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

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

Plaintiffs,

v.

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-O

FIRST AMENDED COMPLAINT

The Affordable Care Act empowers the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration to unilaterally determine the "preventive care" that private health insurance must cover. *See* 42 U.S.C. § 300gg-13. Since the Affordable Care Act's enactment, these agencies have issued numerous pronouncements that force health-insurance issuers and self-insured plans to cover certain forms of "preventive care" without any cost-sharing arrangements such as deductibles and co-pays. In 2011, for example, the Health Resources and Services Administration issued a highly controversial pronouncement that compels private insurance to cover all forms of FDA-approved contraceptive methods, including contraceptive methods that operate as

abortifacients. A few months ago, the U.S. Preventive Services Task Force issued an equally controversial decree that requires private insurance to cover pre-exposure prophylaxis (PrEP) drugs such as Truvada and Descovy starting in 2021.

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

JURISDICTION AND VENUE

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

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

PARTIES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

THE AFFORDABLE CARE ACT'S PREVENTIVE-CARE MANDATES

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

18. A separate provision of the Affordable Care Act requires group health plans and health-insurance issuers to cover "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved," and to do so without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(2) (attached as Exhibit 1).

19. Another provision requires group health plans and health-insurance issuers to cover "with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration," and to cover this preventive care and screenings without any cost-sharing requirements such as deductibles or co-pays. *See* 42 U.S.C. § 300gg-13(a)(3) (attached as Exhibit 1).

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

THE HRSA'S CONTRACEPTIVE MANDATE

21. On August 1, 2011—more than one year after the Affordable Care Act was signed into law—the Health Resources and Services Administration issued guidelines requiring that all FDA-approved contraceptive methods be covered as "preventive care" under 42 U.S.C. § 300gg-13(a)(4). These HRSA guidelines of August 1, 2011, did not go through notice-and-comment rulemaking procedures.

22. In response to the HRSA's decree of August 1, 2011, the Secretary of Health and Human Services, the Secretary of the Treasury, and the Secretary of Labor issued notice-and-comment regulations to implement HRSA's decision to require private insurers to cover contraception. These rules are known as the "Contraceptive Mandate," and they are codified at 45 C.F.R. § 147.130(a)(1)(iv), 29 C.F.R. § 2590.715–2713(a)(1)(iv), and 26 C.F.R. § 54.9815–2713(a)(1)(iv) (attached as Exhibits 2–4).

23. On May 4, 2017, President Trump issued an executive order instructing the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services to amend the Contraceptive Mandate to address conscience-based objections. *See* Executive Order 13798.

24. In response to this order, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services issued a final rule on November 15, 2018, that exempts any non-profit or for-profit employer from the Contraceptive Mandate if it opposes the coverage of contraception for sincere religious reasons. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (November 15, 2018).

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

26. The final rule was scheduled to take effect on January 14, 2019. On January 14, 2019, however, a federal district court in Pennsylvania issued a nationwide preliminary injunction against its enforcement. *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019). The Third Circuit affirmed this nationwide preliminary injunction on July 12, 2019. *See Pennsylvania v. President of the United States*, 940 F.3d 543 (3d Cir. 2019). The Supreme Court granted certiorari and vacated the nationwide injunction in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*,

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

27. In response to the nationwide injunction issued in *Pennsylvania v. Trump*, a lawsuit was filed in the Northern District of Texas to enjoin federal officials from enforcing the Obama-era contraceptive mandate against the religious objectors protected by the Trump Administration's final rule of November 15, 2018. The district court held that the protections conferred in the Trump Administration's final rule were compelled by the Religious Freedom Restoration Act, and permanently enjoined federal officials from enforcing the Contraceptive Mandate against any religious objector protected by the final rule. *See DeOtte v. Azar*, 393 F. Supp. 3d 490 (N.D. Tex. 2019); *see also* Exhibit 5 (final judgment in *DeOtte*). As a result of *DeOtte*, the protections conferred by the Trump Administration's final rule are in full force and effect because they have been incorporated into the *DeOtte* injunction, even though the final rule itself remains subject to litigation.

28. Despite the *DeOtte* injunction, few if any insurance companies are currently offering health insurance that excludes coverage for contraception, and the continued existence of the Contraceptive Mandate restricts the options available to those who wish to purchase health insurance but who do not need or want contraceptive coverage.

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

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

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

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

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

ALLEGATIONS RELATED TO ARTICLE III STANDING

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

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

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

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

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

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

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

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

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

B. Plaintiffs Donovan Riddle and Karla Riddle

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

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

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

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

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

C. Plaintiff Joel Miller

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

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

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

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

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

D. Plaintiff Gregory Scheideman

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

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

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

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

E. Plaintiff Kelley Orthodontics

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

54. Kelley Orthodontics employs numerous individuals as employees.

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

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

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

F. Plaintiff Braidwood Management Inc.

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

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

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

61. Braidwood Management Inc. is self-insured and provides health insurance to its employees. Because Braidwood has more than 50 employees, it is compelled to offer ACA-compliant health insurance to its employees or face heavy financial penalties. *See* 26 U.S.C. § 4980H(c)(2).

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

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

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

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

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

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

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

> evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force

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

> immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved

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

> with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.

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

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

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

> [The President] shall have Power, by and with the Advice and Consent of the Senate, to . . . appoint Ambassadors, other public Ministers and

> Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. art. II § 2.

71. The members of the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration are "officers of the United States," because they exercise "significant authority pursuant to the laws of the United States." *See Buckley v. Valeo*, 424 U.S. 1, 126 (1976) ("[A]ny appointee exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed by s 2, cl. 2, of that Article."); *see also* Jennifer L. Mascott, *Who Are "Officers of the United States"?*, 70 Stan. L. Rev. 443 (2018). The power to unilaterally determine the "preventive care" that all health insurance must cover without cost-sharing qualifies as "significant authority pursuant to the laws of the United States."

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

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

Constitution, there does not appear to be any Act of Congress that "vests" their appointment in the President alone, in the Courts of Law, or in the Heads of Departments—which is needed to escape the constitutional default rule of presidential nomination and Senate confirmation.

74. The statute that establishes the U.S. Preventive Services Task Force, for example, says that "[t]he Director [of the Agency for Healthcare Research and Quality] shall *convene* an independent Preventive Services Task Force . . . to be composed of individuals with appropriate expertise." 42 U.S.C.A. § 299b-4(a)(1) (emphasis added). But this says nothing about how the members of the Task Force are to be *appointed*, and it does not purport to "vest" the appointment of these members in the Director. And in all events, the Director of the Agency for Healthcare Research and Quality would not qualify as a "Head of Department" within the meaning of the Appointments Clause. *See Freytag v. Commissioner of Internal Revenue*, 501 U.S. 868, 886 (1991); *United States v. Germaine*, 99 U.S. 508, 511 (1878).

75. In addition, the plaintiffs have not been able to locate any Act of Congress that "vests" the appointment of the members of the Advisory Committee on Immunization Practices or the Health Resources and Services Administration in the President alone, the Courts of Law, or the Heads of Department. 42 U.S.C. § 217a, for example, authorizes the Secretary of Health and Human Services to "appoint such advisory councils or committees . . . for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary *for the purpose of advising him in connection with any of his functions*." 42 U.S.C. § 217a (emphasis added). But this statute cannot be used to appoint the members of the Advisory Committee on Immunization Practices or the Health Resources and Services Administration now that 42 U.S.C. § 300gg-13(2)–(4) gives binding force to their pronouncements. The members these entities are not "advising" the Secretary on these statutory matters,

and they are no longer being appointed "for the purpose of advising" the Secretary. Instead, they are *deciding* the preventive care that private insurance *must* cover.

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

77. The Court should therefore declare that any and all preventive-care mandates based on a rating, recommendation, or guideline issued by the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, or the Health Resources and Services Administration after March 23, 2010—the date on which the Affordable Care Act was signed into law—are unconstitutional and unenforceable, and it should permanently enjoin the defendants from enforcing them.

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

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

79. Indeed, a court is obligated to adopt this construction of the statute regardless of whether it is ultimately persuaded by the plaintiffs' Appointments Clause arguments, because ambiguities in federal statutes must be interpreted in a manner that will avoid serious constitutional questions. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 842 (2018) ("When a serious doubt is raised about the constitutionality of an act of Congress, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided." (citation and internal quotation marks omitted)); *Ellis v. Bhd. of Ry., Airline & S.S. Clerks, Freight Handlers, Exp. & Station Employees*, 466 U.S. 435, 444 (1984) ("When the constitutionality of a statute is challenged, this Court first ascertains whether the statute can be reasonably construed to avoid the constitutional difficulty."); *Ohio v. Akron Ctr. for Reprod. Health*, 497 U.S. 502, 514 (1990) ("[W]here fairly possible, courts should construe a [state] statute to avoid a danger of unconstitutionality." (citation and internal quotation marks omitted)); *see also Gundy v. United States*, 139 S. Ct. 2116, 2123–24 (2019) (plurality opinion of Kagan, J.); Cass R. Sunstein, *Nondelegation Canons*, 67 U. Chi. L. Rev. 315 (2000) (describing how canons of construction have been used to support nondelegation principles, and urging

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

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

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

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

> evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force

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

> immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved

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

> with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive

> guidelines supported by the Health Resources and Services Administration.

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

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

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

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

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

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

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

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

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

90. If the Court somehow concludes that the U.S. Preventive Services Task Force is exercising executive power rather than legislative power when it unilaterally decrees the "items or services" that health insurance must cover, then 42 U.S.C. § 300gg-13(a)(1) violates Article II's vesting clause by conferring executive power on agency officials who are not subject to Presidential direction, removal, or control.

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

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

42 U.S.C. § 299b-4.

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

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

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

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

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

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

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

> evidence-based items or services that have in effect a rating of "A" or "B" in the *current recommendations* of the United States Preventive Services Task Force

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

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

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

99. 42 U.S.C. § 300gg-13(a)(2) requires private insurance to cover:

> immunizations that *have in effect a recommendation* from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved

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

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

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

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

> with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in *the comprehensive guidelines supported by the Health Resources and Services Administration*.

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

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

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

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

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

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

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

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

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

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

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

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

DEMAND FOR RELIEF

112. The plaintiffs respectfully request that the court:

a. declare that 42 U.S.C. § 300gg-13(a)(1)–(4) violate the Appointments Clause by empowering individuals who have not been appointed in conformity with the Appointments Clause to unilaterally determine the preventive care that health insurance must cover;

b. declare that 42 U.S.C. § 300gg-13(a)(1)–(4) violate Article I of the Constitution by delegating legislative power to the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration without providing an "intelligible principle" to guide the agencies' discretion;

c. declare that 42 U.S.C. § 300gg-13(a)(1) violates Article II's vesting clause by empowering the U.S. Preventive Services Task Force to unilaterally determine that preventive care that health insurance must cover while simultaneously immunizing that agency from the President's direction, removal, or control;

d. in the alternative, declare that 42 U.S.C. § 300gg-13(a)(1), as a matter of statutory interpretation, requires insurers to cover only the items or services that had an "A" or "B" rating from the U.S. Preventive Services Task Force on March 23, 2010, that 42 U.S.C. § 300gg-13(a)(2) requires insurers to cover only the immunizations that were recommended by the Advisory Committee on Immunization Practices as of March 23, 2010, and that 42 U.S.C. § 300gg-13(a)(3)–(4) require insurers to cover only the preventive care and screenings provided for in HRSA guidelines in existence on March 23, 2010;

e. permanently enjoin the defendants from enforcing any coverage mandate based upon an agency rating, recommendation, or guideline that issued after March 23, 2010;

f. declare that the PrEP mandate violates the Religious Freedom Restoration Act, and permanently enjoin the defendants from enforcing it against any individual or employer who objects to the coverage of PrEP drugs for sincere religious reasons;

g. award costs and attorneys' fees under 42 U.S.C. § 1988;

h. award all other relief that the Court deems just, proper, or equitable.

Respectfully submitted.

/s/ Jonathan F. Mitchell

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Dated: July 20, 2020

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

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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; and[1]

(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 238*l* 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 Deparement 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.	§	**Civil Action No. 4:18-cv-00825-O**
	§	
ALEX M. AZAR II et al.,	§	
	§	
Defendants.[1]	§	

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

Final Recommendation Statement

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 Researc 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 hereThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer.

To read the evidence summary in *JAMA*, select hereThis link goes offsite. Click to read the external link disclaimerThis 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 makin 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 har

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 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% (7312) 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 acquisiti 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

Patient Population Under Consideration

This recommendation applies to persons who are not infected with HIV and are at high risk of HIV infection.

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 s 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 a 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 relation 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 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 tha 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 b 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 wit 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 partne 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, wher 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 w 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 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 a 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-vagin 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 hig 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 kno

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 (F 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 fumara 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 hi 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 wh 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 mine 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 an increase condom use among adolescents and adults at increased risk of STIs.[17] The CDC has made several recommendations, including abstinence, reducing one's numbe 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 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.pdfThis link goes offsite. Click to read the external link disclaimerThis 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.pdfThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer.[22] Additional CDC resource on PrEP for both clinicians and consumers are available at https://www.cdc.gov/hiv/risk/prep/index.htmlThis link goes offsite. Click to read the external link disclaimerThis 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/nchhstp/atlasThis li goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer.[24] The USPSTF has issued recommendations on behavio counseling to reduce risk of STIs[17] 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 identifie 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, a 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 regi 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-resis 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 fr 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 r of HIV acquisition continues. Patients may discontinue PrEP for several reasons, including personal preference, decreased risk of HIV acquisition, or adverse medication eff

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. Promot 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 wh 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 marke 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 adhere 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 develope 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 adherenc 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 quanti effectiveness in those populations. Research is needed on the safety and effectiveness of PrEP during pregnancy and breastfeeding. Additional research is needed to deter 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 th 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 Unite 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/La

populations. From 2012 to 2017, HIV incidence rates increased among persons aged 25 to 29 years and among American Indian/Alaska Native and Asian populations.[2]

PrEP is currently not used in many persons at high risk of HIV infection. The CDC estimates that approximately 1.2 million persons were eligible for PrEP in 2015 (492,000 m 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 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, populatio 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 i 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 men[33] 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 r 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, ar 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 t 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 beha 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 se 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-sha 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 PrEP[50] 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 trial[41] enrolled high-risk women and men who have sex with men, and 1 trial[45] enrolled persons who inject drugs. No trial enrolled pregnant women or persons younger than 18 years. Three trials[25, 45, 47] evaluated tenofovir disop fumarate (300 mg), 7 trials[40-42, 46, 48, 49] evaluated tenofovir disoproxil fumarate (300 mg)/emtricitabine (200 mg), 1 trial[50] 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 dos 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 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 o 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 random 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 plac 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 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, 0.5 [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 i 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-driv dosing]).[40-42] One trial[42] reported no HIV events, and a second[41] did not report results for intermittent and daily dosing of PrEP groups separately. The third trial (Interventio 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 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 p 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 a 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, compar 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 effectiven of PrEP was found, with higher levels of adherence associated with greater reduction in risk of HIV acquisition (adherence ≥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 ≤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 observationa 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 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 PrE (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 tha 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 date[53] 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 insura

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 PrE 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 thes 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 differen 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 re 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] report 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 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 fractu 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 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 trial 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 placeb 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 STI

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 Pr 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 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 highli 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 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 H 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 viru 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 wa suggested by the success of antiretroviral agents in preventing mother-to child transmission of HIV and their use as postexposure prophylaxis[65-67] 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 v 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 addres 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-analysis[69] 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.

Recommendations of Others

The 2017 CDC guidelines recommend PrEP with tenofovir disoproxil fumarate/emtricitabine as an HIV prevention option for men who have sex with men, heterosexually act 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 heterosexual 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 combinati 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 fo 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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References:

1. Centers for Disease Control and Prevention (CDC). Estimated HIV Incidence and Prevalence in the United States, 2010–2016. CDC website. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-supplemental-report-vol-24-1.pdfThis link goes offsite. Click to read the external link disclaimerTh link goes offsite. Click to read the external link disclaimer. Published February 2019. Accessed April 16, 2019.
2. Centers for Disease Control and Prevention (CDC). Diagnoses of HIV Infection in the United States and Dependent Areas, 2017. CDC website. https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-2017-vol-29.pdfThis link goes offsite. Click to read the external link disclaimerThis link goe offsite. Click to read the external link disclaimer. Published November 2018. Accessed April 16, 2019.
3. Centers for Disease Control and Prevention (CDC), US Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: A Clinical Practice Guideline. CDC website. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdfThis link goes offsite. Click to read the external lin disclaimerThis link goes offsite. Click to read the external link disclaimer. Published March 2018. Accessed April 16, 2019.
4. Centers for Disease Control and Prevention (CDC). HIV and transgender people. CDC website. https://www.cdc.gov/hiv/group/gender/transgender/index.htmlThis link goe offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. 2019. Accessed April 16, 2019.
5. Patel P, Borkowf CB, Brooks JT, Lasry A, Lansky A, Mermin J. Estimating per-act HIV transmission risk: a systematic review. *AIDS*. 2014;28(10):1509-1519.
6. Reece M, Herbenick D, Schick V, Sanders SA, Dodge B, Fortenberry JD. Condom use rates in a national probability sample of males and females ages 14 to 94 in the United States. *J Sex Med*. 2010;7(suppl 5):266-276.
7. Bavinton BR, Pinto AN, Phanuphak N, et al; Opposites Attract Study Group. Viral suppression and HIV transmission in serodiscordant male couples: an international, prospective, observational, cohort study. *Lancet HIV*. 2018;5(8):e438-e447.
8. Rodger AJ, Cambiano V, Bruun T, et al; PARTNER Study Group. Sexual activity without condoms and risk of HIV transmission in serodifferent couples when the HIV-positive partner is using suppressive antiretroviral therapy. *JAMA*. 2016;316(2):171-181.
9. Rodger AJ, Cambiano V, Bruun T, et al. Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study [published online May 2, 2019]. *Lancet*.
10. Singh S, Song R, Johnson AS, McCray E, Hall HI. HIV incidence, prevalence, and undiagnosed infections in U.S. men who have sex with men. *Ann Intern Med*. 2018;168(10):685-694.
11. Mathers BM, Degenhardt L, Phillips B, et al; 2007 Reference Group to the UN on HIV and Injecting Drug Use. Global epidemiology of injecting drug use and HIV among people who inject drugs: a systematic review. *Lancet*. 2008;372(9651):1733-1745.
12. Friedman MR, Wei C, Klem ML, Silvestre AJ, Markovic N, Stall R. HIV infection and sexual risk among men who have sex with men and women (MSMW): a systematic review and meta-analysis. *PLoS One*. 2014;9(1):e87139.
13. Gilead Sciences. Truvada prescribing information. Gilead Sciences website. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdfThis link goe offsite. Click to read the external link disclaimer. 2018. Accessed April 16, 2019.
14. Mugo NR, Heffron R, Donnell D, et al; Partners in Prevention HSV/HIV Transmission Study Team. Increased risk of HIV-1 transmission in pregnancy: a prospective study among African HIV-1-serodiscordant couples. *AIDS*. 2011;25(15):1887-1895.
15. Centers for Disease Control and Prevention (CDC). HIV and Youth. CDC website. https://www.cdc.gov/hiv/pdf/group/age/youth/cdc-hiv-youth.pdfThis link goes offsite. Cl to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. Published April 2019. Accessed April 16, 2019.
16. Hosek SG, Landovitz RJ, Kapogiannis B, et al. Safety and feasibility of antiretroviral preexposure prophylaxis for adolescent men who have sex with men aged 15 to 17

years in the United States. *JAMA Pediatr*. 2017;171(11):1063-1071.
17. LeFevre ML; US Preventive Services Task Force. Behavioral counseling interventions to prevent sexually transmitted infections: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2014;161(12):894-901.
18. Centers for Disease Control and Prevention (CDC). How you can prevent sexually transmitted diseases. CDC website. https://www.cdc.gov/std/prevention/default.htmThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. 2016. Accessed April 16, 2019.
19. Centers for Disease Control and Prevention (CDC). Syringe services programs. CDC website. https://www.cdc.gov/hiv/risk/ssps.htmlThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. 2018. Accessed April 16, 2019.
20. HIV/AIDS, STIs and pregnancy. The Community Guide website. https://www.thecommunityguide.org/topic/hivaids-stis-and-pregnancyThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. Accessed April 16, 2019.
21. Moyer VA; US Preventive Services Task Force. Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2013;159(1):51-60
22. Centers for Disease Control and Prevention (CDC). US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2017 Update: Clinical Providers' Supplement. CDC website. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdfThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. Published March 2018. Accessed April 16, 2019.
23. Centers for Disease Control and Prevention (CDC). Pre-exposure prophylaxis (PrEP). CDC website. https://www.cdc.gov/hiv/risk/prep/index.htmlThis link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. 2018. Accessed April 16, 2019.
24. Centers for Disease Control and Prevention (CDC). NCHHSTP AtlasPlus. CDC website. https://www.cdc.gov/nchhstp/atlas/This link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. 2017. Accessed April 16, 2019.
25. Grohskopf LA, Chillag KL, Gvetadze R, et al. Randomized trial of clinical safety of daily oral tenofovir disoproxil fumarate among HIV-uninfected men who have sex with men in the United States. *J Acquir Immune Defic Syndr*. 2013;64(1):79-86.
26. Chan PA, Mena L, Patel R, et al. Retention in care outcomes for HIV pre-exposure prophylaxis implementation programmes among men who have sex with men in three US cities. *J Int AIDS Soc*. 2016;19(1):20903.
27. Liu AY, Cohen SE, Vittinghoff E, et al. Preexposure prophylaxis for HIV infection integrated with municipal- and community-based sexual health services. *JAMA Intern Me* 2016;176(1):75-84.
28. Bush S, Magnuson D, Rawlings MK, et al. ASM/ICAAC: racial characteristics of FTC/TDF for pre-exposure prophylaxis (PrEP) users in the US. National AIDS Treatment Advocacy Project website. http://www.natap.org/2016/HIV/062216_02.htm. 2016This link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. Accessed April 16, 2019.
29. Smith DK, Van Handel M, Wolitski RJ, et al. Vital signs: estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition—United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2015;64(46):1291-1295.
30. Sullivan PS, Giler RM, Mouhanna F, et al. Trends in the use of oral emtricitabine/tenofovir disoproxil fumarate for pre-exposure prophylaxis against HIV infection, United States, 2012-2017. *Ann Epidemiol*. 2018;28(12):833-840.
31. Chou R, Evans C, Hoverman A, et al. Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force: Evidence Synthesis No. 178. Rockville, MD: Agency for Healthcare Research and Quality; 2018. AHRQ publication 18-05247-EF-1.
32. Chou R, Evans C, Hoverman A, et al. Preexposure prophylaxis for the prevention of HIV infection: evidence report and systematic review for the US Preventive Services Task Force. *JAMA*. 2019;321(22):2214-2230.
33. Beymer MR, Weiss RE, Sugar CA, et al. Are Centers for Disease Control and Prevention guidelines for preexposure prophylaxis specific enough? formulation of a personalized HIV risk score for pre-exposure prophylaxis initiation. *Sex Transm Dis*. 2017;44(1):48-56.
34. Hoenigl M, Weibel N, Mehta SR, et al. Development and validation of the San Diego Early Test Score to predict acute and early HIV infection risk in men who have sex with men. *Clin Infect Dis*. 2015;61(3):468-475.
35. Menza TW, Hughes JP, Celum CL, Golden MR. Prediction of HIV acquisition among men who have sex with men. *Sex Transm Dis*. 2009;36(9):547-555.
36. Smith DK, Pals SL, Herbst JH, Shinde S, Carey JW. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. *J Acquir Immune Defic Syndr*. 2012;60(4):421-427.
37. Jones J, Hoenigl M, Siegler AJ, Sullivan PS, Little S, Rosenberg E. Assessing the performance of 3 human immunodeficiency virus incidence risk scores in a cohort of black and white men who have sex with men in the South. *Sex Transm Dis*. 2017;44(5):297-302.
38. Lancki N, Almirol E, Alon L, McNulty M, Schneider JA. Preexposure prophylaxis guidelines have low sensitivity for identifying seroconverters in a sample of young black MSM in Chicago. *AIDS*. 2018;32(3):383-392.
39. Smith DK, Pan Y, Rose CE, et al. A brief screening tool to assess the risk of contracting HIV infection among active injection drug users. *J Addict Med*. 2015;9(3):226-232
40. Molina JM, Capitant C, Spire B, et al; ANRS IPERGAY Study Group. On-demand preexposure prophylaxis in men at high risk for HIV-1 infection. *N Engl J Med*. 2015;373(23):2237-2246.
41. Mutua G, Sanders E, Mugo P, et al. Safety and adherence to intermittent pre-exposure prophylaxis (PrEP) for HIV-1 in African men who have sex with men and female s workers. *PLoS One*. 2012;7(4):e33103.
42. Kibengo FM, Ruzagira E, Katende D, et al. Safety, adherence and acceptability of intermittent tenofovir/emtricitabine as HIV pre-exposure prophylaxis (PrEP) among HIV uninfected Ugandan volunteers living in HIV-serodiscordant relationships: a randomized, clinical trial. *PLoS One*. 2013;8(9):e74314.
43. Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. 2012;367(5):399-410.
44. Marrazzo JM, Ramjee G, Richardson BA, et al; VOICE Study Team. Tenofovir-based preexposure prophylaxis for HIV infection among African women. *N Engl J Med*. 2015;372(6):509-518.
45. Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2013;381(9883):2083-2090.
46. Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587-2599.
47. Peterson L, Taylor D, Roddy R, et al. Tenofovir disoproxil fumarate for prevention of HIV infection in women: a phase 2, double-blind, randomized, placebo-controlled trial *PLoS Clin Trials*. 2007;2(5):e27.
48. Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Me* 2012;367(5):423-434.
49. Van Damme L, Corneli A, Ahmed K, et al; FEM-PrEP Study Group. Preexposure prophylaxis for HIV infection among African women. *N Engl J Med*. 2012;367(5):411-42
50. McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet*. 2016;387(10013):53-60.
51. Cottrell ML, Yang KH, Prince HM, et al. A translational pharmacology approach to predicting outcomes of preexposure prophylaxis against HIV in men and women using tenofovir disoproxil fumarate with or without emtricitabine. *J Infect Dis*. 2016;214(1):55-64.
52. Montgomery MC, Oldenburg CE, Nunn AS, et al. Adherence to pre-exposure prophylaxis for HIV prevention in a clinical setting. *PLoS One*. 2016;11(6):e0157742.
53. Landovitz RJ, Beymer M, Kofron R, et al. Plasma tenofovir levels to support adherence to TDF/FTC preexposure prophylaxis for HIV prevention in MSM in Los Angeles, California. *J Acquir Immune Defic Syndr*. 2017;76(5):501-511.
54. Hosek SG, Rudy B, Landovitz R, et al; Adolescent Trials Network (ATN) for HIVAIDS Interventions. An HIV preexposure prophylaxis demonstration project and safety study for young MSM. *J Acquir Immune Defic Syndr*. 2017;74(1):21-29.
55. Mandala J, Nanda K, Wang M, et al. Liver and renal safety of tenofovir disoproxil fumarate in combination with emtricitabine among African women in a pre-exposure prophylaxis trial. *BMC Pharmacol Toxicol*. 2014;15:77.
56. Martin M, Vanichseni S, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Renal function of participants in the Bangkok tenofovir study—Thailand, 2005-2012. *Cli Infect Dis*. 2014;59(5):716-724.
57. Solomon MM, Lama JR, Glidden DV, et al; iPrEx Study Team. Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. *AIDS*. 2014;28(6):851-859.
58. Mugwanya KK, Wyatt C, Celum C, et al; Partners PrEP Study Team. Changes in glomerular kidney function among HIV-1-uninfected men and women receiving emtricitabine-tenofovir disoproxil fumarate preexposure prophylaxis: a randomized clinical trial. *JAMA Intern Med*. 2015;175(2):246-254.
59. Liu AY, Vittinghoff E, Sellmeyer DE, et al. Bone mineral density in HIV-negative men participating in a tenofovir pre-exposure prophylaxis randomized clinical trial in San Francisco. *PLoS One*. 2011;6(8):e23688.
60. Mulligan K, Glidden DV, Anderson PL, et al; Preexposure Prophylaxis Initiative Study Team. Effects of emtricitabine/tenofovir on bone mineral density in HIV-negative persons in a randomized, double-blind placebo-controlled trial. *Clin Infect Dis*. 2015;61(4):572-580.
61. Kasonde M, Niska RW, Rose C, et al. Bone mineral density changes among HIV-uninfected young adults in a randomised trial of pre-exposure prophylaxis with tenofovir

emtricitabine or placebo in Botswana. *PLoS One*. 2014;9(3):e90111.
62. Mugo NR, Hong T, Celum C, et al; Partners PrEP Study Team. Pregnancy incidence and outcomes among women receiving preexposure prophylaxis for HIV prevention randomized clinical trial. *JAMA*. 2014;312(4):362-371.
63. Sierra-Aragón S, Walter H. Targets for inhibition of HIV replication: entry, enzyme action, release and maturation. *Intervirology*. 2012;55(2):84-97.
64. Krakower DS, Mayer KH. Pre-exposure prophylaxis to prevent HIV infection: current status, future opportunities and challenges. *Drugs*. 2015;75(3):243-251.
65. Connor EM, Sperling RS, Gelber R, et al; Pediatric AIDS Clinical Trials Group Protocol 076 Study Group. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. *N Engl J Med*. 1994;331(18):1173-1180.
66. Cardo DM, Culver DH, Ciesielski CA, et al; Centers for Disease Control and Prevention Needlestick Surveillance Group. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med*. 1997;337(21):1485-1490.
67. Mayer KH, Venkatesh KK. Chemoprophylaxis for HIV prevention: new opportunities and new questions. *J Acquir Immune Defic Syndr*. 2010;55(suppl 2):S122-S127.
68. García-Lerma JG, Otten RA, Qari SH, et al. Prevention of rectal SHIV transmission in macaques by daily or intermittent prophylaxis with emtricitabine and tenofovir. *PLoS Med*. 2008;5(2):e28.
69. Traeger MW, Schroeder SE, Wright EJ, et al. Effects of pre-exposure prophylaxis for the prevention of human immunodeficiency virus infection on sexual risk behavior in men who have sex with men: a systematic review and meta-analysis. *Clin Infect Dis*. 2018;67(5):676-686.
70. ACOG Committee Opinion no 595: Committee on Gynecologic Practice: preexposure prophylaxis for the prevention of human immunodeficiency virus. *Obstet Gynecol*. 2014;123(5):1133-1136.
71. World Health Organization (WHO). Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach. 2nd ed. WHO website. https://www.who.int/hiv/pub/arv/arv-2016/en/This link goes offsite. Click to read the external link disclaimerThis link goes offsite. Click to read the external link disclaimer. Published June 2016. Accessed April 16, 2019.

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