No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT INCORPORATED, *et al.*,
Plaintiffs-Appellees,

v.

XAVIER BECERRA, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas, No. 4:20-cv-00283
Hon. Reed O'Connor, United States District Judge

BRIEF OF AMICI CURIAE AMERICAN LUNG ASSOCIATION, ACADEMYHEALTH, ADULT VACCINE ACCESS COALITION, AMERICAN HEART ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, FAMILIES USA, GO2 FOR LUNG CANCER, LUNGEVITY FOUNDATION, PARENTS AGAINST VAPING E-CIGARETTES, PUBLIC CITIZEN, PUBLIC HEALTH LAW CENTER, AND TRUTH INITIATIVE FOUNDATION d/b/a TRUTH INITIATIVE IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL

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June 27, 2023

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

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Pursuant to this Court's Rule 29.2 and Federal Rule of Appellate Procedure 26.1, amici curiae American Lung Association, AcademyHealth, Adult Vaccine Access Coalition, American Heart Association, Campaign for Tobacco-Free Kids, Families USA, GO2 for Lung Cancer, LUNGevity Foundation, Parents Against Vaping E-Cigarettes, Public Citizen, Public Health Law Center, and Truth Initiative Foundation d/b/a Truth Initiative submit this supplemental certificate of interested persons to fully disclose all those with an interest

in this brief and provide the required information as to their corporate status and affiliations.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case, in addition to those listed in the briefs of the parties. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

A. Amicus curiae **American Lung Association** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

B. Amicus curiae **AcademyHealth** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

C. Amicus curiae **Adult Vaccine Access Coalition** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

D. Amicus curiae **American Heart Association** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

E. Amicus curiae **Campaign for Tobacco-Free Kids** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

F. Amicus curiae **Families USA** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

G. Amicus curiae **GO2 for Lung Cancer** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

H. Amicus curiae **LUNGevity Foundation** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

I. Amicus curiae **Parents Against Vaping E-Cigarettes** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

J. Amicus curiae **Public Citizen** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

K. Amicus curiae **Public Health Law Center** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

L. Amicus curiae **Truth Initiative Foundation d/b/a Truth Initiative** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

M. The above-listed amici curiae are represented by **Nicolas A. Sansone** and **Allison M. Zieve** of **Public Citizen Litigation Group**.

/s/ Nicolas A. Sansone
Nicolas A. Sansone

Attorney for Amici Curiae American Lung Association, et al.

June 27, 2023

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Other Authorities

INTEREST OF AMICI CURIAE[1]

Amici curiae American Lung Association, AcademyHealth, Adult Vaccine Access Coalition, American Heart Association, Campaign for Tobacco-Free Kids, Families USA, GO2 for Lung Cancer, LUNGevity Foundation, Parents Against Vaping E-Cigarettes, Public Citizen, Public Health Law Center, and Truth Initiative Foundation d/b/a Truth Initiative are non-profit organizations that work to advance public-health measures that support prevention and treatment of serious medical conditions, including life-threatening heart and lung diseases. Collectively representing millions of members across all fifty states, amici advocate for federal policies that increase access to and utilization of preventive-care measures such as immunizations, cancer screenings, tobacco-cessation programs, and medications that reduce the risk of heart attack and stroke. Given the demonstrated adverse impact that cost-sharing requirements and lack of insurance coverage can have on patients' uptake of these vital forms of care, amici have a strong interest

[1] This brief was not authored in whole or part by counsel for a party, and no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of the brief. Counsel for all parties have consented to its filing.

in ensuring that Americans retain cost-free access to the life-saving services threatened by the judgment below.

SUMMARY OF ARGUMENT

Since its inception in 1984, the U.S. Preventive Services Task Force (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.

Amici disagree with the district court's ruling that Congress's incorporation of the Task Force's recommendations into the ACA violated the Appointments Clause. But even if this Court agrees with that ruling, it should reject the district court's overbroad remedy. Assuming that the district court was correct on the merits, the ratification of the Task Force's current recommendations by the Secretary of Health and Human Services cured any constitutional problem with enforcing insurers'

obligation to provide cost-free coverage for the services included in those recommendations. By categorially barring enforcement of the ACA's coverage requirements for all preventive services the Task Force has recommended since the ACA's enactment, the district court needlessly thwarted congressional will and compromised access to vital healthcare for millions of Americans.

ARGUMENT

I. The Task Force has offered expert, evidence-based recommendations to the medical community for nearly forty years.

A. The Task Force began in 1984 as a temporary twenty-member expert body convened within the Department of Health and Human Services (HHS) by the U.S. 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. The first Task Force published its "comprehensive recommendations" regarding "preventive services for 60 topic areas affecting patients from infancy to old age" in 1989. *Id.* The

following year, the Task Force was reconstituted as a ten-member body composed of family physicians, internists, pediatricians, obstetrician-gynecologists, and methodologists, and was directed to update the preventive-services 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. Task Force, *Procedure Manual*, at 1 (May 2021) (Task Force, *Procedure Manual*), https://tinyurl.com/bdrp29ea.

The Task Force received congressional imprimatur the following year, with the passage of the Healthcare Research and Quality Act of 1999, 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. Task Force, *Procedure Manual* at 2. Today, the Task Force consists of sixteen volunteer members who are appointed 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, four-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 four-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. *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 the "main audience" for the recommendations "is the primary care clinician," the recommendations are also "widely used by policymakers, managed care organizations, public and private payers, quality improvement organizations, research institutions, and patients." 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. Congress incorporated the Task Force's expert recommendations into federal law with the March 23, 2010, passage of the ACA. Recognizing preventive care's critical role in promoting public health, *see infra* at 13–16, Congress built into the ACA a requirement 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 a Task Force recommendation can trigger the ACA's coverage requirement, Congress directed that the recommendations be "independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). In keeping with its 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 bases its recommendations on scientific evidence and not on insurance coverage considerations, *id.* at 6. As the Task Force has explained, "[c]overage decisions are determined by payors and policymakers." *Id.*

II. If this Court holds that the ACA's incorporation of Task Force recommendations violates the Appointments Clause, it should reverse the district court's overbroad remedy.

The district court held that the ACA's incorporation of the Task Force's expert recommendations converted Task Force members into federal officers subject to the requirements of the Appointments Clause. Amici disagree with that conclusion. But regardless of whether Task Force members are officers or nonofficers, HHS Secretary Xavier Becerra—whose appointment is undisputedly valid—ratified all Task Force recommendations in effect as of January 21, 2022. ROA.1094. Ordinarily, "a properly appointed official's ratification of an allegedly improper official's prior action" cures any constitutional defect, "purg[ing] any residual taint or prejudice left over from the allegedly invalid appointment." *Guedes v. Bur. of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019) (per curiam); *accord CFPB v.*

Gordon, 819 F.3d 1179, 1190–91 (9th Cir. 2016). The district court, though, refused to accept the Secretary's ratification as valid, instead fully barring enforcement of a public-health measure that has facilitated access to critical medical care for millions of Americans. This Court should reject that sweeping and unnecessary remedy.

A. As the district court itself correctly recognized, "a properly appointed official can ratify an improperly appointed official's action." ROA.1793. It held, however, that the HHS Secretary lacks legal authority to ratify Task Force recommendations insofar as they impose coverage obligations on insurers because the Secretary has no authority "to decree recommendations unilaterally." ROA.1797. The court's logic does not hold up. While it is true that the Task Force enjoys a guarantee of independence in crafting its recommendations, *see* 42 U.S.C. § 299b-4(a)(6), nothing in that guarantee bars the Secretary from approving the outcome of that independent process, as he has done here.

The district court's suggestion that the HHS Secretary lacks ratification authority because the Task Force "is not part of HHS or any federal agency" was also wrong. ROA.2128. The Task Force was initially created at the discretion of the Public Health Service, *see supra* at 3–4, a

body operating "under the supervision and direction of the [HHS] Secretary." 42 U.S.C. § 202. When the 1999 Act codified the Task Force's functions, Congress maintained the Task Force's position within HHS, placing responsibility for convening the Task Force on the HHS Secretary, "acting through the Director" of a subagency within the Public Health Service. 42 U.S.C. § 299(a); *see id.* § 299b-4(a)(1). Indeed, the district court recognized that the HHS Secretary has authority to remove members of the Task Force. ROA.1808. That conclusion is irreconcilable with the notion that the Task Force is not part of HHS.

The district court's other reasons for rejecting ratification as the proper remedy for the constitutional violation it perceived also lack merit. First, the district court held that, even if the statutory scheme laying out the Task Force's role might be read to "*permit* the Secretary to authorize … [Task Force] recommendations *post hoc*," it "would not *compel* him" to do so. ROA.2128. In addition, the district court expressed concern that ratification of the current recommendations would not adequately cure any constitutional violation because the ACA "would still operate to give [Task Force] ratings the force and effect of law unless and *until* the Secretary decided to ratify … a particular recommendation." *Id.*

These concerns are academic here. Whether enforcement of some future unratified recommendation would violate the Appointments Clause has no bearing on this case, where Plaintiffs challenge enforcement of recommendations that the Secretary *has* ratified. *See* ROA.1094. In fact, the district court itself made the same point in rejecting Plaintiffs' Appointments Clause challenges to other ACA provisions. *See* ROA.1796 (finding it unnecessary to decide whether certain regulatory actions were taken by unconstitutionally appointed officers because "the [HHS] Secretary ha[d] ratified" the actions, curing any potential constitutional defect, and "Article III standing principles d[id] not permit Plaintiffs to challenge an unlawful appointment generally, or to challenge future exercises of unlawful authority").

The district court's view that the Supreme Court's decision in *Collins v. Yellen*, 141 S. Ct. 1761 (2021), supports enjoining enforcement of the Task Force's post-ACA recommendations altogether is wrong for similar reasons. The plaintiffs in *Collins* sought relief from harm that they had allegedly suffered due to a financial agreement negotiated between the Federal Housing Finance Agency (FHFA) and the U.S. Department of Treasury. *Id.* at 1770, 1780. After holding that statutory

protections against the FHFA Director's removal violated constitutional separation-of-powers principles, *id.* at 1770, the Court considered the appropriate remedy. Because the agreement that allegedly gave rise to the plaintiffs' injuries was no longer in effect, the Court did not consider whether prospective relief was proper. *Id.* at 1779–80. As for retrospective relief, the Court declined to invalidate all of the challenged actions that the Director had taken while unconstitutionally protected against removal. *Id.* at 1787. Drawing a contrast with cases involving "a Government actor's exercise of power that the actor did not lawfully possess," the Court emphasized that "[a]ll the officers who headed the FHFA during the time in question were properly *appointed*." *Id.* at 1787–88. Because the officers thus had authority to implement the agreement at issue, the Court limited the plaintiffs' potential recovery to damages stemming from the removal protections themselves. *Id.* at 1788–89.

Nothing in *Collins*'s suggestion that the Court might have ordered a different *retrospective* remedy had the FHFA Director been improperly appointed has any bearing on the appropriate scope of the *prospective* relief sought here. As Plaintiffs have conceded, 42 U.S.C. § 299b-4(a)(1) gives the Task Force authority to make evidence-based recommendations

to the medical community, and all existing Task Force recommendations reflect the valid exercise of that authority. *See* D. Ct. Dkt. 111 at 22–23. And giving effect to the HHS Secretary's independent ratification of the recommendations would render future efforts to enforce insurers' duty to provide cost-free coverage for the recommended services constitutional, *see Guedes*, 920 F.3d at 13, thus fully satisfying Plaintiffs' request for a prospective remedy against the unlawful exercise of executive power.

B. Instead of using the remedial "scalpel" that "Congress would [have] prefer[red]," the district court employed "a bulldozer in curing the constitutional defect [it] identif[ied]," *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2210–11 (2020), barring enforcement of the ACA's coverage requirements with respect to all preventive-care services that received Task Force recommendations following the ACA's enactment. ROA.2131–32. If affirmed, this overbroad remedy would dramatically undermine Congress's aim of ensuring Americans' cost-free access to services that are demonstrably effective in mitigating or preventing life-threatening medical conditions.

Even before the ACA's passage, 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 annually. *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*, Health Affs. (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*, one of the ACA's central innovations was its cost-free coverage requirement for certain preventive care measures, including those services that hold Task Force recommendations. 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 ACA's 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.

By unsettling this guarantee and allowing insurers to impose cost-sharing requirements for—or decline to cover—services that received Task Force recommendations following the ACA's enactment, the district court's remedy put millions of patients at risk of losing cost-free access to critical care and compromised 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 61 percent five-year survival rate for cases caught early falling to just 7 percent for cases caught later. Am. Lung Ass'n, *Lung Cancer Key Findings*, Early Diagnosis (Nov. 17, 2022), 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/47wt749a. Falls

were the leading cause of injury-related mortality among older adults when the recommendation was last updated, causing an estimated 33,000 deaths in 2015 alone. *See* Task Force, *Falls Prevention in Community-Dwelling Older Adults: Interventions*, Rationale (Apr. 17, 2018), https://tinyurl.com/2p9asyxs.

- Behavioral counseling to help pregnant individuals 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). 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 a qualifying rating from the Task Force *before* the ACA's enactment, many recommendations have since undergone important updates. 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 Cardiovascular 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*, 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 recommendation 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).

The health consequences of letting insurers impose cost-sharing requirements for these and numerous other critical services could be serious. To take an example based on just one of the many services threatened by the district court's remedy, statins used to reduce the risk of stroke and cardiac arrest first received a qualifying Task Force rating in 2016. *See supra* at 19. If insurers impose cost-sharing requirements for patients to receive these life-saving medications, research suggests

that patients could 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 (1) providing cost-free coverage for statins to (2) charging $10–$25 copayments to (3) 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 found 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 affected by the district court's remedy. 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 cost-sharing requirements can prevent or deter patients from utilizing medical 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. Even if this Court affirms the district court's constitutional ruling, it should respect Congress's policy aims by rejecting the district court's overbroad remedy in favor of a remedy that addresses the constitutional flaw while preserving the public-health protections Congress rightly deemed crucial.

CONCLUSION

This Court should reverse the district court's judgment.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B)(i) because, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and the Rules of this Court, it contains 4,627 words.

This brief also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 29(a)(4), 32(a)(5), and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Amici Curiae with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit on June 27, 2023, using the Appellate Electronic Filing system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

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