TABLE OF CONTENTS

Page

I. STATEMENT OF INTEREST OF AMICI CURIAE ..... 1

II. SUMMARY OF ARGUMENT ..... 2

III. ARGUMENT ..... 6

A. The ACA and Preventive Health Care ..... 7

B. The History and Role of the USPSTF, ACIP, and HRSA ..... 9

C. The Roles Assigned To USPSTF, ACIP, and HRSA Do Not Violate The Appointments or Vesting Clauses ..... 14

D. The Preventive Services Provision Provides An Intelligible Principle Satisfying the Nondelegation Doctrine ..... 18

IV. CONCLUSION ..... 20

**Other Authorities**

5 C.F.R. § 317.605(b) ..... 11

42 C.F.R. § 457.419(b)(2) ..... 15

45 C.F.R. 147.130 ..... 16

155 Cong. Rec. S12025 (Dec. 1, 2009) ..... 12

*A Rapid Review*, Medical Care Research and Review, 2021 June, https://pubmed.ncbi.nlm.nih.gov/34157906/ (last visited Feb. 3, 2022) ..... 9

American Academy of Pediatrics, Bright Futures, https://brightfutures.aap.org/about/Pages/About.aspx ..... 13

Baucus Address on Health Care Policy Before the National Health Policy Conference, http://www.finance.senate.gov/newsroom/chairman/release/?id=63d38edc-5c34-42af-a12b-bb0a54f8b4e90 (last visited Feb. 3, 2022) ..... 7

Brief, June 2015, https://www.cdc.gov/nccdphp/dch/pdfs/value_based_ins_design.pdf ..... 7

Centers for Disease Control and Prevention, *ACIP Evidence to Recommendation Framework*, https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf ..... 11

Centers for Disease Control and Prevention, CDC Statement on ACIP Booster Recommendations, Press Release, Sept. 24, 2021, https://www.cdc.gov/media/releases/2021/p0924-booster-recommendations.html ..... 16

Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, *History and Evolution of the Advisory Committee on Immunization Practices – United States, 164-2014*, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm ..... 10

CMS.gov, NHE Fact Sheet, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (last visited Feb. 3, 2022) ..... 6

Dai, H. and Khan, A.S., *The Effects of the Affordable Care Act on Health Access among Adults Aged 18-64 Years with Chronic Health Conditions in the United States, 2011-2017*, Journal of Public Health Management and Practice, September 9, 2020 ..... 8

Health Resources & Services Administration, Bright Futures, https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html ..... 12

Health Resources & Services Administration, https://www.hrsa.gov/ ..... 11

HealthCare.gov, Preventive Health Services, https://www.healthcare.gov/coverage/preventive-care.

U.S. Preventive Services Task Force, Our Members, https://www.uspreventiveservicestaskforce.org/uspstf/index.php/about-uspstf/current-members ..... 10

The Washington Post (June 5, 2021), https://www.washingtonpost.com/politics/2021/06/05/record-31-million-americans-have-healthcare-coverage-through-affordable-care-act-white-house-says/ -

## I. STATEMENT OF INTEREST OF AMICI CURIAE

The *amici curiae* are a group of 20 distinguished professors and researchers from the disciplines of economics, public health, health policy, and law, listed in Appendix I, who are experts with respect to the economic and social forces operating in the health care and health insurance markets. *Amici curiae* also includes the American Public Health Association and the Association of American Medical Colleges[1]

The American Public Health Association ("APHA"), which was founded in 1872, is a Washington, D.C.-based professional organization for public health professionals in the United States. The APHA champions the health of all people and all communities; strengthens the profession of public health; shares the latest research and information; promotes best practices; and advocates for public health issues and policies grounded in scientific research. APHA represents more than 22,000 individual members and is the only organization that combines a 150-year perspective, a broad-based member community , and the ability to influence federal policy to improve the public's health.

The Association of American Medical Colleges ("AAMC") is a nonprofit association dedicated to transforming health through medical education, health care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems; and more than 70 academic societies

Amici have closely followed the development, adoption, and implementation of the Affordable Care Act ("ACA"). They are familiar with the structure of the program and the

defects in our health care system this program was enacted to remedy. They understand the importance of preventive health services and screening. They are familiar with health insurance coverage and regulation.

Amici submit this brief to assist this Court to understand the nature and importance of the ACA's requirement that insurers and health plans provide preventive health services and screening and immunization without cost sharing. Amici will also explain why the history and structure of the U.S. Preventive Services Task Force ("USPSTF"), the Advisory Committee on Immunization Practices ("ACIP"), and the Health Resources and Services Administration ("HRSA") make them appropriate organizations for identifying preventive services and why the role of these organizations violates neither the Appointments nor the Vesting Clause of the Constitution. Finally, amici will explain why the language of 42 U.S.C. §300gg-13 provides clear intelligible principles for these entities to exercise their discretion given Congressional understanding of this language.

## II. SUMMARY OF ARGUMENT

The Affordable Care Act revolutionized health care in America. It extended premium tax credits and Medicaid coverage to over 31 million Americans,[2] required coverage of maternity, mental health, and pharmaceutical benefits (often excluded from prior insurance policies) as essential health benefits in the individual and small group markets, and required insurers to cover pre-existing conditions.

One particularly important provision of the ACA, 42 U.S.C. § 300gg-13(a), requires that all non-grandfathered insurers and group health plans cover preventive and screening services without cost-sharing ("Preventive Services Provision"). These services include high value child and adult immunizations, against diseases that include polio and the measles; adult preventive services, such as cervical cancer screening in women age 21 to 65 or colorectal cancer screening in adults age 45 to 75;[3] and well-woman and children's preventive services, such as breastfeeding services and supplies and breast cancer screening.[4]

Specifically, 42 U.S.C. § 300gg-13(a), Coverage of Preventive Services, provides:

> A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—
>
> (1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;
>
> (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and
>
> 3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.
>
> (4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines

---

[3] U.S. Preventive Services Task Force, A & B Recommendations, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-and-b-recommendations (last visited Feb. 3, 2022)

[4] HealthCare.gov, Preventive Health Services, https://www.healthcare.gov/coverage/preventive-care-benefits/ (last visited Feb. 3, 2022); *Access to Preventive Services without Cost-shaHfi*

> supported by the Health Resources and Services Administration for purposes of this paragraph.
>
> (5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

As of 2020, 151.6 million Americans were benefited by this coverage, including almost 13 million Texans.[5]

reduce the incidence of colon cancer and colon cancer-specific mortality. [15] Over a 20 year period, childhood vaccines were projected to prevent 322 million illnesses, 21 million hospitalizations, and 732,000 premature deaths. [16] Provision of breast feeding services and supplies without cost sharing resulted in increased rates and duration of breast feeding, which in turn improves maternal and infant health. [17] Several studies have found that the ACA resulted in improvements in affordability of care, regular care for chronic conditions, medication adherence, and self-reported health. [18]

There is also considerable evidence that the theory of V-BID, as it is applied to preventive services, works—removing cost sharing increases the use of many beneficial services. A recent literature review found that a majority of high value studies showed

---

[15] Lin, J.S., Perdue, L.A., Henrikson, N.B., *et. al.*, *Screening for Colorectal Cancer: An Evidence Update for the U.S. Preventive Services Task Force*, Evidence Syntheses, No. 202, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services

[16]

increases in the use of preventive services where cost sharing was removed, and

well as state programs and services funded under the Title V Maternal and Child Health Block Grant, which HRSA administers.[34] Bright Futures ("BF") is the formal name of the evidence-based pediatric clinical preventive practice guidelines that ultimately were codified in § 2713(a)(3).[35] In addition to its role in BF, HRSA is responsible for identifying preventive services and screenings for women.

Like USPSTF recommendations and those made by ACIP, BF guidelines utilize a methodology for weighing various sources of evidence, ranging from clinical studies to randomized control trials, to arrive at recommendations regarding which services are the most important to offer or provide. Like USPSTF and ACIP, the BF initiative, sponsored by HRSA since 1990 and incorporated into the ACA through 2713(a)(3), establishes a formal process for clinical practice standard setting that doubles as the standard of preventive services coverage – in this case, for infants, children, and adolescents.

From its experience with USPTSF, ACIP, and HRSA (through the BF program), Congress understood the meaning of the term "preventive care and screenings" it used in 42 U.S.C. § 300gg-13. As noted earlier, Congress used the words prevention and preventive hundreds of times in the ACA. In drafting the ACA, Congress obviously

---

[34] Health Resources & Services Administration, Bright Futures, https://mchb.hrsa.gov/maternal-child-health-topics/child-health/bright-futures.html (last visited Feb. 3, 2022)

[35] Section 2713 rests on a series of precedents governing: preventive services generally, § 2713(a)(1), immunization services, § 2713(a)(2), clinical preventive services for infants,

### C. The Roles Assigned To USPSTF, ACIP, and HRSA Do Not Violate The Appointments or Vesting Clauses.

The entire premise of Plaintiffs' argument that these three expert advisory committees violate the Appointments Clause because they "unilaterally dictate the scope of preventive care that private insurers must cover, without any cost-sharing arrangements such as deductible or copays" is misguided ECF No. 45 (Plaintiffs' Brief in Support of Motion for Summary Judgment) at 14; *id* at 19. Plaintiffs point to *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020) to argue that "any doubt" about the sweeping authority given to HRSA to define preventive care has been removed from the equation. ECF No 45 at 19. The problem with Plaintiffs' formula is that it ignores the text and structure of the ACA.[38]

standard for clinical preventive care as it changes over time. As a result, Congress relied on experienced expert committees to identify evolving data, research, and clinical evidence—and use resulting recommendations to inform standards of coverage. Congress was well aware of the methodologies successfully used by USPSTF, ACIP, and HRSA (related to Bright Futures) when it adopted 42 U.S.C. § 300gg-13.

As a result, USPSTF, ACIP, and HRSA do not "unilaterally dictate the scope of preventive care…." Congress clearly dictates the scope of preventive care through its enactment of 42 U.S.C. § 300gg-13, which mandates that the most current evidence-based preventive care should be covered by insurance. These entities—as instructed by Congress—simply identify, through well-established processes, the most current evidence-based preventive care.

It is important to realize that 42 U.S.C. § 300gg-13 is not the first time Congress made the choice to adopt evidencebased practice guidelines and guideline development processes as the standard of coverage. In 1993 Congress amended the Medicaid statute to establish the Centers for Disease Control and Prevention-supported recommendations of the ACIP as the coverage standard for pediatric vaccines. 42 U.S.C. §§ 1396a(a)(62), 1396s(e). This standard, which evolves with immunization practice itself, binds all state Medicaid programs and ensures that immunization coverage for the poorest children reflects expert standard of care. HHS also adopted the ACIP standard as the standard of coverage for children enrolled in Medicaid's companion Children's Health Insurance Program ("CHIP"). 42 U.S.C. § 1397cc(c), 42 C.F.R. § 457.419(b)(2). Similarly, Congress has done the same with over 1200 other standards adopted by private organizations. *See Amerada Hess Pipeline Corp. v. FERC*, 117 F3d 596, 601 (D.C. Cir. 1997).

Plaintiffs concede that if these expert committees "were performing purely advisory functions," then the Appointment Clause (and the Vesting Clause) would not be offended. ECF No. 45 at 22; *see also* ECF No. 14 ¶ 78 (Plaintiffs assert recommendations made prior to March 23, 2010, the enactment date of the ACA, are valid, but those made after enactment are not because the recommendations are now purported mandates). Despite Plaintiffs' attempt to misconstrue the role of

recommendations regarding which services are the most important to offer or provide – in this case, for infants, children, adolescents, and women. The Administrator for HRSA—and therefore any recommendation issued by HRSA—is completely subject to review by the HHS Secretary. As a result, the HHS Secretary, an individual appointed by the President and confirmed by the Senate, has final authority as to any preventive services "supported by" HRSA as set forth in the Preventive Services Provision.

confirmed principal officers. As a result, Plaintiffs' argument related to the Vesting Clause fails as well.

### D. The Preventive Services Provision Provides An Intelligible Principle Satisfying the Nondelegation Doctrine

Although Article I of the Constitution gives Congress exclusive authority to legislate, the courts have long recognized that Congress could not possibly make all the decisions necessary to govern the United States and must necessarily delegate its authority to executive agencies. In the words of Justice Kagan's plurality decision in the most recent delegation case to be considered by the Supreme Court, *Gundy v. United States*:

> But the Constitution does not 'deny [] to the Congress the necessary resources of flexibil

300gg-13 would still be permissible. Justice Gorsuch's dissent in *Gundy* recognized that under even a "narrowed"

## CERTIFICATE OF SERVICE

On February 4, 2022, I caused the foregoing document to be electronically submitted with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have caused service to be made on all parties who have appeared in the case electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

s/Kaylynn Webb

Kaylynn Webb
McDermott Will & Emery LLP
2501 North Harwood Street, Suite 1900
Dallas, TX 75201-1664
214-295-8043
kwebb@mwe.com

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

List of Amici Curiae Health Policy Experts

Deans and Associate Deans

1. Sherry Glied, PhD
   Dean and Professor of Public Service, Robert F. Wagner Graduate School of Public Service, New York University

2. Lynn R. Goldman, MD, MPH, MS
   Michael and Lori Milken Dean of Public Health, Professor, Environmental and Occupational Health, Milken Institute School of Public Health, The George Washington University

3. Adnan A. Hyder, MD, MPH, PhD
   Senior Associate Dean for Research, Professor, Department of Global Health, Director, Center on Commercial Determinants of Health, Milken Institute School of Public Health, The George Washington University

4. Boris D. Lushniak, MD, MPH
   Dean, University of Maryland School of Public Health

5. John T. Monahan, JD
   Interim Dean, School of Nursing and Health Studies, Professor, Department of Medicine, Senior Fellow at McCourt School of Public Policy, Georgetown University

6. Jane Hyatt Thorpe, JD
   Sr. Associate Dean for Academic, Student and Faculty Affairs, Professor of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

Academic Chairs

1. Anne Markus, PhD, MHS, JD
   Professor and Chair, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

Scholars

1. Maureen Byrnes, MPA
   Teaching Instructor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

2. David M. Frankford, JD
   Professor of Law, Rutgers Law School

3. Katie B. Horton, JD, MPH, RN
   Research Professor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

4. Nicole Huberfeld, JD
   Edward R. Utley Professor of Health Law, Boston University School of Public Health, Professor of Law, Boston University School of law

5. Renée M. Landers, JD
   Professor of Law and Faculty Director, Health and Biomedical Law Concentration and Master of Science in Law, Life Sciences Program, Suffolk University Law School

6. Jeffrey Levi, PhD
   Professor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

7. Wendy Mariner, JD, LLM, MPH
   Professor Emerita, Health Law, Bioethics and Human Rights, Boston University School of Public Health

8. Wendy E. Parmet, JD
   Matthews University Distinguished Professor of Law and Professor of Public Policy and Urban Affairs, Northeastern University

9. Sara Rosenbaum, JD
   Harold and Jane Hirsh Professor, Health Law and Policy, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

10. William M. Sage, MD, JD
    James R. Dougherty Chair for Faculty Excellence, School of Law, Professor of Surgery and Perioperative Care, Dell Medical School, The University of Texas at Austin

11. Naomi Seiler, JD
    Associate Research Professor, Department of Health Policy and Management, Milken Institute School of Public Health, The George Washington University

12. Timothy Stoltzfus Jost, JD
    Emeritus Professor, Washington and Lee