

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

John Kelley; Joel Starnes; Gregory Scheideman; Zach Maxwell; Ashley Maxwell; Donovan Riddle; Karla Riddle; Joel Miller; Kelley Orthodontics; and Braidwood Management Inc.,

Plaintiffs,

v.

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

Alex M. Azar II, in his official capacity as Secretary of Health and Human Services; **Steven T. Mnuchin**, in his official capacity as Secretary of the Treasury; **Eugene Scalia**, in his official capacity as Secretary of Labor; **United States of America**,

Defendants.

FIRST AMENDED COMPLAINT

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. 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. A few months ago, 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.

All of these agency-issued preventive-care mandates are unlawful, and some of them violate the Religious Freedom Restoration Act as well. The Court should enjoin the defendants from enforcing any of these agency-issued preventive-care mandates.

JURISDICTION AND VENUE

1. The Court has subject-matter jurisdiction under 28 U.S.C. § 1331 and 28 U.S.C. § 1343.

2. Venue is proper because a substantial part of the events giving rise to the claims occurred in this judicial district. *See* 28 U.S.C. § 1391(b)(2).

PARTIES

3. Plaintiff John Kelley resides in Tarrant County, Texas.

4. Plaintiff Joel Starnes resides in Tarrant County, Texas.

5. Plaintiff Gregory Scheideman resides in Tarrant County, Texas.

6. Plaintiff Zach Maxwell resides in Hood County, Texas.

7. Plaintiff Ashley Maxwell resides in Hood County, Texas.

8. Plaintiff Donovan Riddle resides in Hood County, Texas.

9. Plaintiff Karla Riddle resides in Hood County, Texas.

10. Plaintiff Joel Miller resides in Parker County, Texas.

11. Plaintiff Kelley Orthodontics (“Kelley Orthodontics”) is a professional association located in Tarrant County, Texas.

12. Plaintiff Braidwood Management Inc. (“Braidwood”) is a for-profit, closely held corporation incorporated under the laws of Texas.

13. Defendant Alex M. Azar II is the U.S. Secretary of Health and Human Services. His office is located at 200 Independence Avenue SW, Washington, D.C. 20201. Secretary Azar is sued in his official capacity.

14. Defendant Steven T. Mnuchin is the U.S. Secretary of the Treasury. His office is located at 1500 Pennsylvania Avenue NW, Washington, D.C. 20220. Secretary Mnuchin is sued in his official capacity.

15. Defendant Eugene Scalia is the U.S. Secretary of Labor. His office is located at 200 Constitution Avenue NW, Washington, D.C. 20210. Secretary Scalia is sued in his official capacity.

16. Defendant United States of America is the federal government of the United States of America.

THE AFFORDABLE CARE ACT'S PREVENTIVE-CARE MANDATES

17. 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) (attached as Exhibit 1).

18. A separate provision of the Affordable Care Act requires group health plans and health-insurance issuers 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,” and to do so without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(2) (attached as Exhibit 1).

19. 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) (attached as Exhibit 1).

20. 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) (attached as Exhibit 1).

THE HRSA’S CONTRACEPTIVE MANDATE

21. 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). These HRSA guidelines of August 1, 2011, did not go through notice-and-comment rulemaking procedures.

22. 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) (attached as Exhibits 2–4).

23. 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.

24. 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).

25. 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.

26. 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 and Paul Home v. Pennsylvania*,

No. 19-431 (July 8, 2020), but the litigation over the Trump Administration's rule continues, and the plaintiffs in *Pennsylvania v. Trump* have vowed to seek a new nationwide injunction against the rule on remand.

27. 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); *see also* Exhibit 5 (final judgment in *DeOtte*). 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, even though the final rule itself remains subject to litigation.

28. 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.

THE U.S. PREVENTIVE SERVICES TASK FORCE'S PrEP MANDATE

29. On June 11, 2019—more than nine years after the Affordable Care Act was signed into law—the U.S. Preventive Services Task Force recommended that health insurance cover preexposure prophylaxis (PrEP) drugs without any cost-sharing arrangements such as co-payments or deductibles. The U.S. Preventive Services Task Force gave PrEP an “A” rating, which requires private insurance to cover PrEP drugs

without any cost-sharing arrangements under the terms of 42 U.S.C. § 300gg-13(a)(1). *See* <https://bit.ly/2NyeXJM> (last visited on July 20, 2020) (attached as Exhibit 6).

30. The Task Force's recommendation of June 11, 2019, did not go through notice-and-comment procedures.

31. The Task Force's recommendation does not compel immediate coverage of PrEP drugs, because 42 U.S.C. § 300gg-13(b) requires the Secretary to "establish a minimum interval" between the date of a Task Force recommendation and the plan year for the compulsory coverage must take effect. *See* 42 U.S.C. § 300gg-13(b)(1). This "minimum interval" may not be less than one year. *See* 42 U.S.C. § 300gg-13(b)(2). As a result, compulsory coverage of PrEP drugs will not take effect until 2021.

ALLEGATIONS RELATED TO ARTICLE III STANDING

32. Each of the plaintiffs is suffering injury in fact on account of these coverage mandates.

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

33. Plaintiffs John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell are responsible for providing health coverage for themselves and their respective families.

34. The preventive-care coverage mandates, however, make it impossible for these plaintiffs to purchase health insurance unless they agree to pay for preventive-care coverage that they do not want and do not need.

35. Mr. Kelley, Mr. Starnes, Mr. Maxwell, and Ms. Maxwell do not need or want contraceptive coverage in their health insurance. They do not want or need free STD testing covered by their health insurance because they are in monogamous relationships with their respective spouses. And they do not want or need health insurance

that covers Truvada or PrEP drugs because neither they nor any of their family members are engaged in behavior that transmits HIV. The defendants' enforcement of 42 U.S.C. § 300gg-13, however, makes it impossible for these plaintiffs to purchase less expensive health insurance that excludes this unwanted coverage, thereby inflicting injury in fact.

36. Mr. Kelley, Mr. Starnes, Mr. Maxwell, and Ms. Maxwell also object to contraceptive coverage and the coverage of PrEP drugs on religious grounds. Each of these plaintiffs is a Christian, and they are unwilling to purchase health insurance that subsidizes abortifacient contraception or PrEP drugs that encourage and facilitate homosexual behavior.

37. The federal Contraceptive Mandate continues to inflict injury in fact on these plaintiffs and other religious objectors who wish to purchase health insurance. Although the *DeOtte* injunction permits issuers of health insurance to issue group or individual health-insurance coverage that excludes abortifacient contraception to religious objectors, few if any insurance companies are offering health insurance of this sort. And even if a health insurer were willing to create and offer a policy that excludes abortifacient contraceptive coverage solely for religious objectors, the Contraceptive Mandate drastically restricts the available options on the market to consumers who hold religious objections to abortifacients. The Mandate requires any policy that covers *anyone* who lacks a sincere religious objection to contraception to cover all forms of FDA-approved contraceptive methods, without any deductibles or co-pays. Without the federal Contraceptive Mandate, insurers will have the freedom to offer policies that exclude contraceptive coverage to the general public, just as they did before the Contraceptive Mandate, which will expand the health-insurance options available to consumers who oppose abortifacient contraceptive coverage for sincere religious reasons.

38. Each of these plaintiffs' injuries is caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling private insurance to provide this unwanted coverage.

B. Plaintiffs Donovan Riddle and Karla Riddle

39. Plaintiffs Donovan Riddle and Karla Riddle are responsible for providing health coverage for themselves and their family.

40. Neither Mr. nor Mrs. Riddle has religious or moral objections to any of the FDA-approved contraceptive methods. But they do not want or need contraceptive coverage in their health insurance because Mrs. Riddle had a hysterectomy after giving birth to her daughter 18 years ago.

41. The preventive-care coverage mandates, however, make it impossible for Mr. and Mrs. Riddle to purchase health insurance unless they agree to pay for contraceptive coverage and other preventive-care coverage that they do not want and do not need.

42. The Riddles are unprotected by the *DeOtte* injunction and the Trump Administration's rules that exempt religious and moral objectors from the Contraceptive Mandate, because they do not hold religious or moral objections to any of the FDA-approved contraceptive methods. Their objection to the Contraceptive Mandate is based solely on the fact that they not need or want contraceptive coverage on account of Mrs. Riddle's hysterectomy.

43. Mr. and Mrs. Riddle's injuries are caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling private insurance to provide this unwanted coverage.

C. Plaintiff Joel Miller

44. Plaintiff Joel Miller is responsible for providing health coverage for himself and his family.

45. Mr. Miller does not hold religious or moral objections to any of the FDA-approved contraceptive methods. But he does not want or need contraceptive coverage in his health insurance because his wife is past her childbearing years.

46. The preventive-care coverage mandates, however, make it impossible for Mr. Miller to purchase health insurance unless he agrees to pay for contraceptive coverage and other preventive-care coverage that he does not want or need.

47. Mr. Miller is unprotected by the *DeOtte* injunction and the Trump Administration's rules that exempt religious and moral objectors from the Contraceptive Mandate, because Mr. Miller does not hold religious or moral objections to any of the FDA-approved contraceptive methods. Mr. Miller's objection to the Contraceptive Mandate is based solely on the fact that he does not need or want contraceptive coverage because his wife is past her childbearing years.

48. Mr. Miller's injuries are caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling private insurance to provide this unwanted coverage.

D. Plaintiff Gregory Scheideman

49. Plaintiff Gregory Scheideman is responsible for providing health coverage for himself and his family. 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.

50. The preventive-care coverage mandates, however, make it impossible for Dr. Scheideman to purchase health insurance unless he agrees to pay for preventive-care coverage that he does not want or need.

51. The preventive-care coverage mandates also force Dr. Scheideman's company to pay higher premiums for health insurance that must cover preventive care free of charge as decreed by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration. This deprives Dr. Scheideman of the option of purchasing less expensive health insurance for his employees with less extensive coverage of preventive care.

52. Dr. Scheideman's injuries are caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling private insurance to provide this unwanted coverage.

E. Plaintiff Kelley Orthodontics

53. Kelley Orthodontics is a Christian professional association owned by plaintiff John Kelley.

54. Kelley Orthodontics employs numerous individuals as employees.

55. Kelley Orthodontics wishes to provide health insurance for its employees that excludes coverage of contraception, PrEP drugs, and other preventive care required by the defendants' current interpretation and enforcement of 42 U.S.C. § 300gg-13.

56. The Contraceptive Mandate and the PrEP mandate, and the defendants' current interpretation and enforcement of 42 U.S.C. § 300gg-13, make it impossible for Kelley Orthodontics to purchase health insurance that excludes this unwanted coverage, thereby inflicting injury in fact.

57. Kelley Orthodontics's injury is caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling private insurance to provide this unwanted coverage.

F. Plaintiff Braidwood Management Inc.

58. Dr. Steven F. Hotze is the founder, owner, and CEO of the Hotze Health & Wellness Center. The Hotze Health & Wellness Center is the DBA (“doing business as”) name of Hotze Medical Association P.A., a Texas professional association.

59. The people who work at the Hotze Health & Wellness Center are employed by a separate management company called Braidwood Management Inc. Braidwood Management Inc. is a Texas corporation, and it is owned by a trust of which Dr. Hotze is the sole trustee and beneficiary. Dr. Hotze is also the President, Secretary, Treasurer, and sole member of the Board of Braidwood Management Inc.

60. Braidwood Management Inc. employs approximately 70 individuals, and its employees work at one of the following three business entities, each of which is owned or controlled by Dr. Hotze: the Hotze Health & Wellness Center, Hotze Vitamins, or Physicians Preference Pharmacy International LLC.

61. Braidwood Management Inc. is self-insured and provides health insurance to its employees. 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).

62. Dr. Hotze is a Christian, and he operates his business according to Christian principles and teaching.

63. Dr. Hotze is therefore unwilling to allow Braidwood’s self-insured plan to cover PrEP drugs such as Truvada and Descovy because these drugs facilitate or encourage homosexual behavior, which is contrary to Dr. Hotze’s sincere religious beliefs.

64. Dr. Hotze objects to the other preventive-care coverage mandates imposed by the defendants because Dr. Hotze wants the freedom to decide the extent to which Braidwood’s plan will cover preventive care, and whether it will charge copays or re-

quire preventive care to count toward an annual deductible. The preventive-care coverage mandates deprive Dr. Hotze and Braidwood of these choices and makes the provision of health care to Braidwood's employees more costly and expensive.

65. Braidwood Management Inc.'s injury is caused by the defendants' enforcement of 42 U.S.C. § 300gg-13, and it will be redressed by declaratory and injunctive relief that prevents the defendants from compelling self-insured health plans to provide this unwanted coverage.

CLAIM NO. 1—42 U.S.C. § 300gg-13(a)(1)–(4) VIOLATE THE APPOINTMENTS CLAUSE

66. 42 U.S.C. § 300gg-13(a)(1) requires private insurance 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

67. 42 U.S.C. § 300gg-13(a)(2) requires private insurance 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

68. 42 U.S.C. § 300gg-13(a)(3) requires private insurance 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.

69. 42 U.S.C. § 300gg-13(a)(4) requires private insurance to cover:

with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

70. Each of these four statutes, as currently interpreted, violates the Constitution's Appointments Clause, which 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.

71. 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,” because they exercise “significant authority pursuant to the laws of the United States.” *See 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.”); *see also* Jennifer L. Mascott, *Who Are “Officers of the United States”?*, 70 *Stan. L. Rev.* 443 (2018). The power to unilaterally determine the “preventive care” that all health insurance must cover without cost-sharing qualifies as “significant authority pursuant to the laws of the United States.”

72. Yet none of the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration have been nominated by the President or confirmed by the Senate, as required by the Appointments Clause. In addition, none of the members of these agencies can reasonably be characterized as “inferior officers” when they have been given far-reaching powers to unilaterally decree the preventive care that health insurance must cover without any cost-sharing arrangements.

73. Even if the members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration could somehow be considered “inferior officers” under Article II of the

Constitution, 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.

74. 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).

75. In addition, the plaintiffs have not been able 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.

76. 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.

77. The Court should therefore 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 permanently enjoin the defendants from enforcing them.

78. 42 U.S.C. § 300gg-13(a)(1) can be interpreted to avoid this constitutional problem if the phrase “current recommendations” is construed to refer only to the Task Force recommendations that existed on March 23, 2010—the date on which

the Affordable Care Act was signed into law. 42 U.S.C. § 300gg-13(a)(2)–(4) can likewise be construed to avoid this constitutional problem if they are interpreted to refer only to agency recommendations and guidelines that existed on March 23, 2010. *See* paragraphs 96–107, *infra*; *see also Carcieri v. Salazar*, 555 U.S. 379, 395 (2009). These interpretations of 42 U.S.C. § 300gg-13(a)(1)–(4) will obviate any Appointments Clause problem because the statute will merely incorporate and codify the agencies’ *previous* recommendations, rather than empowering the members of these agencies to unilaterally determine the preventive care that private insurance must cover.

79. Indeed, a court is obligated to adopt this construction of the statute regardless of whether it is ultimately persuaded by the plaintiffs’ Appointments Clause arguments, because ambiguities in federal statutes must be interpreted in a manner that will avoid serious constitutional questions. *See 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.” (citation and internal quotation marks omitted)); *Ellis v. Bhd. of Ry., Airline & S.S. Clerks, Freight Handlers, Exp. & Station Employees*, 466 U.S. 435, 444 (1984) (“When the constitutionality of a statute is challenged, this Court first ascertains whether the statute can be reasonably construed to avoid the constitutional difficulty.”); *Ohio v. Akron Ctr. for Reprod. Health*, 497 U.S. 502, 514 (1990) (“[W]here fairly possible, courts should construe a [state] statute to avoid a danger of unconstitutionality.” (citation and internal quotation marks omitted)); *see also Gundy v. United States*, 139 S. Ct. 2116, 2123–24 (2019) (plurality opinion of Kagan, J.); Cass R. Sunstein, *Nondelegation Canons*, 67 U. Chi. L. Rev. 315 (2000) (describing how canons of construction have been used to support nondelegation principles, and urging

courts use the canons of construction to ensure that statutes are interpreted in a manner that avoids potential nondelegation issues).

80. So the Court should, at the very least, interpret 42 U.S.C. § 300gg-13(a)(1)–(4) to avoid these serious constitutional questions under the Appointments Clause, by declaring that 42 U.S.C. § 300gg-13(a)(1), as a matter of statutory interpretation, requires insurers to cover only the items or services that had an “A” or “B” rating from the U.S. Preventive Services Task Force on March 23, 2010—the date on which the Affordable Care Act was signed into law. It should likewise declare that 42 U.S.C. § 300gg-13(a)(2) requires insurers to cover only the immunizations that were recommended by the Advisory Committee on Immunization Practices on March 23, 2010, and that 42 U.S.C. § 300gg-13(a)(3)–(4) require insurers to cover only the preventive care and screenings provided for in HRSA guidelines in existence on that date. And the Court should enjoin the defendants from enforcing any preventive-care mandate derived from an agency rating, recommendation, or guideline that issued after March 23, 2010.

**CLAIM NO. 2—42 U.S.C. § 300gg-13(a)(1)–(4) VIOLATE THE
NONDELEGATION DOCTRINE**

81. 42 U.S.C. § 300gg-13(a)(1) requires private insurance 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

82. 42 U.S.C. § 300gg-13(a)(2) requires private insurance 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

83. 42 U.S.C. § 300gg-13(a)(3) requires private insurance 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.

84. 42 U.S.C. § 300gg-13(a)(4) requires private insurance to cover:

with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

85. To the extent that 42 U.S.C. § 300gg-13(a)(1)–(4) empower future iterations of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration to unilaterally determine preventive care that private insurance must cover, they unconstitutionally delegate legislative power without providing an “intelligible principle” to guide the agencies’ discretion.

86. The court should therefore declare that 42 U.S.C. § 300gg-13(a)(1)–(4) violate Article I by unconstitutionally delegating legislative power to the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration. The court should further declare that any preventive-care mandate derived from an agency rating, recommendation, or guideline that was issued after March 23, 2010—the date on which the Affordable Care Act was signed into law—is unconstitutional and unenforceable.

87. 42 U.S.C. § 300gg-13(a)(1) can be interpreted to avoid this constitutional nondelegation problem if the phrase “current recommendations” is construed to refer only to the Task Force recommendations that existed on March 23, 2010—the date on which the Affordable Care Act was signed into law. 42 U.S.C. § 300gg-13(a)(2)–(4) can likewise be construed to avoid this constitutional problem if they are interpreted to refer only to agency recommendations and guidelines that existed on March 23, 2010. *See* paragraphs 96–107, *infra*; *see also Carcieri v. Salazar*, 555 U.S. 379, 395 (2009). These interpretations of 42 U.S.C. § 300gg-13(a)(1)–(4) will obviate

any nondelegation problem because the statute will merely incorporate and codify the agencies' *previous* recommendations, rather than empowering the agencies to unilaterally determine the preventive care that private insurance must cover without an "intelligible principle" to guide their discretion.

88. Indeed, a court is obligated to adopt this construction of the statute regardless of whether it is ultimately persuaded by the plaintiffs' nondelegation arguments, because ambiguities in federal statutes must be interpreted in a manner that will avoid serious constitutional questions and avoid conferring unguided discretion on an administrative agency. *See* authorities cited in paragraph 78, *supra*.

89. So the Court should, at the very least, declare that 42 U.S.C. § 300gg-13(a)(1), as a matter of statutory interpretation, requires insurers to cover only the items or services that had an "A" or "B" rating from the U.S. Preventive Services Task Force on March 23, 2010—the date on which the Affordable Care Act was signed into law. The Court should likewise declare that 42 U.S.C. § 300gg-13(a)(2) requires insurers to cover only the immunizations that were recommended by the Advisory Committee on Immunization Practices on March 23, 2010, and that 42 U.S.C. § 300gg-13(a)(3)–(4) require insurers to cover only the preventive care and screenings provided for in HRSA guidelines in existence on that date. And the Court should enjoin the defendants from enforcing any preventive-care mandate derived from an agency rating, recommendation, or guideline that issued after March 23, 2010.

**CLAIM NO. 3—42 U.S.C. § 300gg-13(a)(1)
VIOLATES ARTICLE II'S VESTING CLAUSE**

90. If the Court somehow 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.

91. 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.

92. There is nothing wrong with immunizing a purely advisory committee from presidential direction and control. But the U.S. Preventive Services Task Force ceased to be an advisory committee when Congress enacted 42 U.S.C. § 300gg-13(a)(1), and empowered the Task Force to unilaterally decree the preventive care that health insurance must cover.

93. 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.

94. 42 U.S.C. § 300gg-13(a)(1) can be interpreted to avoid this serious constitutional question under Article II’s vesting clause if the phrase “current recommendations” is construed to refer only to the Task Force recommendations that existed on March 23, 2010—the date on which the Affordable Care Act was signed into law. *See* paragraphs 96–98, *infra*; *see also Carcieri v. Salazar*, 555 U.S. 379, 395 (2009).

This interpretation of 42 U.S.C. § 300gg-13(a)(1) will obviate any problem under Article II’s vesting clause because the statute will merely incorporate and codify the Task Force’s *previous* recommendations, rather than empowering the Task Force members to unilaterally determine the preventive care that private insurance must cover without being subject to the President’s direction, removal, and control.

95. Indeed, a court is obligated to adopt this construction of the statute regardless of whether it is ultimately persuaded by the plaintiffs’ vesting-clause arguments, because ambiguities in federal statutes must be interpreted in a manner that will avoid serious constitutional questions. *See* cases cited in paragraph 78, *supra*.

CLAIM NO. 4—42 U.S.C. § 300gg-13(a)(1)–(4) MUST BE CONSTRUED, AS A MATTER OF STATUTORY INTERPRETATION, TO REFER TO THE RATINGS, RECOMMENDATIONS, OR GUIDELINES THAT EXISTED ON THE DATE THAT THE AFFORDABLE CARE ACT WAS ENACTED INTO LAW

96. 42 U.S.C. § 300gg-13(a)(1) requires private insurance 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

42 U.S.C. § 300gg-13(a)(1) (emphasis added).

97. The phrase “current recommendations of the United States Preventive Services Task Force” must be construed, as a matter of statutory interpretation, to refer to the recommendations of the United States Preventive Services Task Force that existed on March 23, 2010—the date on which the statute was enacted into law—rather than the Task Force recommendations that exist today. *See Carcieri v. Salazar*, 555 U.S. 379, 395 (2009) (holding that the phrase “any recognized Indian tribe *now* under Federal jurisdiction” in the Indian Reorganization Act “unambiguously refers to those tribes that were under the federal jurisdiction of the United States when the IRA was enacted in 1934,” not to those tribes that are under federal jurisdiction today).

98. The canon of constitutional avoidance compels this interpretation of 42 U.S.C. § 300gg-13(a)(1), because the contrary interpretation will violate the Appointments Clause, the non-delegation doctrine, and the vesting clause of Article II, or at least raise serious constitutional questions under each of those constitutional provisions and doctrines. *See* paragraphs 66–94, *supra*.

99. 42 U.S.C. § 300gg-13(a)(2) requires private insurance 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) (emphasis added).

100. The phrase “have in effect a recommendation from the Advisory Committee on Immunization Practices” must be construed, as a matter of statutory interpretation, to refer to the recommendations of the Advisory Committee on Immunization Practices that existed on March 23, 2010—the date on which the statute was enacted into law—rather than the Advisory Committee recommendations that exist today. *See Carcieri*, 555 U.S. at 395.

101. The canon of constitutional avoidance compels this interpretation of 42 U.S.C. § 300gg-13(a)(2), because the contrary interpretation will violate the Appointments Clause and the non-delegation doctrine, or at least raise serious constitutional questions under each of those constitutional provisions and doctrines. *See* paragraphs 66–89, *supra*.

102. 42 U.S.C. § 300gg-13(a)(3) requires private insurance 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*.

42 U.S.C. § 300gg-13(a)(3) (emphasis added).

103. The phrase “comprehensive guidelines supported by the Health Resources and Services Administration” must be construed, as a matter of statutory interpretation, to refer to the guidelines of the Health Resources and Services Administration that existed on March 23, 2010—the date on which the statute was enacted into law—rather than the HRSA recommendations that exist today. *See Carcieri*, 555 U.S. at 395.

104. The canon of constitutional avoidance compels this interpretation of 42 U.S.C. § 300gg-13(a)(3), because the contrary interpretation will violate the Appointments Clause and the non-delegation doctrine, or at least raise serious constitutional questions under each of those constitutional provisions and doctrines. *See* paragraphs 66–89, *supra*.

105. 42 U.S.C. § 300gg-13(a)(4) requires private insurance to cover:

with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in *comprehensive guidelines supported by the Health Resources and Services Administration* for purposes of this paragraph.

106. The phrase “comprehensive guidelines supported by the Health Resources and Services Administration” must be construed, as a matter of statutory interpretation, to refer to the guidelines of the Health Resources and Services Administration that existed on March 23, 2010—the date on which the statute was enacted into law—rather than the HRSA recommendations that exist today. *See Carcieri*, 555 U.S. at 395.

107. The canon of constitutional avoidance compels this interpretation of 42 U.S.C. § 300gg-13(a)(4), because the contrary interpretation will violate the Appointments Clause and the non-delegation doctrine, or at least raise serious constitutional questions under each of those constitutional provisions and doctrines. *See* paragraphs 66–89, *supra*.

**CLAIM NO. 5—THE PrEP MANDATE VIOLATES THE
RELIGIOUS FREEDOM RESTORATION ACT**

108. The PrEP mandate violates the Religious Freedom Restoration Act by forcing self-insured religious employers to underwrite coverage that violates their religious beliefs, and by making it impossible for religious individuals and employers to purchase health insurance that excludes this objectionable coverage. This imposes a substantial burden on the religious freedom of those who oppose homosexual behavior on religious grounds.

109. The PrEP mandate forces religious employers to provide coverage for drugs that facilitate and encourage homosexual behavior, prostitution, sexual promiscuity, and intravenous drug use. It also compels religious employers and religious individuals who purchase health insurance to subsidize these behaviors as a condition of purchasing health insurance. This substantially burdens the exercise of religion. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724–26 (2014); *DeOtte v. Azar*, 393 F. Supp. 3d 490, 509 (N.D. Tex. 2019).

110. There is no compelling governmental interest in providing PrEP drugs at zero marginal cost. And even if there were, there are ways to achieve this goal in a manner that is less restrictive of the plaintiffs' religious freedom.

111. The Court should therefore enjoin the defendants from enforcing the PrEP mandate against the plaintiffs or any other individual or employer who objects to the coverage of PrEP drugs for sincere religious reasons.

DEMAND FOR RELIEF

112. The plaintiffs respectfully request that the court:

- a. declare that 42 U.S.C. § 300gg-13(a)(1)–(4) violate the Appointments Clause by empowering individuals who have not been appointed in conformity with the Appointments Clause to unilaterally determine the preventive care that health insurance must cover;
- b. declare that 42 U.S.C. § 300gg-13(a)(1)–(4) violate Article I of the Constitution by delegating legislative power to the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration without providing an “intelligible principle” to guide the agencies’ discretion;
- c. declare 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 that preventive care that health insurance must cover while simultaneously immunizing that agency from the President’s direction, removal, or control;
- d. in the alternative, declare that 42 U.S.C. § 300gg-13(a)(1), as a matter of statutory interpretation, requires insurers to cover only the items or services that had an “A” or “B” rating from the U.S. Preventive Services Task Force on March 23, 2010, that 42 U.S.C. § 300gg-13(a)(2) requires insurers to cover only the immunizations that were recommended by the Advisory Committee on Immunization Practices as of March 23, 2010, and that 42 U.S.C. § 300gg-13(a)(3)–(4) require insurers to cover only the preventive care and screenings provided for in HRSA guidelines in existence on March 23, 2010;
- e. permanently enjoin the defendants from enforcing any coverage mandate based upon an agency rating, recommendation, or guideline that issued after March 23, 2010;
- f. declare that the PrEP mandate violates the Religious Freedom Restoration Act, and permanently enjoin the defendants from enforcing it against any individual or employer who objects to the coverage of PrEP drugs for sincere religious reasons;
- g. award costs and attorneys’ fees under 42 U.S.C. § 1988;
- h. award all other relief that the Court deems just, proper, or equitable.

Respectfully submitted.

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CERTIFICATE OF SERVICE

I certify that on July 20, 2020, I served this document through CM/ECF upon:

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