

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**,

Defendants.

Case No. 4:20-cv-00283

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 co-pays. *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

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.

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 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.

61. The members of the U.S. Preventive Services Task Force, the Advisory Committee 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 Carciere 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 preventive-care 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 Carciere 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 today).

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 guidelines 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 FDA-approved 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 self-insured 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 their 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 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 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 notice-and-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 objectionable 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-and-comment 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;
- l. 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.

Respectfully submitted.

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Dated: March 29, 2020

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I of Pub. L. 111-148, enacting this section and sections 300gg-12 to 300gg-15, 300gg-16 to 300gg-19, 300gg-93, and 300gg-94 of this title, amending former sections 300gg-11 and 300gg-12 of this title and sections 300gg-21 to 300gg-23 of this title, and transferring section 300gg-13 of this title to section 300gg-9 of this title and sections 300gg-4 to 300gg-7 of this title to sections 300gg-25 to 300gg-28 of this title, respectively] (and the amendments made by this subtitle) shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act [Mar. 23, 2010], except that the amendments made by sections 1002 and 1003 [enacting sections 300gg-93 and 300gg-94 of this title] shall become effective for fiscal years beginning with fiscal year 2010.

“(b) SPECIAL RULE.—The amendments made by sections 1002 and 1003 [enacting sections 300gg-93 and 300gg-94 of this title] shall take effect on the date of enactment of this Act [Mar. 23, 2010].”

§ 300gg-12. Prohibition on rescissions

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not rescind such plan or coverage with respect to an enrollee once the enrollee is covered under such plan or coverage involved, except that this section shall not apply to a covered individual who has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. Such plan or coverage may not be cancelled except with prior notice to the enrollee, and only as permitted under section 300gg-2(b)¹ or 300gg-42(b) of this title.

(July 1, 1944, ch. 373, title XXVII, § 2712, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

REFERENCES IN TEXT

Section 300gg-2(b) of this title, referred to in text, was in the original a reference to section “2702(c)” of act July 1, 1944, which was translated as meaning section 2703(b) of act July 1, 1944, to reflect the probable intent of Congress. Section 2702(c), which is classified to section 300gg-1 of this title, relates to special rules for network plans, while section 2703(b) specifies the reasons for which a health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a health insurance coverage offering in the group or individual market. Section 300gg-2(b) also parallels section 300gg-42(b) which appears in the same context in this section as the reference to section 300gg-2(b).

PRIOR PROVISIONS

A prior section 300gg-12, act July 1, 1944, ch. 373, title XXVII, § 2712, as added Pub. L. 104-191, title I, § 102(a), Aug. 21, 1996, 110 Stat. 1964, which related to guaranteed renewability of coverage for employers in a group market, was renumbered section 2732 of act July 1, 1944, amended, and transferred to subsecs. (b) to (e) of section 300gg-2 of this title, by Pub. L. 111-148, title I, §§ 1001(3), 1563(c)(9), formerly § 1562(c)(9), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 267, 911.

Another prior section 2712 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

¹ See References in Text note below.

§ 300gg-13. Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) 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;

(2) 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; and¹

(3) 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.²

(4) 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.²

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

(July 1, 1944, ch. 373, title XXVII, § 2713, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

¹ So in original. The word “and” probably should not appear.

² So in original. The period probably should be a semicolon.

PRIOR PROVISIONS

A prior section 300gg-13, act July 1, 1944, ch. 373, title XXVII, §2713, as added Pub. L. 104-191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1966, was renumbered section 2709 of act July 1, 1944, and transferred to section 300gg-9 of this title by Pub. L. 111-148, title I, §§1001(3), 1563(c)(10)(C), formerly §1562(c)(10)(C), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 268, 911.

Another prior section 2713 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-14. Extension of dependent coverage

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) Regulations

The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) Rule of construction

Nothing in this section shall be construed to modify the definition of “dependent” as used in title 26 with respect to the tax treatment of the cost of coverage.

(July 1, 1944, ch. 373, title XXVII, §2714, as added Pub. L. 111-148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 132; amended Pub. L. 111-152, title II, §2301(b), Mar. 30, 2010, 124 Stat. 1082.)

PRIOR PROVISIONS

A prior section 2714 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111-152 struck out “(who is not married)” after “adult child”.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-15. Development and utilization of uniform explanation of coverage documents and standardized definitions

(a) In general

Not later than 12 months after March 23, 2010, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage

explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the “NAIC”), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) Requirements

The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) Appearance

The standards shall ensure that the summary of benefits and coverage is presented in a uniform format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) Language

The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) Contents

The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent with subsection (g)) so that consumers may compare health insurance coverage and understand the terms of coverage (or exception to such coverage);

(B) a description of the coverage, including cost sharing for—

(i) each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 18022(b)(1) of this title; and

(ii) other benefits, as identified by the Secretary;

(C) the exceptions, reductions, and limitations on coverage;

(D) the cost-sharing provisions, including deductible, coinsurance, and co-payment obligations;

(E) the renewability and continuation of coverage provisions;

(F) a coverage facts label that includes examples to illustrate common benefits scenarios, including pregnancy and serious or chronic medical conditions and related cost sharing, such scenarios to be based on recognized clinical practice guidelines;

(G) a statement of whether the plan or coverage—

(i) provides minimum essential coverage (as defined under section 5000A(f) of title 26); and

(ii) ensures that the plan or coverage share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs;

(H) a statement that the outline is a summary of the policy or certificate and that

45 C.F.R. § 147.130(a)(1)
Coverage of preventive health services.

(a) Services—

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) 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 with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults 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 (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133.

45 C.F.R. § 147.131

Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) Eligible organizations for optional accommodation. An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii), or 45 CFR 147.133(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a) or 147.133, the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) Transitional rule—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60–days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) General rule—In plan years that begin after January 14, 2019, if contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(d) Optional accommodation—insured group health plans—

(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 or 147.133 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 or 147.133 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 or 147.133 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage. For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) “Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of

higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer].”

(f) Reliance—

(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(g) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(h) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

45 C.F.R. § 147.132

Religious exemptions in connection with coverage of certain preventive health services.

(a) Objecting entities.

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references

to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) Objecting individuals. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to

give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

45 C.F.R. § 147.133

Moral exemptions in connection with coverage of certain preventive health services.

(a) Objecting entities.

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) Objecting individuals. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

(c) Definition. For the purposes of this section, reference to “contraceptive” services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

29 C.F.R. § 2590.715–2713(a)
Coverage of preventive health services.

(a) Services—

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) 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 with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults 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 (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131, 147.132, and 147.133.

26 C.F.R. § 54.9815–2713(a)(1)
Coverage of preventive health services

(a) Services—(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) 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 with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults 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 (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131, 147.132, and 147.133.

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

RICHARD W. DEOTTE et al.,

Plaintiffs,

v.

ALEX M. AZAR II et al.,

Defendants.¹

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Civil Action No. 4:18-cv-00825-O

FINAL JUDGMENT

Judgment is entered in favor of plaintiff Braidwood Management Inc. and the certified plaintiff class that Braidwood represents, consisting of:

Every current and future employer in the United States that objects, based on its sincerely held religious beliefs, to establishing, maintaining, providing, offering, or arranging for: (i) coverage or payments for some or all contraceptive services; or (ii) a plan, issuer, or third-party administrator that provides or arranges for such coverage or payments.

Judgment is further entered in favor of plaintiffs Richard W. DeOtte, Yvette DeOtte, John Kelley, and Alison Kelley, as well as the certified plaintiff class that Mr. DeOtte represents, consisting of:

All current and future individuals in the United States who: (1) object to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs; and (2) would be willing to purchase or obtain health insurance that excludes coverage or payments for some or all contraceptive services from a health insurance issuer, or from a plan sponsor of a group plan, who is willing to offer a separate benefit package option, or a separate policy, certificate, or contract of insurance that excludes coverage or payments for some or all contraceptive services.

¹ Pursuant to Federal Rule of Civil Procedure 25(d), the Court hereby substitutes Patrick Pizzella, Acting Secretary of Labor, as Defendant, in place of Defendant Rene Alexander Acosta, who retired from the position effective July 19, 2019.

Judgment is entered against defendants Alex M. Azar, in his official capacity as Secretary of Health and Human Services; Steven T. Mnuchin, in his official capacity as Secretary of the Treasury; Patrick Pizzella, in his official capacity as Acting Secretary of Labor; and the United States of America. The Court awards the following relief:

The Court **DECLARES** that the Contraceptive Mandate, codified at 42 U.S.C. § 300gg–13(a)(4), 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), violates the Religious Freedom Restoration Act as applied to the Employer Class members. The Court further **DECLARES** that the Contraceptive Mandate violates the Religious Freedom Restoration Act to the extent it prevents the Individual Class members from purchasing health insurance that excludes coverage or payments for contraceptive methods that violate their sincerely held religious beliefs. The Court also concludes that the Employer Class members and the Individual Class members will suffer irreparable harm absent an injunction, that the balance of equities favors injunctive relief, and that the public interest supports the enforcement of the Religious Freedom Restoration Act.

It is therefore **ORDERED** that:

1. Defendants Alex M. Azar II, Steven T. Mnuchin, and Patrick Pizzella, and their officers, agents, servants, employees, attorneys, designees, subordinates, and successors in office, as well as any person acting in concert or participation with them, are **ENJOINED** from enforcing the Contraceptive Mandate, codified at 42 U.S.C. § 300gg–13(a)(4), 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), against any group health plan, and any health insurance coverage provided in connection with a group health plan, that is sponsored by an Employer Class member. If an Employer Class member’s sincere religious objections extend to the coverage of only some but not all contraceptives, then the defendants may

continue to enforce the Contraceptive Mandate to the extent it requires coverage of contraceptive methods that the Braidwood class member does not object to.

2. Defendants Alex M. Azar II, Steven T. Mnuchin, and Patrick Pizzella, and their officers, agents, servants, employees, attorneys, designees, subordinates, and successors in office, as well as any person acting in concert or participation with them, are **ENJOINED** from enforcing the Contraceptive Mandate, codified at 42 U.S.C. § 300gg-13(a)(4), 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), to the extent that the Mandate requires the Individual Class members to provide coverage or payments for contraceptive services that they object to based on their sincerely held religious beliefs, and to the extent that the Mandate prevents a willing health insurance issuer offering group or individual health insurance coverage, and as applicable a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance, or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to a member of the Individual Class) or to any member of the Individual Class, that omits coverage for contraceptive services that the Individual Class member objects to based on that individual's sincerely held religious beliefs.

If an Individual Class member objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the Individual Class member agrees, then the injunction applies as if the Individual Class member objects to all contraceptive services.

3. Nothing in this injunction shall prevent the defendants, or their officers, agents, servants, employees, attorneys, designees, subordinates, and successors in office, as well as any person acting in concert or participation with them, from:

(a) Inquiring about whether any employer (including any member of the Braidwood class) that fails to comply with the Contraceptive Mandate is a sincere religious objector;

(b) Inquiring about whether an individual (including any member of the DeOtte class) who obtains health insurance that excludes coverage for some or all contraceptive methods is a sincere religious objector;

(c) Enforcing the Contraceptive Mandate against employers or individuals who admit that they are not sincere religious objectors; against any group health plan, and any health insurance coverage provided in connection with a group health plan, that is sponsored by an employer who admits that it is not a sincere religious objector; or against issuers or plan sponsors to the extent they provide health insurance to individuals who admit that they are not sincere religious objectors;

(d) Filing notice with this Court challenging any employer or individual who claims to hold sincere religious objections to some or all contraceptive methods, if the defendants reasonably and in good faith doubt the sincerity of that employer or individual's asserted religious objections, and asking the Court to declare that such employer or individual falls outside the scope of the Employer Class or the Individual Class.

SO ORDERED on this **29th day** of **July, 2019**.


Reed O'Connor
UNITED STATES DISTRICT JUDGE

Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis

Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Recommendation Summary

Population	Recommendation	Grade (What's This?)
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition.	A

To read the recommendation statement in *JAMA*, select [here](#)[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#).

To read the evidence summary in *JAMA*, select [here](#)[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#).

See the [Clinical Considerations](#) section for information about identification of persons at high risk and selection of effective antiretroviral therapy.

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Preface

The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Rationale

Importance

An estimated 1.1 million individuals in the United States are currently living with HIV,¹ and more than 700,000 persons have died of AIDS since the first cases were reported in 1981.² In 2017, there were 38,281 new diagnoses of HIV infection reported in the United States; 81% (30,870) of these new diagnoses were among males and 19% (7,312) were among females.² Although treatable, HIV infection has no cure and has significant health consequences.

Identification of Risk Status

Although the USPSTF found inadequate evidence that specific risk assessment tools can accurately identify persons at high risk of HIV acquisition, it found adequate epidemiologic data on risk factors that can be used to identify persons at high risk of acquiring HIV infection.

Benefits of Preventive Medication

The USPSTF found convincing evidence that PrEP is of substantial benefit for decreasing the risk of HIV infection in persons at high risk of HIV infection, either via sexual acquisition or through injection drug use. The USPSTF also found convincing evidence that adherence to PrEP is highly correlated with its efficacy in preventing the acquisition of HIV infection.

Harms of Preventive Medication

The USPSTF found adequate evidence that PrEP is associated with small harms, including kidney and gastrointestinal adverse effects.

USPSTF Assessment

The USPSTF concludes with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial.

Clinical Considerations

Patient Population Under Consideration

Assessment of Risk

Although the USPSTF found no well-validated, accurate tools to assess risk of HIV acquisition, epidemiologic data, Centers for Disease Control and Prevention (CDC) guidelines,³ and enrollment criteria for clinical trials provide guidance on detecting persons who may be at high risk. Persons at risk of HIV infection include men who have sex with men, persons at risk via heterosexual contact, and persons who inject drugs. Within these groups, certain risk factors or behaviors (outlined below) can place persons at high risk of HIV infection.

It is important to note that men who have sex with men and heterosexually active persons are not considered to be at high risk if they are in a mutually monogamous relationship with a partner who has recently tested negative for HIV. In addition, all persons being considered for PrEP must have a recently documented negative HIV test result.

The USPSTF recommends that the following persons be considered for PrEP:

1. Men who have sex with men, are sexually active, and have 1 of the following characteristics:

- A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
- Inconsistent use of condoms during receptive or insertive anal sex
- A sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia within the past 6 months

2. Heterosexually active women and men who have 1 of the following characteristics:

- A serodiscordant sex partner (ie, in a sexual relationship with a partner living with HIV)
- Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (eg, a person who injects drugs or a man who has sex with men and women)
- An STI with syphilis or gonorrhea within the past 6 months

3. Persons who inject drugs and have 1 of the following characteristics:

- Shared use of drug injection equipment
- Risk of sexual acquisition of HIV (see above)

Persons who engage in transactional sex, such as sex for money, drugs, or housing, including commercial sex workers or persons trafficked for sex work, constitute another group at high risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above. Men who have sex with men and women are at risk of HIV acquisition and should be evaluated for PrEP according to the criteria outlined above for men who have sex with men and heterosexually active men.

Transgender women and men who are sexually active may be at increased risk of HIV acquisition and should be considered for PrEP based on the criteria outlined above. Transgender women are at especially high risk of HIV acquisition. The CDC estimates that approximately one-fourth of transgender women are living with HIV, and more than half (an estimated 56%) of black/African American transgender women are living with HIV.⁴ Although trials of PrEP enrolled few transgender women and no trials have been conducted among transgender men, PrEP has been shown to reduce the risk of HIV acquisition during receptive and insertive anal and vaginal sex. Therefore, its use may be considered in all persons (cisgender and transgender) at high risk of sexual acquisition of HIV.

Consistent use of condoms decreases risk of HIV acquisition by approximately 80%⁵ and also decreases the risk of other STIs. However, sexually active adults often use condoms inconsistently.⁶ PrEP should be considered as an option to reduce the risk of HIV acquisition in persons who use condoms inconsistently, while continuing to encourage and support consistent condom use.

To date, in 3 studies, transmission of HIV to a seronegative partner from a partner living with HIV has not been observed when the seropositive partner was being treated with antiretroviral therapy and had a suppressed viral load.⁷⁻⁹ It is not known whether PrEP use further decreases the risk of HIV transmission when a seropositive partner has a documented undetectable viral load.

The risk of acquisition of HIV infection is on a continuum. This risk depends on the likelihood that a specific act or activity will transmit HIV and the likelihood that a sex partner or drug injection partner is living with HIV. The likelihood of HIV transmission is highest with needle-sharing injection drug use and condomless receptive anal intercourse, when condomless insertive anal sex and condomless receptive and insertive penile-vaginal sex have a risk of transmission that is approximately 10- to 15-fold lower than receptive anal intercourse.⁵ One recent study estimated the prevalence of HIV (ie, the likelihood that a partner whose HIV status is unknown is living with HIV) as 12.4% among men who have sex with men and 1.9% among persons who inject drugs,¹⁰ although an earlier systematic review estimated the prevalence of HIV among persons who inject drugs to be much higher (16%).¹¹ The prevalence of HIV among men who have sex with men and women is estimated to be intermediate between that of men who have sex with men and heterosexually active men.¹² Thus, persons at high risk of HIV acquisition via penile-vaginal intercourse, including those with a recent bacterial STI acquired via penile-vaginal intercourse, will generally be at lower absolute risk than persons at high risk via receptive anal intercourse or injection drug use. These are factors that clinicians and patients can consider as they discuss the use of PrEP for HIV prevention.

In addition, risk behaviors should be interpreted in the context of the HIV prevalence in a community or network; that is, risk behaviors in a high-prevalence setting carry a higher risk of acquiring HIV infection than the same behaviors in a low-prevalence setting. The threshold of HIV prevalence below which PrEP has insignificant net benefit is not known.

Preventive Medication

Once-daily oral treatment with combined tenofovir disoproxil fumarate and emtricitabine is the only formulation of PrEP approved by the US Food and Drug Administration (FDA) for use in the United States in persons at risk of sexual acquisition of HIV infection. However, several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP, and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs.³

According to its product label, tenofovir disoproxil fumarate/emtricitabine may be considered for use as PrEP during pregnancy.¹³ No trials of oral PrEP included pregnant women; however, pregnancy is associated with an increased risk of HIV acquisition.¹⁴ CDC guidelines recommend shared decision making for pregnant women who are considering starting or continuing PrEP during pregnancy.

Adolescents at high risk of HIV acquisition could benefit from PrEP, and tenofovir disoproxil fumarate/emtricitabine is approved by the FDA for use as PrEP in adolescents who weigh at least 35 kg.¹³ In addition, young men who have sex with men are at particularly high risk of HIV acquisition.¹⁵ However, no randomized clinical trials (RCTs) of PrEP enrolled adolescents. Limited data suggest that PrEP use is not associated with significant adverse events in adolescents but may be associated with slightly less bone mineral accrual than would be expected.¹⁶ The USPSTF suggests that clinicians weigh all these factors when considering PrEP use in adolescents at high risk of HIV acquisition. In addition, clinicians need to be aware of any local laws and regulations that may apply when providing PrEP to an adolescent minor.

Additional Approaches to Prevention

Several additional approaches for decreasing risk of HIV acquisition are also available. Consistent use of condoms decreases risk of HIV acquisition by approximately 80%⁵

reduces the risk of other STIs. The USPSTF recommends intensive behavioral counseling to reduce behaviors associated with increased risk of STIs and HIV acquisition and increase condom use among adolescents and adults at increased risk of STIs.¹⁷ The CDC has made several recommendations, including abstinence, reducing one's number of sex partners, and consistent condom use, to decrease risk of STIs, including HIV.¹⁸ The CDC also recommends syringe service programs (ie, needle exchange programs) to reduce the risk of HIV acquisition and transmission among persons who inject drugs.¹⁹ The Community Preventive Services Task Force has also issued several recommendations on the prevention of HIV and other STIs.²⁰ Postexposure prophylaxis, started as soon as possible after a possible exposure event, can also decrease the risk of HIV infection.

Screening for HIV infection to detect undiagnosed cases and antiretroviral treatment in persons living with HIV to suppress viral load are both important approaches to decreasing the risk of HIV transmission at the population level, while also benefiting the individual living with HIV. The USPSTF recommends screening for HIV infection in adolescents and adults aged 15 to 65 years, younger adolescents and older adults at increased risk, and all pregnant persons.²¹

Useful Resources

The CDC guidelines on PrEP for the prevention of HIV infection are available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#)³ and <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#).²² Additional CDC resources on PrEP for both clinicians and consumers are available at <https://www.cdc.gov/hiv/risk/prep/index.html>[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#).²³ Community-level HIV prevalence data for the United States are available at <https://www.cdc.gov/nchstp/atlas>[This link goes offsite. Click to read the external link disclaimer](#)[This link goes offsite. Click to read the external link disclaimer](#).²⁴ The USPSTF has issued recommendations on behavioral counseling to reduce risk of STIs¹⁷ and on screening for HIV infection.²¹

Other Considerations

Implementation

The first step in implementing PrEP is identifying persons at high risk of HIV acquisition who may benefit from PrEP. However, identifying persons at risk of HIV can be challenging because of stigma and discrimination against gay, bisexual, transgender, and nonbinary persons, or the lack of a trusting relationship between the patient and clinician. It is important that clinicians routinely take a sexual and injection drug use history for all their patients in an open and nonjudgmental manner. If a person is identified as potentially belonging to a high-risk group, then further discussion can identify behaviors that may make that person an appropriate candidate for PrEP.

The CDC provides a complete discussion of implementation considerations for PrEP, including baseline and follow-up testing and monitoring, time to achieving protection, and discontinuing PrEP.³ A few particularly important points regarding the provision of PrEP are outlined below.

Before prescribing PrEP, clinicians should exclude persons with acute or chronic HIV infection through taking a medical history and HIV testing. The 2-drug antiretroviral regimen used in PrEP, when used alone, is not an effective treatment for HIV infection, and its use in persons living with HIV can lead to the emergence of, or selection for, drug-resistant HIV infection. It is also generally recommended that kidney function testing, serologic testing for hepatitis B and C virus, testing for other STIs, and pregnancy testing (when appropriate) be conducted at the time of or just before initiating PrEP. Ongoing follow-up and monitoring, including HIV testing every 3 months, is also suggested. The time from initiation of PrEP to achieving protection against HIV infection is unknown. Pharmacokinetic data suggest that maximum levels of tenofovir diphosphate (the active form of tenofovir) is reached in 7 days in rectal tissue and in 20 days in blood (peripheral blood mononuclear cells) and vaginal tissue.³ Patients can continue PrEP as long as high risk of HIV acquisition continues. Patients may discontinue PrEP for several reasons, including personal preference, decreased risk of HIV acquisition, or adverse medication effects.

PrEP does not reduce the risk of other STIs. Consistent use of condoms decreases risk of HIV acquisition by approximately 80%⁵ and reduces the risk of other STIs. Promoting consistent condom use is an important component of a successful PrEP program. The CDC also recommends regular screening for STIs in men who have sex with men who are at high risk of STIs, and testing in anyone with signs or symptoms.³

Clinical trials demonstrate a strong connection between adherence to PrEP and its effectiveness in preventing HIV acquisition. Reduced adherence is associated with marked declines in effectiveness. Therefore, adherence support is a key component of providing PrEP. Components of adherence support include establishing trust and open communication with patients, patient education, reminder systems for taking medication, and attention to medication adverse effects and having a plan to address them. Additional information on adherence support is available from the CDC guidelines.^{3, 22} Adherence support is especially important in populations shown to have lower adherence to PrEP, such as young persons and racial/ethnic minorities.²⁵⁻²⁷

It is important for clinicians to recognize that barriers to the implementation and uptake of PrEP exist. These barriers can include structural barriers, such as lack of health insurance, and other factors, such as an individual's willingness to believe that he or she is an appropriate candidate for PrEP or to take PrEP. There are also racial/ethnic disparities in the use of PrEP. One study reported that although black/African American persons account for an estimated 44% of all new HIV infections in the United States, only 10.1% of those who initiated PrEP from 2012 to 2015 were black/African American. Similarly, black women, who are also disproportionately affected by HIV, were more than 4 times less likely to have initiated PrEP than white women.²⁸ These barriers and disparities need to be addressed to achieve the full benefit of PrEP.

Research Needs and Gaps

Research is needed to develop and validate tools that are highly accurate for identifying persons at high risk of HIV acquisition who would benefit from PrEP. When developed and validated, risk assessment instruments should include those populations most at risk of HIV infection, particularly racial/ethnic minorities such as black/African American and Hispanic/Latino populations.

Research is needed on different drug regimens and dosing strategies for PrEP. Several trials investigating different antiretroviral drugs or drug regimens for use as PrEP are ongoing.

Research is needed on factors associated with adherence to PrEP and methods to increase uptake and adherence, especially in populations with lower use of and adherence to PrEP, such as younger persons and racial/ethnic minorities.

Trials or demonstration projects of PrEP in US populations of heterosexual persons, persons who inject drugs, and transgender women and men are needed to better quantify effectiveness in those populations. Research is needed on the safety and effectiveness of PrEP during pregnancy and breastfeeding. Additional research is needed to determine whether the use of PrEP is associated with an increased risk of other STIs. Research is also needed on the long-term safety and effectiveness of PrEP.

Discussion

Burden of Disease

Since the first cases of AIDS were reported in 1981, more than 700,000 persons in the United States have died of AIDS.² The CDC estimates that 1.1 million individuals in the United States are currently living with HIV infection,¹ including an estimated 15% who are unaware of their infection.¹⁰ The annual number of new HIV infections in the United States has decreased from about 41,200 new cases in 2012 to 38,300 in 2017.² Of these new cases of HIV infection in 2017, 81% were among males and 19% were among females.² Groups disproportionately affected by HIV infection in the United States include men who have sex with men, black/African American populations, and Hispanic/Latino populations. From 2012 to 2015, 11% of persons who initiated PrEP were black/African American, 10% were Hispanic/Latino, and 79% were white.²⁹

populations. From 2017 to 2017, HIV incidence rates increased among persons aged 25 to 29 years and among American Indian/Alaska Native and Asian populations.⁴ PrEP is currently not used in many persons at high risk of HIV infection. CDC estimates that 1.2 million persons were eligible for PrEP in 2015 (492,000 men who have sex with men, 115,000 persons who inject drugs, and 624,000 heterosexually active adults),²⁹ and a recent study estimates that 100,282 persons were using PrEP in 2017.³⁰

Scope of Review

For this recommendation, the USPSTF commissioned a systematic review^{31, 32} of the evidence on the benefits of PrEP for the prevention of HIV infection with oral tenofovir disoproxil fumarate monotherapy or tenofovir disoproxil fumarate/emtricitabine (referred to simply as “PrEP” hereafter) and whether the benefits vary by risk group, population subgroup, or regimen or dosing strategy; the diagnostic accuracy of risk assessment tools to identify persons at high risk of HIV acquisition; the rates of adherence to PrEP in primary care settings; the association between adherence and effectiveness of PrEP; and the harms of PrEP when used for HIV prevention.

Effectiveness of Risk Assessment

The USPSTF found 7 studies that evaluated risk assessment tools developed in US cohorts for predicting incident HIV infection—6 studies in men who have sex with men³³ and 1 study in persons who inject drugs.³⁹ The USPSTF found no studies in US cohorts evaluating tools for predicting risk of HIV infection in men and women at increased risk of HIV infection via heterosexual contact. In those studies that reported it, discrimination of the risk prediction instrument was moderate, with an area under the receiver operating characteristic curve of 0.66 to 0.72. However, each study evaluated a different risk prediction tool. Some instruments were not validated in independent cohorts, and several instruments were developed and validated using older (ie, before 2000) cohorts. Most of the studies of risk prediction tools in men who have sex with men were developed in predominantly white populations, and 2 studies found that several of the instruments performed more poorly in black men who have sex with men (area under the receiver operating characteristic curve, 0.49-0.63).^{37, 38} All tools are predicated on knowing that a person belongs to an HIV risk group; no tool has been designed to predict incident HIV infection in persons not already identified as belonging to an HIV risk group.³¹

The USPSTF considered several factors in its assessment of risk of HIV acquisition, including the prevalence of HIV infection within a group and the risk that a specific behavior or action will lead to acquisition of HIV infection. As discussed in the Assessment of Risk section, 1 study estimated the prevalence of HIV infection among men who have sex with men to be 12.4%; persons who inject drugs, 1.9%; and the overall population 13 years and older, 0.4%,¹⁰ although another study estimated a significantly higher prevalence (16%) among persons who inject drugs.¹¹ In terms of risk of HIV acquisition from specific behaviors, receptive anal intercourse without a condom and needle-sharing injection drug use carry the highest risk, whereas insertive anal intercourse, receptive penile-vaginal intercourse, and insertive penile-vaginal intercourse carry lower but not negligible risks of acquiring HIV from a partner or source who is seropositive for HIV.⁵

Effectiveness of Preventive Medication

The USPSTF found 12 RCTs that evaluated the effect of PrEP vs placebo^{25, 40-49} or no PrEP⁵⁰ on the risk of HIV acquisition. One trial was of fair quality because of an open-label design; all other trials were of good quality. Duration of follow-up ranged from 4 months to 4 years. Six trials^{42-44, 47-49} enrolled men and women at increased risk of HIV infection via heterosexual contact, 4 trials^{25, 40, 46, 50} enrolled men who have sex with men or transgender women, 1 trial⁴¹ enrolled high-risk women and men who have sex with men, and 1 trial⁴⁵ enrolled persons who inject drugs. No trial enrolled pregnant women or persons younger than 18 years. Three trials^{25, 45, 47} evaluated tenofovir disoproxil fumarate (300 mg), 7 trials^{40-42, 46, 48, 49} evaluated tenofovir disoproxil fumarate (300 mg)/emtricitabine (200 mg), 1 trial⁵⁰ evaluated tenofovir disoproxil fumarate (245 mg)/emtricitabine (200 mg), and 2 trials^{43, 44} included study groups for both tenofovir disoproxil fumarate (300 mg) alone and tenofovir disoproxil fumarate (300 mg)/emtricitabine (200 mg). PrEP was prescribed daily in 11 trials,^{25, 41-50} and dosing was intermittent or event-driven in 3 trials (including 2 trials that also included daily dosing groups).⁴⁰⁻⁴² Seven trials were conducted in Africa,^{41-44, 47-49} 1 in Thailand,⁴⁵ 2 in Europe or Canada,^{40, 50} and 1 in the United States,²⁵ 1 trial was multinational.⁴⁶ All trials of persons at high risk of HIV infection via heterosexual contact were conducted in Africa, and the only trial of persons who inject drugs was conducted in Thailand.⁴⁵ All trials of PrEP also included behavioral and adherence counseling, and most specified providing condoms to all trial participants.

One small trial reported no cases of HIV infection.⁴² In the other 11 trials, the rate of HIV infection ranged from 1.4% to 7.0% over 4 months to 4 years in participants randomly assigned to placebo or no PrEP and from 0% to 5.6% in those randomly assigned to PrEP. In a meta-analysis of these trials, PrEP was associated with reduced risk of HIV infection compared with placebo or no PrEP (relative risk [RR], 0.46 [95% CI, 0.33-0.66]; absolute risk reduction, -2.0% [95% CI, -2.8% to -1.2%]) after 4 months to 4 years.³²

PrEP was effective across population subgroups defined by HIV risk category. There were no statistically significant differences in estimates of effectiveness for PrEP vs placebo or no PrEP in risk of HIV acquisition when trials were stratified according to whether they enrolled men who have sex with men or transgender women (although the number of transgender persons in trials was small) (4 trials; RR, 0.23 [95% CI, 0.08-0.62]), men and women at increased risk of HIV infection via heterosexual contact (5 trials; RR, 0.51 [95% CI, 0.31-0.97]), or persons who inject drugs (1 trial; RR, 0.52 [95% CI, 0.29-0.92]; $P = 0.43$ for interaction).^{31, 32}

In a meta-analysis of the trials reviewed by the USPSTF, both tenofovir disoproxil fumarate/emtricitabine and tenofovir disoproxil fumarate alone appeared equally effective in decreasing the risk of HIV acquisition (8 trials; RR, 0.44 [95% CI, 0.27-0.72] and 5 trials; RR, 0.49 [95% CI, 0.28-0.84], respectively; $P = 0.79$ for interaction).^{31, 32}

Three included trials investigated alternative dosing strategies (using PrEP less frequently than daily [intermittent dosing] or before and after HIV exposure events [event-driven dosing]).⁴⁰⁻⁴² One trial⁴² reported no HIV events, and a second⁴¹ did not report results for intermittent and daily dosing of PrEP groups separately. The third trial (Intervention Préventive de l'Exposition aux Risques avec et pour les Gays) found that event-driven PrEP dosing was associated with a lower risk of HIV infection compared with placebo in men who have sex with men (RR, 0.14 [95% CI, 0.03-0.63]).⁴⁰ In that trial, men randomly assigned to PrEP took an average of about 4 doses of PrEP per week (15 doses per month), so it is uncertain whether this finding would apply to less frequent use of event-driven dosing. In addition, tenofovir disoproxil fumarate accumulates more rapidly in anal tissue than vaginal tissue,⁵¹ so this study may not be generalizable to other risk groups.

The USPSTF also evaluated the evidence on the relationship between adherence to PrEP and its effectiveness in decreasing risk of HIV infection. Methods for evaluating adherence differed between studies and included patient diaries and self-report, pill counts, adherence monitoring devices, drug levels (eg, plasma or dried blood spots), and prescription fill data.

In the trials of PrEP reviewed by the USPSTF, adherence to PrEP ranged from 30% to 100%, and the RR of HIV infection in participants randomly assigned to PrEP, compared with placebo or no PrEP, ranged from 0.95 to 0.07.^{31, 32} In a stratified analysis of these studies, a strong interaction ($P < 0.00001$) between level of adherence and effectiveness of PrEP was found, with higher levels of adherence associated with greater reduction in risk of HIV acquisition (adherence $\geq 70\%$: 6 trials; RR, 0.27 [95% CI, 0.19-0.39]; adherence $>40\%$ to $<70\%$: 3 trials; RR, 0.51 [95% CI, 0.38-0.70]; and adherence $\leq 40\%$: 2 trials; RR, 0.93 [95% CI, 0.72-1.20]).^{31, 32} There was also a strong association ($P = 0.0005$) between adherence and effectiveness when adherence was analyzed as a continuous variable in a meta-regression.^{31, 32}

Since the effectiveness of PrEP is closely tied to adherence, the USPSTF reviewed the evidence on levels of adherence to PrEP in US-relevant settings. Three observational studies of US men who have sex with men found adherence to PrEP (based on tenofovir diphosphate levels in dried blood spot sampling consistent with ≥ 4 doses/wk) of 66% to 90% over 4 to 48 weeks.^{27, 52, 53} Two observational studies of younger men who have sex with men (mean ages, 20 and 16 years) reported lower rates of adherence to PrEP (based on blood spot sampling) of approximately 50% at 12 weeks, decreasing to 34% and 22% at 48 weeks.^{16, 54} Two studies in US men who have sex with men found that self-reported adherence correlated highly with adherence based on dried blood spot sampling.^{25, 26}

Multivariate analysis of the largest US PrEP implementation study to date⁵³ found that black race was associated with lower adherence than white race (adjusted odds ratio, 0.28 [95% CI, 0.12-0.64]). Having stable housing or having receptive anal sex without a condom with 2 or more partners was associated with increased adherence (adjusted odds ratio, 2.02 [95% CI, 1.14-3.55] and 1.82 [95% CI, 1.14-2.89], respectively). There was no association between age, educational attainment, income level, health insurance

status, and alcohol or drug use and adherence. Only 1.4% of participants enrolled were transgender women, so it is not possible to draw conclusions about adherence to PrEP in this population. The USPSTF found no US studies on factors associated with adherence to PrEP in persons who inject drugs or persons at high risk of HIV infection via heterosexual contact.³¹

Potential Harms of Risk Assessment and Preventive Medication

The RCTs that investigated the effectiveness of PrEP had 4 months to 4 years of follow-up and also reported on the harms of PrEP.^{25, 40-50, 55-62} In a pooled analysis of the studies, PrEP was associated with increased risk of renal adverse events (primarily grade 1 or greater serum creatinine elevation) vs placebo (12 trials; absolute risk difference 0.56% [95% CI, 0.09%-1.04%]). There was no clear difference in risk of kidney adverse events when trials were stratified according to use of tenofovir disoproxil fumarate monotherapy or tenofovir disoproxil fumarate/emtricitabine. Serious renal events were rare, and no trial reported a difference between PrEP and placebo in risk of serious renal events or withdrawals due to renal events.^{31, 32} Six trials^{41, 42, 55-58} evaluated whether renal adverse events while using PrEP were persistent. Three studies^{55, 57, 58} reported return to normal serum creatinine levels after cessation of PrEP, and 2 others^{41, 42} reported normalization of creatinine level without PrEP cessation. In 1 trial, the Bangkok Tenofovir Study of persons who inject drugs, there were 7 cases of grade 2 or greater creatinine level elevation, and all but 1 case resolved after PrEP cessation.⁵⁶

PrEP was associated with increased risk of gastrointestinal adverse events (primarily nausea) vs placebo (12 trials; absolute risk difference, 1.95% [95% CI, 0.48%-3.43%]). Risk of gastrointestinal adverse events increased with both tenofovir disoproxil fumarate monotherapy and tenofovir disoproxil fumarate/emtricitabine,³¹ with risk diminishing over time in 3 trials.^{45, 46, 48} Serious gastrointestinal events were rare in trials reporting this outcome, with no differences between PrEP and placebo.^{44, 46-50}

Tenofovir disoproxil fumarate exposure is associated with bone loss,^{48, 59-61} which could result in increased fracture risk. A meta-analysis of 7 studies that reported on fractures using both study data and updated fracture data reported to the FDA, found a statistically nonsignificant increased risk of fracture in persons randomly assigned to PrEP vs placebo. This result was also heavily weighted by the 1 study of PrEP in persons who inject drugs, which reported a relatively high fracture rate.^{31, 32}

One concern about PrEP is that its use may lead to persons at risk of HIV acquisition not using condoms or engaging in other behaviors that could increase their risk of STIs (behavioral risk compensation). In meta-analyses of the studies reviewed by the USPSTF, there were no differences between PrEP and placebo or no PrEP in risk of syphilis (5 trials; RR, 1.08 [95% CI, 0.98-1.18]), gonorrhea (5 trials; RR, 1.07 [95% CI, 0.82-1.39]), chlamydia (5 trials; RR, 0.97 [95% CI, 0.80-1.18]), or combined bacterial STIs (2 trials; RR, 1.14 [95% CI, 0.97-1.34]).^{31, 32} All of the trials except for 1 were blinded, which could affect risk of STIs if participants who do not know if they are taking PrEP or placebo behave differently than those who know they are taking PrEP. In the 1 open-label trial, there was also no statistically significant association between PrEP and the risk of STIs.

An additional concern is the possibility that the use of antiretroviral drugs as PrEP could lead to the development or acquisition of drug-resistant HIV infection. In 8 trials of PrEP using tenofovir disoproxil fumarate monotherapy or tenofovir disoproxil fumarate/emtricitabine, 3 of 282 patients (1.1%) newly diagnosed with HIV infection while taking PrEP had tenofovir resistance mutations.^{40, 43-47, 49, 50} In 6 trials of PrEP with tenofovir disoproxil fumarate/emtricitabine, 14 of 174 patients (8.0%) newly diagnosed with HIV infection while taking PrEP had emtricitabine resistance mutations.^{40, 43, 44, 46, 48-50} There was 1 case of multiple resistance mutations, which is included in the total number of both tenofovir and emtricitabine resistance mutations. Most resistance mutations (1/2 tenofovir resistance mutations, 8/13 emtricitabine resistance mutations, and 1 case of multiple resistance mutations, or 63% of total cases) occurred in persons who were already infected with HIV on trial enrollment but were not recognized as such. This highlights the importance of testing for HIV and excluding persons with acute or chronic HIV infection before initiating PrEP. The USPSTF found no data on the effect of resistance mutations on clinical outcomes.

No trial of oral PrEP enrolled pregnant women, and women who became pregnant during the course of the trials were withdrawn from participation. Three trials reported on pregnancy outcomes in women who were withdrawn from PrEP because of pregnancy.^{41, 48, 62} Among women who became pregnant in the trials, PrEP was not associated with an increased risk of spontaneous abortion. One trial, the Partners PrEP trial, also found no differences between PrEP and placebo in pregnancy rate, risk of preterm birth, birth anomalies, or postpartum infant mortality.⁶²

Estimate of Magnitude of Net Benefit

The USPSTF found convincing evidence that PrEP is of substantial benefit in decreasing the risk of HIV infection in persons at high risk of HIV acquisition. The USPSTF also found convincing evidence that adherence to PrEP is highly correlated with its efficacy in preventing the acquisition of HIV infection; thus, adherence to PrEP is central to realizing its benefit. The USPSTF found adequate evidence that PrEP is associated with small harms, including renal and gastrointestinal adverse effects. The USPSTF concludes with high certainty that the magnitude of benefit of PrEP with oral tenofovir disoproxil fumarate–based therapy to reduce the risk of acquisition of HIV infection in persons at high risk is substantial.

How Does Evidence Fit With Biological Understanding?

HIV is an RNA retrovirus that infects immune cells, in particular CD4⁺ T cells. Antiretroviral agents interfere with 1 of several steps in viral infection and replication, such as HIV entry into CD4⁺ cells, reverse transcription of viral RNA into DNA, integration of the viral genome into the host genome, and assembly of HIV proteins and RNA into new virions. Tenofovir disoproxil fumarate and emtricitabine are both reverse transcriptase inhibitors and have favorable safety profiles. Tenofovir disoproxil fumarate achieves particularly high concentrations in rectal tissue, and emtricitabine achieves high concentrations in the female genital tract.⁶⁴ The possibility of using PrEP to prevent HIV transmission was suggested by the success of antiretroviral agents in preventing mother-to-child transmission of HIV and their use as postexposure prophylaxis⁶⁵⁻⁶⁷ and was demonstrated in several animal models, including 1 model showing that tenofovir disoproxil fumarate and emtricitabine decreased the risk of rectal transmission of simian immunodeficiency virus in macaques.⁶⁸

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from November 20, 2018, to December 26, 2018. In response to public comment, the USPSTF clarified language describing risk groups and high-risk activities in the Clinical Considerations section. In the same section, the USPSTF also added information about the high burden of HIV in transgender women and the risk of HIV transmission in persons living with HIV who have a suppressed viral load. The USPSTF also added details on the likelihood that specific activities will lead to the transmission of HIV and on the prevalence of HIV in different groups. The USPSTF addressed stigma, barriers to access to care, and racial/ethnic disparities as obstacles to the use of PrEP by persons and groups at high risk.

The USPSTF received comments requesting that it include a meta-analysis⁶⁹ examining the effects of PrEP on the risk of STIs in the evidence reviewed for this recommendation. In response, the USPSTF notes that it reviewed that particular meta-analysis; however, because of methodologic limitations of the studies included in the meta-analysis, such as not adjusting for differential STI testing rates and use of self-report to determine baseline STI rates, it was not included in the body of evidence considered for this recommendation. Last, the USPSTF added the American College of Obstetricians and Gynecologists committee opinion on the use of PrEP to the Recommendations of Others section.

The 2017 CDC guidelines recommend PrEP with tenofovir disoproxil fumarate/emtricitabine as an HIV prevention option for men who have sex with men, heterosexually active men and women, and persons who inject drugs who are at substantial risk of HIV infection, with tenofovir disoproxil fumarate monotherapy as an alternative for heterosexually active men and women and persons who inject drugs and who are at substantial risk.³ The American College of Obstetricians and Gynecologists suggests that, in combination with other proven HIV-prevention methods, PrEP may be a useful tool for women at highest risk of HIV acquisition and that such women should be considered candidates for PrEP.⁷⁰ 2016 World Health Organization guidance recommends offering PrEP containing tenofovir disoproxil fumarate as an additional prevention choice for persons at substantial risk of HIV infection (provisionally defined as HIV incidence higher than 3 cases/100 person-years) as part of HIV prevention approaches.⁷¹

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Current as of: June 2

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

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

(b) County of Residence of First Listed Plaintiff Tarrant (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Jonathan F. Mitchell, Mitchell Law PLLC 111 Congress Avenue, Suite 400, Austin, Texas 78701 (512) 686-3940

DEFENDANTS

Alex M. Azar II, in his official capacity as Secretary of HHS; 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

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship: Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, TORTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 2201, 5 U.S.C. § 706

Brief description of cause: Constitutional challenge to preventive-care coverage mandates in the Affordable Care Act

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE DOCKET NUMBER

DATE

March 29, 2020

SIGNATURE OF ATTORNEY OF RECORD

Jonathan F. Mitchell

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

Case 4:20-cv-00283-O Document 1-7 Filed 03/29/20 Page 2 of 2 PageID 66
INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.