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

John Kelley and Joel Starnes, on behalf of themselves and others similarly situated; Kelley Orthodontics, on behalf of itself and others similarly situated; Braidwood Management Inc., on behalf of itself and others similarly situated,

Plaintiffs,

v.

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, Case No. 4:20-cv-00283

Defendants.

COMPLAINT—CLASS ACTION

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 several of them—such as the mandates to cover contraception and PrEP drugs—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 Kelley Orthodontics ("Kelley Orthodontics") is a professional association located in Tarrant County, Texas.

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

7. 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.

8. 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. 9. 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.

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

THE AFFORDABLE CARE ACT'S PREVENTIVE-CARE MANDATES

11. 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).

12. 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).

13. 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 copays. *See* 42 U.S.C. § 300gg-13(a)(3) (attached as Exhibit 1).

14. 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

15. 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.

16. 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).

17. 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.

18. 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).

19. 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.

20. 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 has granted certiorari to review the Third Circuit's decision, but the nationwide injunction against the enforcement of the Trump Administration's rules remains in effect.

21. In response to this nationwide injunction, 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 the nationwide injunction issued in the *Pennsylvania* litigation.

22. 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 want contraceptive coverage.

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

23. 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 March 29, 2020) (attached as Exhibit 6).

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

25. 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

26. Each of the plaintiffs—John Kelley, Joel Starnes, Kelley Orthodontics, and Braidwood Management Inc.—is suffering injury in fact on account of these coverage mandates, and each of them sues as a class representative to enjoin their enforcement.

A. Plaintiff John Kelley

27. Mr. Kelley is responsible for providing health coverage for himself and his family.

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

29. Mr. Kelley has no desire to purchase health insurance that includes contraceptive coverage because his wife is past her child-bearing years. He does not want or need STD testing covered by his health insurance because he and his wife are monogamous. And he does not want or need health insurance that covers Truvada or PrEP drugs because neither he nor any of his family members is engaged in behavior that transmits HIV. The defendants' enforcement of 42 U.S.C. § 300gg-13, however, makes it impossible for Mr. Kelley to purchase health insurance that excludes this unwanted coverage, thereby inflicting injury in fact.

30. Mr. Kelley is also a Christian, and he is therefore unwilling to purchase health insurance that subsidizes abortifacient contraception or PrEP drugs that encourage homosexual behavior and intravenous drug use.

31. The Contraceptive Mandate continues to inflict injury in fact on Mr. Kelley and other religious objectors who wish to purchase health insurance. Although the

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DeOtte injunction permits issuers of health insurance to issue group or individual health-insurance coverage that excludes contraception to religious objectors, few insurance companies are offering health insurance of that sort. And even if contraceptive-free health insurance were widely available for purchase, the Contraceptive Mandate would still inflict injury in fact on Mr. Kelley and other individual religious objectors by limiting the scope of available health insurance that excludes this unwanted contraceptive coverage.

32. Mr. Kelley sues, along with plaintiff Joel Starnes, as representatives of a class of all current and future individuals and entities in the United States who: (1) purchase or wish to purchase health insurance; and (2) wish to purchase insurance that excludes or limits coverage of some or all of the preventive care required by 42 U.S.C. § 300gg-13.

33. Mr. Kelley'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.

B. Plaintiff Joel Starnes

34. Mr. Starnes is responsible for providing health coverage for himself and his family.

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

36. Mr. Starnes has no desire to purchase health insurance that includes contraceptive coverage. He does not want or need STD testing covered by his health insurance because he and his wife are monogamous. And he does not want or need health insurance that covers Truvada or PrEP drugs because neither he nor any of his family members is engaged in behavior that transmits HIV. The defendants' enforcement of 42 U.S.C. § 300gg-13, however, makes it impossible for Mr. Starnes to purchase health insurance that excludes this unwanted coverage, thereby inflicting injury in fact.

37. Mr. Starnes is also a Christian, and he is therefore unwilling to purchase health insurance that subsidizes abortifacient contraception or PrEP drugs that encourage homosexual behavior or intravenous drug use.

38. The Contraceptive Mandate continues to inflict injury in fact on Mr. Starnes 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 contraception to religious objectors, few if any insurance companies are offering health insurance of this sort. And even if contraceptive-free health insurance were widely available for purchase, the Contraceptive Mandate would still inflict injury in fact on Mr. Starnes and other individual religious objectors by limiting the scope of available health insurance that excludes this unwanted contraceptive coverage.

39. Mr. Starnes sues, along with plaintiff John Kelley, as representatives of a class of all current and future individuals and entities in the United States who: (1) purchase or wish to purchase health insurance; and (2) wish to purchase insurance that excludes or limits coverage of some or all of the preventive care required by 42 U.S.C. § 300gg-13.

40. Mr. Starnes'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.

C. Plaintiff Kelley Orthodontics

41. Kelley Orthodontics is a Christian professional association owned by plaintiff John Kelley. 42. Kelley Orthodontics employs numerous individuals as employees.

43. 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.

44. 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.

45. Kelley Orthodontics sues as representative of a class of all current and future employers in the United States who: (1) purchase or wish to purchase health insurance for their employees; and (2) wish to purchase insurance that excludes or limits coverage of some or all of the preventive care required by 42 U.S.C. § 300gg-13.

46. 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.

D. Plaintiff Braidwood Management Inc.

47. 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.

48. 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.

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49. 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.

50. 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).

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

52. 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 behaviors such as homosexual sodomy, prostitution, and intravenous drug use—all of which are contrary to Dr. Hotze's sincere religious beliefs.

53. Dr. Hotze also objects to other preventive-care mandates that require Braidwood's plan to cover STD screenings and counseling for those engaged in non-marital sexual behavior.

54. Braidwood Management Inc. sues as representative of a class of all current and future employers in the United States who: (1) operate self-insured health plans; and (2) wish to exclude or limit coverage of some or all of the preventive care required by 42 U.S.C. § 300gg-13.

55. 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

56. 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

57. 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

58. 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.

59. 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.

60. Each of these four statutes, as currently interpreted, violates the Constitu-

tion'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.

61. The members of the U.S. Preventive Services Task Force, the Advisory Com-

mittee on Immunization Practices, and the Health Resources and Services Admin-

istration 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."

62. 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.

63. 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.

64. 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).

65. 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.

66. 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.

67. 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.

68. 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 86–97, *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.

69. 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).

70. 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

71. 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

72. 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

73. 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.

74. 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.

75. 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.

76. 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.

77. 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 86–97, *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.

78. 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 68, *supra*.

79. 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

80. 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.

81. 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.

82. 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.

83. 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 preventivecare mandates derived from a Task Force pronouncement that issued after March 23, 2010, should be declared unconstitutional and unenforceable.

84. 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 86–88, *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.

85. 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 68, *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

86. 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).

87. 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 to-day).

88. 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 56–84, *supra*.

89. 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).

90. 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.

91. 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 56–79, *supra*.

92. 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 guide-lines supported by the Health Resources and Services Administration*.

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

93. 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.

94. 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 56–79, *supra*.

95. 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.

96. 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.

97. 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 56–79, *supra*.

CLAIM NO. 5—VIOLATIONS OF THE ADMINISTRATIVE PROCEDURE ACT

98. Section 553 of the Administrative Procedure Act requires federal agencies to issue their rules through notice-and-comment procedures unless an exception applies. *See* 5 U.S.C. § 553.

99. The preventive-care mandates that have been issued by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration all qualify as "rules" under the APA, yet they have failed to go through notice-and-comment procedures as required by section 553.

100. None of the statutory exceptions to notice-and-comment rulemaking are applicable to the preventive-care announcements of the U.S. Preventive Services Task

Force, the Advisory Committee on Immunization Practices, or the Health Resources and Services Administration.

101. The Court should therefore declare that any preventive-care 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, is invalid and unenforceable unless and until it goes through notice-and-comment procedures, and it should hold unlawful and set aside those ratings, recommendations, or guidelines under section 706 of the APA.

102. The Court should further declare that any agency action taken to implement a preventive-care mandate based upon 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, that failed to go through notice-and-comment procedures is invalid and unenforceable, and it should hold unlawful and set aside those agency actions under section 706 of the APA and enjoin the defendants from enforcing them.

CLAIM NO. 6—CONTRACEPTION AND STERILIZATIONS DO NOT QUALIFY AS "PREVENTIVE CARE" UNDER 42 U.S.C. § 300gg-13(a)(4)

103. 42 U.S.C. § 300gg-13(a)(4) authorizes the Health Resources and Services Administration to mandate coverage "with respect to women" of "such additional preventive care and screenings not described in paragraph (1)."

104. On August 1, 2011, the HRSA released guidelines requiring that all FDAapproved contraceptive methods and sterilization for women be covered as "preventive care" under 42 U.S.C. § 300gg-13(a)(4).

105. These HRSA guidelines of August 1, 2011, are unlawful—as are the subsequent regulations that the defendants have issued to implement these HRSA's guidelines—because neither contraception nor sterilization qualifies as "preventive care" under 42 U.S.C. § 300gg-13(a)(4). Pregnancy is not a disease; it is a natural human function that is essential for the survival and propagation of the human race. Drugs and surgeries that are used only for the prevention of pregnancy—and for no other purpose apart from the prevention of pregnancy—are not "preventive care" because they do nothing to prevent disease or illness.¹

106. Women also have the capacity to avoid pregnancy by refraining from sexual intercourse, so neither contraception nor sterilization is needed to "prevent" the onset of pregnancy. Some women are understandably reluctant to rely on abstinence as a birth-control strategy, but an unwillingness to practice abstinence does not create a medical condition that needs to be remedied with "preventive care." Contraception and sterilization are simply devices that enable women who do not wish to become pregnant—but who are unwilling to refrain from sexual intercourse—to engage in sexual intercourse while greatly reducing their risk of pregnancy. That is not "preventive care" of any sort.

107. The HRSA's interpretation of "preventive care" is not entitled to *Chevron* deference because Congress did not delegate interpretive authority over the meaning of this statutory phrase to the HRSA. *See United States v. Mead Corp.*, 533 U.S. 218, 234–35 (2001); *see also* 5 U.S.C. § 706 ("[T]he reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions.").

108. In addition, the canon of constitutional avoidance compels the courts to interpret the phrase "preventive care" in 42 U.S.C. § 300gg-13(a)(4) to exclude con-

^{1.} It may be possible for contraception or sterilization to qualify as "preventive care" in rare situations—such as when a woman's life would be endangered by a future pregnancy or if a woman is taking chemotherapy that would harm her unborn child if she became pregnant. The Contraceptive Mandate, however, sweeps far beyond these situations and compels the provision of contraception solely as a means of birth control.

traception and sterilization. A regime that requires health insurance to cover contraception and sterilization only for women and not for men raises constitutional questions under the Supreme Court's equal-protection jurisprudence, *see* paragraphs 110– 113, *infra*, and courts must interpret statutes to avoid serious constitutional questions whenever it is reasonably possible to do so, *see* authorities cited in paragraph 68, *supra*. The canon of constitutional avoidance also trumps any "*Chevron* deference" that the HRSA might try to claim. *See Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

109. The Court should therefore declare that the Contraceptive Mandate and the HRSA guidelines of August 1, 2011, are not authorized by 42 U.S.C. § 300gg-13(a)(4), and it should permanently enjoin the defendants from enforcing them.

CLAIM NO. 7—THE CONTRACEPTIVE MANDATE VIOLATES THE SUPREME COURT'S EQUAL-PROTECTION JURISPRUDENCE

110. The Contraceptive Mandate compels health insurance to cover contraception and sterilization for women but not for men. This violates the Supreme Court's equal-protection jurisprudence by discriminating between men and women without an "exceedingly persuasive justification." *United States v. Virginia*, 518 U.S. 515, 531 (1996); *Mississippi University for Women v. Hogan*, 458 U.S. 718, 724 (1982).

111. There is no "exceedingly persuasive justification" for compelling coverage of contraception and sterilization for women while denying equivalent coverage of contraception and sterilization for men. Some women want to rely on the birth control used by their male partner—such as condoms or vasectomies—rather than on female contraceptive methods or sterilization procedures, yet the Contraceptive Mandate offers no help to these women or to their partners. *See* Greer Donley, *The Unintended Consequences of the Contraceptive Mandate*, The Atlantic (June 24, 2019), available at https://bit.ly/2RwrvSC (last visited on March 29, 2020) (observing that

"Fifteen to 22 percent of women rely on condoms, while 8 to 9 percent rely on their partner's vasectomy" and that "more women rely on male contraception than rely on the birth-control pill."). Worse, a tubal ligation is more invasive and more risky—and significantly less effective—than a vasectomy. Yet the Contraceptive Mandate creates perverse incentives for couples to opt for tubal ligation, which *must* be provided free of charge, over a vasectomy, which is covered only if the insurer chooses to provide such coverage—and even if the vasectomy is "covered," it is likely to require a co-payment or count toward the annual deductible.

112. In addition, a regime of this sort reinforces traditional stereotypes of women's proper roles by assuming that birth control is a woman's responsibility, and that women and not men are responsible for taking the precautions needed to avoid an unwanted pregnancy. *See* Donley, *supra*; *see also Mississippi University for Women*, 458 U.S. at 729 (disapproving state-imposed distinctions between men and women that "perpetuate . . . stereotyped view[s]" about women's proper roles); Cass R. Sunstein, *Neutrality in Constitutional Law (with Special Reference to Pornography, Abortion, and Surrogacy*), 92 Colum. L. Rev. 1, 35 (1992) (claiming that modern equal-protection doctrine prohibits distinctions between men and women that are based on "constitutionally unacceptable stereotypes about women's natural or appropriate role.").

113. The Court should therefore declare that the Contraceptive Mandate violates the Supreme Court's equal-protection jurisprudence, and it should enjoin the defendants from enforcing it.

CLAIM NO. 8—RFRA VIOLATIONS

114. Many of the agency-imposed preventive-care coverage mandates violate 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 objectionable coverage. This imposes a substantial burden on the exercise of religion.

115. The PrEP mandate, for example, 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).

116. The plaintiffs seek to enjoin the defendants from enforcing any coverage mandate that requires religious employers to underwrite coverage that violates their religious beliefs, or that prevents religious individuals and entities from purchasing health insurance that excludes objectionable coverage. Braidwood Management Inc. sues on behalf of all self-insured employers who object to any of the ACA's preventive-care mandates for sincere religious reasons; Kelley Orthodontics sues on behalf of all religious employers who wish to purchase health insurance for their employees that excludes any of this compulsory preventive-care coverage for sincere religious reasons; and Mr. Kelley and Mr. Starnes sue on behalf of all individuals who wish to purchase health insurance that excludes any of the coverage compelled by the ACA's preventive-care mandates for sincere religious reasons.

117. Braidwood is not challenging the Contraceptive Mandate on behalf of selfinsured employers at this time, because self-insured employers are no longer required to cover contraception on account of the *DeOtte* injunction. *See DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019).

118. Braidwood is, however, challenging the PrEP mandate that is scheduled to take effect in 2021, along with each of the following preventive-care mandates that have already taken effect under 42 U.S.C. § 300gg-13:

Chlamydia Infection screening for sexually active women age 24 or younger and other women at higher risk

Gonorrhea screening for all women at higher risk

Hepatitis B screening for nonpregnant adolescents and adults with a high risk of infection

Hepatitis C screening for adults with a high risk of infection

HIV screening for everyone ages 15 to 65, and other ages at increased risk for infection

Human Papillomavirus (HPV) DNA Test every 3 years for women with normal cytology results who are 30 or older

Immunization for the Human Papillomavirus

Sexually Transmitted Infection (STI) prevention counseling and screening for adolescents and adults at higher risk.

Syphilis screening for persons who are at increased risk for infection

119. Dr. Hotze is unwilling to allow Braidwood's self-insured plan to pay for the screenings, immunizations, counseling, or treatments described in paragraph 118 because they are consequences of a patient's choice to engage in drug use, prostitution, homosexual conduct, or sexual promiscuity—all of which are contrary to Dr. Hotze's sincere religious beliefs. There are health risks associated with drug use, prostitution, homosexual conduct, and sexual promiscuity, but Dr. Hotze is unwilling to allow his health plan to encourage these behaviors by paying for preventive care needed by those who choose to engage in this conduct. Nor will Dr. Hotze will allow employees who choose to jeopardize their health by engaging in drug use, prostitution, homosexual conduct, or sexual promiscuity to impose the costs of their lifestyle choices on his company or their fellow employees. A regime that forces Braidwood to underwrite the screenings, immunizations, counseling, or treatments described in paragraph 118 is a substantial burden on Braidwood's exercise of religion. 120. There is no compelling governmental interest in providing PrEP drugs and the services described in paragraph 118 at zero marginal cost. And even if there were, there are ways to achieve this goal in a manner that is less restrictive of Braidwood's religious freedom.

121. The Court should therefore enjoin the defendants from enforcing the PrEP mandate or any of the other coverage mandates described in paragraph 118 against Braidwood or any other self-insured employer who is unwilling to cover PrEP drugs or any of the services described in paragraph 118 for sincere religious reasons.

122. Kelley Orthodontics wishes to provide health insurance to its employees that excludes the preventive-care coverage described in paragraph 118. But it is currently impossible for Kelley Orthodontics to purchase health insurance that excludes contraceptive coverage, or any of the other objectionable coverage described in paragraph 118. And in 2021, it will become impossible for Kelley Orthodontics to purchase health insurance that excludes coverage of PrEP drugs. This imposes a substantial burden on Kelley Orthodontics's exercise of religion.

123. There is no compelling governmental interest making contraception, PrEP drugs, and the preventive care described in paragraph 118 available at zero marginal cost. And even if there were, there are ways to achieve this goal in a manner that is less restrictive of Kelley Orthodontics's religious freedom.

124. Mr. Kelley and Mr. Starnes wish to purchase health insurance for themselves and their families, but it is currently impossible for them to purchase health insurance that excludes abortifacient contraceptive coverage, or any of the other objectionable coverage described in paragraph 118. And in 2021, it will become impossible for Mr. Kelley and Mr. Starnes to purchase health insurance that excludes coverage of PrEP drugs. Mr. Kelley and Mr. Starnes cannot obtain health insurance for themselves or their families unless they purchase health insurance that covers abortifacient contraception, and that covers "preventive care" for lifestyle choice that violate they sincere religious beliefs. This imposes a substantial burden on their exercise of religion.

125. There is no compelling governmental interest making contraception and the preventive care described in paragraph 118 available at zero marginal cost. And even if there were, there are ways to achieve this goal in a manner that is less restrictive of Mr. Kelley's and Mr. Starnes's religious freedom.

CLASS-ACTION ALLEGATIONS— PURCHASERS OF HEALTH INSURANCE

126. Mr. Kelley and Mr. Starnes bring this class action under Rule 23(b)(2) of the federal rules of civil procedure.

127. The class comprises all current and future individuals and entities in the United States who wish to purchase health insurance that excludes or limits coverage of any of the preventive care required by a rating, recommendation, or guideline issued by the Health Resources and Services Administration, the U.S. Preventive Services Task Force, or the Advisory Committee on Immunization Practices after March 23, 2010. Mr. Kelley and Mr. Starnes seek to represent this class when asserting their constitutional and APA claims against the preventive-care mandates (Claims 1–5), as well as their statutory and equal-protection claims against the Contraceptive Mandate (Claims 6–7).

128. Mr. Kelley and Mr. Starnes also seek to represent a subclass that comprises all current and future individuals and entities in the United States who: (1) purchase or wish to purchase health insurance; and (2) object to the compulsory coverage of contraception, PrEP drugs, or any of the services described in paragraph 118 for sincere religious reasons. Mr. Kelley and Mr. Starnes seek to represent this class when asserting their RFRA claims against the preventive-care mandates (Claim 8).

129. The number of persons in the class and subclass makes joinder of the individual class members impractical.

130. There are questions of law common to the class and subclass. The legal questions common to the class include: (1) Whether 42 U.S.C. § 300gg-13(a)(1)-(4)violate the Appointments Clause; (2) Whether 42 U.S.C. § 300gg-13(a)(1)-(4) unconstitutionally delegate lawmaking powers to the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration; (3) Whether 42 U.S.C. § 300gg-13(a)(1) violates Article II of the Constitution by empowering an entity that is immune from the President's direction and control to unilaterally decide to decide the preventive care that health insurance must cover; (4) Whether 42 U.S.C. \$ 300gg-13(a)(1)-(4)should be construed, as a matter of statutory construction, to refer only to the ratings, recommendations, or guidelines that existed on the date that the Affordable Care Act was enacted into law; (5) Whether the coverage recommendations of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration are required to go through noticeand-comment procedures; (6) Whether contraception and sterilization qualify as "preventive care" under 42 U.S.C. § 300gg-13(a)(4); and (7) Whether the Contraceptive Mandate violates the Supreme Court's equal-protection doctrine. The legal question common to the subclass is whether compulsory coverage of contraception, PrEP drugs, and the services described in paragraph 118 violates the Religious Freedom Restoration Act by making it impossible for individuals to purchase health insurance that excludes the objectionable coverage.

131. Mr. Kelley and Mr. Starnes's claims are typical of other members of the class. Each class member wishes to purchase health insurance that excludes or limits coverage of some or all of the compulsory preventive care, yet is unable to do so on account of the defendants' enforcement of 42 U.S.C. § 300gg-13(a)(1)-(4).

132. Mr. Kelley and Mr. Starnes adequately represent the interests of the class, and they have no interests antagonistic to the class.

133. A class action is appropriate under Rule 23(b)(2) because the defendants are acting on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

CLASS-ACTION ALLEGATIONS—EMPLOYERS THAT WISH TO PURCHASE HEALTH INSURANCE FOR THEIR EMPLOYEES

134. Kelley Orthodontics brings this class action under Rule 23(b)(2) of the federal rules of civil procedure.

135. The class comprises all current and future employers in the United States who: (1) purchase or wish to purchase health insurance for their employees; and (2) wish to purchase health insurance for their employees that excludes or limits coverage of any of the preventive care required by a rating, recommendation, or guideline issued by the Health Resources and Services Administration, the U.S. Preventive Services Task Force, or the Advisory Committee on Immunization Practices after March 23, 2010. Kelley Orthodontics seeks to represent this class when asserting its constitutional and APA claims against the preventive-care mandates (Claims 1–5), as well as its statutory and equal-protection claims against the Contraceptive Mandate (Claims 6–7).

136. Kelley Orthodontics also seeks to represent a subclass that comprises all current and future employers in the United States who: (1) purchase or wish to purchase health insurance for their employees; and (2) object to the compulsory coverage of contraception, PrEP drugs, or any of the services described in paragraph 118 for sincere religious reasons.

137. The number of persons in the class and subclass makes joinder of the individual class members impractical.

138. There are questions of law common to the class and subclass. The legal questions common to the class include: (1) Whether 42 U.S.C. § 300gg-13 unconstitutionally delegates lawmaking powers to the Health Resources and Services Administration, the U.S. Preventive Services Task Force, and the Advisory Committee on Immunization Practices; (2) Whether 42 U.S.C. § 300gg-13(a)(1) violates Article II of the Constitution by empowering an entity that is immune from the President's direction and control to unilaterally decide to decide the preventive care that health insurance must cover; (3) Whether 42 U.S.C. § 300gg-13(a)(1)-(4) violates the Appointments Clause; (4) Whether the coverage recommendations of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration are required to go through noticeand-comment procedures; (5) Whether contraception and sterilization fall within the meaning of "preventive care" in 42 U.S.C. § 300gg-13(a)(4); (6) Whether the Contraceptive Mandate violates the Supreme Court's equal-protection doctrine. The legal question common to the subclass is whether the compulsory coverage of contraception, PrEP drugs, and the services described in paragraph 118 violates the Religious Freedom Restoration Act by making it impossible for employers to purchase health insurance that excludes the objectionable coverage.

139. Kelley Orthodontics's claims are typical of other members of the class. Each class member wishes to purchase health insurance that excludes or limits coverage of some or all of the compulsory preventive care, yet is unable to do so on account of the defendants' enforcement of 42 U.S.C. § 300gg-13(a)(1)-(4). Kelley Orthodontics adequately represents the interests of the class, and it has no interests antagonistic to the class.

140. A class action is appropriate under Rule 23(b)(2) because the defendants are acting on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

CLASS-ACTION ALLEGATIONS—SELF-INSURED EMPLOYERS

141. Braidwood Management Inc. brings this class action under Rule 23(b)(2) of the federal rules of civil procedure.

142. The class comprises all current and future employers in the United States who: (1) operate self-insured health plans; and (2) object to the compulsory coverage of any of the preventive care required by a rating, recommendation, or guideline issued by the Health Resources and Services Administration, the U.S. Preventive Services Task Force, or the Advisory Committee on Immunization Practices after March 23, 2010.

143. Braidwood also seeks to represent a subclass that comprises all current and future employers in the United States who: (1) operate self-insured health plans; and (2) object to the compulsory coverage of contraception, PrEP drugs, or any of the services described in paragraph 118 for sincere religious reasons

144. The number of persons in the class and subclass makes joinder of the individual class members impractical.

145. There are questions of law common to the class and subclass. The legal questions common to the class include: (1) Whether 42 U.S.C. § 300gg-13(a)(1)-(4) violate the Appointments Clause; (2) Whether 42 U.S.C. § 300gg-13(a)(1)-(4) unconstitutionally delegate lawmaking powers to the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration; (3) Whether 42 U.S.C. § 300gg-13(a)(1) violates Article II of the Constitution by empowering an entity that is immune from the President's direction and control to unilaterally decide to decide the preventive care that health insurance must cover; (4) Whether 42 U.S.C. § 300gg-13(a)(1)-(4) should be construed, as a matter of statutory construction, to refer only to the ratings, recommendations, or guidelines that existed on the date that the Affordable Care Act

was enacted into law; (5) Whether the coverage recommendations of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration are required to go through notice-and-comment procedures; (6) Whether contraception and sterilization qualify as "preventive care" under 42 U.S.C. § 300gg-13(a)(4); and (7) Whether the Contraceptive Mandate violates the Supreme Court's equal-protection doctrine. The legal question common to the subclass is whether the compulsory coverage of contraception, PrEP drugs, and the services described in paragraph 118 violates the Religious Freedom Restoration Act by forcing religious employers to underwrite this objection-able coverage.

146. Braidwood's claims are typical of other members of the class. Each class member is seeking to exclude or limit coverage of some or all of the required preventive care, yet is unable to do so on account of the defendants' enforcement of 42 U.S.C. § 300gg-13(a)(1)-(4). Braidwood adequately represents the interests of the class, and it has no interests antagonistic to the class.

147. A class action is appropriate under Rule 23(b)(2) because the defendants are acting on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

DEMAND FOR RELIEF

148. The plaintiffs respectfully request that the court:

a. certify the classes and subclasses described in paragraphs 127–128, 135–136, and 142–143;

- b. 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;
- c. 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;
- d. 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;
- e. 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;
- f. permanently enjoin the defendants from enforcing any coverage mandate based upon an agency rating, recommendation, or guideline that issued after March 23, 2010;
- g. declare that any coverage mandate based on an agency rating, recommendation, or guideline that failed to go through notice-and-comment procedures is invalid and unenforceable;
- h. hold unlawful and set aside any agency rules or agency actions that attempt to implement any coverage mandate based on an agency rating, recommendation, or guideline that failed to go through notice-andcomment procedures, or that was issued after March 23, 2010;
- i. declare that contraception and sterilization do not qualify as "preventive care" under 42 U.S.C. § 300gg-13(a)(4), and permanently enjoin the defendants from enforcing the Contraceptive Mandate;

- j. declare that the Contraceptive Mandate violates the Supreme Court's equal-protection jurisprudence, and permanently enjoin the defendants from enforcing it;
- k. declare that the Contraceptive Mandate, the PrEP mandate, and the compulsory coverage of services described in paragraph 118 violate the Religious Freedom Restoration Act;
- 1. permanently enjoin the defendants from requiring health insurance to cover contraception, PrEP drugs, or any of the services described in paragraph 118;
- m. award costs and attorneys' fees under 42 U.S.C. § 1988;
- n. award all other relief that the Court deems just, proper, or equitable.

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Respectfully submitted.

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