care and clinical research are distinguishable, and there are different 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 for gender dysphoria does not automatically render a patient a subject of a research study (and certainly not a subject of experimentation unmoored from ethical standards); gender-affirming medical care has been known to advance individual patients' best interests and is provided as clinical care for that purpose. The use of the label "experimental" in this context is thus misleading.

Arguments misconceiving how medical knowledge is credibly and rigorously generated, among other things, wrongly suggest that the lack of randomized control trials means the care has not been appropriately vetted. *See, e.g.*, *Eknes-Tucker v. Governor of Alabama*, 80 F.4th 1205, 1217 (11th Cir. 2023) (citing witness emphasizing lack of randomized studies). Not so. There is no one method used to generate medical knowledge in all contexts, 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 are often dependent on the type of care, context, and state of development.

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.

Study methods other than randomized control trials and extended longitudinal studies may be preferable in some circumstances, given that these 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 Childbirth 207 (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 (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. For example, in acknowledging limitations to its analysis, a 2023 open-label randomized clinical trial assessing the effect on gender dysphoria, depression, and suicidality of testosterone therapy compared with no hormone treatment explained that the trial was limited to three months in order to insure that "participants would not be disadvantaged by waiting longer than standard of care waiting times of 3 months for an initial consultation." Brendan J. Nolan et al., *Early Access to Testosterone Therapy in Transgender and Gender-Diverse Adults Seeking Masculinization: A Randomized Clinical Trial*, JAMA Network Open (2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809058.

This principle plainly applies to the treatments for gender dysphoria subject to the Ban: performing randomized, placebo-controlled trials on the efficacy of that treatment would be unethical, because the prevailing view among the medical community based on the existing evidence is that for patients who need it, hormone therapy is superior to a lack of pharmacological treatment. *See id.*

Critiques of the lack of "long-term studies" regarding the safety and efficacy of gender-affirming care are also wrong. In reality, there are many long-term studies supporting the provision of gender-affirming care to treat gender dysphoria, including for minors.[2] Moreover, the underlying premise of this argument—that long-term studies are necessary to prove a treatment's efficacy and safety—is mistaken. 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.

[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), 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.").

An argument that the Health Care Ban is 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." Under the GRADE system, which is often used for presenting summaries of scientific evidence and making clinical practice recommendations, 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); 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 under GRADE thus are descriptive of the underlying method, but they do not necessarily reflect the reliability of the evidence generated. As noted, observational studies are 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* 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, 16 (2022). 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. And with gender-affirming medical care to treat gender dysphoria, 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" as that term is used in the GRADE system can still be reliable and valuable when it comes to clinical practice. *See* McNamara at 15.

"Low-quality" evidence may be and often is sufficient to justify a strong recommendation for clinical care under that same grading system. *See* 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."). Accordingly, the treatment for many other conditions, such as drugs for cancer and hematologic disorders, are widely recommended and used based on similarly "low-quality" evidence, without having been studied through randomized, controlled clinical trials. *See* Anthony J. Hatswell et al., *Regulatory approval of pharmaceuticals without a randomised*

controlled study: analysis of EMA and FDA approvals 1999-2014, BMJ Open (June 30, 2016), https://pubmed.ncbi.nlm.nih.gov/27363818/. Indeed, if the "low-quality" label were enough to render care suspect, 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).

Furthermore, and contrary to the claims of the State and its experts, a medication need not be approved by the FDA for a particular indication to be safe and effective for that indication. 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 indicated, safe and in service of a patient's best interest.[3] *See also Baker v. Smith & Nephew Richards, Inc.*, No. 95-58737, 1999 WL 811334, at *6 (Tex. Dist. Ct. June 7, 1999) ("'[O]ff-label use' is a common part of the practice of medicine").

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

[3] Indeed, the Texas Medical Board and Texas State Board of Pharmacy recently issued a joint statement expressly stating that "[d]rugs are permitted to be prescribed off-label." Texas Medical Board Press Release, https://www.tmb.state.tx.us/dl/3B3CDDE5-17CE-8B2A-8ACC-3ADDED968A01 (Sept. 3, 2021).

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 at their discretion without pharmaceutical companies first having to return to the FDA and seek approval for each indication. *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 id.*; Cong. Rsch. Serv.,

Off-Label Use of Prescription Drugs 4 (Feb. 23, 2021), https://sgp.fas.org/crs/misc/R45792.pdf.

Off-label use of medication is common and "generally accepted." *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 351 (2001); 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 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*, 531 U.S. at 351 & n.5 (explaining that "[o]ff-label usage . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"); 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, Texas has enacted laws to promote and protect off-label prescriptions, as has the federal government. *See, e.g.*, 22 Tex. Admin. Code § 222.4 (permitting nurses to prescribe medication "off-label"); 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 is especially common and important in treating minors. Minors 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").

Thus, off-label use is legal, common, and often essential for delivering medically necessary care. Any suggestion otherwise—including the Sixth Circuit's contention, embraced by the Eleventh Circuit, that off-label use signals that "the FDA is not prepared to put its credibility and testing protocols behind the [drug's] use," *L.W.*, 83 F.4th at 478; *see also Eknes-Tucker*, 80 F.4th at 1225 n.19—greatly misunderstands and misstates how the FDA works.

* * *

In sum, none of the State's proclaimed "justifications" for the Healthcare Ban

regarding the "experimental" nature of the medical care at the center of the Ban hold up to scrutiny. Rather, the State's arguments are based on a fundamental misunderstanding of both how scientific knowledge is generated and the FDA approval process. Contrary to the State's claims, the Healthcare Ban does not prohibit treatment that is "experimental." Treatment methods also 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. Indeed, were the State's erroneous arguments an acceptable basis for excluding medical care coverage, a significant portion of modern medical practice could be excluded from coverage, 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 minors who are transgender.

II. THE HEALTHCARE BAN CONTRAVENES KEY TENETS OF BIOMEDICAL ETHICS.

The Healthcare Ban eliminates a patient's ability to make a decision, together with their medical providers and parents (where patient is a minor), about whether accessing a safe and effective form of treatment is in their best interest. As a result, the Ban 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). 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, and can provide "meaningful guidance" to courts assessing wholesale bans on and/or exclusions of coverage for care. *Contra L.W.*, 83 F.4th at 478. To be clear, *amici* do not invoke these principles to suggest that they provide the legal test pursuant to which judges should "assess the validity of [the Ban]." *Id*. Rather, *amici* discuss how the Ban compromises these principles rather than protecting them. *Amici* have a strong interest in ensuring that courts and policymakers alike have an accurate understanding of bioethics, and the discussion that follows accordingly explains why the Ban is irreconcilable with bioethical principles and therefore why any asserted interest in advancing bioethics should not be credited.

A. The Healthcare Ban Forces Providers to Disregard Patients' Autonomy.

As a general matter, Texas 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, the State has codified a definition of "informed consent"; has rendered the failure to adequately obtain informed consent tortious; and has created a statutory scheme governing how to evaluate such claims. *See, e.g.*, *Binur v. Jacobo*, 135 S.W.3d 646, 653–54 (Tex. 2004) (discussing cause of action involving lack of

informed consent); 22 Tex. Admin. Code § 465.11 (discussing informed consent in psychological treatment). Texas also has enacted a "Right to Try" law, which allows a terminally ill patient, "in consultation" with "the patient's physician" to give "written informed consent" (or, if a minor, the consent by the legal guardian) to use non-FDA approved drugs and medical products in order to treat their illness. Tex. Health & Safety Code §§ 489.051-055. In stark contrast to these laws reflecting the core principle of autonomy, the Health Care Ban attacks 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 Ethics Manual* 170, Annals of Internal Medicine 86 (7th ed. 2019) ("ACP *Ethics Manual*"), 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 include 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 by a patient (and, when a minor, jointly with a parent/guardian) through a process of informed consent and that aligns with a provider's recommendation should be fully respected. Indeed, medical professionals and patients are regularly entrusted to together decide the best course of treatment, including when the treatment has significant risks or permanent effects. 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 justifies denying coverage even though the provider, and the patient (and the patient's parents, when a minor) all agree about the best course of action.[4]

[4] The Health Care Ban expressly allows surgical inventions to be performed on minors with intersex conditions, including infants too young to participate in the decision-making process, even though such procedures have irreversible, long-term consequences and raise serious ethical concerns. *See* Tex. S.B. 14 § 161.703(a)(2); Human Rights Watch, *"I Want to Be Like Nature*

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

B. The Healthcare Ban 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.").[5] Medical professionals in the United States and around the world take oaths and are held to duties that encompass beneficence. 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). Likewise, the United Kingdom's General Medical Council requires physicians to "make the care of your patient your first concern." *Good medical*

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.

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

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 patients 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; App. 286 R. Doc. 283, at 55 (crediting testimony that denying gender-affirming care will cause patients to "needlessly suffer"). 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 care to transgender patients. The Healthcare Ban prohibits providers from administering care that would relieve their patient's suffering. Withholding care for gender dysphoria thus can result in serious harm to patients, contrary to the core principle of beneficence.

In sum, the principle of beneficence obligates providers to remove conditions that will cause harm to others. Beauchamp & Childress at 219. By mandating that providers deny care to their patients with gender dysphoria when the patient seeks that care and the provider deems it medically indicated, the Healthcare Ban forces providers to cause harm to their patients and, thus, to violate their core duty of beneficence.

C. The Healthcare Ban 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. The Healthcare Ban undermines this ethical duty of providers by barring transgender

individuals from receiving gender-affirming care. Specifically, The Health Care Ban denies 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 Ban thus imposes medical strain and financial costs on only those patients.

For example, the Ban, if allowed to go into effect, may force individuals who are transgender 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* App. 30 R. Doc. 1, at 3. These potential 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 Ban exacerbates and reinforces these already significant challenges by preventing transgender individuals 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. Appellees' Br. 12-13, 15; s*ee 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.

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

* * *

The Healthcare Ban is unsupported by biomedical ethics or any of its core principles. To the contrary, the Ban 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 Healthcare Ban contravenes multiple, fundamental principles of biomedical ethics and requires providers to harm their transgender patients. Were the State permitted to enforce the Healthcare Ban, it would open the door to unprecedented State intrusion into medicine and patient rights. This Court should reject such a result and affirm the trial court's ruling.

Dated: January 8, 2024

Respectfully submitted,

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