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

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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The Affordable Care Act empowers the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration to unilaterally determine the "preventive care" that private health insurance must cover. *See* 42 U.S.C. § 300gg-13 (App. 2). Since the Affordable Care Act's enactment, these agencies have issued numerous pronouncements that force health-insurance issuers and self-insured plans to cover certain forms of preventive care without any cost-sharing arrangements such as deductibles and co-pays. In 2011, for example, the Health Resources and Services Administration issued a highly controversial pronouncement that compels private insurance to cover all forms of FDA-approved contraceptive methods, including contraceptive methods that operate as abortifacients (App. 21). In June of 2019, the U.S. Preventive Services Task Force issued an equally controversial decree that requires private insurance to cover pre-exposure prophylaxis (PrEP) drugs such as Truvada and Descovy starting in 2021. (App. 10). The plaintiffs are challenging the legality of these and other preventive-care mandates under the Constitution and the Religious Freedom Restoration Act. And the plaintiffs are entitled to summary judgment, as there are no genuine issues of material fact and the plaintiffs are entitled to judgment as a matter of law.

UNDISPUTED FACTS

The Affordable Care Act requires group health plans and health-insurance issuers to cover "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force," and to cover these items or services without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(1) (App. 2).

A separate provision of the Affordable Care Act requires group health plans and health-insurance issuers to cover "immunizations that have in effect a recommenda-

tion from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved," and to do so without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(2) (App. 2).

Another provision requires group health plans and health-insurance issuers to cover "with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration," and to cover this preventive care and screenings without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(3) (App. 2).

And yet another provision requires group health plans and health-insurance issuers to cover "with respect to women, such additional preventive care and screenings not described in [42 U.S.C. § 300gg-13(a)(1)] as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." These "preventive care and screenings" for women must be provided without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(4) (App. 2).

I. The Contraceptive Mandate

On August 1, 2011—more than one year after the Affordable Care Act was signed into law—the Health Resources and Services Administration issued guidelines requiring that all FDA-approved contraceptive methods be covered as "preventive care" under 42 U.S.C. § 300gg-13(a)(4). In response to the HRSA's decree of August 1, 2011, the Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor issued notice-and-comment regulations to implement HRSA's decision to require private insurers to cover contraception. These rules are known as the "Contraceptive Mandate," and they are codified at 45 C.F.R.

§ 147.130(a)(1)(iv), 29 C.F.R. § 2590.715–2713(a)(1)(iv), and 26 C.F.R. § 54.9815–2713(a)(1)(iv).

On May 4, 2017, President Trump issued an executive order instructing the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services to amend the Contraceptive Mandate to address conscience-based objections. *See* Executive Order 13798. In response to this order, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services issued a final rule on November 15, 2018, that exempts any non-profit or for-profit employer from the Contraceptive Mandate if it opposes the coverage of contraception for sincere religious reasons. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (November 15, 2018).

The final rule also sought to accommodate individuals who object to contraceptive coverage in their health insurance for sincere religious reasons. *See id.* at 57,590 (creating a new provision in 45 C.F.R. § 147.132(b)). Under the original Contraceptive Mandate, individual religious objectors were forced to choose between purchasing health insurance that covers contraception or forgoing health insurance entirely—unless they could obtain insurance through a grandfathered plan or a church employer that was exempt from Contraceptive Mandate. The final rule ensured that individual religious objectors would have the option to purchase health insurance that excludes contraception from any willing health insurance issuer.

The final rule was scheduled to take effect on January 14, 2019. On January 14, 2019, however, a federal district court in Pennsylvania issued a nationwide preliminary injunction against its enforcement. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Third Circuit affirmed this nationwide preliminary injunction on July 12, 2019. *See Pennsylvania v. President of the United States*, 940 F.3d 543 (3d

Cir. 2019). The Supreme Court granted certiorari and vacated the nationwide injunction in *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020), but the litigation over the Trump Administration's rule continues.

In response to the nationwide injunction issued in *Pennsylvania v. Trump*, a lawsuit was filed in the Northern District of Texas to enjoin federal officials from enforcing the Obama-era contraceptive mandate against the religious objectors protected by the Trump Administration's final rule of November 15, 2018. The district court held that the protections conferred in the Trump Administration's final rule were compelled by the Religious Freedom Restoration Act, and permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector protected by the final rule. *See DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019). As a result of *DeOtte*, the protections conferred by the Trump Administration's final rule are in full force and effect because they have been incorporated into the *DeOtte* injunction. Despite the *DeOtte* injunction, few if any insurance companies are currently offering health insurance that excludes coverage for contraception, and the continued existence of the Contraceptive Mandate restricts the options available to those who wish to purchase health insurance but who do not need or want contraceptive coverage.[1]

II. The Plaintiffs

Each of the plaintiffs wishes to obtain or provide health insurance that excludes or limits coverage that is currently required by the preventive-care mandates imposed by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration.

1. *See* notes 7, 13, 20, 24, 32 and accompanying text.

A. Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell

Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell are responsible for providing health coverage for themselves and their respective families.[2] Each of them wants the option of purchasing health insurance that excludes or limits coverage of preventive care that they do not want or need, as well as preventive care that violates their sincere religious beliefs.[3] Each of them also wants the option of purchasing health insurance that limits coverage of preventive care or that imposes copays or deductibles for preventive care, with corresponding adjustments in the monthly premiums, so that they can choose a policy that best suits their needs and the needs of their families.[4]

The defendants are currently requiring health insurers to provide coverage of numerous forms of preventive care that the plaintiffs Kelley, Starnes, and Mr. and Mrs. Maxwell do not want or need, because neither they nor their family members engage in the behaviors or lifestyle choices that makes such preventive care necessary.[5] Plaintiffs Kelley, Starnes, and Mr. and Mrs. Maxwell also object on religious grounds to the compulsory coverage of PrEP drugs, contraception, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use, because this coverage faciliates and encourages homosexual behavior, drug use, and sexual activity outside

2. *See* Kelley Decl. ¶ 4 (App. 33); Starnes Decl. ¶ 4 (App. 39); Zach Maxwell Decl. ¶ 4 (App. 50); Ashley Maxwell ¶ 4 (App. 56).
3. *See* Kelley Decl. ¶ 5 (App. 33); Starnes Decl. ¶ 5 (App. 39); Zach Maxwell Decl. ¶ 5 (App. 50); Ashley Maxwell ¶ 5 (App. 56).
4. *See* Kelley Decl. ¶ 6 (App. 33); Starnes Decl. ¶ 6 (App. 39); Zach Maxwell Decl. ¶ 6 (App. 50); Ashley Maxwell ¶ 6 (App. 56).
5. *See* Kelley Decl. ¶¶ 7–10 (App. 34–36); Starnes Decl. ¶¶ 7–10 (App. 40–42); Zach Maxwell Decl. ¶¶ 7–10 (App. 51–53); Ashley Maxwell ¶¶ 7–10 (App. 57–59).

of marriage between one man and one woman.[6] The defendants' enforcement of the preventive-care mandates is limiting the plaintiffs' ability to obtain health insurance that excludes this unwanted coverage.[7]

B. Plaintiff Joel Miller

Plaintiff Joel Miller is responsible for providing health coverage for himself and his family.[8] Mr. Miller wants the option for purchasing health insurance that excludes or limits coverage of preventive care that he does not want or need.[9] He also wants the option of purchasing health insurance that limits coverage of preventive care or that imposes copays or deductibles for preventive care, with corresponding adjustments in the monthly premiums, so that he can choose a policy that best suits his needs and the needs of his family.[10]

The defendants are currently requiring health insurers to provide coverage of numerous forms of preventive care that Mr. Miller does not want or need, because neither he nor his family members engage in the behaviors or lifestyle choices that makes such preventive care necessary.[11] Mr. Miller also wants to purchase health insurance that excludes coverage of contraception because his wife is past her childbearing years.[12] The defendants' enforcement of the preventive-care mandates is limiting Mr. Miller's ability to obtain health insurance that excludes this unwanted coverage.[13]

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6. Kelley Decl. ¶¶ 11–15 (App. 36–37); Starnes Decl. ¶¶ 11–15 (App. 42–43); Zach Maxwell Decl. ¶¶ 11–15 (App. 53–54); Ashley Maxwell ¶¶ 11–15 (App. 59–60).
7. *See* Kelley Decl. ¶ 20 (App. 37); Starnes Decl. ¶ 16 (App. 43); Zach Maxwell Decl. ¶ 16 (App. 54); Ashley Maxwell ¶ 16 (App. 60).
8. Miller Decl. ¶ 4 (App. 62).
9. Miller Decl. ¶ 5 (App. 62).
10. Miller Decl. ¶ 6 (App. 62).
11. Miller Decl. ¶¶ 7–10 (App. 63–65).
12. Miller Decl. ¶ 10 (App. 64–65).
13. Miller Decl. ¶ 11 (App. 65).

C. Plaintiff Gregory Scheideman

Plaintiff Gregory Scheideman is responsible for providing health coverage for himself and his family.[14] He is also part owner of a business that employs approximately 27 individuals, and he provides health insurance to each of his employees through his company.[15]

Dr. Scheideman wants the option of purchasing health insurance for himself and his family that excludes or limits coverage of preventive care that he does not want or need.[16] He also wants the option of purchasing health insurance for his employees that excludes or limits coverage of preventive care that his partners and he do not want to cover.[17] And Dr. Scheideman wants the option of purchasing health insurance that limits coverage of preventive care or that imposes copays or deductibles for preventive care, with corresponding adjustments in the monthly premiums, so that he can choose a policy that best suits his needs and the needs of his family, and so that his partners and he can choose policies for their employees that best suit the needs of their business.[18]

The defendants are currently requiring health insurers to provide coverage of numerous forms of preventive care that Dr. Scheideman does not want or need, and that neither Dr. Scheideman nor his partners wish to provide to their employees.[19] The defendants' enforcement of the preventive-care mandates is limiting Dr. Scheideman's ability to obtain health insurance that excludes this unwanted coverage.[20]

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14. Scheideman Decl. ¶ 4 (App. 45).
15. Scheideman Decl. ¶ 5 (App. 45).
16. Scheideman Decl. ¶ 6 (App. 45).
17. Scheideman Decl. ¶ 7 (App. 45).
18. Scheideman Decl. ¶ 8 (App. 46).
19. Scheideman Decl. ¶¶ 9–12 (App. 46–48).
20. Scheideman Decl. ¶ 13 (App. 48).

D. Plaintiff Kelley Orthodontics

Kelley Orthodontics is a Christian professional association owned by plaintiff John Kelley.[21] Kelley Orthodontics wishes to provide health insurance for its employees that excludes coverage of contraception, PrEP drugs, and other preventive care that Dr. Kelley does not wish to cover.[22] Dr. Kelley also wants the option of purchasing health insurance for his employees that limits coverage of preventive care or that imposes copays or deductibles for preventive care, with corresponding adjustments in the monthly premiums, so that he can choose a policy that best suits the needs of his business.[23] The defendants' enforcement of the preventive-care mandates is limiting Dr. Kelley's ability to obtain health insurance for his employees that excludes this unwanted coverage.[24]

E. Plaintiff Braidwood Management Inc.

Braidwood Management Inc. is a Christian, for-profit corporation that employs approximately 70 individuals.[25] It is owned by Dr. Steven F. Hotze.[26] Because Braidwood has more than 50 employees, it is compelled to offer ACA-compliant health insurance to its employees or face heavy financial penalties. *See* 26 U.S.C. § 4980H(c)(2).[27]

Braidwood provides health insurance to its employees through a self-insured plan.[28] Dr. Hotze wants Braidwood's self-insured plan to exclude or limit coverage of preventive care that he does not want to provide.[29] Dr. Hotze also wants Braidwood's

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21. Kelly Decl. ¶¶ 12, 16 (App. 36, 37).
22. Kelly Decl. ¶¶ 17–18 (App. 37).
23. Kelly Decl. ¶ 19 (App. 37).
24. Kelley Decl. ¶ 20 (App. 37).
25. Hotze Decl. ¶ 4–5 (App. 67).
26. Hotze Decl. ¶ 4 (App. 67).
27. Hotze Decl. ¶ 5 (App. 67).
28. Hotze Decl. ¶ 6 (App. 67).
29. Hotze Decl. ¶ 7 (App. 68).

self-insured plan to exclude coverage of preventive care that violates his sincere religious beliefs.[30] And Dr. Hotze wants the option of imposing copays or deductibles for preventive care in Braidwood's self-insured plan, so that he can establish an employee health-insurance plan that best suit the needs of his businesses.[31] The defendants' enforcement of the preventive-care mandates is preventing Braidwood from excluding unwanted coverage in its self-insured plan.[32] It is also preventing Braidwood from imposing cost-sharing arrangements (such as co-pays or deductibles) on any of the preventive-care coverage compelled by the defendants.[33]

ARGUMENT

The plaintiffs are entitled to judgment as a matter of law on the undisputed facts of this case.

I. The Plaintiffs Have Standing To Challenge The Preventive-Care Mandates

Each of the plaintiffs wishes to purchase, obtain, or provide health insurance that excludes or limits coverage of preventive care that the defendants are currently forcing insurers to cover without cost sharing.[34] And each of the plaintiffs wants the health-insurance market to offer a range of available options with respect to coverage of preventive care, so that they may choose a policy that best suits their needs and the needs of their family or business.[35] The preventive-care mandates, however, limit the range of health-insurance policies that insurers may legally offer, and make it impossible for the plaintiffs to purchase, obtain, or provide health insurance that excludes

30. Hotze Decl. ¶¶ 8, 14–18 (App. 68, 70).
31. Hotze Decl. ¶ 9 (App. 68).
32. Hotze Decl. ¶ 19 (App. 71).
33. Hotze Decl. ¶ 19 (App. 71).
34. *See* notes 3, 9, 16–17, 22, 29–30 and accompanying text.
35. *See* notes 4, 10, 18, 23, 31 and accompanying text.

or limits coverage of unwanted or unneeded preventive care.[36] The mandates also prevent insurers from competing with each other by offering policies that shift the costs of preventive care to beneficiaries in exchange for lower premiums.[37] This indisputably inflicts injury in fact by reducing and limiting the types of health-insurance policies available on the market. *See Center for Auto Safety v. National Highway Traffic Safety Administration*, 793 F.2d 1322, 1332–34 (D.C. Cir. 1986) (holding that a reduced opportunity to purchase fuel-efficient vehicles established injury in fact); *id.* at 1332 ("NHTSA's low CAFE standards will diminish the types of fuel-efficient vehicles and options available. Without the threat of civil penalties, manufacturers will not be prodded to install as many fuel-saving devices, nor to install them as promptly. As a result, petitioners' members will have less opportunity to purchase fuel-efficient light trucks than would otherwise be available to them."); *Orangeburg, South Carolina v. FERC*, 862 F.3d 1071, 1078 (D.C. Cir. 2017) ("The lost opportunity to purchase a desired product is a cognizable injury, even though Orangeburg *can* purchase, and *has* purchased, wholesale power from another source. . . . [E]ven though Orangeburg can and does purchase wholesale power from another source, the city cannot purchase wholesale power from the provider of its choice *nor* on its preferred terms").

These injuries are "fairly traceable" to the defendants' continued enforcement of the preventive-care mandates. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 134 n.6 (2014) ("Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly traceable to the defendant's conduct."). Before the Affordable Care Act, private insurers offered policies that excluded or limited coverage of preventive care, or that charged copays

36. *See* notes 7, 13, 20, 24, 32 and accompanying text.
37. *See* notes 4, 10, 18, 23, 31, 33 and accompanying text.

or required deductibles for preventive care in exchange for lower premiums.[38] Indeed, the entire reason for the preventive-care mandates was that private insurers were *not* providing cost-free coverage of preventive care on their own initiative or in response to market forces; that is why the defendants are *compelling* insurers to provide this coverage regardless of whether a beneficiary wants or needs it. The present-day absence of private health insurance that excludes or limits coverage of preventive care is a direct result of the preventive-care mandates and the defendants' continued enforcement of them.

Finally, the plaintiffs' injuries are "likely to be redressed" by relief that enjoins the defendants from enforcing the preventing-care mandates. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (a plaintiff needs only to show that it is "likely" that his injury will be redressed by the requested relief); *Larson v. Valente,* 456 U.S. 228, 244, n.15 (1982) ("[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his *every* injury"); *see also Inclusive Communities Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655 (5th Cir. 2019) ("The relief sought needn't completely cure the injury, however; it's enough if the desired relief would lessen it."). The unwillingness of health insurers to cover ACA-mandated preventive care at zero marginal cost before the ACA's enactment is all that is needed to show that it is "likely" that relief will cause insurers to once again offer policies of that sort. And any doubt on this score is dispelled by the market for "short-term, limited

38. Cannon Decl. ¶ 4 (App. 73–74); *see also 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. 41726, 41732–33 (July 19, 2010) (App. 85–86).

duration insurance," which Congress has exempted from the ACA, and in which insurers offer policies that exclude or limit coverage of preventive care that would otherwise be mandated by the ACA.[39]

II. 42 U.S.C. § 300gg-13(a)(1)–(4) Violate The Appointments Clause

The Appointments Clause provides:

> [The President] shall have Power, by and with the Advice and Consent of the Senate, to . . . appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the 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.

U.S. Const. art. II § 2. Yet 42 U.S.C. § 300gg-13(a)(1)–(4) allow the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration to unilaterally determine the preventive care that private insurers must cover. These individuals are "officers of the United States," because they "occupy a continuing position established by law" and exercise "significant authority pursuant to the laws of the United States." *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). Yet none of these officers have been appointed in conformity with the Appointments Clause.

A. The Members Of The U.S. Preventive Services Task Force, The Advisory Committee On Immunization Practices, And The Health Resources And Services Administration Are "Officers Of The United States"

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);

39. Cannon Decl. ¶¶ 5–7 (App. 74–75); *see also* App. 176.

see also Buckley v. Valeo, 424 U.S. 1, 126 (1976) ("[A]ny appointee exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed by s 2, cl. 2, of that Article."); Jennifer L. Mascott, *Who Are "Officers of the United States"?*, 70 Stan. L. Rev. 443 (2018). The members of the U.S. Preventive Services Task Force (PSTF), the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Commission (HRSA) easily qualify as "officers of the United States" under the two-part *Lucia* test.

First, each of these members occupies "a continuing position established by law." The Preventive Services Task Force was established by an Act of Congress in 1984. The Advisory Committee on Immunization Practices was established pursuant to 42 U.S.C. § 217a, which authorizes the Secretary of Health and Human Services to establish "advisory councils or committees." And the Health Resources and Services Administration is an agency of the U.S. Department of Health and Human Services, which was established in 1982 by an HHS reorganization order that consolidated the Health Resources Administration and the Health Services Administration. *See* National Archives, Records of the Health Resources and Services Administration, § 512.1 (August 15, 2016), available at https://bit.ly/3HA8mIO. Each of these entities has therefore been "established by law." And each of these entities has remained in continuous existence since they were first established in 1984 (PSTF), 1964 (ACIP), and 1982 (HRSA). The members of PSTF, ACIP, and HRSA therefore occupy "continuing positions" that are also "established by law." *Lucia*, 138 S. Ct. at 2051; *see also Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 111 (Apr. 16, 2007) ("[A]n office exists where a position that possesses delegated sovereign authority is permanent, meaning that it

is not limited by time or by being of such a nature that it will terminate 'by the very fact of performance.' ").[40]

Second, the members of PSTF, ACIP, and HRSA exercise "significant authority pursuant to the laws of the United States." *Lucia*, 138 S. Ct. at 2051. It is hard to conceive of "authority" more "significant" than the power to unilaterally dictate the scope of preventive care that private insurers must cover, without any cost-sharing arrangements such as deductible or copays. And the members of PSTF, ACIP, and HRSA wield these powers "pursuant to the laws of the United States," as 42 U.S.C. § 300gg-13(a)(1)–(4) explicitly confer this authority upon them.

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40. This is what distinguishes PSTF and ACIP from private institutions or state or foreign governments whose decisions are sometimes incorporated by reference into federal statutes. The government correctly notes that federal laws incorporate by reference recommendations of the American National Standards Institute (ANSI), and some federal criminal offenses are defined by reference to state or foreign law. *See* Mot. to Dismiss, ECF No. 20 at 25 (citing 4 U.S.C. § 119(a)(2), 16 U.S.C. § 3372(a)(2)(A), 18 U.S.C. § 13(a), 42 U.S.C. § 6293(b)(8)). But none of this violates the Appointments Clause, because the members of ANSI and the state and foreign government officials do *not* occupy "a continuing position established by [federal] law." *Lucia*, 138 S. Ct. at 2051. ANSI is a private, non-profit entity that was not created or established by a federal statute. And members of state and foreign governments are obviously not occupying "a continuing position established by [federal] law." *Lucia*, 138 S. Ct. at 2051. One cannot be an "officer of the United States" unless there is a federal *office* to occupy—and the first part of the *Lucia* test ensures that there is a federal "office" that is held by the alleged "officer." *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 73–74 (Apr. 16, 2007) ("We conclude that any position having the two essential characteristics of a federal "office" is subject to the Appointments Clause. That is, a position, however labeled, is in fact a federal office if (1) it is invested by legal authority with a portion of the sovereign powers of the federal government, and (2) it is "continuing." A person who would hold such a position must be properly made an "Officer[] of the United States" by being appointed pursuant to the procedures specified in the Appointments Clause."). There is no doubt, however, that the members of PSTF and ACIP occupy federal offices, because each of these entities was created and established by federal law.

The defendants resist each of these conclusions, but none of their arguments have merit.

1. An "Officer Of The United States" Is Not Required To Be A Paid Employee Of The Federal Government

The defendants deny that the members of the Preventive Services Task Force and the Advisory Committee on Immunization Practices qualify as "officers of the United States" because (according to the defendants) these individuals lack "a continuing and formalized relationship of employment with the United States government." Mot. to Dismiss, ECF No. 20 at 23 (quoting *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749, 757 (5th Cir. 2001)). Both the major premise and the minor premise of this argument are wrong.

The Supreme Court has never held that an "officer of the United States" must hold a "formalized relationship of employment" with the federal government, and the Office of Legal Counsel has explicitly rejected this view in an opinion that binds the Department of Justice. *See Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 78 (Apr. 16, 2007) ("[F]ederal employment is not necessary for the Appointments Clause to apply."); *id.* at 121 (specifically rejecting the notion that "the Appointments Clause does not apply to persons who are not employees of the federal government, even if they are delegated permanent federal authority to enforce federal law.").

More importantly, the Supreme Court has established a two-part test for determining whether someone qualifies as an officer of the United States, and *that* is the standard that lower courts and litigants must apply when considering Appointments Clause claims. *See Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018) (holding that one qualifies as an "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."). Nowhere does this test purport to require an employer–employee relationship between an officer and the federal government.

The defendants, however, rely heavily on *Riley v. St. Luke's Episcopal Hospital*, 252 F.3d 749 (5th Cir. 2001), which asserts that "the constitutional definition of an 'officer' encompasses, at a minimum, a continuing and formalized relationship of employment with the United States Government." *Id.* at 757. *Riley*'s insistence on a formalized employment relationship finds no support in the rulings of the Supreme Court, which ask only whether the individual "occupies a continuing position established by law" and "exercises significant authority pursuant to the laws of the United States." *Lucia*, 138 S. Ct. at 2051. It also contradicts the opinions of the Office of Legal Counsel, which specifically hold that "federal employment is not necessary for the Appointments Clause to apply." *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 78 (Apr. 16, 2007). But *Riley* remains a precedent of the Fifth Circuit, so these statements in *Riley* cannot be dismissed as simply wrong. Instead, they should be interpreted in a manner that mitigates any inconsistency with the views expressed by Supreme Court and the Office of Legal Counsel.

The Court should hold that an individual has a "formalized relationship of employment with the United States government" under *Riley* whenever he "occupies a continuing position established by law"—regardless of whether he receives payment or emoluments for his work. This is a permissible (though not mandatory) interpretation of *Riley*, and this approach would eliminate any inconsistency between *Riley* and *Lucia* (and between *Riley* and the opinions of OLC). The words "employ" and "employment" can be used to describe work that does not involve payment,[41] and the

41. *See, e.g.*, "employ." *Merriam-Webster.com*. 2020. https://www.merriam-webster.com/dictionary/employ (November 15, 2021) (defining "stepfather" as "1a: to make use of (someone or something inactive) *employ* a pen for sketching;

notion that *paid* employment is required to make one an "officer of the United States" is flatly contradicted by original meaning and historical practice. As the Office of Legal Counsel explains:

> [A]ny understanding of an 'office' that would require an 'emolument' akin to the compensation that a person on the regular payroll of the federal government receives would conflict with the original meaning of the Appointments Clause as revealed by earliest practice. In the first decade under the Constitution, most federal officers, particularly those outside the capital, received no compensation from the government, much less a regular one. Instead, they received authority to collect fees . . ."

Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 120 (Apr. 16, 2007).[42] And there is no need to construe the word "employment" in *Riley* (or in other cases) as requiring *payment* from the federal government:

> [T]he general language of these cases allows for an office that does not involve government employment in the modern sense. *Maurice*, for example, said that an office is "*a public charge or* employment," 26 F. Cas.

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

42. *See also Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. Off. Legal Counsel 73, 119 (Apr. 16, 2007) ("[A]n emolument is also a common characteristic of an office, as *Hartwell* indicates, 73 U.S. at 393, but it too is not essential: 'Like the requirement of an oath,' provision for pay 'may aid in determining the nature of the position, but it is not conclusive. . . . As in the case of the oath, the salary or fees are mere incidents and form no part of the office.' Mechem § 7, at 6; see id. at 6 n.3 ('it is not a sine qua non'); Kennon, 7 Ohio St. at 559 ('That compensation or emolument is a usual incident to office, is well known; but that it is a necessary element in the constitution of an office, is not true."); *id.* at 120 ("If Presidents were to serve without pay, as Benjamin Franklin had proposed, *see* James Madison, Notes of Debates in the Federal Convention of 1787, at 51–55 (June 2, 1787) (1987), they would no less hold an office.").

> at 1214 (internal quotation marks omitted; emphasis added), and *Hartwell* defined an office as "*a public station*, or employment," 73 U.S. at 393 (emphasis added). *Maurice*, among others, also does state that an "office is 'an employment,'" 26 F. Cas. at 1214, but such a statement must be read in a contemporaneous rather than anachronistic sense, broadly to include anyone engaged by the government, whether an independent contractor, "employee," or other agent. The pertinent definition of "employ" is:
>
> > To engage in one's service; to use as an agent or substitute in transacting business; to commission and entrust with the management of one's affairs. The president *employed* an envoy to negotiate a treaty. Kings and States *employ* ambassadors at foreign courts.
>
> Noah Webster, *An American Dictionary of the English Language, tit.* Employ (1828). Thus, even an "agreement" to provide services (such as "to make hay" or "plough land") was an "employment."

Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. Off. Legal Counsel 73, 121 (Apr. 16, 2007). It is hard to understand how the Department of Justice can take a position in this Court that so flatly contradicts the pronouncements of the Office of Legal Counsel, and it is even harder to understand why it would not seek an interpretation of *Riley* that is consonant with OLC's views.

2. The Members Of PSTF, ACIP, And HRSA Exercise "Significant Authority Pursuant To The Laws Of The United States"

The defendants also deny that the members of the PSTF, ACIP and HRSA exercise "significant authority pursuant to the laws of the United States." *See* Reply Br. in Support of Mot. to Dismiss, ECF No. 32 at 10. Instead, they attempt to characterize these individuals as technocrats rather than policymakers:

> [T]hese bodies do not "exercise significant authority pursuant to the laws of the United States." In pressing the contrary conclusion, Plaintiffs fundamentally misunderstand the role of the expert bodies who provide the preventive care guidelines and recommendations that, pursuant to ACA, must be covered by insurance. In 42 U.S.C. § 300gg-13(a), *Congress* made the determination that standard contemporary preventive care practices should be covered by insurance without cost sharing. The authority of the expert bodies referenced in the statute is

> limited, and this limited nature of their authority is not changed by the statute's incorporation of their work by reference. Specifically, their limited role is to set forth what contemporary preventive care practices are the prevailing medical standard at a given time. In other words, these expert bodies are not "unilaterally dictat[ing] the scope of preventive care that all private insurers must cover," because Congress has already made that determination. The expert bodies simply have the task of setting forth, in a world where medical science is evolving daily, what practices qualify in the medical field as the current standard of care.

Id. But none of these observations alter the fact that the members of the PSTF, ACIP and HRSA have been given sweeping powers to determine the scope of preventive-care coverage in private health insurance—including the prerogative to resolve highly explosive questions such as contraceptive coverage and the scope of any religious exemptions (or other exemptions) that might be conferred. *See 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."). Indeed, *Little Sisters* removes any doubt on this score, as it recognizes that 42 U.S.C. § 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," and that "HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings." *Id.* at 2380. PSTF and ACIP enjoy similar powers under 42 U.S.C. § 300gg-13(a)(1)–(2), including the power to recognize and confer exemptions to their preventive-care mandates, religious or otherwise. This assuredly qualifies as "significant authority pursuant to the laws of the United States."

B. The Members Of PSTF, ACIP, And HRSA Are Principal Officers Who Must Be Appointed By The President With The Senate's Advice And Consent

Not only are the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services

Administration "officers of the United States," they are *principal* officers who must be appointed by the President with the advice and consent of the Senate.

The distinction between a "principal" officer and an "inferior" officer turns on whether the officer's work is "directed and supervised" by others who have been appointed by the President with the Senate's advice and consent. *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). That direction and supervision is absent here. 42 U.S.C. § 300gg-13(a)(1)–(4) empower PSTF, ACIP, and HRSA—and these entities alone—to determine the preventive care that insurers must cover without cost-sharing arrangements. Neither the Secretary of Health and Human Services, nor any other officer of the United States, has authority to review or countermand any of the preventive-care edicts issued by PSTF, ACIP, or HRSA. *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)). And the absence of any "statutory authority" to review their decisions makes their members principal rather than inferior officers. *See Arthrex*, 141 S. Ct. at 1981 (holding that formal "statutory authority to review" decisions is needed to make one an inferior officer); *id.* at 1983 ("[A]dequate supervision entails review of decisions issued by inferior officers.").

C. The Members Of PSTF, ACIP, And HRSA Have Been Unconstitutionally Appointed, Regardless Of Whether They Are "Principal" Or "Inferior" Officers

If the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration, are principal officers, then their appointments are unconstitutional because

they have not been appointed by the President with the advice and consent of the Senate. But even if they could somehow be passed off as "inferior officers," their appointments remain unconstitutional because there does not appear to be any Act of Congress that "vests" their appointment in the President alone, in the Courts of Law, or in the Heads of Departments—which is needed to escape the constitutional default rule of presidential nomination and Senate confirmation. *See* U.S. Const. art. II § 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 statute that establishes the U.S. Preventive Services Task Force, for example, says that "[t]he Director [of the Agency for Healthcare Research and Quality] shall *convene* an independent Preventive Services Task Force . . . to be composed of individuals with appropriate expertise." 42 U.S.C.A. § 299b-4(a)(1) (emphasis added). But this says nothing about how the members of the Task Force are to be *appointed*, and it does not purport to "vest" the appointment of these members in the Director. And in all events, the Director of the Agency for Healthcare Research and Quality would not qualify as a "Head of Department" within the meaning of the Appointments Clause. *See Freytag v. Commissioner of Internal Revenue*, 501 U.S. 868, 886 (1991); *United States v. Germaine*, 99 U.S. 508, 511 (1878).

The plaintiffs have also been unable to locate any Act of Congress that "vests" the appointment of the members of the Advisory Committee on Immunization Practices or the Health Resources and Services Administration in the President alone, the Courts of Law, or the Heads of Department. 42 U.S.C. § 217a, for example, authorizes the Secretary of Health and Human Services to "appoint such advisory councils or committees . . . for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary *for the purpose of advising him in connection with any of his functions*." 42 U.S.C. § 217a (emphasis added). But this

statute cannot be used to appoint the members of the Advisory Committee on Immunization Practices or the Health Resources and Services Administration now that 42 U.S.C. § 300gg-13(2)–(4) gives binding force to their pronouncements. The members these entities are not "advising" the Secretary on these statutory matters, and they are no longer being appointed "for the purpose of advising" the Secretary. Instead, they are *deciding* the preventive care that private insurance *must* cover.

If the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration were performing purely advisory functions, then their members would not be considered "officers of the United States" and need not be appointed in accordance with the Appointments Clause. *See* Walter Dellinger, *Constitutional Limitations on Federal Government Participation in Binding Arbitration*, 19 U.S. Op. Off. Legal Counsel 208 (1995) ("[T]he members of a commission that has purely advisory functions need not be officers of the United States because they possess no enforcement authority or power to bind the Government." (citation and internal quotation marks omitted)). But the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration are no longer acting in a "purely advisory" role now that 42 U.S.C. § 300gg-13(a) has empowered them to unilaterally determine the preventive care that health insurance must cover without any cost-sharing arrangements. The members of these agencies are undoubtedly "officers of the United States," and they must be appointed consistent with the requirements of Article II, § 2.

D. The Defendants' Suggestion That Any Appointments Clause Problems Have Been "Cured" By Subsequent "Ratification" Of The ACIP and HRSA Preventive-Care Mandates Is Without Merit

The defendants contend that any constitutional problems with the appointment of the ACIP and HRSA members have been "cured" because their decisions have

been "ratified" by the Secretary of Health and Human Services or the Director of the Center for Disease Control and Prevention. *See* Mot. to Dismiss, ECF No. 20 at 19–22. The defendants' ratification argument is untenable.

First, the statute *does not allow* the Secretary of Health and Human Services (or anyone else) to countermand HRSA's guidelines, and the Secretary is given no discretion to accept or reject the guidelines that HRSA produces. When HRSA announces the "preventive care and screenings" that private insurers must cover, the Secretary is *legally obligated* to issue rules and enforce preventive-care mandates in accordance with HRSA's guidelines. Yet the government is trying to pass off the Secretary's compulsory implementation of HRSA's decisions as a voluntary act of "ratification"—even though the text of section 300gg-13(a)(4) makes clear that HRSA holds the whip hand. *See Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) ("On its face, then, [section 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."); *id.* ("HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings."); *id.* at 2381 ("By its terms, the ACA leaves the Guidelines' content *to the exclusive discretion of HRSA*." (emphasis added)).

The statute likewise prohibits the Director of the CDC from overruling the recommendations of ACIP. It *requires* all insurers to cover "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved." 42 U.S.C. § 300gg-13(a)(2). The committee's recommendations are final under the text of the statute, and the government cites no example where the CDC Director has overruled an ACIP recommendation since the enactment of the Affordable Care Act.

Second, even if the HHS Secretary or the CDC Director had the authority to veto or "ratify" HRSA's guidelines or ACIP's recommendations, section 300gg-13(a) would *still* violate the Appointments Clause because it empowers HRSA or ACIP to dictate the preventive care that private insurers must cover *until* an "officer of the United States" acts to approve or revoke 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 establish the default rule on matters of compulsory health-insurance coverage amounts to "significant authority" in and of itself. *See Lucia*, 138 S. Ct. at 2049 (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).

* * *

The members of PSTF, ACIP, and HRSA are "officers of the United States" who have not been appointed in conformity with the Appointments Clause. The Court should declare that any and all preventive-care mandates based on a rating, recommendation, or guideline issued by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, or the Health Resources and Services Administration after March 23, 2010—the date on which the Affordable Care Act was signed into law—are unconstitutional and unenforceable, and it should enjoin the defendants from enforcing them.

III. 42 U.S.C. § 300gg-13(a)(1)–(4) Violate The Nondelegation Doctrine

Statutes that delegate authority to agencies must supply an "intelligible principle" to guide the agency's discretion. *See Whitman v. American Trucking Associations*, 531 U.S. 457, 472 (2001). Yet there is *nothing* in the text of section 300gg-13(a) that purports to guide the discretion of PSTF, ACIP, or HRSA when choosing the preventive care that private insurance must cover. The statute does not even require these

agencies to make these decisions based on the "public interest" or the "public health," and it does not provide *any* factors or considerations that might influence the agency's decisionmaking. Even the statutes that fall along the outermost boundary of constitutionally permissible delegations have at least *something* to guide the agency; this statute has *nothing at all*.

The government suggests that the statute provides an "intelligible principle" because the PSTF has established its *own criteria* for determining which "items or services" receive an "A" or "B" grade. *See* Mot. to Dismiss, ECF No. 20 at 27. But *Whitman* explicitly rejects the idea that an agency can cure the absence of an intelligible principle in a statute by supplying the intelligible principle that Congress failed to provide:

> [W]hen 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." *J.W. Hampton, Jr., & Co. v. United States,* 276 U.S. 394, 409 (1928). We have never suggested that an agency can cure an unlawful delegation of legislative power by adopting in its discretion a limiting construction of the statute. . . . 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 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.

Whitman, 531 U.S. at 472 (emphasis added). The "intelligible principle" must appear in the statute itself, not in any agency-created guidelines.

The government also suggests that the statute provides an "intelligible principle" by allowing PSTF to compel coverage only of "evidence-based items and services,"[43]

43. 42 U.S.C. § 300gg-13(a)(1).

by allowing ACIP to compel coverage only of "immunizations,"[44] and allowing HRSA to compel coverage only of "preventive care and screenings,"[45] and then only of preventive care and screenings for "infants, children, and adolescents,"[46] or "for women."[47] *See* Mot. to Dismiss, ECF No. 20 at 27. This argument confuses a statutory boundary on an agency's authority with the "intelligible principle" needed to guide the agency's discretion 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. *That* is where the absence of an intelligible principle is felt, and the government cannot point to anything in the statute that alleviates this problem.

Finally, the Supreme Court's recent opinion in *Little Sisters* indicates that the justices have at least some discomfort with the delegation in section 300gg-13(a)(4). Consider this passage, which seems to go out of its way to call out the statute as a unique (and uniquely troublesome) delegation:

> On its face, then, [section 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. 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. See, *e.g.*, 18 U.S.C. § 1961(1); 28 U.S.C. § 1603(a). It does not, as Congress did elsewhere in the same section of the ACA, set forth any criteria or standards to guide HRSA's selections. See, *e.g.*, 42 U.S.C. § 300gg–13(a)(3) (requiring "*evidence-informed* preventive care and screenings" (emphasis added)); § 300gg–13(a)(1) ("evidence-based items or services"). It does not, as Congress has done in other contexts, require that HRSA

44. 42 U.S.C. § 300gg-13(a)(2).
45. 42 U.S.C. § 300gg-13(a)(3)–(4).
46. 42 U.S.C. § 300gg-13(a)(3).
47. 42 U.S.C. § 300gg-13(a)(4).

> consult with or refrain from consulting with any party in the formulation of the Guidelines. See, *e.g.*, 16 U.S.C. § 1536(a)(1); 23 U.S.C. § 138. This means that HRSA has virtually unbridled discretion to decide what counts as preventive care and screenings. But the same capacious grant of authority that empowers HRSA to make these determinations leaves its discretion equally unchecked in other areas, including the ability to identify and create exemptions from its own Guidelines.
>
> Congress could have limited HRSA's discretion in any number of ways, but it chose not to do so. Instead, it enacted "'expansive language offer[ing] no indication whatever'" that the statute limits what HRSA can designate as preventive care and screenings or who must provide that coverage.

Little Sisters, 140 S. Ct. at 2380 (some citations omitted). Of course, the Supreme Court did not go so far as to say that section 300gg-13(a)(4) actually violates the nondelegation doctrine. But the Court *did* make clear that the doctrine continues to exist—and that they will continue policing the boundary between permissible and impermissible delegations of lawmaking power. *See Gundy v. United States*, 139 S. Ct. 2116 (2019). If the provisions of section 300gg-13(a)(1)–(4) are held to pass muster under the "intelligible principle" standard, then one must wonder how any statute could possibly fail this court-imposed test.

IV. 42 U.S.C. § 300gg-13(a)(1) Violates Article II's Vesting Clause

If the Court concludes that the U.S. Preventive Services Task Force is exercising executive power rather than legislative power when it unilaterally decrees the "items or services" that health insurance must cover, then 42 U.S.C. § 300gg-13(a)(1) violates Article II's vesting clause by conferring executive power on agency officials who are not subject to Presidential direction, removal, or control. *See Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183, 2197 (2020) ("The entire 'executive power' belongs to the President alone. . . . These lesser officers must remain accountable to the President, whose authority they wield.").

The statute establishing the U.S. Preventive Services Task Force forbids any Presidential influence over the Task Force's recommendations:

> 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.

42 U.S.C. § 299b-4. Of course, there is nothing wrong with immunizing a purely advisory committee from presidential direction and control, and the U.S. Preventive Services Task Force served a purely advisory role before the enactment of the Affordable Care Act in 2010. But the Task Force ceased to be an advisory committee upon the enactment of 42 U.S.C. § 300gg-13(a)(1), which empowered the Task Force to unilaterally decree the preventive care that health insurers must cover.

The Constitution makes no provision for governance by politically unaccountable bureaucrats. The Task Force is either exercising legislative or executive power when it announces the preventive care that health insurance must cover without any cost-sharing arrangements. If these Task Force pronouncements qualify as legislative power, then 42 U.S.C. § 300gg-13(a)(1) violates Article I by conferring lawmaking powers on an agency. And if the Task Force pronouncements qualify as executive power, then 42 U.S.C. § 300gg-13(a)(1) violates Article II by conferring executive power on agency officials who are immune from the President's direction, removal, and control. Either way, the statute is unconstitutional, and any preventive-care mandates derived from a Task Force pronouncement that issued after March 23, 2010, should be declared unconstitutional and unenforceable.

The government denies that 42 U.S.C. § 300gg-13(a)(1) violates Article II's vesting clause by empowering the Preventive Services Task Force to dictate the "items or services" that private insurers must cover, while simultaneously insulating the members of the task force from Presidential direction or control. *See* 42 U.S.C. § 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."). The government denies that the PSTF is exercising *any* type of "legislative" or "executive" power—or even "quasi-legislative power"—because (in the government's view) the PSTF is indistinguishable from the American National Standards Institute (ANSI), or the state and foreign governments whose decision are incorporated by reference into federal statutes. *See* Mot. to Dismiss, ECF No. 20 at 25–26. The government's argument is untenable.

The Preventive Services Task Force is an entity of the federal government. It is funded by the Agency for Healthcare Research and Quality, which appoints its members and provides its support staff.[48] And it was created and established by an Act of Congress in 1984. A government agency of this sort *must* comply with the constitutional rules established in Articles I and II; Congress cannot create independent entities and then empower them to make legally binding decisions independent of Presidential control. *See Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183 (2020). ANSI is a private, non-profit entity that is not part of the federal government and was not created by the federal government. State and foreign governments are not part of the federal government either, so they do not need to comply with constitutional separation-of-powers rules—even when they exercise authority pursuant to a federal statute. State judicial officers, for example, are not required to hold life tenure and salary protection, even when they decide cases arising under a federal statute, because they are entities of their state government and do not exercise "the judicial power of the United States." *See* William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511 (2020). The Supreme Court has never allowed an entity that is part of the federal government to exempt itself from constitutional

48. *See* https://www.ahrq.gov/cpi/about/otherwebsites/uspstf/index.html (last visited on November 15, 2021).

separation-of-powers rules, and the Court's recent decision in *Seila Law* is an emphatic reminder that purely independent federal agencies of the type established in 42 U.S.C. § 300gg-13(a) have no place in our constitutional structure.

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

Plaintiffs Kelley, Starnes, Zach and Ashley Maxwell, Kelley Orthodontics, and Braidwood each hold sincere religious objections to the compulsory coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use.[49] To prevail on their RFRA claim, these plaintiffs need only show that this compulsory coverage substantially burdens their exercise of religion. 42 U.S.C. § 2000bb-1(a). Then the burden shifts to the government to demonstrate that its imposition furthers a "compelling governmental interest" and is the "least restrictive means" of doing so. 42 U.S.C. § 2000bb-1(b)(1)–(2); see also *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 706 (2014) ("RFRA was designed to provide very broad protection for religious liberty.").

A. The Compulsory Coverage Of PrEP Drugs Substantially Burdens The Plaintiffs' Religious Freedom

The compulsory coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use requires employers with more than 50 employees to choose one of the following two options: (1) Provide this coverage in their employees' health insurance; or (2) Pay a heavy financial penalty. *See* 26 U.S.C. § 4980D (imposing a "tax" on employers who refuse to comply with the preventive-care mandate of $100 per employee per day of noncompliance). Braidwood, which has more than 50 employees, must therefore provide health-insurance coverage that violates Dr. Hotze's sincere religious beliefs, or else pay the fines described in section

49. *See* notes 6, 22, 30 and accompanying text.

4980D. The Supreme Court has already held that putting an employer to this choice imposes a "substantial burden" on religious freedom. *See Hobby Lobby*, 573 U.S. at 691. Kelley Orthodontics has fewer than 50 employees, so it must choose between: (1) Providing health insurance to its employees that covers PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use, in violation of Dr. Kelley's sincere religious beliefs; or (2) Refusing to offer any health insurance to its employees. The Supreme Court has held that requiring an employer to drop employee health benefits to avoid complicity in conduct that violates its religious beliefs is likewise a "substantial burden" of the exercise of religion. *See Hobby Lobby*, 573 U.S. at 722–23.

The compulsory coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use also substantially burdens the religious freedom of individual consumers of health insurance, such as Dr. Kelley, Mr. Starnes, and Zach and Ashley Maxwell, because it compels them to choose between subsidizing lifestyles that violate their religious beliefs and foregoing health insurance entirely. *See, e.g.*, *March for Life v. Burwell*, 128 F. Supp. 3d 116, 129–30 (D.D.C. 2015) (Contraceptive Mandate violates the Religious Freedom Restoration Act as applied to individuals who "hold religious beliefs against participating in a health insurance plan that covers contraceptives."); *DeOtte v. Azar*, 393 F. Supp. 3d 490, 509 (N.D. Tex. 2019) (Contraceptive Mandate substantially burdens the religious freedom of individual consumers of health insurance who wish to avoid complicity in contraception, because these individuals "are forced out of either the health-insurance market or their religious exercise."). Under the current regime, every individual who purchases health insurance will pay premiums that subsidize the provision of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use. The only way to avoid this subsidy is to forego health insurance, or to obtain insurance through a church employer or a grandfathered health plan exempt from the

Contraceptive Mandate. It is a "substantial burden" to close off the entire health-insurance market to individuals who are unwilling, for religious reasons, to purchase insurance that is used to subsidize other people's PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use. This compulsory coverage is no different in this regard from a law that requires all private health insurance to cover abortions without any deductibles or co-pays. In each of these worlds, religious objectors are unable to purchase health insurance unless they pay for practices that are anathema to their religious beliefs.

Each of the plaintiffs is asserting complicity-based objections to the coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use, because they do not wish to subsidize or provide insurance that encourages and facilitates homosexual behavior, drug use, or sexual activity outside of marriage between one man and one woman.[50] That unquestionably qualifies as a "substantial burden" on the exercise of their religion, and the Supreme Court has repeatedly held that courts *must* accept a religious objector's complicity-based objections to unwanted health-insurance coverage—no matter how attenuated the complicity may seem to an opposing party or a federal judge. The Court's only task is to determine whether a complicity-based objection is sincere; it may not dismiss a religious objector's sincere complicity objections as unreasonable or "too attenuated." *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 725 (2014); *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020). And each of these plaintiffs has clearly established a complicity-based objection to the compulsory coverage of PrEP drugs, the HPV vaccine, and the screenings and behavioral counseling for STDs and drug use that is rooted in their sincere religious beliefs (or in the case

50. *See* notes 6, 22, 30 and accompanying text.

of Braidwood and Kelley Orthodontics, in the sincere religious beliefs of their owners).[51]

* * *

Having shown a "substantial burden" on the plaintiffs' religious liberty, the burden now shifts to the government to demonstrate that the compulsory coverage of PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use advances a "compelling governmental interest" and is "the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b). This is "the most demanding test known to constitutional law," *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997), and the compulsory-coverage regime comes nowhere close to satisfying this standard.

B. There Is No Compelling Governmental Interest In Forcing Private Insurers To Cover PrEP Drugs Without Any Cost-Sharing Arrangements

The relevant "governmental interest" cannot be described with vague abstractions, such as "promoting public health" or "gender equality." *See Hobby Lobby*, 573 U.S. at 726 (rejecting the government's attempt to frame the "governmental interests" in those terms). Instead, 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." *Id.* at 726–27 (quoting *Gonzales v. O Centro Espírita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006)). The government cannot possibly show that forcing private insurers to provide PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use free of charge is a policy of such overriding importance that it can trump religious-freedom objections.

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51. *See* notes 6, 22, 30 and accompanying text.

The first problem is that the Affordable Care Act does not even require insurers to cover PrEP drugs, the HPV vaccine, or screenings and behavioral counseling for STDs and drug use, because the statute is entirely agnostic on whether any of this should be included within the definition of "preventive care." *See* 42 U.S.C. § 300gg-13(a)(4); App. 220. If there were a "compelling governmental interest" in ensuring access to free PrEP drugs and the HPV vaccine, then would expect to see that policy embodied in the Affordable Care Act or in some other act of Congress. Yet Congress was unwilling to require anyone—religious or non-religious—to provide coverage for PrEP drugs, the HPV vaccine, or screenings and behavioral counseling for STDs and drug use. Instead, Congress shrugged and punted these issues to the U.S. Preventive Services Task Force. *See, e.g.*, *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.").

The second problem is that the Affordable Care Act explicitly exempts "grandfathered" plans from *all* of the preventive-care mandates, including the compulsory coverage of PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use. *See* Pub. L. No. 111-148 § 1251, codified at 42 U.S.C. § 18011(a). So the defendants must explain how the government's interest in ensuring access to zero-cost PrEP drugs was not quite "compelling" enough to prevail over President Obama's desire to allow individuals to keep their existing health-insurance plans,[52] yet *is* compelling enough to prevail over another person's religious freedom. *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

52. *See generally* Michael D. Shear & Robert Pear, *Obama in Bind Trying to Keep Health Law Vow*, N.Y. Times (Nov. 12, 2013), https://nyti.ms/2HFH9JU.

why it has a particular interest in denying an exception to CSS while making them available to others.").

The third problem is that the Affordable Care Act categorically exempts employers with fewer than 50 employees from the requirement to provide health insurance to their employees. *See* 26 U.S.C. § 4980H(c)(2). To be sure, those employers must comply with the preventive-care mandate (and the requirement to provide coverage of PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use) if they *choose* to provide health insurance, but there is no requirement that they provide insurance in the first place. This cannot be squared with the notion that the government has a "compelling" interest in making PrEP drugs and HPV vaccines available to all employees free of charge, and it proves that other policies—such as protecting small businesses from onerous regulatory burdens—can and should prevail over the goal of expanding access to this preventive care.

Of course, some people believe very strongly that everyone (or many people as possible) should have the right to access PrEP drugs and HPV vaccines at no cost to them—and that they should therefore have the prerogative to compel others (including religious objectors) to involve themselves in providing these services. People who subscribe to that view will regard this compulsory coverage as furthering "compelling governmental interests," to which any claim of religious freedom (or any other claim of constitutional right) should give way. But that belief is not reflected in *any* statute enacted by the people's elected representatives—and it is not reflected the Affordable Care Act, which categorically exempts grandfathered plans for *all* of the agency-imposed preventive-care mandates. There is no doubt that the compulsory coverage of PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use furthers important policies, but they are not the type of "compelling" interests that must always prevail over other competing values or policy objectives.

C. Less Restrictive Means Are Available To Advance The Interests Served By The Compulsory Coverage Of PrEP Drugs

Even if one thinks that the government has a "compelling" interest in ensuring access to free PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use, the plaintiffs still prevail because the compulsory-coverage requirement flunks the least-restrictive-means test. There is a simple and obvious alternative that avoids any imposition on the plaintiffs' religious freedom while ensuring that every person in America can obtain PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use at zero marginal cost: The government could require all non-objecting doctors, pharmacists, hospitals, and other health-care providers to provide these services free of charge to any person whose insurance will not cover them, and allow those providers to seek reimbursement from the government for the services that they provide to uninsured or underinsured patients.[53] This regime would eliminate any involvement of religious objectors in the provision of PrEP drugs, the HPV vaccine, and screenings and behavioral counseling for STDs and drug use. It would also ensure that *every* person in America can access these services free of charge, including the uninsured and those with grandfathered plans—all of whom are left in the cold by the present-day iteration of the preventive-care mandates.

Of course, Congress would need to enact legislation to implement this less restrictive alternative. But the least-restrictive-means test does not turn on whether a less restrictive alternative is currently authorized by law. The statute requires the government to use "the least restrictive means" of advancing a compelling interest; it does not limit this requirement to the least restrictive means available under existing law.

53. *Cf. Hobby Lobby*, 573 U.S. 728 ("The most straightforward way of doing this 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.").

See 42 U.S.C. § 2000bb-1(b)(2); *see also Hobby Lobby*, 573 U.S. at 729–30 ("[W]e see nothing in RFRA that supports" the argument that "'RFRA cannot be used to require creation of entirely new programs' . . . and drawing the line between the 'creation of an entirely new program' and the modification of an existing program (which RFRA surely allows) would be fraught with problems."). Courts that apply strict scrutiny in other contexts consider only whether it is possible to imagine a way to accomplish the purported goal in a manner that is less restrictive of constitutional freedoms—and they are entirely unconcerned with whether their imagined alternatives are authorized by existing law. *See, e.g.*, *McCullen v. Coakley*, 134 S. Ct. 2518, 2530 (2014) ("In discussing whether the Act is narrowly tailored, . . . we identify a number of less-restrictive alternative measures that the Massachusetts Legislature *might have adopted*." (emphasis added)); *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520, 546 (1993) ("The proffered objectives . . . *could be achieved by narrower ordinances* that burdened religion to a far lesser degree." (emphasis added)). RFRA's strict scrutiny must be applied with at least as much rigor. *See Hobby Lobby*, 573 U.S. at 728 ("The least-restrictive-means-standard is exceptionally demanding").

CONCLUSION

The plaintiffs' motion for summary judgment should be granted.

Respectfully submitted.

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