IN THE

United States Court of Appeals for the Fifth Circuit

BRAIDWOOD MANAGEMENT, INC., et al.,

Plaintiffs-Appellees/Cross-Appellants,

v.

XAVIER BECERRA, et al.,

Defendants-Appellants/Cross-Appellees.

On Appeal from the United States District Court for the Northern District of Texas

BRIEF FOR AMICI CURIAE THE AMERICAN HOSPITAL ASSOCIATION, FEDERATION OF AMERICAN HOSPITALS, THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, AMERICA'S ESSENTIAL HOSPITALS, AND ASSOCIATION OF AMERICAN MEDICAL COLLEGES IN SUPPORT OF DEFENDANTS-APPELLANTS

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SUPPLEMENTAL STATEMENT OF INTERESTED PARTIES

Pursuant to Fifth Circuit Rule 29.2, the undersigned counsel of record certifies that the following listed persons and entities, in addition to those already listed in the parties' briefs, have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Amici curiae on this brief:

- The American Hospital Association is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.
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- The Federation of American Hospitals is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

Counsel: Kathleen Tenoever

3. The Catholic Health Association of the United States is a non-profit, taxexempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

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 America's Essential Hospitals is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

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5. The Association of American Medical Colleges is a non-profit, taxexempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

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<u>/s/ Sean Marotta</u> Sean Marotta

May 4, 2023

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INTEREST OF AMICI CURIAE

The American Hospital Association, Federation of American Hospitals, The Catholic Health Association of the United States, America's Essential Hospitals, and the Association of American Medical Colleges respectfully submit this brief as *amici curiae*.¹

The American Hospital Association (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. AHA members are committed to improving the health of the communities they serve and to helping ensure that care is available to and affordable for all Americans.

The Federation of American Hospitals is the national representative of more than 1,000 tax-paying community hospitals and health systems throughout the United States. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members.

The Catholic Health Association (CHA) is the national leadership organization for the Catholic health ministry. CHA works to advance the ministry's commitment to a just, compassionate health care system that protects life and advocates for a health care system that is available and accessible to everyone, paying special attention to underserved populations.

¹ All parties have consented to the filing of this brief. We certify that this brief was not authored in whole or part by counsel for any of the parties and that no one other than *amici* and their counsel have contributed money for this brief.

America's Essential Hospitals is dedicated to equitable, high-quality care for all people, including those who face social and financial barriers to care. Consistent with this safety net mission, the association's more than 300 members provide a disproportionate share of the nation's uncompensated care, with threequarters of their patients uninsured or covered by Medicare or Medicaid.

The Association of American Medical Colleges is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members include all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; approximately 400 teaching hospitals and health systems; and more than 70 academic societies.

Preventive health care services are essential for the early diagnosis and treatment of life-threatening illnesses for millions of Americans. *Amici* write to offer guidance, from hospitals' perspectives, on the harmful impact that denying the Government's motion for a partial stay of final judgment pending appeal would have on the American health care system and all who depend on it.

ARGUMENT

The Affordable Care Act (ACA) guarantees access to certain high-quality, evidence-validated clinical preventive services without cost-sharing for over 150 million Americans. These services, which range from cancer screenings to mental-

health interventions, facilitate the early detection and treatment of potentially lifethreatening conditions and reduce health care costs for patients and the public. Congress eliminated out-of-pocket costs for these services because it determined that preventive services are essential for the wellbeing of society and a functioning health care system. The District Court's order unravels that congressional requirement.

A partial stay pending appeal is manifestly in the public interest. Evidencebased preventive-care services free from political influence are essential to patient wellbeing and population health and lead to lower health care costs over the long term. Upending coverage of preventive-care services will increase the risk that acute illnesses or chronic diseases will not be timely detected or treated. Regardless of what this Court decides on the merits, reinstating the ACA's preventive-care requirement down the road will not remedy the harms that Americans would suffer in the interim if a partial stay is not granted. After all, a post-judgment colonoscopy may be too late to save a patient from colorectal cancer that developed during the pendency of this appeal. A future statin will not prevent a heart attack that occurs while the parties are briefing. And a later mental-health screening does not protect a child who commits self-harm before this Court issues its final opinion. As it considers this appeal, the Court should

preserve the expert, nonpartisan medical judgment of the United States Preventive Services Task Force and keep the preventive-services requirement in place.

I. PREVENTIVE-CARE SERVICES SAVE LIVES, IMPROVE HEALTH, AND REDUCE HEALTH CARE COSTS.

The importance of the preventive health care services covered by the ACA cannot be overstated. Estimates show that an increased uptake of recommended preventive services could save over 100,000 additional lives every year. Jared B. Fox & Frederic E. Shaw, *Clinical Preventive Services Coverage and the Affordable Care Act*, 105 (1) Am. J. Pub. Health e7 (Jan. 2015), *available at* https://tinyurl.com/35cd7pry. Preventive services requiring coverage without costsharing under the ACA benefit patients by enabling early detection, management, and treatment of chronic diseases and acute conditions, which can extend and improve patients' lives. The ACA's covered preventive services also benefit the public as a whole by lowering costs for patients, providers, and insurers, leading to more affordable health care for all.

The District Court's decision impedes access to vital preventive services. Because of the District Court's order, millions of patients may suddenly have to pay out-of-pocket or be subject to cost-sharing for a variety of services, including screenings for lung cancer, statins to prevent heart disease, interventions for tobacco use in children and adolescents, screenings for adolescent drug use, interventions for perinatal depression, aspirin use to prevent preeclampsia,

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medications to lower the risk of breast cancer, and Hepatitis B and C screenings. See KFF, Preventive Services Tracker (Apr. 26, 2023), available at https://tinyurl.com/msz9rdky; Larry Levitt et al., Q&A: Implications of the Ruling on the ACA's Preventive Services Requirement (Apr. 4, 2023), available at https://tinyurl.com/28b2rahx.

The preventive health care services affected by the District Court's order are essential to increasing the longevity and quality of life for adults and children. Colorectal cancer screenings, for example, dramatically decrease the mortality rate associated with colorectal cancer, which is the third leading cause of cancer death for men and women. US Preventive Servs. Task Force, Screening for Colorectal Cancer, 325 (19) J. Am. Med. Ass'n 1965, 1966 (May 11, 2021); see also CDC, Colorectal Cancer Screening Tests (Feb. 23, 2023), available at https://tinyurl.com/fp24tjn5. According to estimates, each screening of 1,000 adults aged 45 to 75 years will save 286 to 337 life-years, avert 42 to 61 colorectal cancer cases, and prevent 24 to 28 colorectal cancer deaths each year. *Screening* for Colorectal Cancer, supra, at 1972. The Task Force in May 2021 recommended that colorectal cancer screening start at age 45 instead of 50, making approximately an additional 15 million Americans eligible to benefit from the preventive-care requirement. Off. of Assistant Sec'y for Plan. & Evaluation, Dep't of Health & Hum. Servs., Access to Preventive Services Without Cost-Sharing:

Evidence from the Affordable Care Act 8 (Jan. 2022), available at

https://tinyurl.com/43pcrwnd. If all 15 million received their recommended screenings, at least *360,000* unnecessary deaths would be avoided. The District Court's elimination of cost-free coverage of colorectal screenings for adults aged 45 to 49 will therefore have a substantial impact on patient health, as that age group has seen a 15% increase in colorectal cancer rates over the past two decades. *Screening for Colorectal Cancer, supra*, at 1972.

Children also will be negatively impacted by denying a partial stay pending appeal. In 2022, the Task Force recommended that children aged 8 to 18 years be screened for anxiety. US Preventive Servs. Task Force, *Screening for Anxiety in Children & Adolescents*, 328 (14) J. Am. Med. Ass'n 1438 (Oct. 11, 2022). Early intervention for anxiety helps to prevent panic disorder, certain phobias, and depression later in life. Zara Abrams, *Why The Benefits of Annual Anxiety and Depression Screenings for Kids and Teens Outweigh the Risks*, 54 (1) Monitor on Psych. 21 (Oct. 26, 2022), *available at* https://tinyurl.com/4dfwpbhf. Anxiety screenings in children have become even more important in recent years due to the COVID-19 pandemic's negative impact on children's mental health and the alarming 44% increase in suicidal thoughts and behaviors among youth. *Id*.

In addition to providing vital screenings, the ACA's preventive-care coverage requirement ensures access to life-saving medications. For example, the

ACA guarantees zero-cost access to pre-exposure prophylaxis (PrEP), a highly effective medication used to prevent HIV infection. When taken as prescribed, PrEP reduces the risk of getting HIV through intercourse by 99% and by 74% among people who inject drugs. CDC, *PrEP Effectiveness* (June 6, 2022), *available at* https://tinyurl.com/6fusx9cu. Without zero-cost-sharing access to PrEP, many at-risk populations—particularly Black and Hispanic adults—will face an increased chance of contracting HIV. *See* Laura Skopec & Jessica Banthin, *Free Preventive Services Improve Access to Care* 2 (July 2022), https://tinyurl.com/4zhj622t.

The ACA's preventive-care coverage requirement saves lives and improves population health, saving the public costs in the long term. Maintaining these benefits pending appeal is therefore in the public interest. *See, e.g., Chambless Enters., LLC v. Redfield*, 508 F. Supp. 3d 101, 123 (W.D. La. 2020) (noting that "[i]n balancing the equities and considering the public interest, courts properly decline to second-guess the judgments of public health officials").

II. PATIENTS ARE MUCH LESS LIKELY TO USE PREVENTIVE SERVICES IF THEY HAVE TO PAY.

Cost often drives whether a person will obtain health care. Numerous studies have shown that cost-sharing, even if the amount is relatively modest, deters patients from receiving the preventive services covered by the ACA. Shameek Rakshit et al., *How Does Cost Affect Access to Healthcare?* (Jan. 30,

2023), *available at* https://tinyurl.com/2jwtafb8. Prior to the ACA, patients often had to pay for preventive services up to their deductible amount, which is the limit that a patient must pay before health insurance will pay for the service.

Access to preventive care without cost-sharing removed these barriers. If they return, the risk that patients will skip necessary screenings because of cost is significant. For even insured patients, the average out-of-pocket cost of a critical screening, such as a colonoscopy, could exceed \$1,000 without the coverage requirement if the patient's deductible has not been met. Krutika Amin et al., *Preventive Services Use Among People With Private Insurance Coverage* (Mar. 20, 2023), *available at* https://tinyurl.com/4f3s446j. And the deterrence effect of deductibles on insured households is clear—recent studies show that half of American households cannot afford a typical plan's deductible. *See* Gregory Young et al., *How Many People Have Enough Money to Afford Private Insurance Cost Sharing?* (Mar. 10, 2022), *available at* https://tinyurl.com/42u77xd8.

Patients also are less likely to obtain life-saving medications when subject to cost-sharing. Without the preventive-care requirement in place, patients may have to pay hundreds or even thousands of dollars for medication. A newer and longer-lasting form of injectable PrEP medication, for instance, could cost patients \$400 to \$1,000 in co-pays each month. *See Q&A: Implications, supra*. Although the generic daily PrEP pill is cheaper, patients may still be dissuaded from paying for

the pills, as studies have shown that even a relatively small medical expense can lead to persistent debt. *See* Karen Pollitz et al., *Medical Debt Among People with Health Insurance* (Jan. 7, 2014), *available at* https://tinyurl.com/yamenmrz. And switching to a daily pill form of PrEP creates adherence problems for certain populations that a longer-term injection does not. A partial stay is warranted not just to ensure access to coverage, but also access to cost-sharing-free coverage.

III. PREVENTIVE-CARE RECOMMENDATIONS SHOULD BE BASED ON MEDICAL EVIDENCE, NOT POLITICAL CONSIDERATIONS.

A partial stay pending appeal is also in the public interest because the public benefits from receiving Task-Force recommended preventive services based on medical evidence, not political considerations. Established in 1984, the Task Force is a nongovernmental agency comprised of 16 independent clinicians who serve four-year terms. Barron H. Lerner & Graham Curtiss-Rowlands, *Evidence over Politics – The U.S. Preventive Services Task Force*, 388 N.E. J. Med. 1, 3 (Jan. 5, 2023). The neutral clinicians are generalists—rather than specialists who may have specific biases—and experts in prevention and evidence-based medicine. *See id*.

The ACA requires coverage of preventive-care services that are given an "A" or "B" recommendation by the Task Force. The Task Force determines the grade of a service by assessing its "effectiveness, appropriateness, and cost-effectiveness" based on "scientific evidence." *See* 42 U.S.C. § 299b-4(a)(1). To

ensure that patients receive proper, evidence-based care, the ACA provides that the Task Force should be "independent and, to the extent practicable, not subject to political pressure." *Id.* § 299b-4(a)(6).

Maintaining an independent Task Force serves the public's best interests. Medical practitioners have praised the Task Force's evidence-based recommendations as "an essential safeguard against ongoing threats to the scientific method." *Evidence over Politics, supra*, at 3. Before making a recommendation, the Task Force undertakes a rigorous assessment process that includes analyzing "high-quality evidence (such as data from meta-analyses and randomized, controlled trials)" as well as "studies that may be more prone to bias." *Id.* at 4. The Task Force's insulation from political pressures allows it to make recommendations based purely on evidence rather than non-medical factors that are not in the best interest of the patient.

Indeed, this is why Congress has long strived to insulate medical experts from political pressure. For example, when Congress enacted Medicare in 1965, it expressly prohibited the federal government from "exercis[ing] any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services." 42 U.S.C. § 1395; *see also id.* § 291m (prohibiting the government from exercising supervision or

control over the administration and operation of hospitals). This Court has recognized that these statutes represent Congress's endorsement of "medical selfgovernance" and that federal regulation "may not operate in such a way as to 'supervise or control' medical practice." *United States v. Harris Methodist Fort Worth*, 970 F.2d 94, 99, 101 (5th Cir. 1992).

By removing the Task Force's independence, the District Court opened the door for political considerations to influence medical decision-making. Without this protection, Task Force members may be subject to removal if their decisions ultimately do not conform with the direction of the current political winds. Because it is in the public interest to have medical recommendations made based on evidence and not political considerations, the Court should grant a partial stay pending appeal.

CONCLUSION

The Court should issue a partial stay of the District Court's judgment pending

appeal.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 4, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. I further certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

> <u>/s/ Sean Marotta</u> Sean Marotta

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 2,352 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

This brief also complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman font size 14.

<u>/s/ Sean Marotta</u> Sean Marotta