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:

- 1. 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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- 2. 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.

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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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4. 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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June 27, 2023

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42 U.S.C. § 1395	19
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KFF, Preventive Services Tracker (June 22, 2023), available at https://tinyurl.com/msz9rdky	9, 12
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Donna Moore et al.,  A Thematic Analysis of Stigma and Disclosure for Perinatal Depression on an Online Forum, 3 (2) J. Med. Internet Rsch., Mental Health (2016)	11

### **TABLE OF AUTHORITIES—Continued**

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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 (Jan. 2022), available at https://tinyurl.com/43pcrwnd
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Laura Skopec & Jessica Banthin,  Free Preventive Services Improve Access to Care (July 2022),  https://tinyurl.com/4zhj622t
US Preventive Servs. Task Force,  Interventions to Prevent Perinatal Depression, 321 (6) J. Am. Med. Ass'n 580, 584 (Feb. 12, 2019)
US Preventive Servs. Task Force,  Policy Manual § 9, Engagement With the Public,  Stakeholders, and Partners (July 2017)
US Preventive Servs. Task Force,  Screening for Anxiety in Children & Adolescents,  328 (14) J. Am. Med. Ass'n 1438 (Oct. 11, 2022)
US Preventive Servs. Task Force,  Screening for Colorectal Cancer,  325 (19) J. Am. Med. Ass'n 1965 (May 11, 2021)
US Preventive Servs. Task Force,  Standards for Guideline Development (May 2021),  available at https://tinyurl.com/5n77buap

### **TABLE OF AUTHORITIES—Continued**

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Gregory Young et al.,	
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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*.<sup>1</sup>

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. AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are considered in formulating health policy.

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 to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

The Catholic Health Association (CHA) is the national leadership organization for the Catholic health ministry. Comprised of more than 650

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<sup>&</sup>lt;sup>1</sup> 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.

hospitals and 1,600 long-term care and other health facilities in all fifty States, 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.

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 three-quarters of their patients uninsured or covered by Medicare or Medicaid. Essential Hospitals reach outside their walls to help communities overcome social drivers of poor health, including poverty, homelessness, and food insecurity.

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.

Amici's members are deeply affected by the Nation's health care laws, particularly the Affordable Care Act (ACA). That is why they have filed amicus

briefs in support of the law in the Supreme Court, the courts of appeals, and courts across the Nation. Preventive health care services, particularly those guaranteed to be covered by payers under the ACA, 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 upholding the District Court's decision would have on the American health care system and all who depend on it.<sup>2</sup>

#### **SUMMARY OF ARGUMENT**

For more than a decade, the ACA guaranteed that patients across the United States would have access to certain preventive-care services without out-of-pocket costs like co-insurance, deductibles, and co-payments. The District Court's judgment ends that guarantee. Patients who have relied on the ACA's promise of preventive care without out-of-pocket costs for a variety of lifesaving interventions and screenings may now need to pay for them out of pocket—a significant setback to pre-ACA norms. The District Court's decision prevents the Secretary from implementing the ACA's requirement that private health insurance plans cover the United States Preventive Services Task Force's recommendations for preventive services without cost-sharing, contrary to the ACA's text and Congress's intent. In

<sup>&</sup>lt;sup>2</sup> This brief addresses only the District Court's judgment on the Plaintiffs' Appointments Clause claim, which is the subject of the Government's appeal.

deciding that the Task Force's structure violates the Appointments Clause of the U.S. Constitution, the District Court undermined the Task Force's critical role and opened the door for patients to bear future costs of certain types of preventive-care services as they did before the ACA. This Court should reverse.

Preventive care services and early interventions are essential for improving the quality and longevity of life for millions of individuals. By requiring insurers to provide cost-free access to certain preventive-care services, the ACA facilitates the timely diagnosis and treatment of many physical and mental health conditions. Early detection of diseases often saves lives, improves patient health, and reduces patient suffering.

The District Court's order, which inhibits access without cost-sharing to certain preventive-care services, will have a profound, negative impact on patients across the country.

For instance, the District Court's order will adversely affect pregnant and postpartum women. Under the ACA and current recommendations of the Task Force, eligible women can receive free screenings for perinatal depression and other preventive services. Perinatal depression screenings are especially critical because the condition can harm the health of both the mother and child. And while up to 37% of women suffer from perinatal depression, many women are reluctant to be screened or seek treatment due to stigma or lack of awareness about the

disorder. Reinstating pre-ACA financial barriers on top of these other barriers will compound the risk that pregnant and postpartum women will not receive necessary preventive care.

The District Court's decision also will remove the guarantee of other costfree preventive services for adults and children. These services include anxiety
screenings for children and adolescents, which have become increasingly
important in recent years due to the negative mental health impacts of the COVID19 pandemic and social media on children. Adults will also lose access to cost-free
preventive-care services, some of which are potentially lifesaving. For example,
the District Court's order eliminates the requirement that insurers provide
colorectal cancer screenings and pre-exposure prophylaxis (PrEP) medication
without cost-sharing. These services greatly reduce the mortality rates associated
with colorectal cancer and HIV, respectively, so imposing financial barriers will
likely have a severe impact on the many individuals who are at risk of developing
the diseases.

The adverse health impacts of the District Court's decision will be significant because patients typically do not seek preventive care if there is even a modest financial barrier. Many patients cannot afford to pay a typical health insurance plan's deductible—which averages around \$2,000—nor can they afford certain preventive services, such as colonoscopies and PreP medications, which

can cost over \$1,000 if the patient's deductible has not been met. If forced to pay for services up to a health insurance plan's deductible, many patients will likely forgo them, the health benefits notwithstanding.

Given these severe consequences, this Court should reverse the District Court's Appointments Clause finding and hold that Congress may validly shield the Task Force from political influence in its medical recommendations. Congress recognized the importance of evidence-based preventive care recommendations when it enacted the ACA and decided that the Task Force shall be "independent and, to the extent practicable, not subject to political pressure." This independence is critical for ensuring patients receive care based on science and medical research instead of public opinion.

If the Court agrees with the District Court's Appointments Clause holding, it still should not enjoin the ACA's preventive-care coverage requirement. Instead, the Court should keep the requirement in place and sever the supposedly unconstitutional protection from political oversight that the Task Force presently enjoys. No matter the Court's holding, high-quality, evidence-based preventive care should remain available to patients without cost-sharing.

#### **ARGUMENT**

The ACA guarantees access to certain high-quality, evidence-based 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 life-threatening 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, fiscally prudent health care system. Congress also determined that decisions about necessary preventive services should be insulated from the vicissitudes of daily partisan politics and made solely by experts because access to evidence-based services is essential to patient wellbeing and population health. The District Court unraveled that congressional policy judgment.

This Court should reverse the District Court's Appointments Clause decision. Doing so would maintain millions of Americans' cost-free access to critical preventive services, from cancer screenings to interventions for pregnancy complications. Additionally, this Court should ensure the Task Force continues to make medical recommendations based on scientific evidence. Countless Americans benefit from receiving preventive services based on the Task Force's expert, nonpartisan medical judgment. This Court should preserve those benefits. Without these guarantees in place, patients face a substantially greater risk that their acute illnesses or chronic diseases will not be timely detected or treated. At the very least, the Court should sever the statute so that the Task Force is subject to

the minimum constitutionally required executive branch oversight and leave the preventive-care requirement in place.

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

The importance of ACA-covered preventive health care services 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 covered without cost-sharing 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, aspirin use to prevent preeclampsia, medications to lower the risk of breast cancer, and

Hepatitis B and C screenings. *See* KFF, *Preventive Services Tracker* (June 22, 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 cumulative societal impact of reimposing cost barriers to these services will be monumental, leading to undiagnosed diseases, shorter lifespans, and higher health care costs. And underserved communities and vulnerable populations will be hit the hardest.

This Court should preserve the congressionally mandated cost-free coverage requirement for all "A" and "B" services rated by the Task Force. As the four examples discussed below demonstrate, these services are essential to detecting and treating life-threatening conditions for every segment of the population.

1. The Task Force recommends certain interventions and screenings for pregnant women, many of whom face unique health risks during pregnancy. These preventive-care services promote positive maternal and infant health outcomes by identifying potential problems during the early stages of pregnancy and providing support and guidance until and after childbirth.

Early interventions can help to prevent or mitigate perinatal depression, for instance. Perinatal depression involves the onset of a depressive disorder during pregnancy or following childbirth. This condition—which has become increasingly common in recent years—affects one in seven women in the United

States, with some estimates showing rates as high as 37% during the first year postpartum. US Preventive Servs. Task Force, *Interventions to Prevent Perinatal Depression*, 321 (6) J. Am. Med. Ass'n 580, 584 (Feb. 12, 2019). If left untreated, perinatal depression can have lifelong, adverse impacts on the health of the mother and child. *See id.* at 580.

In 2019, the Task Force recommended that clinicians identify at-risk pregnant and postpartum women and refer them to counseling interventions. *Id.*The Task Force defined the at-risk population as individuals who (1) are less than one year postpartum, (2) do not have a current diagnosis of depression, and (3) face an increased risk of developing depression. *Id.* at 582. Independent studies the Task Force cited show that those at risk of developing perinatal depression may include individuals with a history of personal or family depression, a history of physical or sexual abuse, an unplanned or unwanted pregnancy, pregestational or gestational diabetes, or complications during pregnancy, such as preterm delivery or pregnancy loss. *Id.* 

Based on these medical trials and peer-reviewed studies and publications, the Task Force found "convincing evidence" that counseling interventions were effective in preventing perinatal depression. *Id.* at 580. The most effective interventions included cognitive behavioral therapy and interpersonal therapy, both of which reduce the risk of developing perinatal depression. *Id.* The Task Force

also found positive outcomes for individuals who received interventions involving physical activity, education, and behavioral interventions, such as infant sleep training and expressive writing. *Id.* These positive outcomes were particularly notable in women with a history of depression or current depressive symptoms, as well as mothers who are young, single parents, or economically disadvantaged. *Id.* 

Reducing barriers for medical interventions and counseling is particularly important for preventing and treating perinatal depression. Many pregnant and postpartum women are reluctant to seek out mental-health treatment due to internal and external stigmas, which may cause a new mom to think she is a "bad mother" or fear that others view her as one. Janice H. Goodman, Women's Attitudes, *Preferences, and Perceived Barriers to Treatment for Perinatal Depression*, 36 (1) Birth 60, 61, 67 (Mar. 2009); Donna Moore et al., A Thematic Analysis of Stigma and Disclosure for Perinatal Depression on an Online Forum, 3 (2) J. Med. Internet Rsch., Mental Health (2016). Without early interventions and counseling, many mothers may not be aware that they are at risk of perinatal depression or even know the symptoms of the condition. Women's Attitudes, supra; Thematic Analysis of Stigma, supra. Removing financial barriers facilitates access to these services, especially for low-income patients who face a higher risk of developing perinatal depression and who are less likely to seek out preventive services due to cost. See infra pp. 16-17.

Under the District Court's order, insurers will no longer be required to provide eligible pregnant and postpartum women with cost-free coverage of preventive counseling interventions for perinatal depression, which include cognitive behavioral therapy, such as interventions to manage maladaptive thought patterns, and interpersonal therapy, such as role-playing, decision analysis, and communication analysis. See Interventions to Prevent Perinatal Depression, supra. The District Court's judgment also cut off the guarantee of cost-free access to three other Task Force-recommended services for eligible pregnant and postpartum women: (1) primary care interventions to support breastfeeding; (2) aspirin use to prevent preeclampsia and related morbidity and mortality; and (3) behavioral counseling interventions for healthy weight and weight gain in pregnancy. See Preventive Services Tracker, supra. The District Court judgment will therefore subject pregnant women and new moms to cost-sharing for interventions critical to themselves and their growing families.

2. Children and adolescents, too, will suffer if the District Court is not reversed. 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). The need for youth mental health screenings is serious and immediate. About eight percent of children and teens have an anxiety disorder, and many experience

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 in children has become even more prevalent 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*.

Early intervention helps reduce the short-term and long-term harms associated with anxiety disorders, which include chronic mental and physical health conditions, psychosocial functional impairment, increased risk of substance abuse, and premature mortality. *Screening for Anxiety in Children & Adolescents*, *supra*, at 1441. Children who are screened for anxiety at a young age are much more likely to receive timely and necessary medication and treatment, which can prevent panic disorder, depression, and even certain phobias later in life. *Id.* at 1439.

Without the ACA's preventive-care coverage requirement, there is no guarantee that children will have access to anxiety screenings without cost-sharing. The District Court's decision will thus deprive children of much-needed mental health screenings and interventions at a time they need them the most.

3. The District Court eradicated the ACA's requirement of cost-free access to a wide swath of preventive-care services for adults as well. 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 45-to-49-year-olds have seen a 15% increase in colorectal cancer rates over the past 20 years. Screening for Colorectal Cancer, supra, at 1972.

4. In addition to providing vital screenings, the ACA's preventive-care coverage requirement ensures access to life-saving medications. For example, the ACA guarantees cost-free access to 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% through intravenous drug use. CDC, *PrEP Effectiveness* (June 6, 2022), *available at* https://tinyurl.com/6fusx9cu. Without cost-free 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 protects lives and improves population health, saving the public costs in the long term. This Court should reverse the District Court and uphold the preventive-care coverage requirement.

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

Access to preventive services without cost-sharing is critical, as 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 cost-sharing returns, 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, 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. This Court should reverse the District Court's decision so that patients will have continued access to preventive services that they can afford and use.

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

The District Court's decision will cause further harm to patients because it thwarts the ACA's requirement that the Task Force be "independent and, to the extent practicable, not subject to political pressure." Under the District Court's order, decisions regarding the cost-free coverage of evidence-based preventive-care services can no longer be placed in a body insulated from undue political pressure.

1. 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 clinicians are experts in prevention and evidence-based medicine. *See id.* The Task Force members must abide by strict conflict-of-interest rules to ensure that

recommendations are not influenced by a member's commercial, intellectual, or institutional considerations. US Preventive Servs. Task Force, *Standards for Guideline Development* (May 2021), *available at* https://tinyurl.com/5n77buap.

The ACA requires coverage without cost sharing 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). Indeed, for over a decade, the Task Force made effective, evidence-based recommendations for preventive services without political influence, even as its members remained subject to the Secretary's removal power. *See* Gov't Opening Br. 20.

Maintaining the Task Force's focus on the evidence 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—such as partisan ideology, interest-group lobbying, or drug-or-insurance-company influence—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 self-governance" 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).

Despite its focus on the science, the Task Force prioritizes public engagement and transparency. Shortly after the ACA was enacted, the Task Force started publishing consumer fact sheets for the general public that described the Task Force's draft and final recommendations of newly recommended preventive

services. US Preventive Servs. Task Force, *Policy Manual § 9, Engagement With the Public, Stakeholders, and Partners* (July 2017). The Task Force also solicits input from the public. Through the Task Force's website, a member of the public can nominate new members to serve on the Task Force, suggest new services for the Task Force to consider in future recommendations, and provide comments on draft research plans, evidence reviews, and recommendation statements. *Id.* Thus, while the Task Force may be data-driven, it is by no means isolated.

By concluding the Task Force's structure did not comply with the Appointments Clause, the District Court opened the door for nakedly partisan political considerations to influence the Task Force's medical decision-making in a way that they never have before. Congress intended that the Task Force's recommendations be made based on medical evidence. And as the government explains, the statute permits those evidence-based recommendations to be subject to the Secretary's overall superintendence. *See* Gov't Opening Br. 20-27. To ensure evidence-based recommendations remain in place, the Court should reverse the District Court's Appointments Clause decision.

2. If the Court decides to affirm the District Court's decision on the Plaintiffs' Appointments Clause argument, it should preserve the preventive-care requirement by subjecting the Task Force to the minimum political oversight required by the Constitution.

Instead of attempting to preserve the statutory scheme, the District Court effectively repealed the entire preventive-care services coverage requirement of the ACA by judicial fiat. That radical remedy was unnecessary. The Supreme Court has repeatedly indicated its preference for a tailored remedy rather than a wholesale invalidation when finding a statute violates the Appointments Clause or similar structural constitutional provisions. So, for instance, in *United States v*. Arthrex, Inc., 141 S. Ct. 1970, 1986-87 (2021), the Supreme Court found that insulating administrative patent judge decisions from review by the Director of the Patent and Trademark Office violated the Appointments Clause, but that the "tailored approach" was not to strike down the entire system of *inter partes* patent review, but to allow the Director to review and overturn decisions made by administrative patent judges. Similarly, in Seila Law LLC v. Consumer Financial Protection Bureau, 140 S. Ct. 2183, 2209 (2020), the Court held that the removal restrictions on the Director of the Consumer Financial Protection Bureau violated the separation of powers, but severed the Director's statutory protection from removal rather than hamstringing the entire Bureau. And in *Free Enterprise Fund* v. Public Company Accounting Oversight Board, 561 U.S. 477, 509-510 (2010), the Court held the unique dual-layer removal protection that members of the Public Company Accounting Oversight Board enjoyed violated the separation of powers, but remedied the constitutional violation by making the members removable by the

Securities and Exchange Commission at will rather than abolishing the Board altogether or rendering it advisory.

The same is true here. If the Court does not reject Plaintiffs' Appointments Clause challenge, then the proper remedy is to sever 42 U.S.C. § 299b-4(a)(6), which limits the Secretary's authority over the Task Force. As the Government explains, severing this provision would cure any constitutional defect associated with the structure of the Task Force without eliminating the Task Force's power to recommend treatments for cost-free coverage. Gov't Opening Br. 35-40.

A narrower remedy is especially important given the stakes here. The District Court's decision pulled the rug out from under 150 million Americans who depend on the ACA's guarantee of preventive care services without cost-sharing. Losing free access to these services will inflict widespread harm on the health of every segment of the population, including pregnant women, children, and adults. If the Court decides not to reverse the District Court's Appointments Clause holding in full, then it should at least preserve the well-reasoned judgments made by Congress—and the Secretary—about ensuring access to vital preventive services.

#### **CONCLUSION**

The District Court's judgment with respect to the Appointments Clause should be reversed.

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#### **CERTIFICATE OF SERVICE**

I certify that on June 27, 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.

/s/ Sean Marotta 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 4,781 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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