

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

John Kelley, et al.

Plaintiffs,

v.

Xavier Becerra, et al.,

Defendants.

Case No. 4:20-cv-00283-O

**RESPONSE TO DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT AND REPLY BRIEF IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT**

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The defendants claim that the plaintiffs have failed to prove standing and have failed to demonstrate an entitlement to relief. We will first address the defendants' standing objections and then proceed to the merits.

I. THE PLAINTIFFS HAVE ESTABLISHED STANDING TO CHALLENGE THE CONSTITUTIONALITY OF 42 U.S.C. § 300gg-13(1)–(4) AND THE LEGALITY OF THE COVERAGE MANDATES UNDER RFRA

The plaintiffs have brought a facial constitutional challenge to 42 U.S.C. § 300gg-13(a)(1)–(4). They are claiming that each of these statutory provisions: (1) violates the Appointments Clause by empowering individuals who have not been appointed in conformity with the Constitution to unilaterally determine the preventive care that private health insurers must cover; and (2) violates the nondelegation doctrine by empowering agencies and entities to determine the preventive care that health insurance must cover while failing to provide an “intelligible principle” to guide their discretion. *See* First Amended Complaint, ECF No. 14, ¶ 112(a)–(b). The plaintiffs are also claiming that 42 U.S.C. § 300gg-13(a)(1) violates Article II's vesting clause by empowering the U.S. Preventive Services Task Force to unilaterally determine the preventive care that health insurance must cover while immunizing that agency from the President's direction, removal, or control. *See id.* at ¶ 112(c).

To establish standing, the plaintiffs need only to show that one or more of them is suffering an injury in fact, fairly traceable to the defendants' enforcement of the challenged statutory provisions, and likely to be redressed by the requested relief. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Each of the plaintiffs is seeking the same relief with respect to their constitutional claims against section 300gg-13(a)(1)–(4)—a declaratory judgment and injunction that restrains the defendants from enforcing any preventive-care mandate that issued after March 23, 2010. *See* First

Amended Complaint, ECF No. 14, ¶ 112(a)–(c), (e).¹ The defendants do not deny that each of the plaintiffs is seeking the same relief on these facial constitutional challenges to section 300gg-13(a)(1)–(4), and they do not deny that the one-plaintiff rule applies to these constitutional claims. *See* Aaron-Andrew P. Bruhl, *One Good Plaintiff Is Not Enough*, 67 Duke L.J. 481, 484 (2017) (“[A] court entertaining a multiple-plaintiff case may dispense with inquiring into the standing of each plaintiff as long as the court finds that one plaintiff has standing.”); *id.* at 554–56 (listing Supreme Court cases applying the one-plaintiff rule). So only one plaintiff needs Article III standing to challenge the constitutionality of section 300gg-13(a)(1)–(4) under the Appointments Clause and the non-delegation doctrine—and only one plaintiff needs standing to challenge section 300gg-13(a)(1) under Article II’s vesting clause. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2379 n.6 (2020) (“Under our precedents, at least one party must demonstrate Article III standing for each claim for relief.”); *Department of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019) (“For a legal dispute to qualify as a genuine case or controversy, at least one plaintiff must have standing to sue.”); *Rumsfeld v. Forum for Acad. & Institutional Rights, Inc.*, 547 U.S. 47, 53 n.2 (2006) (“[T]he presence of one party with standing is sufficient to satisfy Article III’s case-or-controversy requirement.”); *Bowsher v. Synar*, 478 U.S. 714, 721 (1986).

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1. The Court has previously ruled that the plaintiffs’ challenge to the Contraceptive Mandate is barred by *res judicata*. *See* Order, ECF No. 35, at 12–16. But the plaintiffs continue to *seek* relief that would enjoin the enforcement of all preventive-care mandates issued after March 23, 2010, even though this Court has ruled that they cannot prevail on the merits with respect to the Contraceptive Mandate. Article III standing analysis looks only to the requested relief, not the relief that a plaintiff will ultimately obtain. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 103 (1998) (asking whether “the requested relief will redress the alleged injury”).

A. At Least One Plaintiff Has Standing To Challenge The Constitutionality Of Section 300gg-13(a)(1)–(4) Under The Appointments Clause And Nondelegation Doctrine, And The Constitutionality Of Section 300gg-13(a)(1) Under Article II’s Vesting Clause

The plaintiff with the easiest case for Article III standing is Braidwood. Braidwood is indisputably suffering Article III injury traceable to section 300gg-13(a)(1)–(4) because the preventive-care mandates have deprived the company of its prerogative to decide whether and to what extent preventive care will be covered in its self-insured plan. Dr. Hotze’s declaration explains in detail how each provision of section 300gg-13(a)(1)–(4) has prevented him from limiting or excluding coverage of preventive care that he does not want to provide, including preventing care that violates his sincere religious beliefs.² He has also explained how the statute has deprived his company of the option to impose copays or deductibles for preventive care.³ The defendants do not contest the truth of Dr. Hotze’s declaration, and they do not deny that the harms described in Dr. Hotze’s declaration establish Article III injury.

The remaining plaintiffs’ standing to challenge the constitutionality of section 300gg-13(a)(1)–(4) rests on the doctrine of purchaser standing, which allows litigants to sue whenever a statute or agency action deprives them of the opportunity to purchase a desired product. *See* Br. in Support of MSJ at 10 (citing *Center for Auto Safety v. National Highway Traffic Safety Administration*, 793 F.2d 1322, 1332–34 (D.C. Cir. 1986), and *Orangeburg, South Carolina v. FERC*, 862 F.3d 1071, 1078 (D.C. Cir. 2017)); *see also* *Weissman v. Nat’l R.R. Passenger Corp.*, 21 F.4th 854, 857–58 (D.C. Cir. 2021); *Consumer Federation of America v. FCC*, 348 F.3d 1009, 1012 (D.C. Cir. 2003) (“[T]he inability of consumers to buy a desired product may con-

2. Hotze Decl. ¶¶ 7–8, 10–18 (ECF No. 46, at 68–70).

3. Hotze Decl. ¶ 9 (ECF No. 46, at 68).

stitute injury-in-fact ‘even if they could ameliorate the injury by purchasing some alternative product.’”); *Competitive Enterprise Institute v. National Highway Traffic Safety Administration*, 901 F.2d 107, 112–13 (D.C. Cir. 1990) (conferring standing on a consumer group to challenge fuel-economy standards that reduced the number and variety of larger vehicles available for sale); *Community Nutrition Institute v. Block*, 698 F.2d 1239, 1246–47 (D.C. Cir. 1983) (conferring standing on consumers to challenge regulations that “deprived” them of “a lower priced alternative to whole milk”), *rev’d on other grounds*, 467 U.S. 340 (1984).

Each of the individual religious-objector plaintiffs (Kelley, Starnes, and Mr. and Mrs. Maxwell) has been injured by the inability to purchase health insurance that excludes or limits coverage of preventive care that violates their sincere religious beliefs.⁴ This injury remains regardless of whether the elimination of preventive-care mandates causes premiums to go up or down, because the compulsory coverage of objectionable preventive care inflicts injury by making the religious-objector plaintiffs complicit in conduct that violates their religious beliefs. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020); *id.* at 2390–91 (Alito, J., concurring); *March for Life v. Burwell*, 128 F. Supp. 3d 116, 128–

4. *See* Kelley Decl. ¶¶ 5–15 (ECF No. 46, at 33–37); *id.* at ¶ 20 (ECF No. 46, at 37) (“The defendants’ enforcement of 42 U.S.C. § 300gg-13 has eliminated my option of obtaining the types of health-insurance policies described in paragraphs 56 and paragraphs 17–19.”); Starnes Decl. ¶¶ 5–15 (ECF No. 46, 39–43); *id.* at ¶ 16 (ECF No. 46, at 43) (“The defendants’ enforcement of 42 U.S.C. § 300gg-13 has eliminated my option of obtaining the types of health-insurance policies described in paragraphs 5–6.”); Zach Maxwell Decl. ¶¶ 5–15 (ECF No. 46, 50–54); *id.* at ¶ 16 (ECF No. 46, at 54) (“The defendants’ enforcement of 42 U.S.C. § 300gg-13 has eliminated my option of obtaining the types of health-insurance policies described in paragraphs 5–6.”); Ashley Maxwell ¶¶ 5–15 (ECF No. 46, 56–60); *id.* at ¶ 16 (ECF No. 46, at 60) (“The defendants’ enforcement of 42 U.S.C. § 300gg-13 has eliminated my option of obtaining the types of health-insurance policies described in paragraphs 5–6.”).

29 (D.D.C. 2015) (“[T]he employee plaintiffs have demonstrated that the [Contraceptive] Mandate substantially burdens their sincere exercise of religion . . . [because] [t]he Mandate, in its current form, makes it impossible for employee plaintiffs to purchase a health insurance plan that does not include coverage of contraceptives to which they object.”); *Wieland v. United States Dep’t of Health & Human Services*, 196 F. Supp. 3d 1010, 1017 (E.D. Mo. 2016) (federal contraceptive mandate substantially burdens the religious freedom of individual consumers of health insurance because “the ultimate impact is that Plaintiffs must either maintain a health insurance plan that includes contraceptive coverage, in violation of their sincerely-held religious beliefs, or they can forgo healthcare altogether”). That injury exists apart from any financial consequences that might accompany a ruling that enjoins the continued enforcement of the preventive-care mandates. The defendants do not deny this point, and they do not deny that the inability to purchase health insurance that excludes religiously or morally objectionable coverage constitutes injury in fact. *See* Defs.’ Br., ECF No. 64, at 20–24 (challenging only traceability and redressability with respect to the religious objectors).

Instead, the defendants try to defeat the religious objectors’ standing by claiming that they failed to establish traceability and causation. The defendants’ argument proceed as follows: (1) The complaint asserts federal RFRA claims against only the Contraceptive Mandate and the compulsory coverage of PrEP drugs; (2) The Court has dismissed the challenge to the Contraceptive Mandate on *res judicata* grounds;⁵ and (3) The compulsory coverage of PrEP drugs is the only remaining religious-freedom injury, and the plaintiffs have failed to prove that this injury is “fairly traceable” to section 300gg-13(a)(1) because they “have not provided factual

5. *See* Order, ECF No. 35, at 12–16.

evidence showing that, but for the Preventive Services Provision, their insurance plans would omit PrEP coverage.” Defs.’ Br., ECF No. 64, at 22; *see also id.* at 20–24.

The allegations of the plaintiffs’ complaint are not relevant at this stage of the litigation. The rules of civil procedure establish a regime of notice pleading, not code pleading,⁶ and it has long been established that litigants may pursue claims and relief in a motion for summary judgment that go beyond the allegations and demands of their complaint. *See* Fed. R. Civ. P. 54(c) (“Every other final judgment should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings.”); *Whole Woman’s Health v. Hellerstedt*, 136 S. Ct. 2292, 2307 (2016) (a request in the complaint to issue “such other and further relief as the Court may deem just, proper, and equitable” is sufficient to preserve claims that go unmentioned in the pleadings);⁷ *Citizens United v. Federal Election Comm’n*, 558 U.S. 310, 333 (2010) (considering and resolving a constitutional challenge to “the facial validity” of a statute, even though a facial challenge had never been brought); *Peterson v. Bell Helicopter Textron, Inc.*, 806 F.3d 335, 340 (5th Cir. 2015) (“Rule 54(c) authorizes district courts to grant any appropriate relief following a general prayer by the plaintiff, even if the plaintiff did not specifically seek it, but only where relief is otherwise

6. *See Johnson v. City of Shelby*, 574 U.S. 10, 12 (2014) (“The federal rules effectively abolish the restrictive theory of the pleadings doctrine, making it clear that it is unnecessary to set out a legal theory for the plaintiff’s claim for relief.” (quoting 5 Charles Alan Wright, et al., *Federal Practice and Procedure* § 1219, p. 277–78 (3d ed. 2004))).

7. In *Hellerstedt*, for example, the Supreme Court affirmed a district court ruling that enjoined the enforcement of a hospital admitting-privileges law across the board—even though the plaintiffs in that case had never even *asked* the district court for that relief at *any* stage of the district-court proceedings. *See Hellerstedt*, 136 S. Ct. at 2307; *id.* at 2330 (Alito, J., dissenting) (“The Court does this even though petitioners . . . did not presume to include such a claim in their complaint. The Court favors petitioners with a victory that they did not have the audacity to seek.”).

legally permitted.”); *Sapp v. Renfro*, 511 F.2d 172, 176, n.3 (5th Cir. 1975) (allowing claim for damages raised for first time on appeal in light of Rule 54(c) and the catchall prayer for relief in plaintiff’s complaint); *Driggers v. Business Men’s Assurance Co. of America*, 219 F.2d 292, 299 (5th Cir. 1955) (“[T]he final judgment should grant the relief to which plaintiff may prove himself entitled, even if he has not demanded such relief in his pleadings.”); 10 Charles Alan Wright & Arthur R. Miller, *Federal Practice & Procedure* § 2664 (4th ed. 2014) (“Because of the second sentence of Rule 54(c), the demand for judgment required by Rule 8(a)(3) loses much of its significance once a case is at issue. If defendant has appeared and begun defending the action, adherence to the particular legal theories of counsel that may have been suggested by the pleadings is subordinated to the court’s duty to grant the relief to which the prevailing party is entitled, whether it has been demanded or not.” (footnotes omitted)). The plaintiffs are allowed to assert RFRA claims that go beyond those mentioned in the complaint, and they may certainly present evidence for *standing* that was not specifically described in the pleadings.

The defendants do not claim that they have been prejudiced by the absence of these RFRA claims and standing arguments in the complaint. And the defendants cite no authority that prevents a plaintiff from asserting new claims in a motion for summary judgment, or presenting additional evidence for standing in summary-judgment briefing. The only cases that the defendants cite are *Fisher v. Metropolitan Life Insurance Co.*, 895 F.2d 1073 (5th Cir. 1990), and *Jackson v. Gautreaux*, 3 F.4th 182 (5th Cir. 2021), which hold only that district courts need not consider new claims presented for the first time in a *response* to a motion for summary judgment—*after* the opposing litigant has already filed his dispositive motion in an attempt to beat back the claims of which he is aware. *See Fisher*, 895 F.2d at 1078 (“This claim was not raised in Fisher’s second amended complaint but, rather, was raised in his response to the defendants’ motions for summary judgment and, as such, was not properly before

the court.”); *Jackson*, 3 F.4th at 188–89 (“[A] claim which is not raised in the complaint but, rather, is raised only in response to a motion for summary judgment is not properly before the court.” (citations and internal quotation marks omitted)). Neither case prevents a plaintiff from asserting new claims in his own motion for summary judgment, before the opposing litigant has the opportunity to rebut those claims in his own motion for summary judgment, and any attempt to extend *Fisher* or *Jackson* to this situation would contradict Rule 54(c), *Hellerstedt*, and *Citizens United*. See, e.g., *Lampton v. Diaz*, 639 F.2d 223, 227 n.14 (5th Cir. 2011) (“Waiver generally will not apply when [an issue] fairly appears in the record as having been raised or decided.” (citation and internal quotation marks omitted)); *In re Liljeberg Enterprises, Inc.*, 304 F.3d 410, 428 n.29 (5th Cir. 2002) (“[A]n argument is not waived on appeal if the argument on the issue before the district court was sufficient to permit the district court to rule on it.”); *Brown v. Ames*, 201 F.3d 654, 663 (5th Cir. 2000) (“To avoid being waived, an argument ‘must be raised to such a degree that the trial court may rule on it.’” (quoting *In re Fairchild Aircraft Corp.*, 6 F.3d 1119, 1128 (5th Cir. 1993))). And neither *Fisher* nor *Jackson* comes anywhere close to suggesting that a litigant is forbidden to produce evidence of standing at the summary-judgment stage that was not described in the complaint.

The more serious problem with the defendants’ argument is that the plaintiffs have brought a facial constitutional challenge to section 300gg-13(a)(1)–(4). That means they are challenging the constitutionality of Congress’s decision to enact these statutory provisions, which purport to empower non-officers (or inferior officers) to impose preventive-care mandates without an intelligible principle to guide their discretion, and which confer similar authority on individuals who are not subject to presidential removal and control. See Nicholas Quinn Rosenkranz, *The Subjects of the Constitution*, 62 Stan. L. Rev. 1209, 1212–38 (2010). To establish standing to bring these facial constitutional claims, the plaintiffs need only to show that the statute has led to

an injury of *any* sort that will be redressed by the requested relief—a judgment that pronounces the statute unconstitutional and enjoins the defendants from enforcing any preventive-care mandate that issued after March 23, 2010. *See, e.g., Americans for Prosperity Foundation v. Bonta*, 141 S. Ct. 2373, 2380 (2021). They do not need to show an injury that is traceable to the mandate to cover PrEP drugs, as the defendants claim. *See* Defs.’ Br., ECF No. 64, at 20–21.⁸

In all events, the plaintiffs *have* proven injuries that are fairly traceable to the PrEP mandate—as well as the existence of section 300gg-13(a)(1)–(4). Braidwood is being compelled to underwrite coverage for PrEP drugs in its self-insured plan, and it is forbidden to amend its plan to exclude this coverage even though the provision of this coverage violates Dr. Hotze’s religious beliefs. *See* Hotze Decl. ¶¶ 10, 14–16 (ECF No. 46, at 68–70). Braidwood is also being compelled to underwrite other forms of coverage that Dr. Hotze does not want to include in Braidwood’s self-insured plan, both for religious and non-religious reasons. *See* Hotze Decl. ¶¶ 7–19 (ECF No. 46, at 68–71). And Braidwood is being forbidden to impose copays or deductibles for any of the preventive care that section 300gg-13(a)(1)–(4) requires it to provide. *See* Hotze Decl. ¶¶ 9, 19 (ECF No. 46, at 68, 71). This is all that is needed to establish standing because Braidwood is seeking the same relief as the other plaintiffs on the constitutional claims. *See Little Sisters*, 140 S. Ct. at 2379 n.6.

The defendants suggest that Braidwood lacks standing because it never produced evidence that the preventive-care mandates affected its premiums. *See* Defs.’ Br., ECF No. 64, at 13. But Braidwood does not need to show that its premiums were affected to establish injury in fact. It is enough for Braidwood to claim that it *wants* to exclude

8. The RFRA claims, by contrast, target only particular preventive-care mandates—and the plaintiffs *do* need to show injury traceable to each objectionable mandate before establishing standing to seek an injunction against their continued enforcement.

or limit the coverage of preventive care required by section 300gg-13(a)(1)–(4), and that the requested relief will allow it to do so. Braidwood does not need to prove that the requested relief will lower premiums, especially when Dr. Hotze’s objections are rooted in his religious convictions rather than a desire to save money. *See* Hotze Decl. ¶¶ 8, 14–18 (ECF No. 46, at 68, 70); *see also* *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 720 (2014) (requiring a corporation to “arrange for . . . coverage” that violates its religious beliefs imposes a substantial burden (and injury in fact) regardless of whether the compulsory coverage saves the corporation money). The mere fact that the preventive-care mandates have limited Braidwood’s power to decide the scope of preventive-care coverage in its self-insured plan suffices to establish standing. *See* *Arizona State Legislature v. Arizona Independent Redistricting Commission*, 576 U.S. 787, 800 (2015) (state constitutional amendment that limits the state legislature’s power over redistricting decisions inflicts Article III injury); *see also* *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1631 (2020) (Sotomayor, J., dissenting) (“[I]njury to a plaintiff’s wallet is not, and has never been, a prerequisite for standing.”).

The defendants also claim that Braidwood lacks standing to challenge the PrEP mandate because Braidwood “presented no evidence that it has been required to make any payment related to PrEP so far.” Defs.’ Br., ECF No. 64, at 13. In the defendants’ view, Braidwood must prove that one or more of its employees will use PrEP drugs and force Braidwood to pay for them before Braidwood can challenge the legality of the coverage mandate. But Braidwood is suffering injury regardless of whether its employees obtain PrEP drugs through its self-insured plan. The requirement to underwrite coverage of PrEP drugs inflicts injury because Dr. Hotze wants Braidwood’s plan to explicitly exclude this coverage, and section 300gg-13(a)(1) and the PrEP mandate deprive him of that option. *See* Hotze Decl. ¶¶ 7–9 (ECF No. 46, at 68). That alone confers standing because it deprives Braidwood of the authority to decide the contents of its self-insured plan and the coverage that it will offer—and it forces

Braidwood to underwrite coverage that violates its religious beliefs. *See Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017) (“[A] litigant suffers an injury to her free exercise rights when the state compels her ‘to do or refrain from doing an act forbidden or required by one's religion, or to affirm or disavow a belief forbidden or required by one's religion.’”) (quoting *Mozert v. Hawkins Cty. Bd. of Educ.*, 827 F.2d 1058, 1066 (6th Cir. 1987)).

Hobby Lobby was not required to prove that its employees would use abortifacient contraception and bill its self-insured plan before challenging the Contraceptive Mandate under RFRA. The mere requirement to provide the objectionable coverage burdened the company’s religious beliefs and inflicted injury in fact. *See Hobby Lobby*, 573 U.S. at 720 (“By requiring the Hahns and Greens and their companies to *arrange for such coverage*, the HHS mandate demands that they engage in conduct that seriously violates their religious beliefs.” (emphasis added)); *see also Wheaton College v. Burwell*, 573 U.S. 958 (2014) (granting relief to an employer that had “religious objections to providing *coverage* for contraceptive services,” without requiring proof that its employees would use the objectionable contraception (emphasis added)). No different result should obtain here.

* * *

The easiest way to dispatch the defendants’ standing objections is to rely on Braidwood’s Article III injuries—which are clear and indisputable—and then observe that the remaining plaintiffs are seeking the same relief as Braidwood: (1) A declaratory judgment that sections 300gg-13(a)(1)–(4) violate the Appointments Clause and the non-delegation doctrine; (2) A declaratory judgment that section 300gg-13(a)(1) violates Article II’s vesting clause; and (3) An injunction against the continued enforcement of any preventive-care coverage mandate that issued after March 24, 2010. There is more that can be said to rebut the defendants’ standing

arguments with regard to the other plaintiffs, but it is unnecessary to reach those issues when the one-plaintiff rule allows the remaining plaintiffs to stay in the case.

II. 42 U.S.C. § 300gg-13(a)(1)–(4) VIOLATE THE APPOINTMENTS CLAUSE

The defendants try to defeat the plaintiffs’ Appointments Clause claim with several different arguments, none of which have merit. We will address the arguments in the order that they appear in the defendants’ brief.

A. The Secretary’s Purported “Ratification” Of The Preventive-Care Mandates Does Not Cure The Appointments Clause Violation

The defendants first contend that the Appointments Clause objections have been obviated by Secretary Becerra’s memo of January 21, 2022, which purports to “ratify” the preventive-care mandates that were previously imposed by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Commission (HRSA). *See* Defs.’ Br., ECF No. 64, at 27–32; App. to Defs.’ MSJ, ECF No. 65, at 2 (“I ratify the below listed guidelines and recommendations for the reasons relied on by the USPSTF, ACIP and the Director of the Centers for Disease Control and Prevention (CDC Director), and the HRSA Administrator in their previously published decisions or analyses regarding the relevant recommendations.”). But there are two fatal and insurmountable problems with the defendants’ ratification argument.

1. The Secretary Has No Statutory Authority To Decide Whether To Ratify Or Reject The Preventive-Care Mandates

The first problem is that the Secretary has no authority to ratify or reject the preventive-care mandates imposed by the U.S. Preventive Services Task Force, ACIP, or HRSA—and section 300gg-13(a)(4) compels the Secretary to implement their decisions whether he approves of them or not. So the Secretary’s purported “ratifica-

tion” is a meaningless act; it is nothing more than an acknowledgement of the statutory obligations imposed upon him by section 300gg-13(a)(4). See *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2381 (2020) (“By its terms, the ACA leaves the Guidelines’ content *to the exclusive discretion of HRSA.*” (emphasis added)). If section 300gg-13(a)(4) *allowed* the Secretary to veto or approve the preventive-care mandates recommended by the U.S. Preventive Services Task Force, ACIP, or HRSA, then the defendants could plausibly argue that Secretary Becerra’s ratification cures any Appointments Clause problems with the regime described in section 300gg-13(a)(4). See *Guedes v. Bureau of Alcohol, Tobacco, Firearms, and Explosives*, 920 F.3d 1, 11 (D.C. Cir. 2019) (rejecting Appointments Clause challenge to an agency rule issued by then-Acting Attorney General Matthew Whitaker, because the rule had been “independently ratified by Attorney General William Barr, whose valid appointment *and authority to ratify* is unquestioned.” (emphasis added)); 26 U.S.C. §§ 7801(a)(1), 7801(a)(2)(A), 7805(a) (empowering the Attorney General to “prescribe all needful rules and regulations for the enforcement of” the National Firearms Act); 18 U.S.C. § 926(a) (empowering the Attorney General to “prescribe only such rules and regulations as are necessary to carry out the provisions of” the Gun Control Act of 1968). But *Guedes* is no help to the defendants because there is no statute that empowers the Secretary to impose preventive-care coverage mandates, or to ratify or overrule the coverage requirements imposed by the U.S. Preventive Services Task Force, ACIP, or HRSA. See *Consumer Financial Protection Bureau v. Gordon*, 819 F.3d 1179, 1191–92 (9th Cir. 2016) (“[F]or 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.*’” (quoting *Federal Election Comm’n v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994) (emphasis in original)); *Federal Election Comm’n v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994) (“[I]t 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.*” (quoting *Cook v. Tullis*, 85 U.S. (18 Wall.) 332, 338 (1874) (emphasis in original)). Neither the defendants nor this Court can re-write the statute by transferring the prerogatives of the U.S. Preventive Services Task Force, ACIP, and HRSA to the Secretary of Health and Human Services, or making their decisions defeasible by a principal officer or cabinet secretary. *See Henry Schein, Inc. v. Archer & White Sales, Inc.*, 139 S. Ct. 524, 528 (2019) (“[W]e are not at liberty to rewrite the statute passed by Congress and signed by the President.”).

The defendants nonetheless insist that the Secretary has authority to “ratify” the coverage mandates imposed by ACIP and HRSA—despite the clear and unambiguous statutory text that makes their decisions final and conclusive. *See* Defs.’ Br., ECF No. 64, at 28–32. Yet the defendants never go so far as to claim that the Secretary can *revoke* a preventive-care coverage mandate imposed by ACIP and HRSA; their argument (as best we can tell) is that the Secretary can ratify but not countermand those decisions. *See id.* at 29 (“The Secretary has the power to ratify any actions taken by his subordinates.”); *id.* at 30 (“The Secretary thus has the power to ratify the decisions of his subordinates in these areas.”). The defendants’ ratification argument also appears to be limited to the coverage mandates imposed by ACIP and HRSA, as opposed to mandates recommended by the U.S. Preventive Services Task Force. *See id.* at 28–32; *id.* at 28 (“Plaintiffs’ argument ignores the identity and structure of ACIP and HRSA and their respective positions within the hierarchy of HHS.”). So there appears to be common ground on at least this much: The Secretary has no statutory authority to “ratify” the coverage mandates imposed by the U.S. Preventive Services Task Force, which is not a component of HHS and is not subject to the Secretary’s supervision. *But see* App. to Defs.’ MSJ, ECF No. 65, at 2 (“I ratify the below listed guidelines and recommendations for the reasons relied on by the USPSTF”).

Yet the defendants cannot identify *any* statute that empowers the Secretary to review, ratify, countermand, or revoke a coverage mandate imposed by ACIP or HRSA. Instead, they claim that the Secretary wields an inherent authority to “ratify” (but not revoke?) the decisions of any person or entity within the Department of Health and Human Services, even when a statute purports to vest final decisionmaking authority in a subordinate institution. But they cite no authority to support this idea, and it has long been settled that Congress may vest final decisionmaking authority in subordinate executive officers without subjecting those decisions to review or override by a cabinet secretary or the President. *See Myers v. United States*, 272 U.S. 52, 135 (1926) (“[T]here may be duties so peculiarly and specifically committed to the discretion of a particular officer as to raise a question whether the President may overrule or revise the officer’s interpretation of his statutory duty in a particular instance.”); *Humphrey’s Executor v. United States*, 295 U.S. 602, 628 (1935) (holding that Congress may empower agencies to act “without executive leave” and “free from executive control”). That remains the case even when the President enjoys the constitutional prerogative to remove an officer who deploys his discretionary powers in a manner not to the President’s liking. *See Myers*, 272 U.S. at 135 (“[E]ven in such a case he may consider the decision after its rendition as a reason for removing the officer, on the ground that the discretion regularly entrusted to that officer by statute has not been on the whole intelligently or wisely exercised.”). The statute means what it says: the Secretary must implement the preventive-care coverage mandates recommended by ACIP and HRSA, and he has no statutory authority to override or ratify their decisions.

The defendants note that *Little Sisters* allowed the Secretary to impose religious and moral exemptions to the Contraceptive Mandate when implementing HRSA’s decision to include contraception within the scope of “preventive care” under section 300gg-13(a)(4). *See* Defs.’ Br., ECF No. 64, at 30–31; *Little Sisters*, 140 S. Ct. at

2379–82. But the Secretary in *Little Sisters* claimed nothing more than a prerogative to “guide HRSA in exercising the discretion afforded to it” in section 300gg-13(a)(4), by “defining the scope of permissible exemptions and accommodations for such guidelines.”⁹ The Secretary did not claim that it could override or in any way second-guess HRSA’s decision to include contraception (or anything else) within the scope of preventive-care coverage required by section 300gg-13(a)(4), and *Little Sisters* did not recognize or uphold any such power. Nor do the defendants claim (as far as we can tell) that the Secretary can unilaterally cancel the Contraceptive Mandate or revoke HRSA’s decision to include contraception within the preventive-care coverage required by section 300gg-13(a)(4). The Secretary’s power to “guide HRSA” by defining “exemptions and accommodations” to its coverage mandates is a far cry from a power to review, ratify, countermand, or revoke a recommendation from ACIP or HRSA regarding the preventive care that must be covered by private insurers under 300gg-13(a)(2)–(4)—and *that* is the type of power that the defendants must establish to defeat the plaintiffs’ Appointments Clause objections.

Finally, the defendants suggest that this Court *must* interpret section 300gg-13(a)(2)–(4) to confer a ratification prerogative on the Secretary because a contrary interpretation would present serious constitutional questions under the Appointments Clause. *See* Defs.’ Br., ECF No. 64, at 32; *see also Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) (“When ‘a serious doubt’ is raised about the constitutionality of an act of Congress, ‘it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided.’”)

9. *Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act*, 82 Fed. Reg. 47,792, 47,794 (October 13, 2017) (“To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines.”).

(quoting *Crowell v. Benson*, 285 U.S. 22, 62 (1932)). But the defendants’ constitutional-avoidance argument fails for two reasons. First, the defendants have failed to identify *any* statutory language that could be construed to give the Secretary a ratification power over the decisions made by ACIP and HRSA. The unambiguous text of section 300gg-13(a)(2)–(4) empowers ACIP and HRSA to decide the preventive care that private insurers must cover—and it requires the Secretary to honor and implement their decisions. The constitutional-avoidance canon is inapplicable absent an identified statutory ambiguity, and courts cannot invoke the canon to rewrite or ignore the enacted statutory text. *See Jennings*, 138 S. Ct. at 842 (“The canon of constitutional avoidance comes into play only when, after the application of ordinary textual analysis, the statute is found to be susceptible of more than one construction. In the absence of more than one plausible construction, the canon simply has no application.” (citations and internal quotation marks omitted)).

Second, the defendants’ proposed interpretation of the statute would not eliminate the Appointments Clause problems. Even if the Secretary had the authority to veto or “ratify” HRSA’s guidelines or ACIP’s recommendations, section 300gg-13(a)(2)–(4) would *still* violate the Appointments Clause because it empowers HRSA or ACIP to dictate the preventive care that private insurers must cover *until* the Secretary formally approves their decisions. That constitutes “significant authority pursuant to the laws of the United States,” even if it remains subject to reversal by an “officer of the United States,” because the power to impose preventive-care mandates on private insurers—even for a limited period of time—amounts to “significant authority” in and of itself. *See Lucia v. SEC*, 138 S. Ct. 2044, 2049 (2018) (holding that the SEC’s administrative law judges qualify as “officers of the United States,” even though their decisions are subject to review by the Commission itself). And the defendants’ proposed interpretation does nothing to eliminate the Appointments Clause problems with section 300gg-13(a)(1), which empowers the U.S. Preventive

Services Task Force—an entity that everyone agrees is outside the Secretary’s control and supervision—to impose preventive-care mandates on private insurers. The constitutional-avoidance canon is inapplicable when a litigant’s proposed interpretation of a statute continues to present constitutional questions for the courts to resolve. *See Jennings*, 138 S. Ct. at 836 (“Under the constitutional-avoidance canon, . . . a court may shun an interpretation that raises serious constitutional doubts and instead may adopt an alternative *that avoids those problems.*” (emphasis added)).

2. Section 300gg-13(a)(2)–(4) And The Coverage Mandates Will Remain Unconstitutional Even If Secretary Becerra Can “Ratify” The Preventive-Care Recommendations Of ACIP and HRSA

There is a second problem with the defendants’ ratification argument, which they do not address in their brief. Even if one were to accept the idea that Secretary Becerra can “ratify” (or disapprove?) the preventive-care coverage recommended by ACIP and HRSA, the statute remains unconstitutional because it continues to empower non-officers (or inferior officers) to impose preventive-care mandates on their own initiative, and it makes the imposition of *any* preventive-care mandate contingent on the approval of ACIP, HRSA, or the U.S. Preventive Services Task Force. So all of these entities continue to wield “significant authority pursuant to the laws of the United States,” and each of their decisionmakers must be appointed in a manner consistent with the Appointments Clause.

Under the defendants’ construction of the statute, ACIP and HRSA coverage recommendations are subject to “ratification” by the Secretary of Health and Human Services. See Defs.’ Br., ECF No. 64, at 27–32. But not even the defendants have gone so far as to suggest that the Secretary (or any other principal officer) can impose a preventive-care coverage mandate *against* the wishes or recommendations of ACIP and HRSA. On the defendants’ view, ACIP and HRSA serve a gatekeeping role in deciding the preventive care that private insurers must cover. Their recommendations

are a necessary (though perhaps not sufficient) condition to imposing a coverage mandate under section 300gg-13(a)(2)–(4). But that *still* qualifies as “significant authority pursuant to the laws of the United States,” because no preventive-care coverage mandate can be imposed under section 300gg-13(a)(2)–(4) unless ACIP or HRSA signs off on it. And that remains the case even if the Secretary has the power to ratify or veto ACIP’s or HRSA’s recommendations. In *Lucia*, for example, the Court held that the SEC’s administrative law judges were “officers of the United States” — *even though* their decisions were subject to review by the Commission itself—and it rejected the notion that this subsequent review or ratification of the ALJ’s decisions could eliminate their status as “officers” or remove the taint of the Appointments Clause violation. *See Lucia*, 138 S. Ct. at 2049; *id.* at 2055 (“[T]he ‘appropriate’ remedy for an adjudication tainted with an appointments violation is a new ‘hearing before a properly appointed’ official.” (quoting *Ryder v. United States*, 515 U.S. 177, 182–83 (1995))).

The defendants barely address *Lucia*, although they do acknowledge the decision in a footnote and attempt to distinguish it by observing that *Lucia* involved a tainted adjudication rather than a rulemaking. *See* Defs.’ Br., ECF No. 64, at 34 n.22. But it is not at all apparent why that should make any difference in determining whether this Court should enjoin the continued enforcement of these “ratified” preventive-care mandates. If the SEC’s ratification of an improperly appointed ALJ’s decision could not “cure” the Appointments Clause violation or remove the taint of the ALJ’s involvement, then why should Secretary Becerra’s purported ratification of the previously announced preventive-care mandates produce such an effect? Especially when the approval of ACIP and HRSA is an essential statutory prerequisite to the enactment of these coverage requirements. The defendants have no answer to any of this, and they do not come to grips with the fact that the Secretary cannot ratify any coverage mandate that ACIP or HRSA has not first approved.

B. The Court Cannot Remedy The Appointments Clause Violations By Conferring A Ratification Prerogative Upon The Secretary

Similar problems plague the defendants' requested remedy for any Appointments Clause problems that might exist with section 300gg-13(a)(1)–(4). Relying on *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021), the defendants insist that the proper remedy for any Appointments Clause violation is for this Court to invent a prerogative for the Secretary to “ratify” the preventive-care coverage recommendations of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration, and then hold that the Secretary’s ratification document of January 21, 2022, obviates the plaintiffs’ Appointments Clause objections to the extant coverage mandates. This proposed remedy is unlawful for many reasons.

The first problem is what we have already discussed: A regime in which the Secretary “ratifies” the recommendations of ACIP, HRSA, and the U.S. Preventive Services Task Force *still violates* the Appointments Clause. Each of these subordinate entities will remain empowered to impose preventive-care mandates on their own initiative, which will take effect and remain in effect *until* the Secretary gets around to issuing his ratification decision. In addition, neither the Secretary—nor any other principal officer of the United States—has any authority to adopt or impose a preventive-care coverage mandate unless ACIP, HRSA, or the U.S. Preventive Services Task Force first recommends it. The defendants envision a regime in which *both* the Secretary and the subordinate entities have gatekeeping functions in deciding which preventive care the private insurers must cover. But that means that ACIP, HRSA, and the U.S. Preventive Services Task Force still wield “significant authority pursuant to the laws of the United States,”¹⁰ because no preventive-care mandate can take effect

10. *Buckley v. Valeo*, 424 U.S. 1, 126 (1976) (per curiam).

without their recommendation and approval. And it does nothing to make the “principal officers” at ACIP, HRSA, or the Preventive Services Task Force into “inferior officers,” because no principal officer will have any ability to review or countermand their decisions *not* to adopt a preventive-care mandate. *See Arthrex*, 141 S. Ct. at 1981. Finally, even if the defendants’ proposed remedy could somehow convert every “principal officer” at ACIP, HRSA, and the Preventive Services Task Force into an “inferior officer,” the regime would *still* violate the Appointments Clause because there is no statute that “vests” the appointment of these individuals in the President alone, the Courts of Law, or the Heads of Department.

The situation in *Arthrex* was different because the court-imposed remedy made *every* decision by the Administrative Patent Judges reviewable by the Director of the Patent and Trademark Office—regardless of which direction the decision took. A decision denying the validity of a patent was subject to plenary review by the Senate-confirmed Director in the same manner as a decision upholding the patent’s validity. *See Arthrex*, 141 S. Ct. at 1986 (“Decisions by APJs must be subject to review by the Director.”). The Court’s remedy therefore ensured that the decisions of Administrative Patent Judges would *always* be subject to review by a principal officer, and the APJs would have no ability to render an unreviewable decision on anything pertaining to a patent’s validity. The defendants’ proposed remedy, by contrast, allows for principal-officer review only of decisions to recommend preventive-care coverage, and it leaves ACIP, HRSA, or the Preventive Services Task Force with unreviewable discretion when they decline to enact or recommend new coverage mandates. In addition, there was no dispute in *Arthrex* that the Administrative Patent Judges were appointed as “inferior officers” in a manner consistent with Article II. *See Arthrex, Inc.*, 141 S. Ct. at 1983 (acknowledging the Administrative Patent Judges’ “status as inferior officers”). In this case, by contrast, the relevant individuals in ACIP, HRSA, and the U.S. Preventive Services Task Force have not been appointed as “inferior officers,”

because there is no statute vesting their appointment in the President alone, the Courts of Law, or the Heads of Department.

The second problem with the defendants' requested remedy is that a federal court simply does not have the power to invent and confer a ratification prerogative on the Secretary. Courts issue judgments between litigants when resolving cases, and those judgments may include a declaration of the parties' rights¹¹ or an injunction that restrains a litigant from taking particular actions. The defendants make no effort to explain how their requested remedy can take the form of an injunction or declaration of the plaintiffs' or defendants' rights.

A final problem is that the plaintiffs have not asked for this remedy, and it is not clear how the plaintiffs could have Article III standing to pursue or obtain such a remedy. The plaintiffs claim to be injured by the Secretary's *enforcement* of the preventive-care mandates, not by his failure to ratify them. *See* First Amended Complaint, ECF No. 14. A remedy from this Court that does not redress any of the plaintiffs' injuries is incompatible with Article III. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 107 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court."); *Collins v. Mnuchin*, 938 F.3d 553, 611 (5th Cir. 2019) (Oldham, J., concurring in part and dissenting in part) ("[O]ur Court does not have the power under Article III to order a remedy that does not redress Plaintiffs' injuries.").

11. *See* 28 U.S.C. § 2201 (empowering federal courts to "declare the rights and other legal relations of any interested party seeking such declaration").

C. The HRSA Administrator, The Members Of ACIP, And The Members Of The U.S. Preventive Services Task Force Have Been Unconstitutionally Appointed

The defendants also contend that there is no need to rely on Secretary Becerra's ratification document because all of the relevant actors have been appointed in a manner consistent with Article II. None of their arguments have merit.

1. The Members Of ACIP Have Been Unconstitutionally Appointed

The defendants claim that we should consider not the appointments of the ACIP members, but the appointment of the CDC Director. *See* Defs.' Br., ECF No. 64, at 37 (“[I]t is the CDC Director's appointment that is relevant with respect to ACIP.”). According to the defendants, ACIP serves as a “federal advisory committee” established under 42 U.S.C. § 217a, which exists solely for the purpose of advising the Secretary of Health and Human Services and the Director of the CDC. *See* Defs.' Br., ECF No. 64, at 4–5. The defendants note that ACIP's advisory recommendations may take effect only if they are adopted by the CDC Director. *See id.* at 5; *see also* App. to Defs.' MSJ, ECF No. 65, at 148–52 (charter of ACIP). And they insist that ACIP's immunization-coverage recommendations under section 300gg-13(a)(2) likewise cannot take effect absent approval from the Director of the CDC.

The defendants' stance is incompatible with the text of section 300gg-13(a)(2). Although the defendants are correct to observe that ACIP *was* a purely advisory committee prior to March 23, 2010, that changed when the President signed the Affordable Care Act into law. Section 300gg-13(a)(2) gives ACIP's “recommendations” binding force, and ACIP is no longer acting in an “advisory” capacity when it “recommends” immunizations. The Affordable Care Act gives ACIP the power to dictate the immunizations that private insurers *must* cover, transforming what was once a purely advisory body into an entity that wields “significant authority pursuant to the laws of the United States.”

The defendants claim that the ACIP Charter allows the CDC director to “review” ACIP’s recommendations before they take effect,¹² but the ACIP Charter cannot override the text of section 300gg-13(a)(2). It is also far from clear that the language in the ACIP Charter even allows the CDC director to countermand section 300gg-13(a)(2) by freeing private insurers from the requirement to cover vaccines that ACIP recommends. The ACIP Charter merely says that “Recommendations made by the ACIP are reviewed by the CDC Director”;¹³ it does not say that the CDC Director may veto vaccine recommendations that he disagrees with, or that non-approved vaccine recommendations are no longer binding on private insurers under section 300gg-13(a)(2).

The members of ACIP are “principal officers” because section 300gg-13(a)(2) empowers them to unilaterally determine the immunizations that private insurers must cover, and the statute requires that their “recommendations” take effect without subjecting their work to the direction and supervision of a principal officer. *See Edmond v. United States*, 520 U.S. 651, 662–63 (1997) (“[I]nferior officers’ 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.”); *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1980 (2021) (same). It is undisputed that the mem-

12. *See* Defs.’ Br., ECF No. 64, at 37–38.

13. App. to Defs.’ MSJ, ECF No. 65, at 148; *see also id.* (“The ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the Morbidity and Mortality Weekly Report (MMWR). The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations. Upon the licensure of any vaccine or any new indication for a vaccine, the committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.”).

bers of ACIP have not been appointed in conformity with the Constitution’s requirements for principal officers. Yet the defendants’ only response to our principal-officer argument is to claim that the Secretary of Health and Human Services can direct and supervise ACIP’s vaccine recommendations by “ratifying” them—even though the statute gives the Secretary no such power and any attempt to override ACIP’s vaccine recommendations or free private insurers from their statutory obligation to cover the recommended vaccines would be a flagrant violation of unambiguous statutory text.

And even if the members of ACIP could somehow be passed off as “inferior officers,” their appointments remain unconstitutional because there is no Act of Congress that “vests” those appointments in the President, the Courts of Law, or the Heads of Department. *See* U.S. Const. art. II, § 2, cl. 2 (“Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.”). The defendants note that members of ACIP are “selected by the Secretary,”¹⁴ but they fail to identify any federal statute that vests their appointment in Secretary. The defendants can point only to the ACIP charter, which says that ACIP members “shall be selected by the Secretary and shall be invited to serve for overlapping terms of up to four years.” App. to Defs.’ MSJ, ECF No. 65, at 151. But the ACIP charter is not a “law” enacted by “Congress.” And the defendants cannot rely on 42 U.S.C. § 217a because that statute authorizes the Secretary to make appointments only to “such *advisory* councils or committees . . . *for the purpose of advising him* in connection with any of his functions.” 42 U.S.C. § 217a (emphasis added). ACIP is no longer a purely advisory committee after the enactment of the Affordable Care Act, because it is now empowered to *decide* the preventive care that private insurance *must* cover.

14. *See* Defs.’ Br., ECF No. 64, at 5.

2. The Administrator Of HRSA Has Been Unconstitutionally Appointed

The administrator of HRSA is a “principal officer” for the same reason. Sections 300gg-13(a)(3) and (a)(4) empower HRSA to unilaterally determine the preventive care that private insurers must cover, and HRSA’s preventive-care recommendations are not subject to the direction or supervision of the Secretary or any other principal officer. *See Little Sisters*, 140 S. Ct. at 2381 (“By its terms, the ACA leaves the Guidelines’ content *to the exclusive discretion of HRSA.*” (emphasis added)). The defendants think the administrator of HRSA should be deemed an “inferior officer” because the administrator lacks tenure protections and “serves at the pleasure of the Secretary.” *See* Defs.’ Br., ECF No. 64, at 38. But removability is *not* the test for determining one’s status as a “principal” or “inferior” officer. Cabinet secretaries lack tenure protections and serve at the pleasure of the President, but their removability at will does not make them into “inferior” officers. And the civil-service protections that low-level bureaucrats enjoy does not convert those individuals into “principal” officers. *See Myers*, 272 U.S. at 173–74. One’s status as an “inferior” officer depends on whether the individual’s *work* is “directed and supervised” by principal officers—not on whether the officer is subject to at-will removal. *See Edmond v. United States*, 520 U.S. 651, 662–63 (1997) (“[I]nferior officers’ 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.”); *Arthrex*, 141 S. Ct. at 1980 (same). The HRSA administrator’s preventive-care recommendations are not subject to any such direction or supervision, as the statute makes HRSA’s determinations conclusive regarding the preventive care that private insurers must cover. The administrator of HRSA is therefore a principal officer, and he has not been appointed in conformity with the Appointments Clause.

Even if one were to indulge the defendants' assumption that the HRSA administrator is an "inferior" officer, his appointment remains unconstitutional because there is no law enacted by Congress that "vests" his appointment in the President alone, the Courts of Law, or the Heads of Department. The defendants claim that the Reorganization Plan No. 3 of 1966 "vests" the administrator's appointment in the Secretary, but the statute says only that:

The Secretary may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this reorganization plan by any officer, employee, or agency of the Public Health Service or of the Department of Health, Education, and Welfare.

5 U.S.C. § App. 1 Reorg. Plan 3 1966 (emphasis added). This statutory provision merely empowers the Secretary to authorize others to perform functions "transferred to him." It says nothing about how those officers, employees, or agencies that perform those functions should be appointed. And it nowhere purports to modify the default rule of Presidential appointment with the Senate's advice and consent—nor does authorize the Secretary to modify that constitutional default rule on behalf of Congress. And even if the statute *did* delegate this congressional authority to the Secretary, the defendants do not point to any "provision" made by the Secretary that purports to vest the appointment of the HRSA administrator in the Secretary alone.

Finally, the defendants are flatly wrong to claim that the HRSA Administrator is exercising "authority vested in the Secretary and delegated to [HRSA] by the Secretary." Defs.' Br., ECF No. 64, at 39. The HRSA Administrator is exercising authority that was delegated directly to HRSA by Congress in sections 300gg-13(a)(3) and (a)(4). The statutory language specifically vests HRSA—and not the Secretary—with the power to determine the preventive care and screenings that private insurers must cover. And that delegation of authority came directly from Congress; the Secretary had no role in vesting or delegating any of these powers.

3. The Members Of U.S. Preventive Services Task Force Have Been Unconstitutionally Appointed

The defendants deny that the members of the U.S. Preventive Services Task Force qualify as “officers of the United States,”¹⁵ but none of their arguments hold water. An individual qualifies as a “officer of the United States” if they: (1) “occupy a continuing position established by law”; and (2) “exercise significant authority pursuant to the laws of the United States.” *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). The defendants do not acknowledge or apply this two-part test from *Lucia*, but the members of the Task Force comfortably satisfy each prong.

a. The Members Of The Task Force “Occupy A Continuing Position Established By Law”

The defendants never get around to denying that the Task Force members “occupy a continuing position established by law,”¹⁶ as they never even acknowledge this prong of the *Lucia* test. Instead, they beat around the bush by observing that the Task Force is not a federal “agency” or part of an “executive body”¹⁷—all of which may have some bearing on whether the Task Force members “occupy a continuing position established by law” but are far from dispositive of the question. The Court in *Lucia* chose its words carefully: An officer of the United States must “occupy a continuing position established by law.” *Lucia*, 138 S. Ct. at 2051. So this Court must resolve whether the “position” occupied by the Task Force members is: (1) “continuing” and (2) “established by law.”

The U.S. Preventive Services Task Force was created in 1984—and Congress has since codified a statute that recognizes and perpetuates its continued existence by requiring the director of the Agency for Healthcare Research and Quality (AHRQ)

15. See Defs.’ Br., ECF No. 64, at 39–45.

16. *Lucia*, 138 S. Ct. at 2051.

17. Defs.’ Br., ECF No. 64, at 40.

to “convene” the Task Force and ensure that it is “composed of individuals with appropriate expertise”:

The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the “Task Force”) to be composed of individuals with appropriate expertise.

42 U.S.C. § 299b-4(a)(1) (attached as Exhibit 1). The statute goes on to describe the duties of the Task Force,¹⁸ the agency’s role in supporting the work of the Task Force,¹⁹ a statutory assurance of independence from political pressure,²⁰ and an automatic authorization of annual appropriated funds.²¹

How can this *not* qualify as a “continuing” position? An Act of Congress ensures the continued existence of the Task Force by requiring the director to “convene” it and establishing annual appropriations into the indefinite future. This is not a one-time gig or a short-term, non-renewable contract, but an office that will remain in perpetual existence unless and until Congress amends the statute. *See, e.g., United States v. Germaine*, 99 U.S. 508, 511–12 (1878) (holding that doctors called upon to conduct various physical exams were not “officers” because their duties were “occasional or temporary” rather than “continuing and permanent.”). The “position” occupied by the Task Force members is indisputably “continuing,” even if the membership of the Task Force cycles and the tenure of individual members ends. *See Officers*

18. 42 U.S.C. § 299b-4(a)(2).

19. *See* 42 U.S.C. § 299b-4(a)(3) (“The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide’s recommendations.”).

20. *See* 42 U.S.C. § 299b-4(a)(6) (“All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.”).

21. *See* 42 U.S.C. § 299b-4(a)(7) (“There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.”).

of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 111 (Apr. 16, 2007) (“‘[C]ontinuance’ is not ‘permanence’”).

The closest that the defendants come to addressing the “continuing position” issue is their citation of *Riley v. St. Luke’s Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001), which claims that an “officer” must have “a continuing and formalized relationship of *employment* with the United States Government.” *Id.* at 757 (emphasis added). The defendants interpret *Riley* to mean that an officer must be *paid* for his work, and that unpaid government officials cannot be regarded as officers no matter how much power they wield. *See* Defs.’ Br., ECF No. 64, at 42; *id.* (“Any role staffed by part-time volunteers is, by definition, not a ‘continuing and formalized relationship of employment with the United States Government’”). This interpretation of *Riley* is untenable, as we explained in our opening brief, and it directly contradicts the views of the Office of Legal Counsel, which emphatically rejects the notion that paid employment is necessary for “officer” status.” *See* Pls.’ Br. in Supp. of MSJ, ECF No. 45, at 16–18; *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 120 (Apr. 16, 2007). *Riley*’s reference to “employment” need not be construed to require *paid* employment, and the government is certainly “employing” the members of the Task Force by assigning them the statutory duties described in 42 U.S.C. § 299b-4(a)(2) and appropriating money for those purposes—even if the members of the Task Force are not drawing a salary or stipend for that work.²² More importantly, *Lucia* looks to whether the Task Force members oc-

22. *See, e.g.*, “employ.” *Merriam-Webster.com*. 2020. <https://www.merriam-webster.com/dictionary/employ> (March 28, 2022) (defining “employ” as “1a: to make use of (someone or something inactive) *employ* a pen for sketching; b: to use (something, such as time) advantageously a job that *employed* her skills; c(1): to use or engage the services of; (2): to provide with a job that pays wages or a salary; 2: to devote to or direct toward a particular activity or person *employed* all her energies to help the poor.”); *see also* *Officers of the United States*

occupy a “continuing *position*” established by law—*not* to whether they occupy a “continuing position of paid employment.” The “positions” that the Task Force members occupy are indisputably “continuing” positions, and the defendants never argue to the contrary.

b. The Members Of The Task Force “Exercise Significant Authority Pursuant To The Laws Of The United States”

The only remaining question is whether the Task Force members “exercise significant authority pursuant to the laws of the United States.” *Lucia*, 138 S. Ct. at 2051. Here, too, the government avoids acknowledging this requirement of the two-prong *Lucia* test, and offers some desultory observations without tying its points back to the touchstone of “significant authority.” *See* Defs.’ Br., ECF No. 64, at 39–45. That the Task Force members serve as volunteers, for example, has nothing to do with the significance of the authority that they wield. *See id.* at 39.

The defendants also deny that section 300gg-13(a)(1) gives the Task Force “policymaking discretion,” or that it “authorizes” the Task Force “to make decisions about insurance coverage.” *Id.* at 40. But that is obviously untrue; section 300gg-13(a)(1), by its very terms, empowers the Task Force to decide the preventive care that private insurers must cover, because it compels private insurers to cover every item or service with an “A” or “B” rating in the Task Force’s recommendations. *See* 42 U.S.C. § 300gg-13(a)(1). The Task Force—and the Task Force alone—holds the power to decide whether every non-grandfathered private insurer must cover PrEP drugs without any cost-sharing arrangements. It is hard to fathom how that fails to qualify as “significant authority pursuant to the laws of the United States.” The defendants claim

Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 121 (Apr. 16, 2007).

that these powers conferred upon the Task Force reflect *Congress's* judgment to “incorporate [the] evolving standards of this body,”²³ but the fact remains that Congress *gave* these far-reaching powers to the Task Force—and Congress’s motivations for doing so have nothing to do with whether Task Force holds “significant authority pursuant to the laws of the United States.”

The defendants once again try to analogize section 300gg-13(a)(1) to federal statutes that incorporate evolving recommendations of the American National Standards Institute (ANSI), as well as federal criminal offenses that are defined by reference to state or foreign law. *See* Defs.’ Br., ECF No. 64, at 41. The complete answer is that the members of ANSI and the state or foreign governments do *not* occupy “a continuing position established by [federal] law,”²⁴ so they flunk the first requirement of the *Lucia* test. *See* Pls.’ Br. in Supp. of MSJ, ECF No. 45, at 20–21. All of this was explained in our opening brief. *See id.* In addition, the authority that these statutes confer upon ANSI and state and foreign governments are far less “significant” than the powers that the Task Force wields under section 300gg-13(a)(1).

Finally, the defendants suggest that the Task Force members would not qualify as “officers of the United States” under OLC’s current interpretation of the Appointments Clause. *See* Defs.’ Br., ECF No. 64, at 43. The defendants note that the 2007 OLC opinion had this to say when describing a House Judiciary Committee report from 1899:

The Committee reasoned that a public office requires a delegation of sovereign authority, which “involves necessarily the power to (1) legislate, or (2) execute law, or (3) hear and determine judicially questions submitted.”

Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 85 (Apr. 16, 2007). The defendants claim that the Task Force

23. *See* Defs.’ Br., ECF No. 64, at 40.

24. *Lucia*, 138 S. Ct. at 2051.

lacks any of those three enumerated powers, and that its members therefore do not hold a “public office” under the views of OLC. *See* Defs.’ Br., ECF No. 64, at 43.

The problem with this argument is that OLC opinion goes on to say that the existence of an “office” is *not* necessary for the Appointments Clause to apply. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 78 (Apr. 16, 2007) (“[T]he applicability of the [Appointments] Clause does not depend on whether Congress has formally and directly created an ‘office.’ ”). And in all events, the members of the Task Force *are* wielding executive (or “quasi-legislative”) powers, because Congress has delegated to the Task Force the prerogative to determine the preventive care that private insurers must cover. *See Gundy v. United States*, 139 S. Ct. 2116, 2123–24, 2129–30 (2019) (plurality opinion of Kagan, J.). The defendants try to pass off the Task Force members as technocrats rather than policymakers, but section 300gg-13(a)(1) gives the Task Force sweeping powers to determine the scope of preventive-care coverage in private health insurance—including the prerogative to resolve explosive culture-war questions such as the compulsory coverage of PrEP drugs and the scope of any religious exemptions that might be conferred. *Cf. Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) (holding that 42 U.S.C. § 300gg-13(a)(4) gives HRSA not only the authority to determine the “preventive care and screenings” that must be covered but also “the ability to identify and create exemptions from its own Guidelines.”). Decisions of this sort will *always* involve “cost/value judgments,”²⁵ despite the defendants’ protestations to the contrary.

25. Defs.’ Br., ECF No. 64, at 45.

III. 42 U.S.C. § 300gg-13(a)(1) VIOLATES ARTICLE II'S VESTING CLAUSE

The defendants try to defeat the plaintiffs' vesting-clause claim by reiterating their stance that the Task Force members wield neither "legislative" nor "executive" powers—and are nothing more than cogs in a mechanical, "evidence-based" decision-making process. *See* Defs.' Br., ECF No. 64, at 45. But this contention is just as implausible when used to rebut the plaintiffs' vesting-clause claim. The Task Force members are resolving value-laden policy questions that implicate homosexual rights and religious freedom, and the extent to which health insurance should bear the costs of other people's irresponsible behavior. The Constitution does not allow these types of decisions to be made by a headless fourth branch of government—and it cannot tolerate an statutory provision that insulates the Task Force members from presidential removal or control. *See United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1979 (2021); *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183, 2191–92 (2020); *Myers v. United States*, 272 U.S. 52, 135 (1926).

The defendants also claim that the proper "remedy" is to allow the Secretary to "ratify" the previously announced Task Force recommendations, which (in the defendants' view) will obviate any constitutional problems caused by Article II's vesting clause. *See* Defs.' Br., ECF No. 64, at 46. But this remedy does nothing to cure the President's lack of a removal power over the Task Force members, which is constitutionally required under *Seila Law* and *Myers*. It also fails to remove the taint of the unconstitutional process that produced the previous Task Force recommendations. Those recommendations had been offered at a time when Task Force members operated under an unconstitutional guarantee of political independence and without any fear of presidential removal. Given that a Task Force recommendation is necessary to implement a preventive-care mandate, the process should start afresh with Task Force

members who are unaffected by the statutory promise of political insulation described in 42 U.S.C. § 299b-4.

It continues to remain unclear to us how a federal court can incorporate the defendants' proposed remedy into a judgment that can award only declaratory or injunctive relief between the parties. And it remains unclear how this remedy—which the plaintiffs have never requested—could redress any of the injuries that the plaintiffs have alleged or established under Article III. *See supra*, at 20–22.

IV. 42 U.S.C. § 300gg-13(1)–(4) VIOLATES THE NONDELEGATION DOCTRINE

The defendants correctly observe that the Supreme Court and the Fifth Circuit have upheld very broad delegations of authority to administrative agencies. *See* Defs.' Br., ECF No. 64, at 48–54. But the non-delegation doctrine is not extinct, and the Supreme Court's ruling in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020), makes clear that the doctrine remains judicially enforceable.

The problem with the delegation of authority in section 300gg-13(a)(1)–(4) is that there is no “intelligible principle” in the language of the statute that purports to guide the discretion of the U.S. Preventive Services Task Force, ACIP, or HRSA in deciding which preventive care and services should be covered. The defendants note that section 300gg-13(a)(1) requires covered preventive care to have an “A” or “B” rating from the U.S. Preventive Services Task Force,²⁶ but the Task Force has unlimited discretion to change its criteria for those ratings. The defendants also note that statutory provisions enacted before the Affordable Care Act confer duties on the Task Force and provide an intelligible principle for carrying out those duties,²⁷ but the responsibilities describe in those pre-ACA statutes have nothing to do with the Task

26. *See* Defs.' Br., ECF No. 64, at 50.

27. *See* Defs.' Br., ECF No. 64, at 50.

Force’s responsibility to determine the scope of compulsory preventive-care coverage under the ACA. *See* 42 U.S.C. § 299b-4(a)(2) (enumerating the pre-ACA duties of the Preventive Services Task Force). And a requirement that the items and services be “evidence-based” does nothing, as everything is based on “evidence” of some sort, and the required intelligible principle must tell the Task Force is *how* it should assess the evidence when deciding whether to award an “A” or “B” rating. Nothing of the sort is provided in the statute.

Sections 300gg-13(a)(2)–(4) suffer from similar problems, and the defendants try to create an intelligible by noting that subsection (a)(2) allows ACIP to compel coverage only of “immunizations,”²⁸ that subsections (a)(3) and (a)(4) allow HRSA to compel coverage only of “preventive care and screenings,”²⁹ and then only of preventive care and screenings for “infants, children, and adolescents,”³⁰ or “for women.”³¹ But this argument continues to equate a *boundary* on the scope of an agency’s authority with the *intelligible principle* needed to guide the agency’s discretion within those statutory boundaries. The government’s reliance on HRSA’s efforts to cabin its own discretion is similarly misguided,³² as an agency cannot cure a congressional failure to provide an intelligible principle in the statutory language by creating or imposing those constraints on its own initiative. *See Whitman v. American Trucking Associations*, 531 U.S. 457, 473 (2001) (“The idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory. The very choice of which portion of the power to exercise—that is to say, the prescription of the standard that Congress

28. 42 U.S.C. § 300gg-13(a)(2).

29. 42 U.S.C. § 300gg-13(a)(3)–(4).

30. 42 U.S.C. § 300gg-13(a)(3).

31. 42 U.S.C. § 300gg-13(a)(4).

32. *See* Defs.’ Br., ECF No. 64, at 52.

had omitted—would *itself* be an exercise of the forbidden legislative authority. Whether the statute delegates legislative power is a question for the courts, and an agency’s voluntary self-denial has no bearing upon the answer.”).

The cases cited by the government all involved statutes in which *some* semblance of an “intelligible principle” appeared in the statutory language. Statutes that instruct agencies to determine and recover “excessive profits” from military contractors,³³ or to set “fair and equitable” commodities prices,³⁴ or to regulate in a manner consistent with “public interest, convenience, or necessity,”³⁵ describe at least some standard for the agency to follow or aspire to. Section 300gg-13(a)(1)–(4) has nothing of this sort to provide guidance to the agency, and it appears to authorize the Preventive Services Task Force, ACIP, and HRSA to mandate coverage for whatever preventive care they want. The defendants note that HRSA’s decisions will remain subject to arbitrary-and-capricious review under the APA,³⁶ but that does not salvage an unconstitutional delegation of authority. Merely telling an agency not to act in an arbitrary or capricious manner does not establish an “intelligible” principle.

V. THE COMPULSORY COVERAGE OF PREP DRUGS, THE HPV VACCINE, AND THE SCREENINGS AND BEHAVIORAL COUNSELING FOR STDS AND DRUG USE VIOLATES THE RELIGIOUS FREEDOM RESTORATION ACT

The defendants deny that the plaintiffs have established a “substantial burden” on their exercise of religion because they insist that the plaintiffs’ complicity objections are factually unsupported. *See* Defs.’ Br., ECF No. 64, at 54–55. But it *does not matter* whether the plaintiffs are correct in believing that the compulsory coverage of PrEP drugs and objectionable preventive care will actually encourage behavior that

33. *Lichter v. United States*, 334 U.S. 742, 785-86 (1948).

34. *Yakus v. United States*, 321 U.S. 414, 420 (1944) (quotation marks omitted).

35. *National Broadcasting Co. v. United States*, 319 U.S. 190, 225–26 (1943).

36. *See* Defs.’ Br., ECF No. 64, at 53.

violates their religious beliefs. As long as they sincerely *believe* that purchasing or providing insurance that includes this coverage will make them complicit in conduct that contradicts their religious beliefs, a court *cannot* inquire further and ask whether those beliefs are supported with factual evidence. The Supreme Court made this as clear as can be in both *Hobby Lobby* and *Little Sisters*:

[I]n *Hobby Lobby*, . . . we made it abundantly clear that, under RFRA, the Departments must accept the sincerely held complicity-based objections of religious entities. That is, they could not “tell the plaintiffs that their beliefs are flawed” because, in the Departments’ view, “the connection between what the objecting parties must do . . . and the end that they find to be morally wrong . . . is simply too attenuated.”

Little Sisters, 140 S. Ct. at 2383 (quoting *Hobby Lobby*, 573 U.S. at 723–24); *see also* *id.* at 2390 (Alito, J., concurring) (“If 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.”); *id.* (Alito, J., concurring) (“It is undisputed that the *Little Sisters* have a sincere religious objection to the use of contraceptives and that they also have a sincere religious belief that utilizing the accommodation would make them complicit in this conduct. As in *Hobby Lobby*, ‘it is not for us to say that their religious beliefs are mistaken or insubstantial.’”); Amy J. Sepinwall, *Conscience and Complicity: Assessing Pleas for Religious Exemptions in Hobby Lobby’s Wake*, 82 U. Chi. L. Rev. 1897, 1900 (2015) (“[T]he mere fact that *Hobby Lobby* *believed* that it would be complicit, no matter how idiosyncratic its belief, sufficed to qualify it for an exemption.” (emphasis in original)). Each of the religious-objector plaintiffs has submitted declarations attesting to their *belief* that that the objectionable coverage mandates will make them complicit in conduct that violates their religious beliefs, and the defendants are not questioning the sincerity of those beliefs or the truth of the sworn declarations. Nothing more is needed to establish a substantial burden under RFRA.

The defendants are surely right to observe that the government has a “compelling interest” in preventing the spread of infectious disease,³⁷ but that is not the correct way to frame the relevant governmental interest in a RFRA dispute. A court must “‘look beyond broadly formulated interests’ and . . . ‘scrutinize the asserted harm of granting specific exemptions to particular religious claimants’—in other words, to look to the marginal interest in enforcing the contraceptive mandate in these cases.” *Hobby Lobby*, 573 U.S. at 726–27 (quoting *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006)). And the defendants cannot show that their efforts to force all private insurers to provide coverage for PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use—with *no* religious exemptions for anyone—is a policy of such overriding importance that it can tolerate no exceptions for religious objectors, especially when the ACA’s preventive-care coverage regime exempts grandfathered plans and exempts employers with fewer than 50 employees from the requirement to offer health insurance to their employees. *See Fulton v. Philadelphia*, 141 S. Ct. 1868, 1882 (2021) (holding that the existence of exceptions “undermines the City’s contention that its non-discrimination policies can brook no departures” and faulting the city for “offer[ing] no compelling reason why it has a particular interest in denying an exception to CSS while making them available to others.”).

Finally, the defendants are wrong to suggest that we somehow forfeited our “less restrictive means” proposal by failing to offer it in discovery. *See* Defs.’ Br., ECF No. 64, at 59. Under RFRA, the burden of demonstrating a compelling governmental interest and the absence of a less restrictive means of furthering that compelling governmental interest rests entirely with the government. *See* 42 U.S.C. § 2000bb-1(b) (“Government may substantially burden a person’s exercise of religion *only if it*

37. *See* Defs.’ Br., ECF No. 64, at 57.

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.” (emphasis added)); *DeOtte v. Azar*, 332 F.R.D. 173, 188 (N.D. Tex. 2019) (“The text of the statute makes plain that only the federal government can ‘demonstrate’ that this burden is ‘(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.’ *Id.* § 2000bb-1(b).”). The plaintiffs have no obligation to produce evidence demonstrating that their proposed alternative will be less burdensome to their religious freedom. They need only to propose that alternative and force the government to demonstrate why it fails to qualify as a “less restrictive means” of advancing its supposedly compelling interest.³⁸

CONCLUSION

The defendants’ motion for summary judgment should be denied, and the plaintiffs’ motion for summary judgment should be granted.

Respectfully submitted.

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38. We agree with the defendants that any relief that the Court awards on the RFRA claims should be no more burdensome than necessary to provide complete relief to each of the named plaintiffs. *See, e.g., Califano v. Yamasaki*, 442 U. S. 682, 702 (1979) (“[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.”); Defs.’ Br., ECF No. 64, at 60 n.41.

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CERTIFICATE OF SERVICE

I certify that on March 28, 2022, I served this document through CM/ECF

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§ 299b-4. Research supporting primary care and access in..., 42 USCA § 299b-4

 KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Negative Treatment Reconsidered by Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services, 11th Cir.(Fla.), Aug. 12, 2011
 KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

| |
|---------------------------------------------------------------------------|
| United States Code Annotated |
| Title 42. The Public Health and Welfare |
| Chapter 6A. Public Health Service (Refs & Annos) |
| Subchapter VII. Agency for Healthcare Research and Quality (Refs & Annos) |
| Part B. Health Care Improvement Research (Refs & Annos) |

42 U.S.C.A. § 299b-4

§ 299b-4. Research supporting primary care and access in underserved areas

Effective: March 23, 2010

Currentness

(a) Preventive Services Task Force

(1) Establishment and purpose

The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the “Task Force”) to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the “Guide”), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community

§ 299b-4. Research supporting primary care and access in..., 42 USCA § 299b-4

organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.

(2) Duties

The duties of the Task Force shall include--

(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;

(B) at least once during every 5-year period, review¹ interventions and update² recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;

(C) improved integration with Federal Government health objectives and related target setting for health improvement;

(D) the enhanced dissemination of recommendations;

(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide³ recommendations; and

(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(3) Role of Agency

The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide's recommendations.

(4) Coordination with Community Preventive Services Task Force

The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(5) Operation

Operation.⁴ In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of Appendix 2 of Title 5.

(6) Independence

§ 299b-4. Research supporting primary care and access in..., 42 USCA § 299b-4

All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.

(7) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(b) Primary care research

(1) In general

There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the “Center”) that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

(2) Research

In carrying out this section, the Center shall conduct and support research concerning--

§ 299b-4. Research supporting primary care and access in..., 42 USCA § 299b-4

- (A) the nature and characteristics of primary care practice;
- (B) the management of commonly occurring clinical problems;
- (C) the management of undifferentiated clinical problems; and
- (D) the continuity and coordination of health services.

CREDIT(S)

(July 1, 1944, c. 373, Title IX, § 915, as added Pub.L. 106-129, § 2(a), Dec. 6, 1999, 113 Stat. 1659; amended Pub.L. 111-148, Title IV, § 4003(a), Mar. 23, 2010, 124 Stat. 541.)

Footnotes

1
So in original. Probably should be “review of”.

2
So in original. Probably should be “updating of”.

3
So in original. Probably should be “Guide’s”.

4
So in original.

42 U.S.C.A. § 299b-4, 42 USCA § 299b-4

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Current through P.L. 117-102.

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