September 8, 2022

ATTORNEY GENERAL RAOUL ISSUES STATEMENT ON COURT DECISION THAT JEOPARDIZES ACCESS TO PREVENTIVE MEDICAL CARE

Chicago — Attorney General Kwame Raoul today issued the following statement in response to a decision by the U.S. District Court for the Northern District of Texas in Braidwood Management Inc. v. Xavier Becerra, a case challenging the Affordable Care Act's preventive care provisions, which require private health insurers to cover certain preventive care services. The court held in part that the provisions requiring health insurance coverage of pre-exposure prophylaxis (PrEP) – medication that, when taken as prescribed, reduces the risk of contracting HIV by approximately 99% – violated the rights of an employer with a religious objection. In January, Raoul led a coalition of 20 attorneys general in filing an amicus brief defending the law.

"Instead of upholding the Affordable Care Act's expansion of access to lifesaving preventive medical care, the court has chosen to jeopardize access to PrEP medications, endangering the lives of at-risk populations throughout Illinois. With HIV continuing to disproportionally affect members of the LGBTQ+ community and communities of color, this decision represents a direct assault on these communities.

"Access to preventive medical care improves the health outcomes of patients and reduces the strain on our already overburdened health care delivery systems. I will continue to defend the Affordable Care Act in court against attempts to dismantle vital provisions that ensure access to needed medical care services for Illinois residents."

January 28, 2022

ATTORNEY GENERAL RAOUL LEADS DEFENSE OF KEY PROVISIONS OF THE AFFORDABLE CARE ACT

Chicago — Attorney General Kwame Raoul today led a coalition of 20 attorneys general in filing an amicus brief in Kelley v. Becerra, defending key provisions of the Affordable Care Act (ACA) that guarantee access to preventive care for millions of Americans.

Raoul's brief, filed in the U.S. District Court for the Northern District of Texas, defends the ACA's preventive services provisions, which require private health insurers to cover certain preventive care services, including contraceptive care and prophylactic anti-HIV care, free of charge. In the brief, Raoul and the coalition argue that the preventive services provisions have improved health outcomes for residents and urge the court to reject the plaintiffs' challenges.

"Eliminating the preventive services provisions from the Affordable Care Act would have devastating consequences for both the individuals who utilize these services, the overall health and welfare of residents, and the stability of already overburdened statewide public health systems," Raoul said. "I will continue to fight attempts to repeal any part of the Affordable Care Act and diminish access to health care for Illinois residents."

The plaintiffs in the case are employers who wish to offer their employees health insurance that does not cover certain preventive services, most notably contraceptive care and prophylactic anti-HIV care, and employees who wish to purchase health insurance that does not cover such services. They argue that the provisions should be eliminated because they violate individuals' rights under the Religious Freedom Restoration Act (RFRA) and violate the U.S. Constitution's Appointments Clause.

The ACA's preventive services provisions require employers to cover certain preventive care services, and the provisions incorporate recommendations made by three expert bodies – the U.S. Preventive Services Task Force (PSTF), the CDC's Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA) – in defining the services that must be covered. The plaintiffs argue that the provisions violate the appointments clause because those expert bodies have not been appointed by the president and confirmed by the Senate. In today's brief, Raoul and the coalition argue that the federal government may rely on recommendations made by experts of this kind without violating the appointments clause. The attorneys general also argue that the plaintiffs have failed to establish that providing these preventive services substantially burdens private insurers' religious beliefs.

Raoul and the coalition further argue that, since being enacted in 2010, the ACA's preventive services provisions have had a positive impact on both residents' individual health and states' health care systems. Raoul and the attorneys general explain that millions of Americans have relied on the preventive services provisions to obtain no-cost preventive care, which has improved not only the health of those individuals, but public health outcomes more broadly. States have also come to rely on these provisions in building and strengthening their own public health systems. Raoul and the coalition argue that if the court were to invalidate the preventive services provisions, it could destabilize and overburden state public-health systems – including interfering with their abilities to effectively respond to the COVID-19 pandemic – which would have significant consequences for all Americans.

Joining Raoul in the brief are the attorneys general of California, Colorado, Connecticut, Delaware, the District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington.

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT INC. et al.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 4:20-cv-00283-O**
	§	
XAVIER BECERRA et al.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION & ORDER

Before the Court are Plaintiffs' Motion for Summary Judgment (ECF Nos. 44–46), filed November 15, 2021; Defendants' Combined Response and Cross-Motion for Summary Judgment (ECF Nos. 62–65), filed January 28, 2022; Plaintiffs' Combined Response and Reply (ECF No. 74), filed March 28, 2022; and Defendants' Reply (ECF No. 83), filed May 26, 2022. The Court held a hearing on the motions on July 26, 2022. Having considered the motions, arguments, and applicable law, the Court **ORDERS** that motions are **GRANTED in part** and **DENIED in part**.

I. BACKGROUND

A. The Law

The Patient Protection and Affordable Care Act ("ACA") requires most private health insurance to cover certain "preventive care." 42 U.S.C. § 300gg-13. Specifically, group health plans and health insurance issuers must "provide coverage for and shall not impose any cost sharing requirements for" four categories of preventive care. *Id.* The ACA empowers three agencies affiliated with the Department of Health and Human Services ("HHS") to determine what services fall within those four categories. *Id.*

First, the U.S. Preventive Services Task Force ("PSTF") recommends "evidence-based items or services that have in effect a rating of 'A' or 'B.'" *Id.* § 300gg-13(a)(1). Second, the Advisory Committee on Immunization Practices ("ACIP") recommends certain immunizations. *Id.* § 300gg-13(a)(2). Third, the Health Resources and Services Administration ("HRSA") issues "comprehensive guidelines" with respect to infants, children, and adolescents for "evidence-informed preventive care and screenings." *Id.* § 300gg-13(a)(3). And fourth, HRSA issues "comprehensive guidelines" with respect to women for "such additional preventive care and screenings" not covered under § 300gg-13(a)(1). *Id.* § 300gg-13(a)(4). Private health insurance must cover the services identified by the three agencies under these categories.[1] *Id.* § 300gg-13(a).

1. PSTF

PSTF is a body of volunteers "with appropriate expertise" to make healthcare recommendations. 42 U.S.C. § 299b-4(a)(1). The Director of the Agency for Healthcare Research and Quality ("AHRQ"), an agency within HHS, "convene[s]" PSTF. *Id.* The purpose of PSTF is 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.* By statute, PSTF and its members "shall be independent and, to the extent practicable, not subject to political pressure." *Id.* § 299b-4(a)(6).

In 2019, PSTF recommended pre-exposure prophylaxis ("PrEP") drugs to prevent HIV infection. *See* Defs.' App. 385, ECF No. 65. PSTF issued an "A" recommendation for PrEP drugs for individuals who are at high risk of HIV acquisition, which meant that health insurance plans must cover PrEP drugs under 42 U.S.C. § 300gg-13(a)(1). *See* Pls.' App. 12, ECF No. 46. The

[1] The Court refers to § 300gg-13(a)(1) through (a)(4) collectively as the "preventive-care mandates."

regulations delayed implementation of the coverage until June 2020. *See* 45 C.F.R. § 147.130(b)(1).

2. ACIP

The HHS Secretary created ACIP as an advisory council under 42 U.S.C. § 217a(a) to provide guidance to HHS on vaccines. *See* Defs.' App. 152, ECF No. 65. ACIP reports to the Director of the Centers for Disease Control and Prevention ("CDC"), who exercises delegated authority from the HHS Secretary. *See id.* (first citing 42 U.S.C. § 243; and then citing *id.* § 247b). A vaccine recommendation from ACIP "is considered in effect after it has been adopted by the Director of the [CDC]." 45 C.F.R. § 147.130(a)(1)(ii). Once the CDC Director adopts a vaccine recommendation, ACIP publishes the recommendation in a weekly report. *See* Defs.' App. 152, ECF No. 65.

ACIP recommends the HPV vaccine to prevent new HPV infections and HPV-associated diseases, including some cancers. In 2007, ACIP began recommending the HPV vaccine for females ages eleven to twelve. *See* CDC, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)* (Mar. 23, 2007), https://www.cdc.gov/mmwr/PDF/rr/rr5602.pdf. ACIP currently recommends the HPV vaccine for all children ages eleven to twelve, plus various catch-up vaccination plans for older populations. *See* Elissa Meites et al., *Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices* (Aug. 16, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf. Health insurance plans must cover the HPV vaccine under 42 U.S.C. § 300gg-13(a)(2).

3. HRSA

The HHS Secretary created HRSA to provide direction to programs and activities within HHS. *See* Health Resources and Services Administration; Statement of Organization, Functions,

and Delegations of Authority, 47 Fed. Reg. 38,409 (Aug. 31, 1982). HRSA is directed by an Administrator who reports to the Assistant Secretary of HHS. *Id.* at 38,410. The HRSA Administrator, like the CDC Director, is a non-career political appointee whose employment may be terminated by the agency at any time. *See* 5 C.F.R. § 317.605; Defs.' App. 42, ECF No. 65.

In 2010, HRSA promulgated a series of comprehensive guidelines for infants, children, and adolescents. The guidelines include counseling for alcohol abuse, screening and behavioral counseling for sexually transmitted infections, screening and behavior interventions for obesity, and counseling for tobacco use. *See Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act*, 75 Fed. Reg. 41,726, 47,740–55 (July 19, 2010). "[A] recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS." *Coverage of Certain Preventive Services Under the Affordable Care Act*, 80 Fed. Reg. 41,318, 41,322 (July 14, 2015).

In 2011, HRSA promulgated additional guidelines requiring nonexempt employers to cover "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." RIN 1545-BJ60, 77 Fed. Reg. 8,725, 8,725 & n.1 (Feb. 15, 2012) (citation and internal quotation marks omitted). Those guidelines became known as the contraceptive mandate. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). Health insurance plans must cover the services recommended by HRSA under 42 U.S.C. § 300gg-13(a)(3) and (a)(4).

B. The Parties

Plaintiffs are six individuals and two businesses who challenge the legality of the preventive-care mandates under the Constitution and the Religious Freedom Restoration Act ("RFRA"). Each Plaintiff wishes to obtain or provide health insurance that excludes or limits coverage currently required by the preventive-care mandates. They object to the services required by the preventive-care mandates for a mixture of religious and economic reasons.

Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell provide health coverage for themselves and their families. They want the option to purchase health insurance that excludes or limits coverage of PrEP drugs, contraception, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use. *See* Pls.' App. 35–37, 41–43, 52–54, 58–60, ECF No. 46. They say neither they nor their families require such preventive care. *Id.* They also claim that compulsory coverage for those services violates their religious beliefs by making them complicit in facilitating homosexual behavior, drug use, and sexual activity outside of marriage between one man and one woman. *Id.* at 38, 44, 53, 59.

Plaintiff Joel Miller likewise provides health coverage for himself and his family. Like the other Plaintiffs, Miller wants the option to purchase health insurance that excludes or limits coverage of preventive care that "he does not want or need." *Id.* at 66–67. Miller's wife "is past her childbearing years," and neither he nor his family members "engage in the behaviors that makes [sic] this preventive treatment necessary." *Id.* at 67.

Plaintiff Gregory Scheideman provides health coverage for himself, his family, and the employees of his company, Fort Worth Oral Surgery. Scheideman wants the option to purchase health insurance that excludes or limits coverage of services currently required by the preventive-care mandates. *Id.* at 47–49. Scheideman says neither he nor his family members require such

preventive care. *Id.* at 48–50. In addition, Scheideman and his business partners do not want to cover such care for their employees. *Id.*

Plaintiff Kelley Orthodontics provides health insurance for its employees. Kelley Orthodontics is a Christian professional association that wishes to provide health insurance for its employees that excludes coverage of preventive care such as contraceptives and PrEP drugs. *Id.* at 39. Plaintiff John Kelley, the owner of Kelley Orthodontics, says that providing such coverage violates his religious beliefs. *Id.*

Plaintiff Braidwood Management Inc. is a Christian for-profit corporation owned by Steven Hotze. *Id.* at 69. Braidwood provides health insurance to its approximately seventy employees through a self-insured plan, and Hotze wishes to provide health insurance for Braidwood's employees that excludes coverage of preventive care such as contraceptives and PrEP drugs. *Id.* at 70–71. Hotze, like Plaintiffs Kelley, Starnes, and the Maxwells, objects to coverage of those services on religious grounds. *Id.* at 72–73. Hotze also wants the option to impose copays or deductibles for preventive care in Braidwood's self-insured plan. *Id.* at 70, 73. Plaintiffs argue that Defendants' enforcement of the preventive-care mandates limits their ability to obtain or provide insurance that excludes their unwanted coverage.

Defendants are the Secretary of HHS, Xavier Becerra; the Secretary of the Treasury, Janet Yellen; the Secretary of Labor, Martin Walsh; and the United States. The three individual Defendants are sued in their official capacities for their roles in enforcing the preventive-care mandates.

C. The Litigation

Plaintiffs' First Amended Complaint asserts five claims. Plaintiffs allege that (1) the preventive-care mandates violate the Appointments Clause; (2) the preventive-care mandates

violate the nondelegation doctrine; (3) 42 U.S.C. § 300gg-13(a)(1) violates the Vesting Clause; (4) the preventive-care mandates, as a matter of statutory interpretation, apply only to ratings, recommendations, or guidelines in place at the time Congress passed the ACA; and (5) the PrEP mandate violates RFRA. *See* 1st Am. Compl., ECF No. 14. The Court dismissed Plaintiffs' statutory interpretation claim for failure to state a claim, and it dismissed Plaintiffs' religious objections to the contraceptive mandate as barred by res judicata.[2] *See* Order, ECF No. 35.

Plaintiffs moved for summary judgment on the remaining claims. *See* Pls.' Summ. J. Mot., ECF No. 44. Defendants responded and cross-moved for summary judgment. *See* ECF Nos. 62, 63. Defendants argue the Court should dismiss the amended complaint because Plaintiffs lack standing and, alternatively, because Defendants prevail on the merits. *See* Defs.' Summ. J. Br., ECF No. 64. The parties exchanged briefs, and the Court held a hearing on July 26, 2022. The motions are ripe for review.

In sum, the issues before the Court are (1) whether Plaintiffs have standing; (2) whether PSTF, ACIP, and HRSA violate the Appointments Clause; (3) whether PSTF members have removal protections that violate Article II's Vesting Clause; (4) whether PSTF, ACIP, and HRSA violate the nondelegation doctrine; and (5) whether the PrEP mandate violates RFRA.

II. LEGAL STANDARD

Summary judgment is appropriate only where the pleadings and evidence show "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is not "a disfavored procedural shortcut, but rather

[2] Plaintiffs' lawsuit in *DeOtte v. Nevada*, No. 4:18-cv-00825, barred their claims against the contraceptive mandate in this case. *See* Order 12–16, ECF No. 35. On August 31, 2022, the Court dismissed *DeOtte* as moot in accordance with the Fifth Circuit's mandate issued that day. *See* Order, ECF No. 118, Case No. 4:18-cv-00825. In light of the judgment in *DeOtte*, Plaintiffs now wish to pursue their claims against the contraceptive mandate in this case. *See* Not. of Supp. Authority, ECF No. 91.

. . . an integral part of the Federal Rules as a whole, which are designed 'to secure the just, speedy and inexpensive determination of every action.'" *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quoting Fed. R. Civ. P. 1). A genuine dispute of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "[T]he substantive law will identify which facts are material." *Id.* The movant must inform the court of the basis for its motion and identify the portions of the record that reveal there are no genuine disputes of material fact. *Celotex*, 477 U.S. at 323.

The court must view the evidence in the light most favorable to the nonmovant. *Ion v. Chevron USA, Inc.*, 731 F.3d 379, 389 (5th Cir. 2013). "Moreover, a court must draw all reasonable inferences in favor of the nonmoving party and may not make credibility determinations or weigh the evidence." *Id.* And if there appears to be some support for disputed allegations, such that "reasonable minds could differ as to the import of the evidence," the court must deny the motion for summary judgment. *Anderson*, 477 U.S. at 250.

The opposing party must "identify specific evidence in the record and . . . articulate the precise manner in which that evidence supports his or her claim." *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998). If a party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," the court must grant summary judgment. *Celotex*, 477 U.S. at 322. In that situation, no genuine dispute of material fact can exist, as the failure to establish an essential element of the claim "necessarily renders all other facts immaterial." *Id.* at 323.

III. ANALYSIS

A. Standing

The U.S. Constitution limits the jurisdiction of federal courts to "Cases" and

"Controversies." U.S. Const., art. III, § 2. The case-or-controversy limitation requires plaintiffs seeking relief in federal court to show they have constitutional standing to pursue their claims. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). "Constitutional standing has three elements: (1) an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent; (2) a causal connection between the injury and the conduct complained of; and (3) the likelihood that a favorable decision will redress the injury." *Croft v. Governor of Tex.*, 562 F.3d 735, 745 (5th Cir. 2009) (quoting *Lujan*, 504 U.S. at 560). At the summary judgment stage, a plaintiff "must 'set forth' by affidavit or other evidence 'specific facts,'" establishing the elements of standing. *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

As Plaintiffs point out, Braidwood presents the easiest case for standing. *See* Pls.' Resp. 10, ECF No. 74. Braidwood self-insures its seventy employees and must therefore provide ACA-compliant health insurance. *See* 26 U.S.C. § 4980H(c)(2). Through the preventive-care mandates, ACA insurance policies must cover, among other things, PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use. Hotze objects to those services on both religious and non-religious grounds, claiming they facilitate and encourage homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman. *See* Pls.' App. 72, ECF No. 46. Hotze says that providing this coverage in Braidwood's self-insured plan violates his religious beliefs by making him complicit in encouraging those behaviors. *Id.*

Braidwood has demonstrated several Article III injuries. First, the mandates deprive Braidwood of the ability to choose whether and to what extent its insurance plan covers preventive care. When a plaintiff is the object of the challenged government action, "there is ordinarily little question" that the action has caused injury. *Lujan*, 504 U.S. at 561–62. The ACA requires

Braidwood to cover the preventive services mandated under § 300gg-13. *See* 26 U.S.C. § 4980H(c)(2). Braidwood is also prohibited from imposing cost-sharing arrangements, such as deductibles or co-pays, for those services. *See* 42 U.S.C. § 300gg-13(a). Hotze wants Braidwood's plan to exclude or limit coverage for the preventive-care services mandated under § 300gg-13, but Braidwood cannot exclude coverage for those services without violating the law. *See* Pls.' App. 70–72, ECF No. 46.

Second, the mandates force Braidwood to underwrite coverage for services to which it holds sincere religious objections. This injury is distinct from the pocketbook injury Braidwood would incur in paying for the objectionable services. Because Braidwood self-insures, Hotze believes that offering coverage is itself a tacit endorsement of the behaviors that he believes the services encourage. *See* Pls.' App. 72, ECF No. 46. Many courts have already addressed this type of injury, recognizing that the contraceptive mandate caused an injury in fact because it rendered plaintiffs "complicit in a scheme aimed at providing coverage to which they have a religious objection." *Archdiocese of St. Louis v. Burwell*, 28 F. Supp. 3d 944, 951 (E.D. Mo. 2014) (citation and internal quotation marks omitted) (collecting cases). Indeed, "it is beyond question" that religious employers have Article III standing to challenge a government mandate that infringes on their religious liberties "by requiring them to lend what their religion teaches to be an impermissible degree of assistance to the commission of what their religion teaches to be a moral wrong." *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1154 (10th Cir. 2013) (Gorsuch, J., concurring), *aff'd sub nom. Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014). Hotze's declaration establishes that the preventive-care mandates compel behavior that violates his religious beliefs, which is sufficient evidence of an injury in fact. *See Lujan*, 504 U.S. at 561.

Third, Braidwood faces a penalty for failing to comply with the mandates. Because Braidwood has more than fifty employees, it faces a tax of $100 per day for each employee not covered in accordance with the ACA. *See* 26 U.S.C. §§ 4980D, 4980H. Requiring religious employers to choose between complying with a service coverage mandate and paying a penalty imposes a substantial burden on religious freedom, and an injury in fact. *See Hobby Lobby Stores*, 573 U.S. at 719–20.

Defendants' counterarguments are unpersuasive. Defendants claim that Plaintiffs limited their religious objections to the PrEP mandate. They argue that the Court should thus consider only alleged injuries pertaining to the PrEP mandate. *See* Defs.' Cross Summ. J. Br. 31–32, ECF No. 64. Plaintiffs concede that their RFRA claims are limited to the PrEP mandate.[3] But Plaintiffs still suffer *injury* based on their religious objections to the other mandates. Plaintiffs claim that the various preventive-care mandates violate the Appointments Clause, the Vesting Clause, and the nondelegation doctrine. Braidwood's standing to assert those claims is based on the injuries discussed: in sum, that § 300gg-13 requires Braidwood to cover services it does not wish to cover for both religious and non-religious reasons. That Braidwood limited its RFRA claim to the PrEP mandate does not mean that it waived all claims of injury based on its religious objections. Even as to its non-RFRA claims, Braidwood's religious objections are "legally protected interest[s]."

[3] Plaintiffs' initial complaint asserted RFRA claims against compulsory coverage of the various services Plaintiffs found objectionable, including PrEP drugs, contraception, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use. *See* Compl. 27–31, ECF No. 1. Plaintiffs' amended complaint drops all but one of those RFRA claims, challenging only the PrEP mandate. *See* 1st Am. Compl., ECF No. 14. Plaintiffs nevertheless moved for summary judgment on their claims that compulsory coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use violates RFRA. *See* Pls.' Summ. J. Br. 35–42, ECF No. 45. Defendants argue that Plaintiffs are bound by their amended complaint, and thus the Court may consider Plaintiffs' RFRA challenges only as to the PrEP mandate. *See* Defs.' Cross Summ. J. Br. 31–32, ECF No. 64. The parties disputed that point in the briefing, but at the hearing Plaintiffs conceded that their RFRA challenges are limited to the PrEP mandate. *See* H. Trans. 24–25 (Rough Draft).

Lujan, 504 U.S. at 560. Braidwood has established by competent evidence that § 300gg-13 invades those interests. Those invasions are "concrete and particularized" and "actual or imminent," which means that Braidwood has suffered an injury in fact. *Id.*

Defendants' remaining arguments against Braidwood's standing proceed on the incorrect premise that Braidwood's injuries must pertain to covering PrEP drugs. Even adopting that incorrect premise, however, Defendants' arguments are unpersuasive. Defendants point out that Braidwood has not provided evidence that it has paid for or will likely pay for PrEP drugs. In Defendants' view, that makes Braidwood's injury hypothetical. Until Braidwood is faced with paying for PrEP drugs, it "operates only under a legal obligation to cover PrEP if such a claim is submitted, and an abstract legal obligation is insufficient to establish standing." *See* Defs.' Cross Summ. J. Br. 34, ECF No. 64 (citing *Barber v. Bryant*, 860 F.3d 345, 357 (5th Cir. 2017)).

Defendants misunderstand Braidwood's injury. Braidwood is not merely alleging a traditional "pocketbook injury." *California v. Texas*, 141 S. Ct. 2104, 2114 (2021). Distinct from his risk of pecuniary harm, Hotze asserts an ongoing dignitary harm, claiming that merely "*providing this coverage* in Braidwood's self-insured plan would make [him] complicit" in behaviors that violate his religious beliefs. Pls.' App. 72, ECF No. 46. Therefore, Braidwood faces not only a potential future injury in the form of paying for preventive care, but also a current injury in the form of underwriting services that violate Hotze's religious beliefs. Braidwood's numerous injuries are of the kind that courts have consistently found appropriate for Article III adjudication.

The next two standing requirements—causation and redressability—are even more straightforward. Braidwood "must satisfy the 'causation' and 'redressability' prongs of the Art. III minima by showing that the injury 'fairly can be traced to the challenged action' and 'is likely to be redressed by a favorable decision.'" *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). Again,

when a plaintiff suffers injury as the object of the challenged government action, "there is ordinarily little question that the action . . . has caused him injury, and that a judgment preventing . . . the action will redress it." *Lujan*, 504 U.S. at 561–62. Section 300gg-13 prohibits Braidwood from excluding coverage and imposing cost-sharing arrangements for various services to which it objects. And Braidwood faces a significant tax for not complying with the law. *See* 26 U.S.C. §§ 4980D, 4980H. Braidwood seeks declaratory and injunctive relief to prevent Defendants from enforcing the preventive-care mandates against it. There is no doubt that Braidwood's injuries are fairly traceable to Defendants' enforcement of the preventive-care mandates and that granting Braidwood's requested relief would likely redress its injuries. Indeed, Defendants conceded at oral argument that assuming Braidwood has suffered an injury (which Defendants contest), that injury is traceable and redressable. Braidwood has standing to pursue its claims.

Plaintiffs argue that because Braidwood has standing, the Court need not inquire into the standing of the other Plaintiffs. *See* Pls.' Resp. 10, ECF No. 74. For purposes of resolving these summary judgment motions, Plaintiffs are correct. As previously discussed, Braidwood has standing for all its claims. And because all Plaintiffs bring the same claims as Braidwood, the Court may address the merits of each claim. *See Town of Chester v. Laroe Ests., Inc.*, 137 S. Ct. 1645, 1650–51 (2017) ("At least one plaintiff must have standing to seek each form of relief requested in the complaint."). But when it comes to granting relief, each Plaintiff must show it has standing to obtain the relief sought. *See id.* at 1650; *Arizona v. Biden*, 31 F.4th 469, 483 (6th Cir. 2022) (Sutton, C.J., concurring) ("A valid Article III remedy operates with respect to specific parties, not with respect to law in the abstract," which "is why courts generally grant relief in a party-specific and injury-focused manner." (cleaned up)). For the remaining Plaintiffs to show standing, "much more is needed," because, unlike Braidwood, their asserted injuries "arise[] from

the government's allegedly unlawful regulation (or lack of regulation) of someone else." *Lujan*, 504 U.S. at 562. The parties offered to file supplemental briefs addressing the scope of relief and standing for the remaining Plaintiffs. For now, the Court proceeds to the merits.

B. Appointments Clause

The Appointments Clause lays out the permissible methods of appointing "Officers of the United States." U.S. Const. art. II, § 2, cl. 2. Principal officers must be nominated by the President and confirmed by the Senate. *Id.* But Congress can authorize the appointment of "inferior Officers" by the President alone, the courts, or "the Heads of Departments." *Id.*

Plaintiffs argue that the members of PSTF, ACIP, and HRSA are principal officers who must be appointed by the President and confirmed by the Senate. *See* Pls.' Summ. J. Br. 24–25, ECF No. 45. At the very least, Plaintiffs say, those agencies are comprised of inferior officers whose appointments may be vested in an agency head. *See id.* at 25–27. Regardless, Plaintiffs argue that the appointment process for members of all three agencies does not satisfy either constitutional method for appointing officers of the United States. *See id.* at 24–27. Defendants dispute all those claims. According to Defendants, the appointment processes for members of PSTF, ACIP, and HRSA are constitutionally permissible. *See* Defs.' Summ. J. Br., ECF No. 64. In any event, Defendants argue, the HHS Secretary's ratification of the challenged provisions nullifies Plaintiffs' Appointments Clause challenges. *Id.* at 38–45. The Court begins by addressing ratification, which narrows the issues.

1. The HHS Secretary ratified the directives of ACIP and HRSA, but not of PSTF.

Several circuits have held that a properly appointed official can ratify an improperly appointed official's action. The D.C. Circuit has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim,

resolves the claim on the merits by 'remedying the defect' (if any) from the initial appointment." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (D.C. Cir. 2019) (cleaned up). The Second, Third, and Ninth Circuits agree. *See NLRB v. Newark Elec. Corp.*, 14 F.4th 152, 160–63 (2d Cir. 2021); *Kajmowicz v. Whitaker*, 42 F.4th 138, 152 (3d Cir. 2022); *CFPB v. Gordon*, 819 F.3d 1179, 1191 (9th Cir. 2016).

Questions of ratification are "at least presumptively governed by principles of agency law." *FEC v. NRA Pol. Victory Fund*, 513 U.S. 88, 98 (1994). One basic principle is that "for a ratification to be effective, 'it is essential that the party ratifying should be able not merely to do the act ratified at the time the act was done, *but also at the time the ratification was made*.'" *Gordon*, 819 F.3d at 1191 (quoting *NRA Pol. Victory Fund*, 513 U.S. at 98). At the very least, the party ratifying must have "the capacity to act at the time of ratification." *Id.* (citing Restatement on Agency (Third) § 4.04 cmt. b). Those principles resolve the ratification issues presented here.

First, the Secretary ratified the ACIP recommendations that Plaintiffs challenge. ACIP, as part of the Public Health Service, is "under the supervision and direction of the Secretary." 42 U.S.C. § 202. ACIP reports to the CDC Director, who exercises delegated authority from the Secretary. *See* 42 U.S.C. §§ 243, 247b. "'The power to superintend,' [Alexander Hamilton] explained, 'must imply a right to judge and direct,' thereby ensuring that 'the responsibility for a wrong construction rests with the head of the department, when it proceeds from him.'" *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1983 (2021) (quoting 3 *The Works of Alexander Hamilton* 559 (J. Hamilton ed. 1850)). In recognition of that principle, Defendants claim that "the Secretary is empowered to direct ACIP's recommendation of specific vaccines." Defs.' Supp. Filing 2, ECF No. 86. And because a vaccine recommendation from ACIP "is considered in effect after it has been adopted by the Director of the [CDC]," the Secretary has authority over what vaccines are

covered under § 300gg-13(a)(2). 45 C.F.R. § 147.130(a)(1)(ii). The Secretary ratified ACIP's recommendations that Plaintiffs challenge.[4] *See* Defs.' App. 6, ECF No. 65. Because he has authority to require, reject, or alter ACIP's recommendations, the Secretary's ratification of the challenged ACIP provisions remedies any appointment defects of ACIP regarding those recommendations. *See Guedes*, 920 F.3d at 13.

Likewise, the Secretary ratified the HRSA guidelines that Plaintiffs challenge. Like ACIP, HRSA is part of the Public Health Service and thus "under the supervision and direction of the Secretary." 42 U.S.C. § 202. HRSA is directed by an Administrator who, like the CDC Director, is answerable to the Secretary. *See* 47 Fed. Reg. at 38,410. The Secretary is thus "empowered to direct HRSA to include particular care and screenings in the guidelines they support under 42 U.S.C. § 300gg-13(a)(3) and (a)(4)," as Defendants admit. Defs.' Supp. Filing 1, ECF No. 86. The Secretary ratified the HRSA guidelines that Plaintiffs challenge,[5] which remedies any appointment defects of HRSA regarding those guidelines. *See Guedes*, 920 F.3d at 13.

Plaintiffs raise several counterarguments. First, Plaintiffs argue that the Secretary has no authority to ratify the agencies' actions because § 300gg-13(a) "compels" the Secretary to implement the agencies' decisions. Pls.' Resp. Br. 19–21, ECF No. 74. Plaintiffs are correct that the Secretary "shall" enforce insurance coverage for the services identified by the three agencies. *See* 42 U.S.C. § 300gg-13. But § 300gg-13(a) contains no language removing or modifying the Secretary's background authority over ACIP and HRSA as to the services themselves. Indeed, Congress recognized that it was legislating against that background structure by referring to "recommendations" and "guidelines." ACIP has authority (given to it by the Secretary) to provide vaccine recommendations, which are subject to the absolute control of the Secretary. So, too, with

[4] The parties do not dispute that Secretary Xavier Becerra is a constitutionally appointed principal officer.
[5] Defs.' App. 6, ECF No. 65.

HRSA. If Congress intends to alter the fundamental details of a regulatory scheme, courts "expect it to speak with the requisite clarity to place that intent beyond dispute." *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849 (2020) (quoting *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1626–27 (2018)). Section 300gg-13(a) is devoid of any clear statement stripping the Secretary of his authority over ACIP and HRSA.

Second, Plaintiffs argue that even if the Secretary has ratified the challenged actions, § 300gg-13(a) would still violate the Appointments Clause because ACIP's and HRSA's actions are effective even before a constitutionally appointed officer ratifies them. Pls.' Summ. J. Br. 29, ECF No. 45. In other words, Plaintiffs say that ratification cannot cure the appointment problems because ACIP and HRSA are still exercising "significant authority pursuant to the laws of the United States" until their decisions are ratified. *Lucia v. SEC*, 138 S. Ct. 2044, 2049 (2018) (holding that the SEC's administrative law judges are "officers of the United States," even though their decisions are subject to review by the SEC itself). But Article III standing principles do not permit Plaintiffs to challenge an unlawful appointment generally, or to challenge future exercises of unlawful authority. Plaintiffs' injuries must be traceable to government *action*. And the Secretary has ratified the particular actions of ACIP and HRSA that Plaintiffs complain of.

Plaintiffs' argument attacks the very principle of ratification. If Plaintiffs are correct, post hoc approval by an appropriate government actor cannot retroactively cure an earlier exercise of authority that was constitutionally defective. But the circuits have so far unanimously agreed that ratification may cure Appointment Clause problems, and Plaintiffs do not present a compelling reason to deviate from the consensus. The Secretary effectively ratified the ACIP and HRSA actions that Plaintiffs challenge, so the Court need not address the Appointments Clause issues regarding those two agencies. The Court thus **GRANTS** partial summary judgment in favor of

Defendants on Claim 1 of the Amended Complaint as to 42 U.S.C. § 300gg-13(a)(2), (a)(3), and (a)(4).

PSTF is different. According to Defendants, the Secretary may not direct PSTF to "give a specific preventive service an 'A' or 'B' rating, such that it would be covered pursuant to 42 U.S.C. § 300gg-13(a)(1)." Defs.' Suppl. Filing 3, ECF No. 86. That is because all PSTF members "and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). The Secretary, a political actor, thus does not have authority to direct what services are covered under § 300gg-13(a)(1). Arguably, the phrase "to the extent practicable" permits some level of direction by the Secretary. *Id.* But whatever that phrase means, it does not provide an exception for the Secretary to decree recommendations unilaterally. That exception would swallow the rule that "recommendations" must be "independent" and "not subject to political pressure." *Id.* Because the Secretary lacks authority to determine or direct what services receive an "A" or "B" rating, he cannot ratify PSTF's decisions on that subject. *See Gordon*, 819 F.3d at 1191. Defendants implicitly recognize as much by arguing that only the ACIP and HRSA ratifications were effective—not PSTF. *See* Defs.' Summ. J. Br. 39–43, ECF No. 64. The Court must therefore address the Appointments Clause challenge to PSTF.

2. The members of PSTF are officers of the United States.

A person is an officer of the United States if he (1) occupies a "'continuing' position established by law" and (2) exercises "significant authority pursuant to the laws of the United States." *Lucia*, 138 S. Ct. at 2051 (internal quotation marks and citations omitted). The members of PSTF satisfy both criteria.

First, PSTF members occupy a continuing position established by law. Congress requires the Director of AHRQ to "convene" PSTF by assembling a group of "individuals with appropriate

expertise." 42 U.S.C. § 299b-4(a)(1). Congress described the purpose of PSTF, assigned its duties, authorized appropriations for its activities, and insulated it from political pressure. *See id.* § 299b-4. Regulations lay out extensive qualifications for the members, who serve four-year terms. *See Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)*, 87 Fed. Reg. 2436, 2436–37 (Jan. 14, 2022). These positions will continue until Congress amends or repeals the statute creating them. They are "public station[s], or employment, conferred by the appointment of government." *United States v. Hartwell*, 73 U.S. 385, 393 (1867).

The PSTF positions are "continuing and permanent" rather than "occasional or temporary." *Lucia*, 138 S. Ct. at 2051. Among other things, PSTF must submit yearly reports to Congress and other agencies identifying gaps in research and recommending areas for further examination. 42 U.S.C. § 299b-4(a)(2)(F). At least once every five years, PSTF must review interventions and update recommendations. *Id.* These congressionally created duties are regular, not occasional. *Cf. United States v. Germain*e, 99 U.S. 508, 511–12 (1878) (holding that a civil surgeon tasked with assisting the Commissioner of Pensions was not an officer in part because he was "only to act when called on by the Commissioner of Pensions in some special case"); *Auffmordt v. Hedden*, 137 U.S. 310, 326–27 (1890) (holding that a merchant appraiser valuing goods for the customs service was not an officer of the United States because he had "no general functions, nor any employment which ha[d] any duration as to time, or which extend[ed] over any case further than as he [was] selected to act in that particular case").

Defendants argue that PSTF members are not officers because their work is "part-time." Defs.' Summ. J. Br. 64, ECF No. 64. But the difference between a temporary position and a permanent position has more to do with "ideas of tenure and duration" than with the relative workload of the job. *Lucia*, 138 S. Ct. at 2051 (cleaned up). PSTF members serve four-year terms

in a statutorily created position to carry out regular duties assigned by Congress. That role is nothing short of "a continuing and formalized relationship of employment with the United States Government." *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc). Regardless, to the extent courts consider the relative workload a position requires, the duties of PSTF members cannot be brushed aside as minimal. PSTF applicants must have "adequate time to contribute substantively to the work products of [PSTF]." 87 Fed. Reg. at 2437. The members meet three times a year for two days in Washington, D.C. (paid for by the taxpayer). *Id.* But a "significant portion" of their work occurs between meetings. *Id.* Members must expect frequent emails, "multiple conference calls each month," and interaction with stakeholders. *Id.* Indeed, "members devote approximately 200 hours a year outside of in-person meetings" to carrying out their duties. *Id.* The part-time nature of the PSTF positions, even if relevant, does not indicate that the positions are occasional or temporary.

Defendants also argue that PSTF members are not officers because they do not receive compensation for their service. *See* Defs.' Summ. J. Br. 53, ECF No. 64. In *Riley*, the Fifth Circuit observed that "Supreme Court precedent has established that the constitutional definition of an 'officer' encompasses, at a minimum, a continuing and formalized relationship of employment with the United States Government." *Riley*, 252 F.3d at 757 (first citing *Auffmordt*, 137 U.S. at 327; and then citing *Germain*e, 99 U.S. at 511–12). Defendants argue that by "employment," the Fifth Circuit means *paid* employment. But neither the word "employment" nor the surrounding context in *Riley* implies that compensation is a necessary element of an office. The merchant in *Auffmordt* was not an officer *in part* because he was paid on a case-by-case basis and received no "continuing emolument." *Auffmordt*, 137 U.S. at 327. The surgeon in *Germain*e was not an officer *in part* because his payment was by commission prescribed by regulation, not "regular

appropriation." *Germain*e, 99 U.S. at 511. And the qui tam plaintiffs in *Riley* were not officers because, "[f]or instance," they did "not draw a government salary." *Riley*, 252 F.3d at 757.

The cases demonstrate that monetary compensation is one aspect among many relevant to determining whether a position is "continuing and formalized." *Id.* But employment positions take many forms, offering different terms, hours, compensation, and responsibilities. *See Germain*e, 99 U.S. at 511 ("[T]he term embraces the ideas of tenure, duration, emolument, and duties."). To be sure, the absence of a regular salary makes the PSTF positions appear less "continuing and formalized" than a salaried position, other things being equal. *Riley*, 252 F.3d at 757. But it is not dispositive, particularly when the members receive at least some compensation for travel to meetings and trainings. *See* 87 Fed. Reg. at 2437.

The Supreme Court and Fifth Circuit have not set a minimum-hours requirement for officers of the United States. Nor have they forbidden an officer from holding other employment. Nor have they required a particular form of compensation. Rather, courts consider various characteristics to determine whether the nature of the position is continuing and formalized. *See Lucia*, 138 S. Ct. at 2051; *Riley*, 252 F.3d at 757. Congress created PSTF, assigned it various duties, and requires its regular employment. The positions are fixed by statute and will continue indefinitely. Members must be specially qualified, and they are selected in a competitive process. They serve four-year terms that require meetings, research, drafting, and many other responsibilities. They receive compensation in support of their travel for in-person meetings, which they hold three times a year. These qualities indicate that PSTF members occupy a "'continuing' position established by law." *Lucia*, 138 S. Ct. at 2051.

Second, PSTF members exercise significant authority pursuant to the laws of the United States. This second step "focuse[s] on the extent of power an individual wields in carrying out his

assigned functions." *Lucia*, 138 S. Ct. at 2051. PSTF has authority to determine what preventive-care services receive an "A" or "B" rating. Private insurers must cover all services with an "A" or "B" rating. 42 U.S.C. § 300gg-13(a)(1). Therefore, PSTF has authority to determine what preventive-care services private insurers must cover. That includes the authority to determine the scope of any religious or nonreligious exemptions. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) (holding that § 300gg-13(a)(4) gives HRSA the authority to determine "the ability to identify and create exemptions from its own Guidelines").

PSTF's authority over insurance policies is significant. Just as special trial judges of the U.S. Tax Court can issue the final decision in "comparatively narrow and minor matters" before them, PSTF exercises final authority over its narrow domain. *Lucia*, 138 S. Ct. at 2052 (internal quotation marks omitted) (quoting *Freytag v. Commissioner*, 501 U.S. 868, 873 (1991)). Whether insurance providers must cover PrEP drugs and countless other preventive services depends entirely on whether PSTF recommends them. PSTF wields a power to compel private action that resembles legislative authority. At the very least, it is on par with agency actions subject to approval by an agency head, which typically proceed through notice and comment procedures. But PSTF, unencumbered by the Administrative Procedure Act, "exercise[s] significant discretion" in determining what services insurance providers must cover. *Freytag*, 501 U.S. at 882. That degree of authority is "so 'significant' that it [is] inconsistent with the classifications of 'lesser functionaries' or employees." *Id.* at 881 (quoting *Go-Bart Importing Co. v. United States*, 282 U.S. 344, 352 (1931)). PSTF thus exercises "significant authority pursuant to the laws of the United States." *Lucia*, 138 S. Ct. at 2051.

Defendants try to avoid that conclusion by insisting that PSTF makes "recommendations," not law. "PSTF's recommendations," Defendants argue, "are not exercises of the Executive or Legislative Power. They are 'evidence-based' scientific recommendations about the contemporary standard of care in preventive medicine." Defs.' Summ. J. Br. 56, ECF No. 64. But Defendants rely on a false dichotomy. That PSTF makes "scientific recommendations" says nothing about whether it exercises legislative power. Before Congress enacted the ACA, PSTF's recommendations were *merely* recommendations. Now, those recommendations have the force and effect of law. What PSTF "recommends" will bind insurance providers as forcefully as any law or regulation. And as the Supreme Court said of HRSA, PSTF "has virtually unbridled discretion to decide what counts as preventive care." *Little Sisters of the Poor*, 140 S. Ct. at 2380.

Defendants also point out that PSTF is tasked with determining the rating of individual preventive services, not decreeing what ratings are covered by insurance. Congress made the decision to give PSTF's recommendations the *effect* of required coverage. In other words, what matters are PSTF's "purposes," not the "incidental" effects of PSTF carrying out those purposes. Defs.' Summ. J. Br. 56, ECF No. 64. *Lucia* says otherwise. What matters is "the extent of *power* an individual *wields* in carrying out his assigned functions." *Lucia*, 138 S. Ct. at 2051 (emphases added). Whatever PSTF's assigned functions are (or whatever PSTF *thinks* its assigned functions are) is secondary to the power it wields in carrying out those functions.[6] And that power is nothing short of dictating what preventive services insurance providers *must* cover. It is more troubling,

[6] It is also "beside the point" that PSTF's decisions serve other non-significant functions. *Freytag v. Commissioner*, 501 U.S. 868, 882 (1991). "The fact that an inferior officer on occasion performs duties that may be performed by an employee not subject to the Appointments Clause does not transform his status under the Constitution." *Id.*

not less, that Defendants insist the agency wielding that power is apparently not even cognizant of doing so.[7] An officer is no less an officer because he is oblivious to the power he wields.

Defendants also argue § 300gg-13(a) is no different than the numerous other times Congress has incorporated materials by reference into law. But the organizations involved in all Defendants' examples are private, state, or foreign entities.[8] None of the organizations occupy a "'continuing' position established by law" in the federal government. *Lucia*, 138 S. Ct. at 2051. Defendants' examples do not present Appointments Clause problems, then, because none pass even the first part of the *Lucia* test. PSTF members, in contrast, serve in an agency created by federal law. And, perhaps more importantly, § 300gg-13(a) differs from Defendants' examples in its "capacious grant of authority" to the agencies "to make these determinations," while leaving their "discretion equally unchecked in other areas." *Little Sisters of the Poor*, 140 S. Ct. at 2380. In short, Defendants' argument "ignores the significance of the duties and discretion" of PSTF. *Freytag*, 501 U.S. at 881.

PSTF members occupy a continuing position established by law and exercise significant authority pursuant to the laws of the United States. *See Lucia*, 138 S. Ct. at 2051. They are therefore officers of the United States.

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[7] *See* Defs.' Reply Br. 34, ECF No. 83 ("True, the PSTF's recommendations may be used for important purposes, including, as Congress has decided, being incorporated within certain insurance coverage. But PSTF members themselves are not tasked with considering what is appropriate about insurance at all, nor are they tasked with making discretionary decisions about insurance . . . .").

[8] *See* 4 U.S.C. § 119(a)(2) (requiring electronic databases established by states to "be provided in a format approved by the American National Standards Institute's Accredited Standards Committee X12"); 16 U.S.C. § 3372(a)(2)(A) (rendering unlawful the importation "any fish or wildlife taken, possessed, transported, or sold in violation of any law or regulation of any State or in violation of any foreign law"); 18 U.S.C. § 13(a) (criminalizing certain acts that "although not made punishable by any enactment of Congress, would be punishable if committed . . . within the jurisdiction of the State . . . by the laws thereof in force at the time of such act"); 42 U.S.C. § 6293(b)(8) (requiring test procedures for water closets and urinals to comply with standards set by the American Society of Mechanical Engineers).

3. The members of PSTF are unconstitutionally appointed.

Because PSTF members are officers of the United States, their appointments must comply with Article II. Principal officers must be nominated by the President and confirmed by the Senate, while inferior officers may be appointed by the President alone, the courts, or the heads of departments, if Congress permits. U.S. Const. art. II, § 2, cl. 2.

"Whether one is an 'inferior' officer depends on whether he has a superior." *Edmond v. United States*, 520 U.S. 651, 662 (1997). In other words, the difference between principal and inferior officers is one of relationship, not of authority. *See id.* ("The exercise of 'significant authority pursuant to the laws of the United States' marks, not the line between principal and inferior officer for Appointments Clause purposes, but rather . . . the line between officer and nonofficer."). Inferior officers, then, are "officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Id.* at 663.

PSTF members are principal officers. The AHRQ Director "convene[s]" PSTF, but he is not necessarily part of PSTF, whose members are otherwise "independent." 42 U.S.C. § 299b-4(a)(1), (a)(6). In that regard, PSTF is different from ACIP and HRSA, which are subject to the Secretary's control. *See supra* Section III.B.1. PSTF is not even part of HHS, or any other agency. *See* Defs.' Summ. J. Br. 51, ECF No. 64. AHRQ has no oversight or supervision role over PSTF, and AHRQ's function is merely to "provide ongoing administrative, research, and technical support." 42 U.S.C. § 299b-4(a)(3). The AHRQ Director is appointed by the Secretary, but he neither directs nor supervises PSTF or its members. *See id.* § 299(a). PSTF members are thus not inferior officers because they are not "directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Edmond*, 520

U.S. at 663. PSTF members have no superior, so they are principal officers under Article II. *Id.* at 662.

Because PSTF members are principal officers, they must be appointed by the President and confirmed by the Senate. *See* U.S. Const. art. II, § 2, cl. 2. The PSTF members indisputably fail that constitutional requirement. The members are "convene[d]" by the AHRQ Director. 42 U.S.C. § 299b-4(a)(1). Defendants point to no other statute or regulation governing their selection. Presumably, the AHRQ Director selects new members or delegates the task to other AHRQ employees. *See* 87 Fed. Reg. at 2437 ("Nominated individuals will be selected for [PSTF] on the basis of how well they meet the required qualifications and the current expertise needs of [PSTF]."). Regardless, PSTF members are not presidentially appointed.

Even if PSTF members were inferior officers, their selection would still violate the Appointments Clause. Congress can vest the appointment of inferior officers by the President alone, the courts, or the heads of departments. U.S. Const. art. II, § 2, cl. 2. If the power to "convene" PSTF is commensurate with the power to appoint its members, then Congress arguably vested the appointment of PSTF members in the AHRQ Director. *See* 42 U.S.C. § 299b-4(a)(1). The AHRQ Director is not the President or an officer of the courts, so the only question is whether he is one of the "Heads of Departments" mentioned in Article II. He is not. "[T]he term 'Department' refers only to a part or division of the executive government, as the Department of State, or of the Treasury, expressly created and given the name of a department by Congress." *Freytag*, 501 U.S. at 886 (cleaned up). Defendants do not dispute that the AHRQ Director is not a head of a department as understood in Article II.

Regardless of whether PSTF members are principal or inferior officers, they are unconstitutionally appointed. Defendants dispute that PSTF members are officers of the United

States, but they do not resist the conclusion that the selection of PSTF members does not comply with the Appointments Clause procedures.

* * *

In dressing up legal directives as expert recommendations, Defendants overlook the constitutional importance of the power those recommendations wield. Congress may create agencies to recommend healthcare services to public and private entities. Doing so rarely poses constitutional problems because the recommendations do not bind American citizens. Under Defendants' theory, Congress may then backfill those recommendations with the force and effect of law, complete with hefty penalties for noncompliance. Not only that, but Congress can also mandate that all *future* recommendations have the force and effect of law, and it can make those recommendations unreviewable by anyone else. Perhaps Congress may do those things consistent with the Constitution. But when it does, Congress confers *power* on those who, before, were making mere recommendations. The Constitution says that individuals exercising that kind of power must be appointed by politically accountable officers. "[T]he Appointments Clause of Article II is more than a matter of 'etiquette or protocol'; it is among the significant structural safeguards of the constitutional scheme." *Edmond*, 520 U.S. at 659. PSTF's appointment process deviates from Article II's requirements, so the Court **GRANTS** partial summary judgment in favor of Plaintiffs on Claim 1 of the Amended Complaint as to 42 U.S.C. § 300gg-13(a)(1).

The Court will take further briefing on the appropriate remedy, but one point is worth resolving here. Defendants say the proper remedy, if PSTF members are unconstitutionally appointed, is to allow the Secretary to ratify the actions of PSTF. *See* Defs.' Summ. J. Br. 57–58, ECF No. 64. But Defendants have disclaimed that the Secretary has any authority over PSTF. And without authority, there can be no ratification. *See Gordon*, 819 F.3d at 1191. Defendants'

argument would make sense, for example, in the context of an ACIP recommendation that the Secretary *could* ratify but had *not yet* ratified. But as for PSTF, the Secretary's ratification is meaningless. *See supra* Section III.B.1. A second ratification would be equally meaningless.

C. Removal

Article II vests the "executive Power" in the President, who must "take Care that the Laws be faithfully executed." U.S. Const. art. II, §§ 1, 3. "The entire 'executive Power' belongs to the President alone." *Seila L. LLC v. CFPB*, 140 S. Ct. 2183, 2197 (2020). Because it would be impossible for the President to carry out the vast responsibility of the office by himself, Article II implies that the President may appoint lesser executive officers to assist him in his duties. *Id.* "That power, in turn, generally includes the ability to remove executive officials, for it is 'only the authority that can remove' such officials that they 'must fear and, in the performance of [their] functions, obey.'" *Id.* (alteration in original) (quoting *Bowsher v. Synar*, 478 U.S. 714, 726 (1986)).

Congress may restrict the President's removal power over certain executive officers, to an extent. Inferior officers, for example, "may retain some amount of for-cause protection from firing." *Jarkesy v. SEC*, 34 F.4th 446, 463 (5th Cir. 2022) (citing *Morrison v. Olson*, 487 U.S. 654, 691–92 (1988)). "Likewise, even principal officers may retain for-cause protection when they act as part of an expert board." *Id.* (citing *Seila L.*, 140 S. Ct. at 2192).

Plaintiffs' removal claim fails because they do not identify any removal restrictions on PSTF members. Plaintiffs point to the provision requiring that all PSTF members "and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure." 42 U.S.C. § 299b-4(a)(6). But that language does not provide PSTF members tenure or insulate them from removal. Plaintiffs provide no persuasive argument as to why the provision should be construed in the direction of a constitutional violation. *See Clark v.*

Martinez, 543 U.S. 371, 381 (2005) (discussing the canon of constitutional avoidance). Quite simply, no statute forbids the President, Secretary, or AHRQ Director from firing any member of PSTF. And without any removal restrictions, there is no removal problem under Article II.

That conclusion might appear to be in tension with the Court's earlier conclusion that the Secretary lacks authority to ratify PSTF decisions. Recall that the Secretary does not have authority to direct what services are covered under § 300gg-13(a)(1), in part because of the political-insulation language in § 299b-4(a)(6). *See supra* III.B.1. The phrase "to the extent practicable" arguably permits the Secretary some amount of control, but the Court did not construe the phrase to permit the Secretary to direct what services are covered. The political-insulation language thus prohibits the Secretary from directing what services are covered under § 300gg-13(a)(1), but it does not prohibit the Secretary or the President from removing PSTF members. Those interpretations are consistent for at least two reasons.

First, the statute grants PSTF unilateral authority, but not indefinite tenure. Congress granted PSTF complete discretion to make its decisions. AHRQ's role is merely to provide administrative, research, and technical support for PSTF. Even without the political-insulation language, it is not clear that the Secretary would have the authority to direct what services are covered under § 300gg-13(a)(1). In contrast, Article II vests the President with the background authority to remove executive officials. Unless Congress strips that authority for a particular officer (and does so in a constitutionally permissible manner), the President retains removal authority over that officer. The Court's interpretation of § 299b-4(a)(6) is thus consistent with the statutory context (which gives PSTF authority over covered services) and consistent with the constitutional background (which gives the President authority to remove executive officers).

Second, no party advanced a construction of the political-insulation language that would permit the Secretary to decree covered services under § 300gg-13(a)(1). Defendants concede that the "Secretary may not, consistent with § 299b-4(a)(6), direct that the PSTF give a specific preventive service an 'A' or 'B' rating, such that it would be covered pursuant to 42 U.S.C. § 300gg-13(a)(1)." Defs.' Suppl. Filing 3, ECF No. 86. The canon of constitutional avoidance "is a tool for choosing between competing plausible interpretations of a statutory text, resting on the reasonable presumption that Congress did not intend the alternative which raises serious constitutional doubts." *Clark*, 543 U.S. at 381. All parties' interpretations of the Secretary's authority over PSTF invite Appointments Clause problems. In contrast, the parties do offer competing interpretations of the political-insulation language as it relates to the removal issue.

The removal analysis is unnecessarily complicated by the fact that the members of the PSTF are unconstitutionally appointed. As a general rule, officers are subject to removal by the same actor who appointed them, subject to any other restrictions imposed by Congress. *See, e.g.*, *Seila L.*, 140 S. Ct. at 2197. If the PSTF members had been properly appointed by the President as principal officers, or properly appointed by the Secretary of Health and Human Services as inferior officers, then the Court's conclusion that they could be removed by those same appointing actors would be more readily apparent, even when factoring in the political-insulation language of § 299b-4(a)(6). It is unsurprising that Congress's novel regulatory scheme produces novel legal problems.

In sum, PSTF members do not have statutory tenure. They are removable at will. The Court thus **GRANTS** summary judgment in favor of Defendants as to Claim 3 of Plaintiffs' Amended Complaint.

D. Nondelegation

The Constitution vests "[a]ll legislative Powers herein granted . . . in a Congress of the United States." U.S. Const. art. 1, § 1. The text "permits no delegation of those powers" to the other two branches of government. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001). Under the doctrine of nondelegation, "when Congress confers decisionmaking authority upon agencies Congress must 'lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform.'" *Id.* (alteration in original) (quoting *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928). A conferral of decisionmaking authority is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). "Given that standard, a nondelegation inquiry always begins (and often almost ends) with statutory interpretation." *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality opinion). That process requires courts to evaluate the statute's text, context, purpose, and factual background. *Am. Power & Light*, 329 U.S. at 104.

Plaintiffs argue that the preventive-care mandates violate the nondelegation doctrine. Plaintiffs say that PSTF, ACIP, and HRSA are all exercising decisionmaking authority with no "intelligible principle" to guide them. Pls.' Summ. J. Br. 29–32, ECF No. 45. Section 300gg-13(a) compels coverage of certain "evidence-based items and services" identified by PSTF, "immunizations" recommended by ACIP, and "evidence-informed preventive care and screenings" designated by HRSA. 42 U.S.C. § 300gg-13(a). Plaintiffs argue that the statute provides no standards guiding the agencies' decisions as to which items, services, immunizations, care, and screenings they can recommend. The statute confers authority on the agencies to decide

what preventive services are covered, but it lacks, Plaintiffs say, any principle guiding their decisionmaking—let alone an intelligent one.

At least as to HRSA, the Supreme Court has hinted that it may agree with Plaintiffs. The Court recognized that § 300gg-13(a)(4) "grants sweeping authority to HRSA to craft a set of standards defining the preventive care that applicable health plans must cover." *Little Sisters of the Poor*, 140 S. Ct. at 2380. "But the statute is completely silent as to what those 'comprehensive guidelines' must contain, or how HRSA must go about creating them. The statute does not, as Congress has done in other statutes, provide an exhaustive or illustrative list of the preventive care and screenings that must be included." *Id.* (quoting 42 U.S.C. § 300gg-13(a)(4)). Nor does the statute "set forth any criteria or standards to guide HRSA's selections." *Id.* The Court pointed out that even some of the other subsections of § 300gg-13(a) at least require "evidence-based" or "evidence informed" determinations. *Id.*; *see* 42 U.S.C. § 300gg-13(a)(1), (a)(3). Additionally, the ACA does not "require that HRSA consult with or refrain from consulting with any party in the formulation of the Guidelines." *Little Sisters of the Poor*, 140 S. Ct. at 2380. Taken together, "[t]his means that HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings." *Id.* The Supreme Court thus concluded "that the ACA gives HRSA broad discretion to define preventive care and screenings and to create the religious and moral exemptions." *Id.* at 2381. The Supreme Court ultimately did not address whether HRSA violates the nondelegation doctrine, noting that no party raised the issue. *Id.* at 2382.

Plaintiffs rely on the Supreme Court's observations in *Little Sisters of the Poor*, but they overlook binding Fifth Circuit precedent. In *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436 (5th Cir. 2020), the Fifth Circuit addressed a nondelegation challenge to the Family Smoking and Tobacco Control Act. Congress delegated to the Secretary of the Food and Drug Administration the power

to "deem" which tobacco products should be subject to the Act's mandates. 21 U.S.C. § 387a(b). The plaintiffs in *Big Time Vapes* argued that "Congress didn't provide 'any parameters or guidance whatsoever' to guide the Secretary's exercise of that discretion." *Big Time Vapes*, 963 F.3d at 443. The panel disagreed, holding that Congress had delineated (1) "its general policy" in the statute, (2) the public agency that is to apply that policy, and (3) the boundaries of the delegated authority. *Id.* at 444–45. The same is true here. Congress has delineated its general policy with respect to the preventive-care mandates, the public agencies applying the preventive-care mandates, and the boundaries of the delegated authority.

First, Congress has delineated a general policy to expand insurance coverage for various preventive services. The preventive-services provision outlines the "minimum" level of coverage that insurance plans must offer. 42 U.S.C. § 300gg-13(a). Congress then chose to incorporate the directives of existing agencies—PSTF, ACIP, and HRSA—to set the baseline services that insurance policies must cover. Because the agencies preexisted the ACA, Congress had already outlined an express purpose for each agency. PSTF exists 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." 42 U.S.C. § 299b-4(a)(1). ACIP exists "for the purpose of advising" the HHS Secretary on his role to "assist States and their political subdivisions in the prevention and suppression of communicable diseases." *Id.* §§ 217a(a), 243(a), 1396s(e). HRSA's history is more complicated, but it can be traced to Title V of the Social Security Act of 1935, passed for "the purpose of enabling each State to extend and improve, as far as practicable under the conditions in such State, services for promoting the health of mothers and children,

especially in rural areas and in areas suffering from severe economic distress." 49 Stat. 620, 629 (1935).[9]

The parties' briefs do not discuss Congress's policy in any notable detail. But the statute's text, context, and relevant factual background indicate a general policy to expand preventive-services coverage for a variety of medical services. Generally, "Congress's purpose in this section was to mandate coverage of certain health insurance items." *Leal v. Azar*, No. 2:20-cv-185, 2020 WL 7672177, at *16 (N.D. Tex. Dec. 23, 2020) (ruling that § 300gg-13(a)(4) does not violate the nondelegation doctrine), *vacated sub nom. on other grounds Leal v. Becerra*, No. 21-10302, 2022 WL 2981427 (5th Cir. July 27, 2022). The evidence shows that Congress delineated a general policy to guide the agency action.

Second, Congress has clearly delineated the public agencies to apply that policy. The statute explicitly names the agency responsible for each type of directive: PSTF recommends preventive services that have an "A" or "B" rating; ACIP recommends immunizations; HRSA recommends preventive care and screenings for infants, children, and adolescents; and HRSA also recommends additional preventive care and screenings for women. 42 U.S.C. § 300gg-13(a). No party disputes that Congress clearly identified the agency responsible for the decisionmaking.

[9] Over the years, Congress and the President organized and reorganized the agencies responsible for implementing various Congressional health programs. In 1973, exercising authority under those reorganization plans, the Secretary of Health, Education, and Welfare (later to become the HHS Secretary) created the Health Services Administration ("HSA") and the Health Resources Administration ("HRA"). *See* Public Health Service, 38 Fed. Reg. 18,261 (July 9, 1973). HSA's purpose was to "provide a national focus for programs and health services for all people of the United States with emphasis on achieving the integration of service delivery and public and private financing systems to assure their responsiveness to the needs of individuals and families in all levels of society." Health Services Administration, 39 Fed. Reg. 10,463 (Mar. 20, 1974). HRA's purpose was to "provide[] leadership with respect to the identification, deployment and utilization of personnel, educational, physical, financial and organizational resources in the achievement of optimal health services for the people of the United States." Health Resources Administration, 39 Fed. Reg. 1,456 (Jan. 9, 1974). In 1982, the HHS Secretary consolidated HSA and HRA into the modern HRSA. *See* Health Resources and Services Administration; Statement of Organization, Functions, and Delegations of Authority, 47 Fed. Reg. 38,409 (Aug. 31, 1982).

Third, Congress limited the authority it delegated. Start with PSTF. Section 300gg-13(a)(1) requires that the "items or services" be "evidence-based" and "have in effect a rating of 'A' or 'B' in the current recommendations of [PSTF]." Congress provided further instructions on how PSTF is to develop its recommendations: the agency must "review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services." *Id.* § 299b-4(a)(1). Likewise, ACIP's authority is limited to "immunizations." *Id.* § 300gg-13(a)(2). HRSA's authority is split into two categories: First, "with respect to infants, children, and adolescents," HRSA's "preventive care and screenings" must be "evidence-informed" and provided for in their "comprehensive guidelines." *Id.* § 300gg-13(a)(3). Second, "with respect to women," HRSA's "preventive care and screenings" not covered by PSTF must also be provided for in their "comprehensive guidelines." *Id.* § 300gg-13(a)(4). Congress has demarcated the boundaries of agency decisionmaking in the statute.

Plaintiffs recognize that the agencies' discretion is bounded, but they argue that Congress did not provide an intelligible principle within those boundaries. "Limiting the scope of HRSA's powers to 'preventive care and screenings,' for example, does nothing to provide guidance when HRSA is deciding *which* 'preventive care' and *which* 'screenings' will be covered." Pls.' Summ. J. Br. 31, ECF No. 45. But the Fifth Circuit has all but foreclosed the distinction between boundaries and principles, upholding even a delegation of the power to "deem" which tobacco products should be subject to various mandates because Congress had cabined the delegation to narrow categories. *Big Time Vapes*, 963 F.3d at 443–45. Plaintiffs do not address *Big Time Vapes*.

A brief note is appropriate on *Jarkesy v. SEC*, 34 F.4th 446 (5th Cir. 2022), which the Fifth Circuit released during the parties' briefing. The panel in *Jarkesy* held that Congress violated the nondelegation doctrine when it gave the Securities and Exchange Commission unfettered authority

to choose whether to bring enforcement actions in Article III courts or within the agency. *Id.* at 459. The panel held that the decision to bring an action in an agency tribunal instead of in an Article III court is legislative in nature. *Id.* at 461–62 (citing *Crowell v. Benson*, 285 U.S. 22, 50 (1932)). The panel then held that Congress's delegation of that legislative authority lacked an intelligible principle because "Congress offered *no guidance* whatsoever." *Id.* at 462. Even the agency agreed that Congress had "given it exclusive authority and absolute discretion to decide whether to bring securities fraud enforcement actions within the agency instead of in an Article III court." *Id.* at 462. This case, however, is not one in which Congress has offered "no guidance." Congress's guidance may be minimal, and the power conferred may be significant. But the authority granted to the agencies falls within the constitutional parameters outlined by the Supreme Court and the Fifth Circuit.

Plaintiffs' nondelegation argument relies almost entirely on the majority's reflections on HRSA in *Little Sisters of the Poor*. "The Court might well decide—perhaps soon—to reexamine or revive the nondelegation doctrine. But we are not supposed to read tea leaves to predict where it might end up." *Big Time Vapes*, 963 F.3d at 447 (cleaned up). The Court thus **GRANTS** summary judgment in favor of Defendants as to Claim 2 of Plaintiffs' Amended Complaint.

E. Religious Freedom Restoration Act

Plaintiffs claim that the PrEP mandate violates RFRA.[10] This Section resolves only Braidwood's claim as to the PrEP mandate. The Court will take further briefing on the scope of the relief, standing of the other Plaintiffs, and the other Plaintiffs' RFRA claims.

RFRA generally prohibits the government from "substantially burden[ing] a person's exercise of religion even if the burden results from a rule of general applicability." 42 U.S.C.

[10] Plaintiffs narrowed their RFRA claim to the PrEP mandate. *See supra* note 3.

§ 2000bb-1(a). To claim protection under RFRA, Braidwood "must show that (1) the relevant religious exercise is grounded in a sincerely held religious belief and (2) the government's action or policy substantially burdens that exercise by, for example, forcing [Braidwood] to engage in conduct that seriously violates [its] religious beliefs." *Ali v. Stephens*, 822 F.3d 776, 782–83 (5th Cir. 2016) (cleaned up). If Braidwood carries that burden, the government "*may* substantially burden a person's exercise of religion *only if* it demonstrates that application of the burden to the person (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b) (emphases added).

The PrEP mandate substantially burdens the religious exercise of Braidwood's owners. Braidwood is a for-profit corporation owned by Steven Hotze. Pls.' App. 69, ECF No. 46. Hotze objects to providing coverage for PrEP drugs because he believes that (1) the Bible is "the authoritative and inerrant word of God," (2) the "Bible condemns sexual activity outside marriage between one man and one woman, including homosexual conduct," (3) providing coverage of PrEP drugs "facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman," and (4) providing coverage of PrEP drugs in Braidwood's self-insured plan would make him complicit in those behaviors. *Id.* at 72. Yet the ACA *requires* Braidwood to provide coverage for PrEP drugs. *See* 26 U.S.C. § 4980H(c)(2); 42 U.S.C. § 300gg-13(a)(1); 45 C.F.R. § 147.130(b)(1). If Braidwood does not provide coverage for PrEP drugs, it faces a substantial monetary penalty. *See* 26 U.S.C. §§ 4980D, 4980H. It is well established—and Defendants do not contest—that putting employers to this choice imposes a substantial burden on religious exercise. *See Hobby Lobby Stores*, 573 U.S. at 725–26.

Rather than disputing the law, Defendants dispute Hotze's beliefs. They argue that Hotze's claim that PrEP drugs facilitate various kinds of behavior is an empirical one that requires factual support. *See* Defs.' Summ. J. Br. 66–67, ECF No. 64. But Defendants inappropriately contest the *correctness* of Hotze's beliefs, when courts may test only the *sincerity* of those beliefs. The Supreme Court has "made it abundantly clear that, under RFRA, [HHS] must accept the sincerely held complicity-based objections of religious entities." *Little Sisters of the Poor*, 140 S. Ct. at 2383. Defendants may not "tell the plaintiffs that their beliefs are flawed" because the connection between the morally objectionable conduct and complicity in the conduct "is simply too attenuated." *Hobby Lobby Stores*, 573 U.S. at 723–24. In other words, "[i]f an employer has a religious objection to the use of a covered contraceptive, and if the employer has a sincere religious belief that compliance with the mandate makes it complicit in that conduct, then RFRA requires that the belief be honored." *Little Sisters of the Poor*, 140 S. Ct. at 2390 (Alito, J., concurring).

Braidwood has shown that the PrEP mandate substantially burdens its religious exercise. The burden thus shifts to Defendants to show that the PrEP mandate furthers a compelling governmental interest and is the least restrictive means of furthering that interest. Defendants have not carried that burden.

1. Defendants have not shown that the PrEP mandate furthers a compelling governmental interest.

Defendants claim a compelling interest in reducing the spread of HIV, a potentially fatal infectious disease. *See* Defs.' Summ. J. Br. 68, ECF No. 64. PrEP drugs reduce the risk of getting HIV from sex by about 99%, and from injection drug use by about 74%. Defs.' App. 385, ECF No. 65. And because HIV is a contagious disease, the benefits of PrEP use by a portion of the population extend to the broader public. *See id.* 385–86. PrEP prescriptions can be expensive, costing as much as $20,000 per year. *Id.* at 387. Defendants argue that the PrEP mandate is a cost-

effective solution at inhibiting the spread of HIV. Braidwood does not dispute the government's compelling interest in preventing the spread of infectious disease, the severity of HIV, or the effectiveness of PrEP drugs. *See* Pls.' Resp. Br. 46, ECF No. 74.

But Defendants frame the interest too broadly. "RFRA requires the Government to demonstrate that the compelling interest test is satisfied through application of the challenged law 'to the person'—the particular claimant whose sincere exercise of religion is being substantially burdened." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 430–31 (2006). That requires courts "to look to the marginal interest" in enforcing the government mandate in similar cases. *Hobby Lobby Stores*, 573 U.S. at 727.

As an initial matter, Defendants' argument is at odds with their insistence that the PrEP mandate is merely a "recommendation." *See supra* Section III.B.2. Defendants claim a compelling interest in forcing employers to cover PrEP drugs in their insurance policies. But Congress did not reflect that interest in the ACA. Instead, Congress reflected an interest in compelling coverage for whatever PSTF happens to recommend as having an "A" or "B" rating. 42 U.S.C. § 300gg-13(a)(1). PSTF, meanwhile, "does not articulate the position of the United States government," and is entirely agnostic on what services insurance policies ought to cover. Defs.' Summ. J. Br. 15, ECF No. 64. In fact, PSTF recommends PrEP drugs only "to persons who are at high risk of HIV acquisition." Pls.' App. 12, ECF No. 46. Neither Congress nor PSTF expressed the compelling interest that Defendants now put forward. *See Little Sisters of the Poor*, 140 S. Ct. at 2392 (Alito, J., concurring) ("We can answer the compelling interest question simply by asking whether *Congress* has treated the provision of free contraceptives to all women as a compelling interest.").

More importantly, Defendants do not show a compelling interest in forcing private, religious corporations to cover PrEP drugs with no cost-sharing and no religious exemptions. Defendants provide no evidence of the scope of religious exemptions, the effect such exemptions would have on the insurance market or PrEP coverage, the prevalence of HIV in those communities, or any other evidence relevant "to the marginal interest" in enforcing the PrEP mandate in these cases. *Hobby Lobby Stores*, 573 U.S. at 727. Moreover, the ACA's exemptions for grandfathered plans[11] and employers with fewer than fifty employees[12] undermines Defendants' claim of the "critical importance of reducing barrier to PrEP access." Defs.' Summ. J. Br. 70, ECF No. 64; *see Fulton v. City of Phila.*, 141 S. Ct. 1868, 1882 (2021). Defendants outline a generalized policy to combat the spread of HIV, but they provide no evidence connecting that policy to employers such as Braidwood, nor do they provide evidence distinguishing potential religious exemptions from existing secular exemptions. Thus, Defendants have not carried their burden to show that the PrEP mandate furthers a compelling governmental interest.

2. Defendants have not shown that the PrEP mandate is the least restrictive means of furthering their stated interest.

Even if Defendants had satisfied the compelling-interest prong, they have not shown that the PrEP mandate is the least restrictive means of furthering that interest. "The least-restrictive-means standard is exceptionally demanding . . . ." *Hobby Lobby Stores*, 573 U.S. at 728. Regarding the contraceptive mandate, the Supreme Court held that the "most straightforward way" of ensuring access to contraceptives "would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Id.* Likewise, Defendants have not

[11] 42 U.S.C. § 18011(a).
[12] 26 U.S.C. § 4980H.

shown that the government would be unable to assume the cost of providing PrEP drugs to those who are unable to obtain them due to their employers' religious objections.

Defendants' only response is that Braidwood waived this argument by not providing evidence of this proposed alternative in discovery. *See* Defs.' Summ. J. Br. 70, ECF No. 64. But Defendants, not Plaintiffs, bear the burden of demonstrating that applying the PrEP mandate to Braidwood "is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b)(2). "[I]f a less restrictive means is available for the Government to achieve its goals, the Government must use it." *Holt v. Hobbs*, 574 U.S. 352, 365 (2015) (citation and internal quotation marks omitted) (interpreting the Religious Land Use and Institutionalized Persons Act). Defendants have not demonstrated that the PrEP mandate is the least restrictive means of furthering their articulated interest. The Court thus **GRANTS** summary judgment in favor of Braidwood as to Claim 5 of Plaintiffs' Amended Complaint. The Court reserves ruling on Claim 5 as to the remaining Plaintiffs.

IV. CONCLUSION

Braidwood has standing to pursue its claims, so the Court is able to resolve most of the issues in this case. Accordingly, the Court rules as follows:

1) PSTF violates the Appointments Clause. The Court **GRANTS** Plaintiffs' summary judgment motion and **DENIES** Defendants' summary judgment motion on Claim 1 as to 42 U.S.C. § 300gg-13(a)(1). The Court reserves ruling on the appropriate remedy.

2) HRSA and ACIP do not, on this record, violate the Appointments Clause. The Court **DENIES** Plaintiffs' summary judgment motion and **GRANTS** Defendants' summary judgment motion on Claim 1 as to 42 U.S.C. § 300gg-13(a)(2) through (a)(4). The Court thus **DISMISSES** Claim 1 as to 42 U.S.C. § 300gg-13(a)(2) through (a)(4).

3) PSTF does not violate Article II's Vesting Clause. The Court **DENIES** Plaintiffs' summary judgment motion and **GRANTS** Defendants' summary judgment motion on Claim 3. The Court thus **DISMISSES** Claim 3.

4) The preventive services provisions do not violate the nondelegation doctrine. The Court **DENIES** Plaintiffs' summary judgment motion and **GRANTS** Defendants' summary judgment motion on Claim 2. The Court thus **DISMISSES** Claim 2.

5) The PrEP mandate violates Braidwood's rights under RFRA. The Court **GRANTS** Plaintiffs' summary judgment motion and **DENIES** Defendants' summary judgment motion on Claim 5 as to Braidwood. The Court reserves ruling on Claim 5 as to the remaining Plaintiffs and reserves ruling on the appropriate remedy.

6) The parties indicated they would file supplemental briefing on the scope of relief, standing for the remaining Plaintiffs as it relates to the scope of relief, and the claims relating to the contraceptive mandate. The parties shall file a joint status report by **September 9, 2022**, outlining the remaining issues to be decided and proposing a schedule for the remaining briefing.

SO ORDERED this **7th day** of **September, 2022**.

Reed O'Connor
UNITED STATES DISTRICT JUDGE

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

JOHN KELLEY, et al., Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al., Defendants.	Case No. 4:20-cv-00283-O Judge Reed O'Connor

BRIEF OF AMICI STATES ILLINOIS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, THE DISTRICT OF COLUMBIA, HAWAII, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, AND WASHINGTON IN SUPPORT OF THE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT PURSUANT TO LOCAL RULE 7.2(b)

KWAME RAOUL
Attorney General of Illinois
Christopher G. Wells
Alex Hemmer
Elizabeth H. Jordan (Illinois Bar No. 6320871, *pro hac vice* motion pending)
Office of the Illinois Attorney General
100 W. Randolph St.
Chicago, IL 60601
(312) 814-3000
elizabeth.jordan@ilag.gov

(*Complete counsel list appears on signature pages.*)

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INTRODUCTION AND INTEREST OF AMICI STATES

The Amici States of Illinois, California, Colorado, Connecticut, Delaware, The District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington ("Amici States") submit this brief in support of Defendants Xavier Becerra, in his official capacity as Secretary of Health and Human Services; Janet Yellen, in her official capacity as Secretary of the Treasury; Martin Walsh, in his official capacity as Secretary of Labor; and the United States of America.

The Amici States have a vital interest in protecting the health and welfare of their citizens, an interest substantially advanced by the challenged provisions of the Affordable Care Act (the "Act"). The Amici States have directly benefitted from and continue to depend on the Act's preventive services provisions, 42 U.S.C. § 300gg-13(a)(1)-(4), which have improved public health outcomes for their residents. The Amici States also operate public health agencies and offer guidance to health insurers within their jurisdictions. They are therefore interested in the outcome of this litigation for the additional reason that they have expended considerable time and resources to implement the Act's requirements, and should the plaintiffs prevail, Amici States will be required to expend additional resources to provide guidance and healthcare if the challenged provisions are enjoined. If the Court were to invalidate the preventive services provisions, that result could destabilize the Amici States' public health systems—including interfering with their abilities to meaningfully respond to the COVID-19 pandemic—which would have a significant effect on their residents. The Amici States thus urge the Court to reject the plaintiffs' sweeping challenges to the Affordable Care Act's preventive services provisions.

ARGUMENT

I. The preventive services provisions have improved public health outcomes within the Amici States, engendered substantial reliance interests, and created a strong public interest weighing against an injunction.

The plaintiffs challenge the Affordable Care Act's preventive services provisions, which collectively require private insurers to "provide coverage for" and "not impose any cost sharing requirements for" certain preventive health services. 42 U.S.C. § 300gg-13(a)(1)-(4). As the plaintiffs seek to enjoin the federal government from enforcing those provisions, the Court must consider the equities, including the public's interest in the government's continued ability to enforce the provisions. *See Winter v. Natural Res. Def. Council*, 555 U.S. 7, 32 (2008) (explaining that "[a]n injunction is a matter of equitable discretion" and that courts must "pay particular regard for the public consequences in employing" that remedy). As this brief explains, the equities weigh strongly in favor of denying the plaintiffs' requested relief—particularly now, as the provisions strengthen the ability of the federal, state, and local governments to respond to the COVID-19 pandemic.

Since their enactment in 2010, these provisions have had a significant and positive impact on Amici States and their residents. Over the last decade, millions of Americans have relied on the preventive services provisions to obtain no-cost preventive care, improving not only their own health and welfare, but public health outcomes more broadly. The Amici States have likewise come to rely on these provisions in building their public health systems over the last decade. The plaintiffs' desired relief would turn back the clock on these reforms.

A. The preventive services provisions have improved public health outcomes for the Amici States' residents.

The preventive services provisions have achieved Congress's primary goal: They have expanded access to low-cost preventive services among people who need those services most and,

in doing so, shifted the national legal framework around public health. Prior to the enactment of the Affordable Care Act, that framework was largely individualized and reactive, focused on treating and curing disease rather than improving population health and preventing the contraction of illness. John Aloysius Cogan, *The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J. OF L. MED. ETHICS 355 (2011). This individualized, cure-focused model of healthcare was partially the result of a nationally fragmented legal landscape: Private insurers were regulated by a range of vertical and horizontal laws and rules from states and the federal government, none of which incentivized insurers to support public health considerations. *Id.* at 359-362.

Since the passage of the Act—and, in particular, the preventive services provisions challenged here—preventive services have become significantly more available and accessible to those individuals who need them most. Most basically, 71 million people now have access to free vaccines, cancer screenings, and primary care, among other services. Nadia Chait & Sherry Glied, *Promoting Prevention Under the Affordable Care Act*, 39 ANN. REV. PUB. HEALTH 507 (2018), at 514. A range of academic studies suggests that individuals who have access to no-cost preventive services use them: One study of over 60,000 insured adults, for instance, found a significant increase in the uptake of blood pressure checks, cholesterol checks, and flu vaccinations in the wake of the Affordable Care Act's implementation. Xuesong Han, et al., *Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing as Part of the Affordable Care Act in the United States?*, 78 PREVENTIVE MED. 85 (2015). The preventive services provisions, in other words, have had their intended effect: They have improved access to health services for the Amici States' residents and millions of others like them. Enjoining those provisions would significantly limit access to those important preventive services.

But the improvement in public-health outcomes the Amici States have witnessed is not limited to those Americans who directly use the preventive services covered by the Act. Rather, the preventive services provisions have also alleviated financial and other burdens placed on state public health systems, allowing those systems to better address and prevent other serious public health issues.

Most notably, the Amici States, like a majority of states, run and fund local public health clinics that serve their residents (primarily medically underserved or low-income residents). *See, e.g.*, D.J. Landry et al., *Public Health Departments Providing Sexually Transmitted Disease Services*, 28 FAMILY PLANNING PERSPECTIVES 161 (1995). Before the enactment of the preventive services provisions, states were required to devote substantial budgetary resources to supplying preventive services at such clinics. The preventive services provisions, however, have allowed state public health departments to bill insurance providers when insured people visit state-run health clinics providing vaccinations and other services. *See* Chait & Glied, *supra*, at 517 (citing a study showing that 42% of patients at one public health clinic were insured at the time of their visit but chose the health clinic for confidentiality and convenience purposes). Public health agencies that are able to bill insurance carriers for substantial portions of their caseloads "increase their capacity by allowing for the redirection of funds that would have previously been used on these services." *Id*. States have used this additional departmental capacity to focus on "more traditional public health functions, . . . including disease surveillance." *Id.* This, in turn, has allowed states' public health departments to develop and deploy additional health interventions, expanding and improving health outcomes for all residents.

Similarly, the inclusion of pre-exposure prophylaxis ("PrEP") medication, which helps prevent HIV and AIDS, in the list of preventive services covered by the Act—a medication the

plaintiffs specifically target, Pls.' MSJ, ECF 45, at 30—likewise has had substantial public health benefits for the Amici States and their residents. By the end of 2019, an estimated 1,189,700 people in the United States were HIV-positive, and over 10% of those HIV-positive individuals were unaware of their infection. U.S. Department of Health and Human Services, HIV.gov, *U.S. Statistics*.[1] That same year, over 15,000 HIV-positive individuals died. *Id.* As HIV is generally spread via close contact between individuals, the most effective measures of decreasing infection rates and managing care are at the local level, including through state public health departments. *See* Panagiotoglou et al., *Building the Case For Localized Approaches To HIV: Structural Conditions And Health System Capacity To Address The HIV/AIDS Epidemic In Six US Cities*, 22 AIDS BEHAV. 3071 (2018) (describing city-level "HIV microepidemics" and advocating for targeted, local HIV interventions). Many Amici States have established programs of this nature; for example, the Illinois Department of Public Health's HIV and AIDS Section maintains and funds a PrEP medication assistance program for individuals who need last-resort access to the medication. The preventive services provisions enable these programs by making insurers the first line of defense against HIV and AIDS; without these provisions, the demand placed on state and local governments for preventive services might disrupt their ability to provide safety-net services of this kind.

The result of the preventive services provisions has thus been, in part, to reduce the overall burden placed on state and local public health systems, freeing those systems to pursue other public health interventions. As an example, states with available resources were able to undergo rigorous contact-tracing programs at the start of the COVID-19 pandemic, while states and regions without public health resources or states experiencing other public health crises were not able to respond

[1] https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics (last updated June 2, 2021).

as quickly or thoroughly. *See, e.g.,* Melvin et al., *The Role of Public Health in COVID-19 Emergency Response Efforts from a Rural Health Perspective*, 17 PREVENTING CHRONIC DISEASE 1 (2020), at 3 (describing challenges of under-resourced and understaffed community health centers, including challenges with contact tracing and providing staff with personal protective equipment); *see also* Jennifer Seelig, *The Need for Contact Tracing Continues*, ABC NEWS10 (June 3, 2021) (describing New York's robust contract-tracing program, reaching 83% of people who tested positive and 88% of their contacts, with 7,430 contact-tracing staff statewide).[2] As states enter the third year of the pandemic, it is imperative that they do not lose the progress in improving public health outcomes that was made possible in part through the preventative services provisions.

B. States have expended time and resources implementing the preventive services provisions.

The preventive services provisions are important to the Amici States for a second reason: many have expended considerable resources creating legal and regulatory infrastructures to support the provisions. If the court were to invalidate the preventive services provisions, this infrastructure would be disrupted, frustrating the Amici States' efforts to help implement Congress' vision and requiring them to operate in limbo during a critical period for public health.

To take one example, many states have passed statutes and promulgated regulations expressly incorporating the recommendations of the advisory boards that the plaintiffs challenge. Illinois, for instance, has promulgated a regulation paralleling the challenged provision that requires insurers governed by state law to cover at no cost the same preventive services recommended by the United States Preventive Services Task Force (PSTF), Advisory Committee

[2] https://www.news10.com/news/local-news/the-need-for-contact-tracing-continues/. All websites last visited January 28, 2022.

on Immunization Practices (ACIP), and Health Resources and Services Administration (HRSA). *See* Ill. Admin. Code 2001.8(a)(1)(A)-(C). Other states have taken similar steps. *See, e.g.*, N.Y. Ins. Law § 3216(g)(17)(E); Cal. Health & Saf. Code, § 1367.002(a); 18 Del. Code § 3558(b); Va. Code Ann. § 38.2-3438-3442; D.C. Code § 31-3834.02(a)(2); N.J. Stat. § 17B:26-2.1mm; Md. Code Ann., Ins. § 15-1A-10.

If the plaintiffs' challenge to the preventive services provisions succeeds, these regulating bodies and advisory panels will be enjoined from performing the duties Congress gave them in the Affordable Care Act, necessitating costly and burdensome changes to the states' own regulatory frameworks for determining which services must be covered by those private insurers governed by state law.[3] Further, even states that have not implemented laws mirroring the Affordable Care Act's preventive services provisions have enjoyed the benefits afforded by those provisions. Invalidating the challenged provisions will require those states to reassess their regulatory frameworks for private insurers operating in their jurisdictions. This type of overhaul would impose significant burdens on states at a time when public health agencies and infrastructure can ill afford such disruption.

II. The plaintiffs' challenges to the preventive services provisions fail.

The plaintiffs seek to enjoin the preventive services provisions on two primary bases: that they violate the Appointments Clause and that, at least as applied to certain preventive services,

[3] The fact that some states have enacted provisions that, like those challenged here, require private insurers to cover certain preventive services does not mean that these states would not be affected by a judgment setting aside the Affordable Care Act's preventive services provisions. For example, these state-law insurance requirements do not apply to self-insured employer health plans, which cover more than half of all Americans. *See* 29 U.S.C. §§ 1144(a), (b)(2)(A); Sonfeld et al., *U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, 2002*, 36 PERSP. SEXUAL & REPRO. HEALTH 72, 76 (2004). So many of the Amici States' residents are covered only by the Affordable Care Act's requirements, not by the state-law requirements those states have independently imposed.

they violate the plaintiffs' rights under the Religious Freedom Restoration Act ("RFRA"), 20 U.S.C. § 2000bb *et seq*.; Pls.' MSJ at 12–24, 30–37.[4] Each of these arguments fails on the merits and should be rejected. The plaintiffs' Appointments Clause claims fail because the members of the advisory committees Congress tasked with identifying preventive services are not "officers of the United States." And the plaintiffs' RFRA claims fail because the specific preventive services challenged by the plaintiffs do not substantially burden their religious rights and are, in any event, the least restrictive means to meeting a compelling government interest.

A. The plaintiffs' Appointment Clause claims fail because members of the PSTF, ACIP, and HRSA are not "officers of the United States."

The plaintiffs' primary argument is that the preventive services provisions are unconstitutional because they draw on "recommendations" issued by the members of the PSTF and ACIP—two advisory entities—and on "guidelines" issued by HRSA, a subdivision of the U.S. Department of Health and Human Services. Pls.' MSJ at 12–24. According to the plaintiffs, the members of PSTF and ACIP and the HRSA Administrator are "officers of the United States," but they have not been appointed in the manner required by the Appointments Clause. The plaintiffs' premise is incorrect. The members of PSTF and ACIP and the HRSA Administrator lack both the formal, continuous relationship with the federal government and the degree of authority necessary to be "officers" within the meaning of the Appointments Clause.

An individual "must occupy a 'continuing' position established by law" to qualify as an "officer" within the meaning of the Appointments Clause. *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). The Fifth Circuit has interpreted "officer" to require "a continuing and formalized

[4] The plaintiffs also argue briefly that the challenged provisions violated the nondelegation doctrine and the Vesting Clause. Pls.' MSJ 24-30. The Court should reject those arguments on the grounds identified by the defendants.

relationship of employment with the United States Government," *Riley v. St. Luke's Episcopal Hosp.*, 252 F.3d 749, 757 (5th Cir. 2001) (en banc). An "officer" must also "exercise significant authority pursuant to the laws of the United States." *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam); *accord Lucia*, 138 S. Ct. at 2051. Members of the PSTF and ACIP fail both requirements. They are neither federal employees, nor do they exercise "continuing" authority. In addition, none of the individuals identified by the plaintiffs exercise "significant authority pursuant to" federal law. The plaintiffs' Appointment Clause claims therefore fail.

1. Members of the PSTF, ACIP, and HRSA lack a formal, continuous relationship with the federal government.

The plaintiffs' challenges to the role entrusted to members of the PSTF and ACIP fail at the outset because the members of these advisory entities lack "a continuing and formalized relationship of employment with the United States Government." *Riley*, 252 F.3d at 757.

In *Riley*, the Fifth Circuit, sitting en banc, held that *qui tam* relators are not "officers of the United States" requiring appointment consistent with the Clause because relators "do not draw a government salary and are not required to establish their fitness for public employment." *Id.* at 758. In reaching that conclusion, the en banc panel relied in part on the Supreme Court's decisions in *Auffmordt v. Hedden*, 137 U.S. 310 (1890), and *United States v. Germaine*, 99 U.S. 508 (1878), each of which concluded that private individuals whose services were used by the federal government only intermittently were not "officers of the United States."

The same is true here. The volunteer members of the PSTF do not have a formalized relationship of employment with the United States. They are not afforded emoluments and do not draw a government salary; instead, they generally maintain full-time practices of medicine (or other professional activities) while lending their expertise to the federal government and the states. *See* 85 Fed. Reg. 711, 712 (Jan. 7, 2020) (PSTF members are all "volunteers and do not receive

any compensation beyond support for travel to in-person meetings."). Similarly, ACIP is comprised primarily of non-federal employees, who likewise do not receive salaries for their participation. *See* U.S. Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices (ACIP): Charter*.[5] Both advisory entities likewise provide only intermittent services to the federal government, much like the individuals in *Auffmordt* and *Germaine*. *See Riley*, 252 F.3d at 757-58. The volunteer members of each entity by necessity do not have a "continuing and formalized relationship of employment with the United States," as *Riley* requires, *id.* at 757. The plaintiffs' challenge with respect to the PSTF and ACIP fails on that basis alone.

Recognizing that *Riley* requires dismissal of the bulk of their Appointments Clause claims, the plaintiffs ask the Court to ignore or rewrite it, insisting that it "finds no support in" the Supreme Court's recent opinion in *Lucia*. Pls.' MSJ at 16. As the plaintiffs acknowledge, however, *id.*, this Court lacks the power to decline to apply binding Fifth Circuit precedent, and the plaintiffs' suggestion that the Court merely "interpret[]" *Riley* in their preferred manner, *id.* at 16-17, fares little better.[6] *Riley*'s reliance on the fact that the *qui tam* relators there lacked a "formalized . . . employment" relationship with the federal government—in the Fifth Circuit's words, that they did not "draw a government salary" and were "not required to establish their fitness for public employment," 252 F.3d at 757-58—was an essential premise of its holding, not merely dictum that the Court may "interpret" away. Pls.' MSJ at 16. This Court is bound to apply *Riley*.

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[5] https://www.cdc.gov/vaccines/acip/committee/charter.html (last updated July 14, 2020).

[6] The plaintiffs also ask the Court to ignore or rewrite *Riley* because it "contradicts" a 2007 opinion of the Office of Legal Counsel. Pls.' MSJ 16 (citing *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 78 (Apr. 16, 2007)). But the Office of Legal Counsel's opinions are, of course, not binding on the Court, so there is no need to read *Riley* in light of the 2007 opinion.

In any event, there is no tension between *Riley* and *Lucia*. *Riley* rests in large part on the Supreme Court's decision in *Germaine*, which, as the Court explained in *Lucia*, "held that 'civil surgeons' (doctors hired to perform various physical exams) were" not officers "because their duties were 'occasional and temporary' rather than 'continuing and permanent.'" 138 S. Ct. at 2051 (quoting *Germaine*, 99 U.S. at 511–12). The plaintiffs suggest that the Supreme Court's description of *Germaine* in *Lucia* establishes that there is no requirement that a federal officer "receive[] payment or emoluments for his work." Pls.' MSJ at 16. But this aspect of the analysis was not at issue in *Lucia*, which focused on whether the administrative law judges (ALJs) at issue in that case "exercised significant authority" under federal law. 138 S. Ct. at 2051; *accord id.* at 2053 (noting that "everyone . . . agree[d]" in *Lucia* that the ALJs held a "continuing office established by law"). Regardless, *Germaine*'s ultimate conclusion—that a private citizen empaneled for "occasional and intermittent" service to the federal government is not an officer of the United States, 99 U.S. at 512—is consistent with both *Lucia* and *Riley*. Under *Germaine*, *Lucia*, and *Riley*, the non-employee members of the PSTF and ACIP are not federal officers.

The plaintiffs' contrary argument would deem every advisory committee convened by statute to satisfy at least the first part of *Lucia*'s test. The federal government maintains an average of 1,000 advisory boards with varying duties, time commitments, and levels of required expertise. *See* Fed. Advisory Committee Act (FACA) Database, U.S. GSA (2021).[7] Some, like the National Advisory Council on Innovation and Entrepreneurship advising the Department of Commerce, are meant to function partially as community engagement boards and are tasked with facilitating federal dialogue with the innovation, entrepreneurship, and workforce development communities. *See* U.S. Economic Development Administration, National Advisory Council on Innovation and

[7] https://www.facadatabase.gov/FACA/FACAPublicPage.

Entrepreneurship (NACIE) (2021).[8] Others, like the Advisory Committee for Biological Sciences within the National Science Foundation, are bodies tasked with reviewing highly technical information and making recommendations to government agencies and branches. *See* National Science Foundation, Directorate for Biological Sciences Advisory Committee (BIO AC) (2021).[9] These committees reflect the federal government's recognition that elected officials often do not possess the level of specific, technical, or scientific expertise necessary to cover all topics that the federal government must regulate. But under the plaintiffs' view, the members of each of these committees—or, at the very least, any committee convened by statute—occupy "continuing positions" that are "established by law" and so are one step toward being deemed "officers of the United States." Pls.' MSJ 13. That cannot be right.

2. Members of the PSTF and ACIP, and the HRSA Administrator, lack the level of authority required to be "officers" within the meaning of the Appointments Clause.

Even if the plaintiffs were correct that "officers" need not have an employment relationship with the federal government, their Appointments Clause challenges would still fail because PSTF, ACIP, and HRSA do not exercise "significant authority" under federal law, *Lucia*, 138 S. Ct. at 2051. They merely issue recommendations or guidelines regarding the preventive services that private insurers must cover.

Lucia, which the plaintiffs heavily rely on, confirms that the "significant authority" requirement is not met here. At issue in *Lucia* was the constitutionality of the appointment of SEC ALJs—adjudicative officers that wielded "nearly all the tools of federal trial judges." 138 S. Ct. at 2053. The Court answered the question whether the ALJs exercised "significant authority" under

[8] https://www.eda.gov/oie/nacie/.

[9] https://www.nsf.gov/bio/advisory.jsp.

federal law by reference to its prior opinion in *Freytag v. Commissioner*, 501 U.S. 868 (1991), holding that the ALJs enjoyed substantially the same power as the "special trial judges" (STJs) at issue in *Freytag* and so were "officers of the United States." As evidence of the "significant" authority wielded by both kinds of adjudicative officers, the Court cited core responsibilities held by STJs and ALJs, such as receiving evidence and examining witnesses at hearings, taking pre-hearing depositions, administering oaths, ruling on motions, regulating the course of hearings and the conduct of counsel, ruling on the admissibility of evidence, and issuing subpoenas. 138 S. Ct. at 2053. The Court also relied on ALJs' and STJs' power to enforce compliance with certain orders and to punish contumacious conduct "by means as severe as excluding the offender from the hearing." *Id.*

Neither the PSTF and ACIP members nor the HRSA Administrator are given any authority comparable to that discussed in *Lucia*. They cannot compel individuals or businesses to appear anywhere or to answer any questions. They cannot issue definitive rulings with respect to rights and responsibilities. They cannot themselves regulate any conduct whatsoever. They have no enforcement authority at all—not even to enforce their own recommendations. As the Act reflects these entities merely issue "recommendations" and "guidelines." 42 U.S.C. § 300gg-13(a)(1)-(4). They and their members are not officers of the United States.

The plaintiffs' primary counterargument is that Congress has required private insurers to cover preventive services and has tasked the advisory entities and HRSA with identifying what those services are. Pls.' MSJ 14-15, 18-19. But Congress has not entrusted these entities with "significant discretion" on matters of policy or practice, as in *Lucia*, 138 S. Ct. at 2052. Instead, *Congress* has made the judgment that private insurers should have to cover certain preventive services at no charge. It has merely tasked the PSTF, ACIP, and HRSA with exercising their expert

judgment to make "recommendations" and issue "guidance" regarding the exact services that should be covered. 42 U.S.C. § 300gg-13(a)(1)-(4). In that sense, these entities' roles are no different than those of the private organizations whose standards Congress frequently incorporates into federal law. *See, e.g.*, 4 U.S.C. § 119(a)(2) (requiring certain databases to be "provided in a format approved by the American National Standards Institute's Accredited Standards Committee"); 42 U.S.C. § 6293(b)(8) (requiring certain test procedures to "be the test procedures specified in ASME A112.19.6–1990"). The plaintiffs' only response is that these standard-setting organizations are not chartered by federal statute. Pls'. MSJ, at 14 n.40. But the question whether an individual has a sufficiently formalized relationship with the federal government to constitute being an "officer" is distinct from whether he or she is entrusted with the authority that accompanies such a position. *See Lucia*, 138 S. Ct. at 2051. The plaintiffs' position appears to be that any private entity whose recommendations are incorporated into federal law has been delegated "significant authority" under federal law. *Id.* That would amount to an unprecedented incursion into Congress' ability to rely on expert entities in setting policy.

B. The plaintiffs' RFRA claims fail.

The plaintiffs' RFRA claims, which are levied only at the requirement that private insurers cover PrEP medication, *see* Compl. ¶¶ 108-111, also fail.[10] RFRA generally prohibits the federal government from "substantially burden[ing] a person's exercise of religion" unless it establishes that the practice in question "is in furtherance of a compelling governmental interest" and "is the least restrictive means of furthering" that interest. 42 U.S.C. § 2000bb-1(a), (b); *see Little Sisters*

[10] The plaintiffs' motion for summary judgment appears to cast a wider net, arguing that they have also asserted meritorious RFRA claims against a range of other preventive services, including "screenings and behavioral counseling for STDs and drug use." Pls.' MSJ, ECF 45, at 30. But the plaintiffs' complaint pleads an RFRA claim only against the requirement to cover PrEP, Compl. ¶¶ 108-111, and they cannot amend the complaint in their motion for summary judgment.

of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2383 (2020). Here, the plaintiffs' RFRA claims fail on multiple grounds.

First, the plaintiffs have failed to establish that the requirement that private insurers cover PrEP medication "substantially burdens" their religious beliefs. The plaintiffs do not articulate any specific religious objection to PrEP medication itself. *See* Pls.' MSJ at 31; *see also, e.g.*, App. 36 (plaintiff Kelley's attestation regarding his religious beliefs). Rather, the plaintiffs explain that they object to "subsidizing lifestyles that violate their religious beliefs," Pls.' MSJ at 31—namely, "homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman," *id.* at 32—which they assert that providing PrEP medication does. But the plaintiffs provide no evidentiary support for their assertion that requiring insurers to cover PrEP medication without cost sharing in fact facilitates or encourages any of the identified conduct. Absent any such evidence, the plaintiffs cannot establish that any burden on their religious beliefs is "substantial," as required by RFRA. The plaintiffs' mere assertion that they believe such a connection to exist is not sufficient.

The plaintiffs analogize this case to *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), which upheld a RFRA claim brought against a requirement that private health insurers cover contraceptives. Pls.' MSJ at 31–32. But the plaintiffs in *Hobby Lobby* specifically objected to the medication that insurers were required to cover. *See* 573 U.S. at 691 (explaining that the plaintiffs had "religious objections to abortion," and held religious beliefs that the four contraceptive methods at issue terminated pregnancies). Here, by contrast, the plaintiffs at bottom object not to the actual covered medication, but to voluntary conduct that they assert—without

evidentiary support—is facilitated by the provision of that medication. *Hobby Lobby* provides no support for such an attenuated claim.[11]

The plaintiffs assert that, under *Hobby Lobby* and subsequent cases, the Court "*must* accept [their] complicity-based objections to unwanted health-insurance coverage," "no matter how attenuated" those objections may seem. Pls.' MSJ at 32. That is incorrect. Although Amici States do not question the sincerity of the plaintiffs' religious objections (at least understood as objections to certain "lifestyles" that they associate with HIV-positive status, Pls.' MSJ at 31), the sincerity of a RFRA plaintiff's belief is an analytically distinct question from whether challenged government conduct imposes a "substantial burden" on that belief. That much is evident from RFRA's text, which expressly requires that there be a "substantial[] burden" on a person's "exercise of religion." 42 U.S.C. § 2000bb-1(a), (b). *Cf. United States v. Lee*, 455 U.S. 252, 257 (1982) ("Not all burdens on religion are unconstitutional.").[12] The plaintiffs' suggestion appears to be that a substantial burden exists any time a litigant sincerely believes that it does. As multiple courts of appeals have explained, however, that argument "collapse[s] the distinction between beliefs and substantial burden, such that the latter could be established simply through the sincerity of the former." *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 217 (2d Cir. 2015), *vacated*,

[11] The plaintiffs' speculation is also incorrect, as PrEP is used by many people for many reasons, including by married heterosexual people who are or may be HIV-positive and want to ensure that their children are not born with HIV. The plaintiffs make no argument as to how this situation—a recognized diagnostic purpose of PrEP, *see* U.S. Preventive Services Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection*, 321 J. AM. MED. ASS'N 2203, 2206 (2019) [hereinafter PSTF, *PrEP Recommendation*]—could be understood to encourage behavior to which they object.

[12] Nor does the legislative history of RFRA support the plaintiffs' assertions. *See Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1176 (10th Cir. 2015) (explaining that Congress "added the word 'substantially'" to RFRA's text during the drafting process "to clarify that only some burdens would violate the act"), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016).

136 S. Ct. 2450 (2016); *see also, e.g.*, *Geneva Coll. v. Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422, 442 (3d Cir. 2015) ("RFRA's reference to substantial burdens expressly calls for a qualitative assessment of the burden that the accommodation imposes on . . . the exercise of religion."), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016); *Little Sisters of the Poor*, 794 F.3d at 1176; *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C. Cir. 2014), *vacated sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016). If "RFRA plaintiffs need only to assert that their religious beliefs were substantially burdened" in order to force the government to defend its actions through the strict-scrutiny lens, "federal courts would be reduced to rubber stamps." *Catholic Health Care Sys.*, 796 F.3d at 218. No court has required that result.

Second, the requirement that private insurers cover PrEP medication without cost sharing is justified by a "compelling governmental interest." 42 U.S.C. § 2000bb-1(b). As the PSTF has explained, over 30,000 individuals are diagnosed with HIV each year, and over 15,000 HIV-positive individuals died in 2019. PSTF, *PrEP Recommendation*, *supra*, at 2204, 2208; *see also U.S. Statistics*, *supra* note 1. PrEP medication is highly effective, yet it "is currently not used [by] many persons at high risk of HIV infection." PSTF, *PrEP Recommendation*, *supra*, at 2208-209. The government has a compelling interest in ensuring that individuals have access to life-saving medication. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996). The plaintiffs do not genuinely dispute that the federal government *could* have a compelling interest in requiring private insurers to cover the cost of preventive services of all kinds, including PrEP medication; their main objection is that Congress failed to specify that PrEP medication *in particular* must be covered by insurers. As explained, however, Congress reasonably and constitutionally asked a range of expert advisory entities to issue "recommendations" and "guidance" regarding the exact services that insurers should cover. That determination does not undercut the "compelling" nature of the federal

government's interest in ensuring that services like PrEP are made available without cost sharing to individuals who need them.

Finally, the preventive services provisions are the least restrictive means Congress could have chosen to ensure meaningful access to PrEP (and similar preventive services). The plaintiffs' only suggestion to the contrary is that Congress could establish an elaborate new program that would allow non-objecting providers to "seek reimbursement from the government for the services that they provide to uninsured or underinsured patients," Pls.' MSJ 36—that is, an entirely new system of public health insurance targeted only at preventive care. But plaintiffs identify no case to have imposed injunctive relief on the federal government on the thought that Congress could simply have established an entirely new administrative apparatus instead. *Cf. Sherbert v. Verner,* 374 U.S. 398, 408 (1963) (describing proposed exemption that, "while theoretically possible, appeared to present an administrative problem of such magnitude . . . that [it] would have rendered the entire statutory scheme unworkable"). The plaintiffs point to *Hobby Lobby* for the proposition that such an analysis is permissible, *see* Pls.' MSJ 36-37, but the language on which they rely is dicta on which the Court ultimately did "not rely . . . in order to conclude that" the regulations there violated RFRA, *Hobby Lobby*, 573 U.S. at 730. In any event, the reality is much starker: Granting the plaintiffs the relief they seek and allowing them to not provide (or pay for) insurance that would cover PrEP would deepen residents' financial reliance on state and local public health systems and upend progress made toward putting an end to the HIV epidemic. *Supra* pp. 2-7. RFRA does not require that result.

CONCLUSION

The plaintiffs' motion for summary judgment should be denied, and the defendants' cross-motion for summary judgment should be granted.

Date: January 28, 2022

Respectfully submitted,

KWAME RAOUL
Attorney General of Illinois

/s/ Elizabeth H. Jordan
Christopher G. Wells
Alex Hemmer
Elizabeth H. Jordan (Illinois Bar No. 6320871, *pro hac vice* motion pending)
Office of the Illinois Attorney General
100 W. Randolph St.
Chicago, IL 60601
(312) 814-3000
elizabeth.jordan@ilag.gov

Counsel list continues on next page

ROB BONTA
Attorney General of California
1300 I Street
Sacramento, CA 95814

PHILIP WEISER
Attorney General of Colorado
1300 Broadway, 10th Floor
Denver, CO 80203

WILLIAM TONG
Attorney General of Connecticut
165 Capitol Avenue
Hartford, CT 06106

KATHLEEN JENNINGS
Attorney General of Delaware
Carvel State Building, 6th Floor
820 N. French Street
Wilmington, DE 19801

KARL A. RACINE
Attorney General for the District of Columbia
One Judiciary Square
441 4th Street, NW, Suite 630 South
Washington, D.C. 20001

HOLLY T. SHIKADA
Attorney General of Hawai'i
425 Queen Street
Honolulu, HI 96813

AARON FREY
Attorney General of Maine
6 State House Station
Augusta, ME 04333

BRIAN E. FROSH
Attorney General of Maryland
200 Saint Paul Place
Baltimore, MD 21202

MAURA HEALEY
Attorney General of Massachusetts
One Ashburton Place
Boston, MA 02108

DANA NESSEL
Attorney General of Michigan
P.O. Box 30212
Lansing, MI 48909

AARON D. FORD
Attorney General of Nevada
Old Supreme Ct. Bldg.
100 N. Carson St.
Carson City, NV 89701

ANDREW J. BRUCK
Acting Attorney General of New Jersey
25 Market Street, Box 080
Trenton, NJ 08625

HECTOR BALDERAS
Attorney General of New Mexico
408 Galisteo Street
Santa Fe, MN 87501

LETITIA A. JAMES
Attorney General of New York
28 Liberty Street
New York, NY 10005

JOSHUA H. STEIN
Attorney General of North Carolina
North Carolina Department of Justice
114 W. Edenton Street
Raleigh, NC 27603

ELLEN F. ROSENBLUM
Attorney General of Oregon
1162 Court Street NE
Salem, OR 97301

JOSH SHAPIRO
Attorney General of Pennsylvania
Office of Attorney General
Strawberry Square
Harrisburg, PA 17120

PETER F. NERONHA
Attorney General of Rhode Island
150 South Main Street
Providence, RI 02903

THOMAS J. DONOVAN, Jr.
Attorney General of Vermont
109 State Street
Montpelier, VT 05609

ROBERT W. FERGUSON
Attorney General of Washington
P.O. Box 40100
Olympia, WA 98504

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2022, the foregoing proposed *amicus* brief was filed on the Court's electronic filing system with a motion for leave of Court to file. Notice of this filing therefore will be sent to all parties for whom counsel has entered an appearance through the Court's electronic filing system, and Parties may access this filing through the Court's system.

Date: January 28, 2022

s/ *Elizabeth H. Jordan*
Elizabeth H. Jordan
IL Bar #6320871 (*pro hac vice* motion pending)