No. 24-316

IN THE
Supreme Court of the United States

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,
Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, ACADEMYHEALTH, AIDS HEALTHCARE FOUNDATION, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, FAMILIES USA, GO2 FOR LUNG CANCER, PARENTS AGAINST VAPING E-CIGARETTES, PUBLIC HEALTH LAW CENTER, AND TRUTH INITIATIVE FOUNDATION d/b/a TRUTH INITIATIVE IN SUPPORT OF PETITIONERS

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INTEREST OF AMICI CURIAE[1]

Amici curiae Public Citizen, AcademyHealth, AIDS Healthcare Foundation, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, Families USA, GO2 for Lung Cancer, Parents Against Vaping E-Cigarettes, Public Health Law Center, and Truth Initiative Foundation d/b/a Truth Initiative are nonprofit organizations that work to advance public-health measures and support the prevention and treatment of serious medical conditions. Collectively representing millions of people across all 50 states, amici advocate for federal policies that increase access to and utilization of life-saving preventive-care measures such as cancer screenings, tobacco-cessation programs, and medications that reduce the risk of HIV and AIDS.

Amici submit this brief to explain that the Patient Protection and Affordable Care Act provisions that guarantee patients' access to cost-free coverage for preventive-care measures recommended by the U.S. Preventive Services Task Force are both lawful and critically important for public health. This Court's precedents establish that Congress may incorporate the evidence-based findings of disinterested expert bodies like the Task Force into law without implicating the Appointments Clause of the U.S. Constitution. Amici have a strong interest in defending Congress's decision to follow such a course here, given the vital role that the cost-free coverage that Congress mandated for recommended preventive services plays in protecting the health of millions of

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[1] This brief was not written in any part by counsel for a party. No one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of the brief.

Americans who may otherwise be deterred from accessing life-saving care.

SUMMARY OF ARGUMENT

The parties to this case debate the wrong question: whether members of the U.S. Preventive Services Task Force (Task Force) are inferior or principal officers of the United States within the meaning of the Appointments Clause. Under this Court's precedents, the proper answer to the first question presented in this case—whether the structure of the Task Force violates the Appointments Clause—is no, because the medical experts who periodically take part in the Task Force's recommendations about clinical preventive-health services are not officers of the United States at all, and the Appointments Clause says nothing about how they may or must be appointed.

Since its inception in 1984, the Task Force has had one central task: to make expert recommendations to the medical community about which preventive-care measures have been reliably shown to promote patient health. These evidence-based recommendations cover dozens of potentially life-saving clinical services. In 2010, Congress endorsed the recommendations' reliability by incorporating them into the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119, and requiring covered insurers to provide cost-free coverage for the recommended services. Even after the ACA's passage, the Task Force's recommendations are directed to the medical community and are based solely on scientific evidence, not on policy considerations about insurance coverage.

Congress's decision to tie the scope of insurers' coverage obligations to the Task Force's clinical recommendations did not convert the Task Force's

members into federal officers subject to the Appointments Clause. To begin with, a member of the Task Force—which is convened periodically on a volunteer basis for a limited factfinding purpose—does not hold a federal "office" in the first place. And either way, the Task Force does not have significant authority to execute or apply federal law. As this Court's decisions have long recognized, disinterested experts whom Congress has empowered to make discrete, empirical judgments on matters within their professional expertise do not perform the enforcement or policymaking duties that implicate the Appointments Clause—even where those judgments trigger legal consequences. In holding that the Task Force's members are improperly appointed federal officers, the decision below departed from this longstanding principle and cast constitutional doubt on numerous other legal provisions that incorporate the work of expert professional bodies into federal law.

Affirming the erroneous decision below would vitiate Congress's sound judgment about how best to protect public health. In enacting the ACA's preventive-care provisions, Congress recognized that early diagnosis and treatment of serious medical conditions can dramatically improve health outcomes and can save money and lives. In the years since the ACA's enactment, millions of Americans have come to rely on cost-free access to a wide range of preventive services, including medications that reduce the risk of heart attack and stroke, screenings that can reduce the risk of dying from lung cancer, and counseling that can promote healthy pregnancies. Research shows that the imposition of cost-sharing requirements for these and other preventive services would sharply reduce the rate at which patients access them, thus

reviving the public-health risks that Congress permissibly (and wisely) sought to address in the ACA. Because the Constitution does not require such a disruptive result, this Court should reverse.

ARGUMENT

I. The Task Force is an expert body of health-care professionals that has offered objective, evidence-based recommendations to the medical community for over forty years.

A. The Task Force originated in 1984 as a temporary 20-member expert body convened within the Department of Health and Human Services (HHS) by the Public Health Service to "develop[] recommendations for clinicians on the appropriate use of preventive interventions, based on a systematic review of evidence of clinical effectiveness." Task Force, *Guide to Clinical Preventive Services: Report of the U.S. Preventive Services Task Force*, Overview (2d ed. 1996), https://tinyurl.com/admzts59. In 1989, the first Task Force published its "comprehensive recommendations" regarding "preventive services for 60 topic areas affecting patients from infancy to old age." *Id.* The following year, the Task Force was reconstituted as a 10-member body composed of family physicians, internists, pediatricians, obstetrician-gynecologists, and methodologists, and was directed to update the recommendations based on the most recent scientific evidence. *Id.* The Task Force's second iteration finished its work in 1996, and a third iteration was convened in 1998 to make recommendations on a rolling basis. *See* Task Force, *Procedure Manual* at 1 (May 2021) (Task Force, *Procedure Manual*), https://tinyurl.com/24nfkf9p.

In 1999, the Task Force received congressional imprimatur with the passage of the Healthcare Research and Quality Act, Pub. L. No. 106-129, 113 Stat. 1653 (1999 Act). *See* Task Force, *Procedure Manual*, app. I, at 56. The 1999 Act established the Agency for Healthcare Research and Quality (AHRQ) within the Public Health Service, *see* 1999 Act, § 2(a), 113 Stat. at 1653, and it empowered the AHRQ Director to "periodically convene a Preventive Services Task Force … composed of individuals with appropriate expertise" to "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations," *id.* § 2(a), 113 Stat. at 1659, *codified as amended at* 42 U.S.C. § 299b-4(a)(1). The AHRQ has continuously maintained the Task Force as a standing body since 2001. *See* Task Force, *Procedure Manual* at 2. Today, the Task Force consists of 16 volunteer members who serve on a rotating basis for staggered terms. *Id.* at i, 2. Members are "nationally recognized experts in prevention, evidence-based medicine, and primary care who are also skilled in the critical evaluation of research and the implementation of evidence-based recommendations in clinical practice." *Id.* at 2.

The Task Force's clinical recommendations derive from a rigorous 4-step process that incorporates input from federal health agencies, partner organizations representing primary care clinicians and other stakeholders, and the general public. *See id.* at 7–12. First, the Task Force selects a preventive-care topic to prioritize based on factors such as "the topic's importance for public health" and "the potential

impact of [a] recommendation." Task Force, *USPSTF: Who We Are & How We Work*, at 3 (2022) (Task Force, *Who We Are*), https://tinyurl.com/22e9ewek. Second, the Task Force partners with "an academic or research organization with expertise in conducting systematic evidence reviews" to draft a research plan, which the Task Force finalizes after a 4-week public comment period. *Id.* Third, the partner organization's researchers "gather, review, and analyze evidence on the [selected] topic from high-quality studies published in peer-reviewed scientific journals," after which the Task Force assesses the findings, creates a draft recommendation, and opens the draft to public comment. *Id.* Last, the Task Force finalizes the recommendation based on the evidence review and public comments and assigns the recommendation a letter grade to indicate its strength. *Id.*

Task Force recommendations now "cover more than 80 preventive service topics for people across the lifespan—from vision screening in young children, to heart disease prevention in adults, to colorectal cancer screening in older adults." *Id.* at 1. While "policy-makers, managed care organizations, public and private payers, quality improvement organizations, research institutions, and patients" all draw insights from the Task Force's work, "the main audience for Task Force recommendations is the primary care clinician." Task Force, *Procedure Manual* at 2; *see also* 42 U.S.C. § 299b-4(a)(1) (defining the recommendations' main audience as "individuals and organizations delivering clinical services").

B. In the 2010 ACA, Congress incorporated some of the Task Force's expert recommendations into federal law. Recognizing that preventive care plays a critical role in promoting public health, *see infra* at pp.

15–17, Congress required that insurers cover certain preventive services without passing on any portion of the cost to the patient. Among the services included within this coverage requirement are all "evidence-based items or services" that hold an "A" or "B" grade from the Task Force. 42 U.S.C. § 300gg-13(a)(1). An "A" grade represents "high certainty that the net benefit" of a given service "is substantial," while a "B" grade represents "high certainty that the net benefit is moderate or … moderate certainty that the net benefit is moderate to substantial." Task Force, *Grade Definitions* (June 2018), https://tinyurl.com/3mcx9hsu.

Although the Task Force's clinical recommendations can trigger the ACA's coverage requirement, Congress directed that the recommendations remain "independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). Accordingly, and consistent with its longstanding mission of "provid[ing] primary care clinicians and their patients with information about the benefits and harms of a wide range of preventive services so that together they can make informed health care decisions that are best for each patient," Task Force, *Who We Are* at 1, the Task Force continues to base its recommendations on scientific and medical evidence, not on insurance coverage considerations, *id.* at 6. As the Task Force has explained, "[c]overage decisions are determined by payors and policymakers." *Id.*; *see* Task Force, *USPSTF: An Overview* (2021), https://tinyurl.com/mryspuua ("Although the [ACA] created a link between [Task Force] recommendations and insurance coverage requirements, the Task Force makes its recommendations based solely on the scientific evidence.").

II. The ACA's incorporation of Task Force recommendations does not convert Task Force members into federal officers subject to the Appointments Clause.

The Appointments Clause of the U.S. Constitution sets out the methods for validly installing "Officers of the United States," including any "inferior Officers." U.S. Const. art. II, § 2, cl. 2. Respondents here argue that the structure of the Task Force violates the Appointments Clause. In the court of appeals, however, neither the parties nor the court addressed the threshold question whether the Task Force members are federal "officers" who are subject to the Appointments Clause in the first place, as the parties "dispute[d] only whether Task Force members are 'principal' or 'inferior' officers." Pet. App. 12a. The court then held that the Task Force members are "principal officers of the United States who have not been validly appointed under … [the] Constitution," *id.* at 2a, and enjoined Petitioners from requiring Respondents to comply with the ACA's directive to provide cost-free coverage for preventive services that the Task Force has recommended since the ACA's enactment or will recommend in the future, *see id.* at 47a. But despite the parties' agreement below, this Court should address the threshold question, encompassed in the first question presented, whether Task Force members are officers at all. They are not.

Not every person who occupies a role set out in a federal statute is an officer of the United States. The concept of an office "embraces the ideas of tenure, duration, emolument, and duties" that are "continuing and permanent, not occasional or temporary." *United States v. Germaine*, 99 U.S. 508, 511–12 (1878). And even where a person occupies a federal position that

does hold these characteristics, that person is not subject to the Appointments Clause's requirements if the person's statutory duties entail "appropriate legislative functions" or objective expert factfinding, *Buckley v. Valeo*, 424 U.S. 1, 128 (1976) (per curiam), rather than "significant authority" to execute or enforce federal law, *id.* at 126. Here, Task Force members are not federal officers, both because they do not hold federal offices and, in any event, because their circumscribed factfinding roles would not bring them within the ambit of the Appointments Clause.

A. Nearly 150 years ago, this Court held in a pair of cases that a person who periodically performs specific tasks that aid the government is not an officer subject to the Appointments Clause. *See Auffmordt v. Hedden*, 137 U.S. 310, 326–28 (1890); *Germaine*, 99 U.S. at 512. In reaching this holding, *Germaine* and *Auffmordt* relied on the definition of a "public officer" in this Court's seminal decision in *United States v. Hartwell*, 73 U.S. 385 (1868). There, the Court equated an "officer" with one who holds an "office," and went on to say: "An office is a public station, or employment, conferred by the appointment of government. The term embraces the ideas of tenure, duration, emolument, and duties." *Id.* at 393. Applying that understanding of the term, *Germaine* and *Auffmordt* held the Appointments Clause inapplicable to persons who performed work to aid the government but were not appointed to employment as holders of public offices with the characteristics of continuing tenure, duration, emoluments, or duties.

Task Force members do not hold federal offices. The members are all professionals who volunteer to perform occasional factfinding work as part of the Task Force outside of their regular employment with

universities, hospitals, and other workplaces. *See* Task Force, *Our Members*, https://tinyurl.com/2v2r92pm (linking to the biographies of the current Task Force members). They convene as the Task Force just three times per year, *see* Task Force, *Procedure Manual* at 2, with the limited purpose of making clinical recommendations to healthcare providers based on "scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services," 42 U.S.C. § 299b-4(a)(1).

The Task Force's duties "are *not* continuing and permanent, and they *are* occasional and intermittent." *Germaine*, 99 U.S. at 512. The Task Force is "only to act when called on by [AHRQ]." *Id.*; *see* 42 U.S.C. § 299b-4(a)(1) (calling on the AHRQ Director to "convene" the Task Force). The Task Force "is required to keep no place of business for the public use" and its members "give[ ] no bond and take[ ] no oath." *Germaine*, 99 U.S. at 512. Meanwhile, "[n]o regular appropriation is made to pay [the] compensation" of the Task Force, which consists of volunteers. *Id.* A Task Force member is "removable … at [the] pleasure" of the HHS Secretary, and "[t]here is no penalty for his absence from duty or refusal to perform." *Id.* Consequently, the Task Force members do not occupy federal offices.

This conclusion follows even though the role of the Task Force is set out in a federal statute. In *Germaine*, civil surgeons appointed by the Commissioner of Pensions were not federal officers even though a statute empowered the Commissioner to hire them for "the periodical examination of pensioners" and provided that they "shall be paid" for their services. *Id.* at 508 (emphasis omitted). And in *Auffmordt*, merchant appraisers appointed by the Secretary of the

Treasury were not federal officers even though their duties (which determined the amounts of import duties owed by those who brought goods into the United States) were established by federal statute, too. 137 U.S. at 312. What mattered instead was that neither a civil surgeon nor a merchant appraiser was "a 'person employed'" in the federal government but rather was "an expert" who had "no general functions, nor any employment which has any duration as to time, or which extends over any case further than as he [was] selected to act." *Id.* at 326–27.

Put simply, without a federal office to hold, neither the surgeons nor the appraisers could plausibly be federal officers, inferior or principal. The same is true of the Task Force members.

B. Task Force members are not federal officers for the additional reason that they lack "significant authority" to execute or enforce federal law. *Buckley*, 424 U.S. at 126. Although this standard "is no doubt framed in general terms," *Lucia v. SEC*, 585 U.S. 237, 245 (2018), this Court has held that the Appointments Clause is not implicated where Congress provides for a federal worker who performs "appropriate legislative functions," *Buckley*, 424 U.S. at 128, or who is "an expert, selected as such," to bring his or her "special knowledge" to bear conclusively on empirical matters affecting private citizens' rights and duties. *Auffmordt*, 137 U.S. at 326–27. With respect to the Task Force, Congress has done exactly what this Court's precedents permit: It has charged the Task Force—a group of volunteer experts—with evaluating the body of contemporary scientific literature and making disinterested, evidence-based recommendations for healthcare providers regarding effective preventive measures. 42 U.S.C. § 299b-4(a)(1). In

making those factual judgments about clinical best practices, Task Force members do not wield significant federal authority.

This conclusion finds strong support in this Court's *Auffmordt* decision. That case addressed a statute that empowered merchant appraisers to assess the value of imported goods under certain circumstances for purposes of calculating the amount of customs duties owed on the goods. *See* 137 U.S. at 312. Although the statute "ma[de] the decision of the appraisers final," *id.* at 329, the Court held that the appraisers were not officers, but "expert assistant[s] to aid in ascertaining the value of the goods." *Id.* at 327. In so holding, the Court emphasized the circumscribed "duties and discretion," *Freytag v. Commissioner*, 501 U.S. 868, 881 (1991), of the appraisers, who were "selected for [their] special knowledge in regard to the character and value of the particular goods in question" and had "no general functions" or power "to act except as [they] may be designated" to discharge the narrow responsibilities of an expert factfinder. *Auffmordt*, 137 U.S. at 327; *see United States v. Arthrex, Inc.*, 594 U.S. 1, 22 (2021) (suggesting that members of ad hoc adjudicatory bodies authorized by early federal patent statutes "may not have even [held] offices" for purposes of the Appointments Clause because they "assembled to resolve a single issue" and held "limited power" despite making "final decisions" on discrete matters within their expert authority).

Task Force members' statutory duties resemble those of *Auffmordt*'s appraisers far more closely than they resemble the duties of functionaries whom this Court has held to be officers. Like the appraisers, Task Force members are required to draw on their profess-

ional expertise to make discrete factual determinations on specific empirical matters. Unlike the administrative law judges and special trial judges held to be officers in *Lucia* and *Freytag*, Task Force members do not wield quasi-judicial authority by "presiding over adversarial hearings," *Lucia*, 585 U.S. at 247, in which they "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders," *id.* (quoting *Freytag*, 501 U.S. at 881–82). And unlike the Federal Election Commission—whose members were held to be officers in *Buckley*—the Task Force has no power to "formulate general policy," create legal safe harbors by issuing advisory opinions on regulated parties' legal compliance, make discretionary exceptions to congressional mandates, or perform "direct and wide ranging" enforcement activities. *Buckley*, 424 U.S. at 110–11 (citation omitted).

That Congress has now tied the scope of insurers' coverage obligations to the Task Force's factual judgments about clinical efficacy—just as Congress tied the amount of importers' customs duties to merchant appraisers' factual judgments about the value of the importers' goods—does not change the nature of the Task Force's functions. Both before and after the ACA's enactment, the Task Force conducted the same expert assessment of scientific evidence, applying the same criteria to make clinical recommendations to healthcare providers through the same multi-step process. The Task Force makes no legal or policy judgments about whether particular forms of care should be provided without charge to insured patients, issues no directives to insurers (or, indeed, to anyone), and plays no role in enforcing any

legal obligations that Congress may attach to its recommendations.

Rather, recognizing that the Task Force's expert determinations on factual matters had yielded reliable results over the two decades leading up to the ACA's enactment, *Congress* decided that insurers must cover preventive services that the Task Force determines are medically effective. Incorporation of an expert body's work into federal law is commonplace. *See, e.g.*, 15 U.S.C. § 8003(c)(1)(A)(i) (requiring "each public pool and spa in the United States" to comply with certain privately promulgated "performance standard[s], or any successor standard"); 42 U.S.C. § 1395i-3(d)(4)(A) (requiring "skilled nursing facilit[ies]" to comply with "accepted professional standards and principles"); *id.* § 7385s-2(b) (directing certain "minimum impairment rating[s]" for workers' compensation purposes to "be determined in accordance with" American Medical Association standards); 20 C.F.R. § 702.601(b) (defining "disability" for workers' compensation purposes by incorporating standards from "the most currently revised edition" of an American Medical Association publication); 40 C.F.R. § 707.60(c)(2)(ii) (providing that a chemical substance is "considered to be a known or potential human carcinogen" for regulatory purposes if it holds a certain classification from the World Health Organization's International Agency for Research on Cancer); 49 C.F.R. § 393.108(b) (providing that the "manufacturer's markings" are dispositive as to the lawful "working load limit[]" of a tiedown used to secure cargo).

Affirming the court of appeals' holding that the Task Force members are federal officers would thus call into question the validity of any number of

existing legal requirements. Going forward, moreover, Congress would be foreclosed from relying on the empirical judgments of expert professional bodies unless it dramatically expanded the federal workforce by creating officer roles for those bodies' members. As this Court has long recognized, the Constitution does not require this destabilizing result. The Court should hold that Task Force members are not federal officers.

III. Affirming the holding below would thwart an important and effective congressional effort to protect public health.

Beyond undermining longstanding precedent and sowing jurisprudential disruption, affirming the lower court's constitutional holding would imperil Congress's critical efforts to protect the health—and potentially the lives—of millions of Americans. Congress has made the sound decision that Americans should have cost-free access to preventive-care measures that expert clinicians have recognized as having a demonstrated track record of efficacy in improving clinical outcomes. Affirming the decision below would strip that access from millions of citizens and create precisely the public-health risks that Congress has acted decisively to prevent.

Even before the ACA, the medical community had long recognized an important role for "[h]igh-quality preventive care" in "help[ing] Americans stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce costs." Ctrs. for Medicare & Medicaid Servs., *Background: The Affordable Care Act's New Rules on Preventive Care* (July 14, 2010) (CMS, *Background*), https://tinyurl.com/yefyrsek. Reputable expert studies showed that targeted lifestyle changes and early detection could reduce the incidence of and

mortality from chronic diseases like diabetes and cancer by up to 70 percent. *See* Steven H. Woolf, *The Price Paid for Not Preventing Diseases*, *in* Inst. of Med. of the Nat'l Acads., *The Healthcare Imperative: Lowering Costs and Improving Outcomes* 220, 221 (2010), https://tinyurl.com/vb4nss25. And the National Commission on Prevention Priorities estimated that more effective provision of just five preventive measures could save 100,000 lives per year. *Id.* at 222–23. Experts also recognized the high economic "price paid for inadequate emphasis on prevention," *id.* at 223, amounting by some calculations to hundreds of billions of dollars per year. *See, e.g.*, *id.*; Michael V. Maciosek, et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, 29 Health Affs. 1656, 1656 (Sept. 2010), https://tinyurl.com/z3a422pd (abstract) (reporting at the time of the ACA's enactment that greater use of twenty "proven clinical preventive services" could save billions of dollars and "more than two million life-years annually").

Despite the "proven benefits" of preventive care, "financial barriers"—including insurance coverage gaps or cost-sharing measures like copayments and deductibles—deterred people from receiving services like "cancer screenings, immunizations for their children and themselves, and well-baby check-ups." CMS, *Background*. In the wake of the 2007 global financial crisis, 26.5 percent of Americans participating in a National Bureau of Economic Research study reported a reduction in their use of routine medical care, while 70 percent of the American Hospital Association's member hospitals reported fewer patient visits "as family budgets remain[ed] tight and patients continue[d] to delay or forgo care."

Robert Pear, *Economy Led to Cuts in Use of Health Care*, N.Y. Times (Aug. 16, 2010), https://tinyurl.com/nbym72zx.

With Americans "us[ing] preventive services at about half the recommended rate," CMS, *Background*, Congress acted decisively to require that insurers provide cost-free coverage for certain preventive care measures, including those services that hold Task Force recommendations as a result of their proven clinical efficacy. Due to the new law, approximately 76 million Americans became eligible for expanded coverage for preventive services. HHS, Off. of the Ass't Sec'y for Planning & Eval., *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, at 1 (June 27, 2014), https://tinyurl.com/zh4rdwac. Since then, vast numbers of people have relied on the guarantee of cost-free coverage for preventive services, with about 60 percent of insured Americans—roughly 100 million people—utilizing such services in 2018. Krutika Amin, et al., *Preventive Services Use Among People with Private Insurance Coverage*, Peterson-KFF Health Sys. Tracker (Mar. 20, 2023), https://tinyurl.com/5n8ctmts.

Affirming the decision below would unsettle the guarantee that Congress made to the American people and allow insurers to impose cost-sharing requirements for—or decline to cover—services that have received Task Force recommendations, in some cases for more than a decade, based on objective scientific evidence of clinical efficacy. This result would put millions of patients at risk of losing cost-free access to critical care and compromise clinical efforts to control cancer, reduce the spread of disease, and address other public-health concerns. For example:

- Lung cancer screening for certain adults first received a qualifying rating in 2013. *See* Task Force, *Lung Cancer: Screening* (Dec. 31, 2013), https://tinyurl.com/5bve6cts. Access to screening is vital because early detection dramatically affects health outcomes, with a 64 percent five-year survival rate for cases caught early falling to just 9 percent for cases caught later. Am. Lung Ass'n, *Lung Cancer Key Findings*, Early Diagnosis (Nov. 13, 2024), https://tinyurl.com/yndkd8xr.
- Hepatitis B and C screenings received qualifying ratings in 2013 and 2014. *See* Task Force, *Hepatitis B Virus Infection: Screening, 2014* (June 18, 2014), https://tinyurl.com/3rdba82k; Task Force, *Hepatitis C: Screening* (June 15, 2013), https://tinyurl.com/4mjhrr9y. Both viruses are "major causes of acute and chronic liver disease," and early detection enables infected individuals "to receive the necessary care and treatment to prevent or delay progression of liver disease," while reducing transmission rates and new infections. World Health Org., *Guidelines on Hepatitis B and C Testing* (Feb. 16, 2017), https://tinyurl.com/5n8ac8t6.
- Physical therapy to help certain older adults reduce the risk of falling first received a qualifying rating in 2012. *See* Task Force, *Falls Prevention in Older Adults: Counseling and Preventive Medication* (May 15, 2012), https://tinyurl.com/yv9ukh6e. Falls were the leading cause of injury-related mortality among older adults when the recommendation was last

updated, causing an estimated 38,742 deaths in 2021 alone. *See* Task Force, *Falls Prevention in Community-Dwelling Older Adults: Interventions*, Importance (June 4, 2024), https://tinyurl.com/33vbbzm6.

- Behavioral counseling to help pregnant people maintain a healthy body weight first received a qualifying rating in 2021. *See* Task Force, *Healthy Weight and Weight Gain in Pregnancy: Behavioral Counseling Interventions* (May 25, 2021), https://tinyurl.com/yvude329. This recommendation addresses a sharp increase in obesity rates during pregnancy from 13 percent in 1993 to 24 percent in 2015, with particularly high rates among Alaska Native/American Indian, Black, and Hispanic women. *Id.* ("Importance" dropdown). As the Task Force explained, "[e]xcess weight at the beginning of pregnancy and excess gestational weight gain" are associated with "adverse … health outcomes" for both the pregnant individual and the infant. *Id.*; *see also* Patrick M. Catalano, et al., *Obesity and Pregnancy: Mechanisms of Short Term and Long Term Adverse Consequences for Mother and Child*, The BMJ (Feb. 8, 2017), https://tinyurl.com/yc8yaanz (reporting that obesity increases the risk of spontaneous miscarriage and of "congenital anomalies" such as neural tube defects, limb reductions, and cardiovascular issues).

Even among services that had received a qualifying rating from the Task Force based on the body of clinical evidence *before* the ACA's enactment, many recommendations have since undergone

important updates as a result of the evolving state of the scientific record. For example:

- When the ACA went into effect, the Task Force's preventive recommendations regarding lipid disorders that could lead to coronary heart disease were limited to screening for certain adults. *See* Task Force, *Lipid Disorders in Adults (Cholesterol, Dyslipidemia): Screening* (Dec. 30, 2013), https://tinyurl.com/24sn6nvu (June 2008 recommendation). In 2016, the Task Force updated the recommendation to include prescription of a statin. *See* Task Force, *Statin Use for the Primary Prevention of Cardio-vascular Disease in Adults: Preventive Medication* (Nov. 13, 2016), https://tinyurl.com/2p9f9mth. Statins are potentially life-saving medications that "[s]cientific studies and years of use all over the world have proven … [to] reduce a person's chances of having a heart attack or stroke" by up to 50 percent. CDC*, The Scoop on Statins: What Do You Need to Know?* (Sept. 27, 2021), https://tinyurl.com/3wab5skn.
- The Task Force first recommended certain tobacco smoking cessation measures for adults in 1996. Task Force, *Tobacco Use Prevention: Counseling, 1996* (Jan. 1, 1996), https://tinyurl.com/3edus3er. When the ACA took effect, the Task Force's recommended interventions for adults who use tobacco products included use of all pharmacotherapy treatments that had been approved by the Food and Drug Administration, in addition to individual and phone counseling. Task Force, *Tobacco Use in Adults and Pregnant Women: Counseling*

and Interventions, Clinical Considerations (Apr. 15, 2009), https://tinyurl.com/54h4rw5h. In 2015, the Task Force added group counseling to its recommendations. Task Force, *Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*, Clinical Considerations (Sept. 21, 2015), https://tinyurl.com/mv469en5; *see also* Task Force, *Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions*, Practice Considerations (Jan. 19, 2021), https://tinyurl.com/mtt9syz5 (maintaining group counseling as a recommended service). The update aligns the Task Force recommendation with the Public Health Service's Clinical Practice Guidelines. *See* HHS, Pub. Health Serv., *Treating Tobacco Use and Dependence: 2008 Update*, at 7 (May 2008), https://tinyurl.com/3zppmyfn. The United States Surgeon General found that group counseling, along with pharmacotherapy, is one of the most effective ways to help someone quit smoking, thus mitigating the leading cause of preventable death and disease in the United States. HHS, Pub. Health Serv., *Smoking Cessation: A Report of the Surgeon General*, at 522 (2020), https://tinyurl.com/24cc7erw.

- When the ACA went into effect, the Task Force recommended screening adults aged 50–75 for colorectal cancer. *See* Task Force, *Colorectal Cancer: Screening* (Oct. 15, 2008), https://tinyurl.com/4xsveypy. Based on new evidence of "a recent trend for increasing risk of colorectal cancer in … adults younger than 50 years," the Task Force updated its recommend-

ation in 2021 to include adults aged 45–49. *See* Task Force, *Colorectal Cancer: Screening*, Practice Considerations (May 18, 2021), https://tinyurl.com/54w9u4x2. This update is expected to "increase life-years gained and decrease colorectal cancer cases and deaths compared with beginning screening at age 50 years." *Id.*

- When the ACA went into effect, the Task Force recommended screening for type 2 diabetes only for certain adults with elevated blood pressure. *See* Task Force, *Diabetes Mellitus (Type 2) in Adults: Screening* (June 15, 2008), https://tinyurl.com/mr23xvz6. The Task Force has since reviewed "new lifestyle intervention studies" and updated its recommendation to include screening for abnormal blood glucose levels in overweight or obese adults irrespective of blood pressure, explaining that the "new body of evidence" gave it "increased confidence" in such measures' efficacy. Task Force, *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening*, Update of Previous USPSTF Recommendation (Oct. 26, 2015), https://tinyurl.com/2p8z43u6.
- When the ACA went into effect, the Task Force recommended HIV screening only for pregnant women and for adolescents and adults at increased risk of infection. *See* Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening, 2005* (July 5, 2005), https://tinyurl.com/yeyp28zv. But "based on studies … address[ing] previous evidence gaps," the Task Force later updated its

recommendation to cover screening for all people aged 15–65. Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening*, Update of Previous USPSTF Recommendation (Apr. 15, 2013), https://tinyurl.com/ysscnfpu. This "expanded HIV screening could identify a substantial number of persons with previously undiagnosed HIV infection," *id.*, enabling them to begin life-saving treatment and take steps to "substantially decrease[]" transmission risk, *id.* ("Rationale" dropdown).

Serious health consequences would result from lifting Congress's directive that insurers not impose cost-sharing requirements for these and specified other critical services. To take an example based on just one of the many services threatened by the decision below, if insurers could pass on to patients charges for receiving life-saving statins, research suggests that many patients would discontinue use, despite the health risks. *See, e.g.*, Teresa B. Gibson, et al., *The Effects of Prescription Drug Copayments on Statin Adherence*, Am. J. of Managed Care (Sept. 1, 2006), https://tinyurl.com/mv6ucnpz (explaining that "higher prescription drug copayments are associated with lower statin adherence").

One "natural experiment" study examined what happened when an insurance plan covering all British Columbia residents over the age of 65 moved from providing cost-free coverage for statins, to charging \$10–\$25 copayments, and then to charging 25 percent coinsurance payments. Sebastian Schneeweiss, et al., *Adherence to Statin Therapy Under Drug Cost Sharing in Patients with and Without Acute Myocardial Infarction*, 115 Circulation 2128, 2128

(2007), https://tinyurl.com/yc3u6ttc. The study determined that, "[r]elative to full-coverage policies, adherence to new statin therapy was significantly reduced … under a fixed copayment policy … and the subsequent coinsurance policy." *Id.* Significantly, "[s]udden changes to full out-of-pocket spending … almost doubled the risk of stopping statins." *Id.*

More broadly, according to a recent survey, 40 percent of American adults would be unable or unwilling to pay out of pocket for the majority of the evidence-backed preventive services protected by Congress and threatened by the decision below. Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care If ACA Coverage Falls Through*, Morning Consult (Mar. 8, 2023), https://tinyurl.com/5xu5fvf8. This figure underscores the well-established principle that when insurers do not cover the cost of vital preventive services, patients are often prevented or deterred from utilizing those services. *See* Rajender Agarwal, et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 Health Affs. 1762, 1766 (Oct. 2017), https://tinyurl.com/mrekw95f (reporting, "consistent with a large body of evidence on cost sharing," that deductibles can cause patients to "forgo needed care," including preventive care); Mitchell D. Wong, et al., *Effects of Cost Sharing on Care Seeking and Health Status: Results from the Medical Outcomes Study*, 91 Am. J. Pub. Health 1889, 1889 (Nov. 2001), https://tinyurl.com/2p8ftt4s ("Requiring patients to pay a portion of their medical bill out of pocket[] … sharply reduces their use of health care resources."); *cf.* Karishma Srikanth, et al., *Associated Costs Are a Barrier to HIV Preexposure Prophylaxis Access in the United States*, 112 Am. J.

Pub. Health 834, 835 (June 2022), https://tinyurl.com/mr2skuye (explaining how "actual and perceived cost barrier[s]" can inhibit use of prophylactic HIV medications and increase the "transmission and prevalence of HIV").

Congress attempted to ameliorate the demonstrated, severe public-health effects of cost barriers by enacting the requirement that covered insurers provide cost-free coverage for services that hold a Task Force recommendation. Affirming the court of appeals' erroneous constitutional holding would revive the grave public-health risks that Congress permissibly—and wisely—sought to confront in the ACA.

CONCLUSION

The Court should reverse the judgment of the court of appeals.

Respectfully submitted,

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