

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION

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

**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.<sup>1</sup> *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

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<sup>1</sup> 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.<sup>2</sup> *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

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<sup>2</sup> 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.<sup>3</sup> 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].”

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<sup>3</sup> 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 ‘remediating 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.<sup>4</sup> *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,<sup>5</sup> 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

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<sup>4</sup> The parties do not dispute that Secretary Xavier Becerra is a constitutionally appointed principal officer.

<sup>5</sup> 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. Germaine*, 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 *Germaine*, 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 *Germaine* was not an officer *in part* because his payment was by commission prescribed by regulation, not “regular

appropriation.” *Germaine*, 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 Germaine*, 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.<sup>6</sup> And that power is nothing short of dictating what preventive services insurance providers *must* cover. It is more troubling,

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<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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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<sup>7</sup> *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 . . .").

<sup>8</sup> *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.

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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).<sup>9</sup>

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.

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<sup>9</sup> 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.<sup>10</sup> 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.

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<sup>10</sup> 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<sup>11</sup> and employers with fewer than fifty employees<sup>12</sup> 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

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<sup>11</sup> 42 U.S.C. § 18011(a).

<sup>12</sup> 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