IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

JOHN KELLEY, *et al*.,	)	
	)	
Plaintiffs,	)	
	)	Case No. 4:20-cv-00283-O
v.	)	
	)	
XAVIER BECERRA, *et al*.,	)	Judge Reed O'Connor
	)	
Defendants.	)	
	)	
	)	
	)	

***AMICI CURIAE* BRIEF OF 20 HEALTH POLICY EXPERTS,**
THE AMERICAN PUBLIC HEALTH ASSOCIATION,
AND THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES
IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

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

[1] *Amici* affirms that no counsel for any party authored this brief in whole or in part; no party or party's counsel contributed money to fund preparation or submission of the brief; and no one contributed money to fund the preparation or submission of this brief. Counsel for all parties have consented to the filing of this brief.

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.

[2] Amy B. Wang, *Record 31 million Americans have health-care coverage through Affordable Care Act, White House says*, The Washington Post (June 5, 2021), https://www.washingtonpost.com/politics/2021/06/05/record-31-million-americans-have-health-care-coverage-through-affordable-care-act-white-house-says/ (last visited Feb. 3, 2022)

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

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[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-sharing: Evidence from the Affordable Care Act* (Issue Brief No. HP-2022-01). Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, January 2022, https://www.aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf (last visited Feb. 3, 2022)

> 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] These coverage requirements have also helped increase access to preventive care, including colon cancer screening, vaccination, and blood pressure and cholesterol screening.[6] Preventive screenings and interventions such as those covered by the ACA are critical to keeping patients healthy and improving long-term health outcomes.

Plaintiffs in this case challenge these requirements. Some Plaintiffs are individuals who purchase coverage in the individual insurance market while others are businesses that purchase coverage in the group health insurance market or are self-insured. ECF No. 14 (First Amended Complaint) ¶¶ 33-65. Some object to the preventive services mandates for religious reasons, in particular objecting to contraceptive coverage and coverage of PrEP (an HIV prevention drug). *Id.*; *id.* at ¶¶ 21-31, 108-111. Other Plaintiffs object for economic reasons, claiming that the preventive services mandate raises the cost of insurance coverage. *See, e.g., id.* ¶¶ 35, 51, and 64. All claim that they do not want or need certain preventive services, but that the Preventive Services Provision makes it impossible for them to purchase insurance that does not cover preventive services without cost sharing. *Id.* ¶¶ 34, 41, 46, 50, 56, and 64.

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[5] *Id.*
[6] *Id.*

Plaintiffs' first amended complaint raises a number of objections to the Preventive Services Provision. These include, but are not limited to, the contention that the role Congress assigned to members of USPSTF, ACIP, and HRSA violate the Appointments and Vesting Clauses of Article II, § 2 of the United States Constitution and the nondelegation doctrine. *Id.* ¶¶ 66-111.

On August 7, 2020, Defendants moved to dismiss the complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Procedure. ECF No. 20 (Motion to Dismiss). On February 25, 2021, this Court granted Defendants' motion to dismiss in part. This Court dismissed Plaintiffs' statutory interpretation claims and dismissed the claims of the plaintiffs who asserted religious objections to the contraceptive coverage requirement as *res judicata*. ECF No. 35 (Order) at 1. This Court denied Defendants' motion to dismiss in all other respects. *Id.* Two plaintiffs subsequently withdrew their claims voluntarily. ECF No. 47 (Joint Stipulation of Dismissal).

Subsequently, the parties filed cross-motions for summary judgement. ECF No. 44, 62. Relevant to this brief,[7] the parties take conflicting views as to the impact the Appointments and Vesting Clauses and the nondelegation doctrine have on the validity of the Preventive Services Provision. *Id.* As discussed in detail below, given the history and structure of the ACA and USPSTF, ACIP, and HRSA, *Amici* urge this Court to grant Defendants' Motion for Summary Judgment as to Plaintiffs' claims. The roles of these three entities—to make recommendations and provide guidelines on immunizations and preventive services and screenings—violate neither the Appointments or Vesting Clauses of the Constitution, nor the nondelegation doctrine as the statutory language provides

[7] Amici do not address arguments or claims related to standing or the Religious Freedom Restoration Act.

clear intelligible principles for these entities to exercise their discretion given Congressional understanding of this language.

III. ARGUMENT

Health care costs are very high in the United States by any measure. In 2020, the United States spent $4.1 trillion dollars on health care.[8] One strategy for controlling health care costs is to give consumers "skin in the game"—to ensure through the use of deductibles, copayments, and coinsurance that consumers themselves limit health care expenditures.[9] A problem with this approach, however, is that consumers are not experts, and tend to cut high-value care as well as low-value care.[10] A value-based insurance design ("V-BID") uses expert research to identify high-value services and reduces or eliminates consumer cost-sharing for these services. Thus, consumers are incentivized to use high value care and disincentivized to use low-value health care without being forced to use any particular form of care. The Preventive Services Provision, found at 42 U.S.C. § 300gg-13, is based on value-based insurance design and is intended to promote high-value preventive services, which ultimately will improve health and will lower health care costs.[11]

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[8] 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)

[9] Timothy S. Jost, Health Care at Risk, 18-19 (2007)

[10] *Id* at 123.

[11] Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Understanding Value-Based Insurance Design, Issue Brief, June 2015, https://www.cdc.gov/nccdphp/dch/pdfs/value_based_ins_design.pdf (last visited Feb. 3, 2022)

A. The ACA and Preventive Health Care

Congress concluded in drafting the ACA that appropriate evidence-based preventive healthcare screenings, vaccinations, immunizations, and counseling are high-value services, the use of which should be encouraged through eliminating cost sharing.[12] From the beginning, prevention was a central focus of the Affordable Care Act. As early as 2007, Senator Max Baucus, who as chair of the Senate Finance Committee was the lead drafter of the ACA, identified prevention as one of five key principles of health reform.[13] The word prevention appears 233 times in the Affordable Care Act and the word preventive 108 times. An entire title of the ACA is devoted to "prevention of chronic disease and improving public health." When drafting the ACA, Congress clearly delineated its general policy of promoting prevention.

The expert bodies designated by 42 U.S.C. § 300gg-13 identify evidence as to the effectiveness of particular preventive services, screenings, and immunizations that insurers and group health plans must cover without cost sharing, often for particular populations (such as children or adults over a certain age). There is clear evidence that that the preventive services, screenings, and immunizations they have identified in fact improve health and save lives.[14] Colon cancer screening in accordance with the recommendations of USPSTF for individuals between 45 and 70 has been shown to

[12] National Conference of State Legislatures, Value-Based Insurance Design, updated Feb. 20, 2018, https://www.ncsl.org/research/health/value-based-insurance-design.aspx (last visited Feb. 3, 2022)
[13] Baucus Address on Health Care Policy Before the National Health Policy Conference, http://www.finance.senate.gov/newsroom/chairman/release/?id=63d38d5c-bc34-42af-a12b-b0a54f8b4e90 (last visited Feb. 3, 2022)
[14] *See supra*, note 4

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

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[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] Whitney, C. G., Zhou, F., Singleton, J., & Schuchat, A., *Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013*, Morbidity and Mortality Weekly Report, 2014 Apr. 25; 63(16): 352, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584777/ (last visited Feb. 3, 2022)

[17] Ip, S., Chung, M., Raman, G., Chew, P., *et. al.*, *Breastfeeding And Maternal And Infant Health Outcomes In Developed Countries*, Evidence Reports Technology Assessments, 2007 Apr.; (153):1-186, https://pubmed.ncbi.nlm.nih.gov/17764214/ (last visited Feb. 3, 2022); Women's Preventive Service Initiative, *Evidence Summary: Breastfeeding Services and Supplies,* https://www.womenspreventivehealth.org/wp-content/uploads/Breastfeeding-Services-and-Supplies.pdf (last visited Feb. 3, 2022); Patnode, C.D., Henninger, M.L., Senger, C.A., *et al.*, *Primary Care Interventions To Support Breastfeeding*, *Updated Systematic Review for the U.S. Preventive Services Task Force*, Evidence Syntheses, No. 143, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services

[18] Sommers, B., Maylone, B., Blendon, R.J., *et al.*, *Three-Year Impacts of the Affordable Care Act: Improved Medical Care and Health among Low-Income Adults*, Health Affairs, June 2017, Volume 36(6):1119-28, https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0293 (last visited Feb. 3, 2022); 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

increases in the use of preventive services where cost sharing was removed, and substantial increases for persons who were financially vulnerable.[19]

Further, Congress made it clear as to the entities that were to apply this principle of promoting prevention and clearly defined the tasks that these entities were supposed to undertake. Congress tasked USPSTF as responsible for identifying preventive services and screenings, ACIP as responsible for identifying appropriate vaccines, and HRSA to identify women's and children's preventive services and screenings.[20] 42 U.S.C. § 300gg-13(a)(4). The boundaries of the discretion of USPSTF, ACIP, and HRSA are clearly defined: all guidelines and recommendations must be based on scientific evidence, and each must cover a specific population.

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

In 1984, Congress created the U.S. Preventive Services Task Force ("USPSTF"), which is now supported by the Agency for Health Care Research and Quality (AHRQ).[21] USPTF is charged with: (1) rigorously evaluating the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services and (2) formulating/updating recommendations regarding the appropriate provision of preventive services.[22] It

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[19] Norris, H., Richardson, H.M., Benoit, M-A.C., *et al.*, *Utilization Impact of Cost-Sharing Elimination for Preventive Care services: A Rapid Review*, Medical Care Research and Review, 2021 June, https://pubmed.ncbi.nlm.nih.gov/34157906/ (last visited Feb. 3, 2022).

[20] Because HRSA is an agency of the federal government, the issue of delegation to a private entity in *Texas v. Rettig*, 993 F.3d 408 (5th Cir. 2021) is not presented here.

[21] 42 U.S.C. § 299b-4. The AHRQ is a federal agency within HHS, whose role, in part, is to "provide ongoing administrative, research, and technical support for the operations of [USPSTF], including coordinating and supporting the dissemination of the recommendations of the [USPSTF], ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the [USPSTF]'s recommendations." 42 U.S.C. § 299b-4(a)(3).

[22] 42 U.S.C. § 299b-4(a)(1).

currently consists of 16 volunteer members selected by the Director of AHRQ.[23] Its 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.[24] The mission of USPSTF is to improve the health of Americans by making "evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications."[25] These recommendations arise from a scale known as "Grade" which identifies preventive services procedures and based on a detailed evidentiary review, assigns them a letter grade (A-D), which ranges from "offer or provide this service" to "Discourage the use of this service."[26] An "A" or "B" grade for a particular procedure comes with an "offer or provide this service" recommendation. While USPSTF pioneered earlier versions, the Grade scale and evidentiary review process now in use has been in existence since 2007.

The Advisory Committee on Vaccination Practices ("ACIP") has existed since 1964.[27] Originally, ACIP was established as a technical advisory committee to the U.S. Public Health Service and received formal designation as a federal advisory committee in

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[23] 42 U.S.C. § 299b-4.
[24] U.S. Preventive Services Task Force, Our Members, https://www.uspreventiveservicestaskforce.org/uspstf/index.php/about-uspstf/current-members (last visited Feb. 3, 2022)
[25] U.S. Preventive Services Task Force, About the USPSTF, https://uspreventiveservicestaskforce.org/uspstf/about-uspstf (last visited Feb. 3, 2022)
[26] U.S. Preventive Services Task Force, Methods and Processes, Grade Definitions, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions (last visited Feb. 3, 2022)
[27] 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 (last visited Feb. 3, 2022)

1972 under the Federal Advisory Committee Act.[28] It is currently composed of 15 voting members, including the chair, who are external to the federal government; six non-voting members representing government agencies, and 27 non-voting members representing healthcare specialty organizations.[29] Members are appointed by the Secretary for the U.S. Department of Health and Human Services ("HHS") and are selected from authorities who are knowledgeable in the fields of immunization practices and public health. The ACIP meets 3 times a year. It develops recommendations to the Centers for Disease Control and Prevention ("CDC") on appropriate use of vaccines.[30] Its vaccine recommendations are developed using an explicit evidence-based method considering the balance of benefits and harms, type or quality of evidence, values and preferences of the people affected, and health economic analyses.[31]

The Health Resources and Services Administration ("HRSA") is an agency of the HHS.[32] It is led by an Administrator, who is appointed by the HHS Secretary, and removable at will.[33] In 1990, HRSA, together with the Health Care Financing Administration (now Centers for Medicare and Medicaid Services ("CMS")) developed the Bright Futures Program to provide evidence-based pediatric preventive services guidelines for the Medicaid program (and later Children's Health Insurance Program) as

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[28] *Id.*
[29] U.S. Department of Health and Human Services, Charter of the Advisory Committee on Immunization Practices, https://www.cdc.gov/vaccines/acip/committee/acip-charter.pdf (last visited Feb. 3, 2022)
[30] *Id.*
[31] *Id.*; 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 (last visited Feb. 3, 2022)
[32] Health Resources & Services Administration, https://www.hrsa.gov/ (last visited Feb. 3, 2022); *see also* https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html (last visited Feb. 3, 2022)
[33] *See* 5 C.F.R. § 317.605(b).

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

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[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, children, and adolescents, § 2713(a)(3), and women, § 2713(a)(4). Specifically, (a)(4) provides that "with respect to women, such additional preventive care and screenings not described in paragraph (1) [USPSTF] as provided for in comprehensive guidelines supported by [HRSA]." From the Senate floor debates on subsection (a)(4), it appears that Congress specifically chose HRSA as a gap-filler for preventive services for women because HRSA is a federal agency under the control of the Secretary of Health and Human Services, who had taken a strong position in support of women's preventive health service. 155 Cong. Rec. S12025 (Dec. 1, 2009) (remarks of Sen. Boxer).

understood what preventive health services were. *F.A.A. v. Cooper*, 566 U.S. 284, 292 (2012) (a "cardinal rule of statutory construction" is when Congress employs a term of art, "it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken") (internal quotations omitted). For example, legislation creating the AHRQ in 1990 had described the mission of the U.S. Preventive Services Task force to:[36]

> 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.

Further, Congress was well aware of the methodologies successfully used by USPSTF and ACIP when it adopted 42 U.S.C. § 300gg-13. It was also aware of similar work done by HRSA in crafting its "Bright Futures" guidelines. The work and history of BF, in particular, explains why it was HRSA and not, for example, the CDC that was tasked by lawmakers. HRSA is the home of maternal and child health bureau whose roots date to the 1912 Children's Bureau and is the logical source of expertise on women's health policy development.[37] CDC is best known for its investigative work, but is not a home to maternal/women's and child health policy as is HRSA. So, the reference to the pediatric standard in 42 U.S.C. § 300gg-13(a)(3) is indicative of Congress's desire for the same sort of robust evidentiary process used successfully in other contexts.

[36] Public Law 106-129, December 6, 1999, 113 Stat. 1653 (106th Congress)
[37] American Academy of Pediatrics, Bright Futures, https://brightfutures.aap.org/about/Pages/About.aspx (last visited Feb. 3, 2022)

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]

Medical knowledge regarding the effectiveness of health care, including clinical preventive services, is in a constant state of dynamic evolution. For this reason, Congress elected to develop a preventive services' benefit whose scope is tied to the evolving preventive care evidence base rather than standing as a defined, static list of covered procedures. The Preventive Services Provision, therefore, mandates a series of preventive benefit developmental processes rather than the ultimate coverage standard per se. The evolving standard of coverage is intended to align with the evidence-based practice

[38] In addition, Plaintiffs misconstrue the Justices' view as to who had the *final* authority as set forth in *Little Sisters*. *See, e.g., Little Sisters of the Poor Saints Peter & Paul Home*, 140 S. Ct. at 2386 ("We hold today that the Departments had the statutory authority to craft that exemption, as well as the contemporaneously issued moral exemption."); *see id.* at 2387-88 (Alito, J. with Gorsuch, J., concurring) (noting that "the relevant Departments" instructed HRSA to create an exemption for religiously-affiliated entities); *see also id.* at 2403 (Ginsburg, J. with Sotomayor, J., dissenting) ("Under new rules drafted not by HRSA, but by the IRS, EBSA, and CMS, any 'non-governmental employer'—even a publicly traded for-profit company—can avail itself of the religious exemption previously reserved for houses of worship.").

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 evidence-based 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 USPSTF, ACIP, and HRSA, these entities are simply providing recommendations—as they have done for decades. It was Congress that decided to accept those recommendations and incorporate them into law.

For example, 42 U.S.C. § 300gg-13(a)(2) only requires coverage of vaccines with an ACIP recommendation "in effect." Under the relevant regulatory provision, 45 C.F.R. § 147.130, "a recommendation from the ACIP is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention [who is appointed by the executive branch], and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention." ACIP, that is, does not exercise sovereign power, but merely makes a recommendation to the CDC, which does exercise the power. Although CDC usually accepts ACIP recommendations, it is not a rubber stamp. In September 2021, the CDC expanded on ACIP's recommendation for access to COVID-19 booster shots,[39] demonstrating its independent review authority.

The same is true for preventive services "supported by" HRSA. HRSA guidelines utilize a methodology for weighing various sources of scientific evidence to arrive at

[39] 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 (last visited Feb. 3, 2022)

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.

In contrast to ACIP and HRSA, USPSTF is an independent entity that does not possess or exercise executive authority. The mandate for USPSTF, found at 42 U.S.C. § 299b-4, provides that the independent experts:

> shall 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, to be published in the Guide to Clinical Preventive Services...***for*** individuals and organizations delivering clinical services,...***Congress*** and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives.

(emphasis added). In other words, USPSTF is directed to provide recommendations to Congress related to preventive services, and in turn, Congress decided, when it enacted 42 U.S.C. § 300gg-13, to adopt these recommendations for care that insurance companies must cover.

Finally, as to the Vesting Clause, USPSTF, ACIP, and HRSA do not directly enforce their standards against insurers and group plans. Enforcement of 42 U.S.C. § 300gg-13 falls to CMS with respect to insurers and to the Employee Benefit Services Administration of the Department of Labor and Internal Revenue Service with respect to group plans. *See* 26 U.S.C. § 4980D; 26 U.S.C. § 9815; 29 U.S.C. § 1132(a)(5); 29 U.S.C. § 1185a; *see also* 42 U.S.C. § 300gg-22. The heads of these three departments are appointed and

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 flexibility and practicality [that enable it] to perform its function[s].' [citation] Congress may 'obtain [] the assistance of its coordinate Branches'—and in particular, may confer substantial discretion on executive agencies to implement and enforce the laws. [citation] '[I]n our increasingly complex society, replete with ever changing and more technical problems,' this Court has understood that 'Congress simply cannot do its job absent an ability to delegate power under broad general directives.'

139 S. Ct. 2116, 2123 (2019). Because of this the Court has, again in the words of Justice Kagan,:

> . . . held, time and again, that a statutory delegation is constitutional as long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.' [citation]
>
> Given that standard, a nondelegation inquiry always begins (and often almost ends) with statutory interpretation. The constitutional question is whether Congress has supplied an intelligible principle to guide the delegee's use of discretion. So, the answer requires construing the challenged statute to figure out what task it delegates and what instructions it provides.
>
> * * *

> 'It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.' [citation] And beyond context and structure, the Court often looks to 'history [and] purpose' to divine the meaning of language.

Id. at 2123-26. Under this standard, the Court has for over 80 years not held that a delegation violates the Constitution and has only done so twice in its history. *See Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935); *A. L. A. Schechter Poultry Corporation v. United States*, 295 U.S. 495 (1935).

The most recent Fifth Circuit authority on delegation takes exactly the same position. In *Big Time Vapes v. FDA*, 963 F.3d 436 (5th Cir. 2020) *cert denied* 2021 WL 2302098, at *1 (U.S. June 7, 2021), the court upheld a delegation to the FDA, stating:

> Delegations are constitutional so long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized [to exercise the authority] is directed to conform.' [citation] It is 'constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of th[e] delegated authority.'

963 F.3d at 441-42. Here, Congress articulated an "intelligible principle," which USPSTF, ACIP, and HRSA have applied in determining which preventive health services and screenings and immunizations must be covered by non-grandfathered health plans without cost sharing. They must be evidence-based and preventive. Congress understood from past experience what was meant by these terms and provided intelligible principles based on this experience.

Plaintiffs argue that in recent Supreme Court cases, however, some Justices have opined that the intelligible principles requirement is too broad and should be narrowed. *See, e.g., Gundy*, 139 S. Ct. at 2131 (Gorsuch, J., dissenting). Even should the Supreme Court abandon or narrow the intelligible principle doctrine, the delegation in 42 U.S.C. §

300gg-13 would still be permissible. Justice Gorsuch's dissent in *Gundy* recognized that under even a "narrowed" delegation doctrine, "as long as Congress makes the policy decisions when regulating private conduct, it may authorize another branch to "fill up the details." 139 S. Ct. at 2136. Later in his dissent, he analogizes this to the "major questions doctrine," which prohibits Congress from delegating authority to the executive concerning questions "of deep economic and political significance." *Id*. at 2141.

In enacting the ACA, Congress made the major decision that all health plans and insurers must provide preventive care and screening without cost sharing. Given the clear fact that medical knowledge, including clinical preventive services, is in a constant state of dynamic evolution, USPSTF, ACIP, and HRSA were merely given the task to "fill up the details" as to which preventive care and screenings and immunizations should be recommended for coverage.

IV. CONCLUSION

For the forgoing reasons, *amici* respectfully urge this Court to grant summary judgment for Defendants.

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Respectfully submitted,

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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).

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