No. 24-316

In the Supreme Court of the United States

ROBERT F. KENNEDY, JR., SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS

v.

BRAIDWOOD MANAGEMENT, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

JOINT APPENDIX

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

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

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 MERICA, DEFENDANTS

Filed: July 20, 2020

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 arrange-

ments 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 copays. *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 va-

cated 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 copayments 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 reli-

gious 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 contracep-

tive 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 require 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 Prac-

> tices 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 en-

acted into law—rather than the HRSA recommendations that exist today. *See Carcieri*, 555 U.S. at 395.

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

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

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

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

110. There is no compelling governmental interest in providing PrEP drugs at zero marginal cost. And even

if there were, there are ways to achieve this goal in a manner that is less restrictive of the plaintiffs' religious freedom.

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

DEMAND FOR RELIEF

112. The plaintiffs respectfully request that the court:

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

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

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

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

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

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

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

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

Respectfully submitted.

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Dated: July 20, 2020

The Affordable Care Act's preventive services provision, Section 2713 of the Public Health Service Act, 42 U.S.C. § 300g-13(a)(1)-(4), requires that group health plans and health insurance issuers provide coverage without cost-sharing for preventive services recommended by or contained in guidelines supported by the United States Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA). Through this provision, Congress recognized the scientific expertise of these entities. Litigation has been brought questioning the authority under which these entities have issued recommendations and guidelines for preventive services that the Affordable Care Act requires health plans and issuers to cover without cost-sharing. To resolve questions raised in litigation and out of an abundance of caution, for purposes of coverage under the statute, I ratify the below listed guidelines and recommendations for the reasons relied on by the USPSTF, ACIP and the Director of the Centers for Disease Control and Prevention (CDC Director), and the HRSA Administrator in their previously published decisions or analyses regarding the relevant recommendations. This action is not intended to suggest any legal defect or infirmity in the authority of these entities to issue preventive service guidelines and recommendations.

- Evidence-based clinical preventive services that have in effect a rating of "A" or "B" in the recommendations of the USPSTF as of the date of this ratification, with the exception of the 2016 USPSTF recommendation on screening for breast cancer, set forth in Exhibit A, attached;

- Immunizations that have in effect a recommendation from ACIP and the CDC Director with respect to the individual involved as of the date of this ratification, set forth in Exhibit B, attached;
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by HRSA as of the date of this ratification, set forth in Exhibit C, attached; and
- With respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported by HRSA for purposes of 42 U.S. Code § 300gg-13(a) as of the date of this ratification, set forth in Exhibit D, attached.

Pursuant to my authority as Secretary of Health and Human Services, and based on my independent and considered review of the actions and decisions listed above, I hereby affirm and ratify the above recommendations and guidelines.

/s/ XAVIER BECERRA
XAVIER BECERRA

January 21, 2022
Date

Section 1. Overview of U.S. Preventive Services Task Force Structure and Processes

1.1 Purpose

The U.S. Preventive Services Task Force's (USPSTF's) mission is to improve the health of people nationwide by making evidence-based recommendations about clinical preventive services and health promotion.

This Procedure Manual documents the methods used by the Task Force to ensure that its recommendations and the reviews on which they are based are of consistently high quality, methodologically sound, scientifically defensible, reproducible, unbiased, and well documented.

The USPSTF is assisted in fulfilling its mission by the Agency for Healthcare Research and Quality (AHRQ), which provides scientific, administrative, and dissemination support to the USPSTF, and by AHRQ-designated Evidence-based Practice Centers (EPCs), which develop the evidence reviews, evidence summaries, and other documents that inform the USPSTF's deliberations. In addition to documenting the USPSTF's methods, this Manual also provides a summary overview of the methods used by AHRQ and EPC staff to support the USPSTF.

1.2 Intended Audience

The Procedure Manual is a user's manual for everyone on the USPSTF team—including AHRQ and EPC staff in addition to Task Force members. It is designed primarily for internal use as a guide to developing USPSTF recommendations, but may also be of interest to researchers, methodologists, and members of the public. It is intended to be a "living" document that is constantly updated as methods and processes evolve.

In developing this Manual, the Task Force drew, in part, from a series of articles published by its members, past members, AHRQ staff, and other researchers. A list of these sources is provided in Section 10. Researchers and methodologists seeking further details on the Task Force's methodology may find these articles useful as a complement to the Manual.

1.3 History of the USPSTF

The USPSTF, first convened by the U.S. Public Health Service in 1984, is a leading independent panel of nationally recognized non-Federal experts in prevention and evidence-based medicine. Programmatic support for the Task Force was transferred to AHRQ in 1995. The Affordable Care Act of 2010 reauthorized the USPSTF with a slightly different and expanded mandate. Due to the Nation's greater emphasis on prevention, insurers are now required to cover preventive services that are recommended by the USPSTF with a grade of A or B, along with those recommended by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP), Bright Futures, and the Health Resources and Services Administration's (HRSA's) guidelines for women's health. The Affordable Care Act requires insurers to cover these services with no deductible and no co-pay (**Appendix I**).

The first Task Force concluded its work in 1989 with the publication of the "Guide to Clinical Preventive Services." A second Task Force, appointed in 1990, concluded its work with the release of the second edition of the "Guide to Clinical Preventive Services" in December 1996. In 1998, members of the third Task Force were appointed for 5-year terms. The third Task Force released its recommendations incrementally.

Since 2001, the Task Force has featured a rolling panel of members appointed for 4 years, with a portion of the membership being replaced each year. Additionally, Task Force methods were described in a special issue of the *American Journal of Preventive Medicine* that year, including methods for developing recommendations on behavioral counseling and use of analytic frameworks. (See Section 10 for reference.) Following this publication, the Task Force began systematically using analytic frameworks to structure literature reviews and develop recommendations on every topic.

The Task Force now releases its recommendations both incrementally and in periodic publications similar to the "Guide to Clinical Preventive Services."

1.4 Scope of Work

Since its inception almost 30 years ago, the USPSTF has worked to fulfill its mission of improving the health of all Americans by making evidence-based recommendations about clinical preventive services and health promotion.

The Task Force comprehensively assesses evidence and makes recommendations about the effectiveness of clinical primary and secondary preventive services, including screening tests, counseling about healthful behaviors, and preventive medications for children, adolescents, adults, older adults, and pregnant women.

Its recommendations focus on interventions to prevent disease, so they only apply to persons without signs or symptoms of the disease or condition under consideration. USPSTF recommendations address services offered in the primary care setting or services referred by primary care professionals.

While the main audience for Task Force recommendations is the primary care clinician, the recommendations also have relevance for and are widely used by policymakers, managed care organizations, public and private payers, quality improvement organizations, research institutions, and patients.

1.5 USPSTF Members

There are currently 16 members on the Task Force. Members are nationally recognized experts in prevention, evidence-based medicine, and primary care who are also skilled in the critical evaluation of research and the implementation of evidence-based recommendations in clinical practice. Members' fields of practice include behavioral health, family medicine, geriatrics, internal medicine, pediatrics, obstetrics and gynecology, and nursing. Currently the Task Force is led by a Chair and two Vice-Chairs. Details on the roles and responsibilities of the Task Force members are provided in **Appendix IV**.

1.5.1 Selection of USPSTF Members

Each year, the AHRQ Director selects new members to replace those members who are completing their appointments. Anyone can nominate a new Task Force member at any time on the Task Force Web site.

The nomination process and required qualifications are described on the Task Force Web site. As of December 2013, the required minimum qualifications are as follows.

Demonstrated knowledge, expertise, and national leadership in the following areas:

1. The critical evaluation of research published in peer-reviewed literature and in the methods of evidence review
2. Clinical prevention, health promotion, and primary health care
3. Implementation of evidence-based recommendations in clinical practice, including at the clinician-patient level, practice level, and health system level

Some USPSTF members without primary health care clinical experience may be selected based on their expertise in methodological issues, such as meta-analysis, analytic modeling, or clinical epidemiology. For individuals with clinical expertise in primary health care, additional qualifications in methodology would enhance their candidacy.

To obtain a diversity of perspectives, AHRQ particularly encourages nominations of women, members of minority populations, and persons with disabilities.

Applicants must have no substantial conflicts of interest, whether financial, professional, or intellectual, that would impair the scientific integrity of the work of the USPSTF and must be willing to complete regular conflict of interest disclosures.

Applicants must also have the ability to work collaboratively with a team of diverse professionals who support the mission of the USPSTF. Applicants must have adequate time to contribute substantively to the work products of the USPSTF.

1.5.2 Terms of Members

In 2001 the USPSTF transitioned to a standing Task Force. Currently, members are invited to serve for a 4-year term, with a possible 1-year extension. New members are selected each year to replace those who have completed their appointments.

1.6 USPSTF Meetings

The Task Force meets three times a year, in March, July, and November. Meetings are by invitation only. Representatives from USPSTF partner agencies and organizations have standing invitations. Special guests are invited to attend meetings for specific purposes.

Formal votes are taken for major procedural and methodological decisions, and for draft and final recommendations. Votes may be taken for other decisions at the discretion of the Chair. Detailed voting rules are provided in Section 7.4. Key provisions are as follows:

1. All motions on recommendations (at any stage) requiring a vote are passed when two thirds of the current Task Force membership vote "yes."
2. Motions on procedural, methodological, and other decisions which require a vote are passed when a majority of current Task Force membership votes "yes."
3. Votes are submitted as "yes," "no," "abstain," or "absent." Votes are taken by voice, hand, or email, without secret ballots.
4. Members recused for reason of potential conflict of interest are recorded as recused and do not vote.

5. In votes that are less than unanimous, there are no minority reports.
6. A vote must be held to reconsider the grade of a previously voted draft or final recommendation statement. Two thirds of the current Task force membership must approve the request to reconsider. If the request to reconsider is approved, the topic leads review and present the evidence supporting the motion. The Task Force then votes on the new recommendation either in person or by email.

1.7 Conflict of Interest

1.7.1 Introduction

The public must have confidence in the integrity of the process by which the Task Force makes its recommendations.[1] The reputations of the Task Force members as highly regarded researchers, clinicians, and academicians contribute to this objective and must be protected if the Task Force recommendation statements are to be accepted and implemented. It is also essential that Task Force deliberations benefit from members' vigorous exchange of perspectives that are derived from and shaped by the member's research and/or practice experiences.

The intent of requesting disclosure of any potential conflict of interest is to ensure that the USPSTF provides a balanced, independent, objective, and scientifically rigorous product (including its recommendation statements) by understanding other interests that could po-

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[1] Institute of Medicine, Clinical Practice Guidelines We Can Trust (2011). Available at http://iom.nationalacademies.org/reports/2011/clinical-practice-guidelines-we-can-trust.aspx. Accessed 11/10/15.

tentially influence the work and decision-making of its members. The USPSTF requires each member to disclose all information regarding any possible financial and non-financial conflicts of interest prior to each meeting for all topics under development or that will be discussed at each meeting. Previous disclosures for continuing topics must also be updated to reflect changes in a member's situation since the form was last completed.

It is important to note that disclosures are not considered actual conflicts of interest until the value and nature of the disclosure is reviewed by the Task Force chairs.

1.7.2 Process for Completing Disclosure Forms

The USPSTF Disclosure Form will be completed by Task Force members prior to each meeting to provide information on potential financial and non-financial conflicts of interest related to USPSTF topics under consideration. Task Force members are expected to provide full disclosure for new topics and topics in development, as well as an updated disclosure that reflects changes in their situation for continuing topics.

All members are expected to provide full disclosure of their own interests as well as the interests of immediate family members (which includes their spouse/partner, dependent children, and parents) and those of other close personal relationships.

The period of disclosure is 36 months prior to the date of form completion. The exception is publications related to the topic, for which there is no time limit, and research grants, for which the period of disclosure is 36 months from the end of the grant period. Completed Disclosure Forms will be kept on file. Further infor-

mation on each type of disclosure required is provided below.

Disclosure of Significant Financial Interests

Financial disclosures refer to relationships with entities that could influence, or give the appearance of influencing, the outcome of a USPSTF decision. Entities could be individuals, organizations and corporations, or other groups with established or future business in the matter of a USPSTF decision. A relevant financial interest is a situation in which a Task Force member, immediate family member, or close personal relation has the potential for direct or indirect * * *

* * * * *

7.2 Recommendation Grades

The Task Force applies grades to all of its recommendations and may issue multiple grades on a topic to address specific subpopulations. The Task Force can issue a grade of A, B, C, or D, as described in Table 4. When evidence is insufficient to make a recommendation, the Task Force issues an "I statement."

Table 4. How to Interpret Task Force Recommendation Grades

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.

C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of	Read the Clinical Considerations section of the USPSTF Recommendation Statement.

	benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

After full consideration and decision on both certainty and magnitude of net benefit, the topic leads discuss the appropriate grade for the service in the targeted population, using the scoring matrix in **Table 5**.

Table 5. U.S. Preventive Services Task Force Recommendation Grade Grid: Certainty of Net Benefit and Magnitude of Net Benefit

Certainty of Net Benefit	**Magnitude of Net Benefit**			
	Substantial	**Moderate**	**Small**	**Zero/ Negative**
High	**A**	**B**	**C**	**D**
Moderate	**B**	**B**	**C**	**D**
Low	Insufficient			

The Task Force values consistency in our process for determining grades. Changes in the grade when updating a previously published recommendation should have a strong rationale that stems directly from our process of determining grades (i.e. there is a difference in cer-

tainty or magnitude that warrants a change in grade). After the leads discuss the adequacy of the evidence on calls leading to the vote at the TF meeting, the leads identify any grade changes and discuss the rationale for proposed grade change.

A grade may result in a change from a previous Task Force recommendation because of one or more of the following: 1) a change in methods and/or analytic framework since the last recommendation statement; 2) a change in the definition of a grade (i.e. change in C grade definition); 3) evidence has increased or decreased and results in a change in the certainty or magnitude of net benefit, or has made the issuance of a grade less relevant. This may occur when there is a change in our understanding about the applicability of older evidence or international evidence; 4) new methods and/or new evidence regarding subpopulations. The TF strives to avoid a narrow "I" grade for a subpopulation when there is a grade for the overall population and no strong rationale exists that the subpopulation would be different from the larger population. Grade changes may also result from changes in context (clinical context, societal values for specific outcomes, and context of intervention and treatment). In this case, while the analytic frame work is largely similar to the prior framework, something has changed in the contextual issues. It is important that the Task Force communicate in its recommendation statement how the changes in the above factors or context affect our rating of certainty and magnitude and why this results in a grade that is different than a previously published grade.

Before the grading discussion, the Task Force is provided with an oral presentation summarizing the evi-

dence to supplement the full evidence review provided by the EPC. Following clarification of any questions regarding the evidence, the Task Force then hears from the topic leads regarding their proposal for a grade. After full debate and consideration of grading options, the Task Force Chair calls for a motion for a draft recommendation grade (go to Section 7.4 for voting procedures). The leads refine the draft recommendation with final language before it is released for public comment (go to Section 9 for more information on public comment).

To help readers better understand the Task Force's judgment about the certainty of the evidence, the net benefit of implementation, and the overall recommendation about the use of each preventive service, the Task Force provides its rationale and statements about clinical considerations in the recommendation statement. While an "I statement" is considered a statement and not a recommendation, these topics are accompanied by the same type of rationale and clinical considerations as grade A, B, C, or D recommendations.

For clarity, consistency, and usability, Task Force recommendations follow a standard, structured format.

Each recommendation statement is also accompanied by a one-page clinical summary, which provides a table of key information about the recommendation, including the population of interest, recommendation, risk assessment, screening or intervention of interest, treatment, balance of benefits and harms, and other relevant USPSTF recommendations.

A fact sheet for each recommendation is also prepared for consumers. The Task Force also produces additional fact sheets, summary tables, infographics, and videos

when appropriate to further explain recommendations to diverse audiences.

7.3 Process for Public Comment on Task Force Documents

To increase the clarity, transparency, and utility of its recommendation statements to primary care providers and the public, the Task Force shares drafts of its research plans, evidence reviews, and recommendation statements for public comment. The comments are considered in finalizing the documents. The procedures for posting draft materials for public comment are described in Section 9.

All comments received through the public comment process are shared with the topic leads for their review and consideration before finalizing the document. All Task Force members have access to the full text of all comments; a disposition table summarizing the comment themes and the proposed Task Force response; and the revised research plan, evidence review, or recommendation statement.

7.4 Voting

Formal votes are taken for major procedural and methodological decisions, for draft recommendations before posting, for final recommendations, and for statements about clinical practice. Votes may be taken for other decisions at the discretion of the Chair(s).

7.4.1 General Voting Procedures

All motions on recommendations (at any stage) requiring a vote are passed when two thirds of the current Task Force membership vote "yes." Votes are taken by voice, hand, or email, without secret ballots.

Motions on procedural, methodological, and other decisions requiring a vote are passed when a majority of current Task Force membership votes "yes."

Votes are submitted as yes, no, abstain, or absent.

Members recused by reason of potential conflict of interest are recorded as recused and do not vote.

In votes that are less than unanimous, there are no minority reports.

The result of a vote is recorded in the meeting minutes, though the count of "yes," "no," and "abstain" votes is not recorded.

7.4.2 Voting on Draft Recommendations

At a meeting of the full Task Force (usually in person), the presiding Chair accepts motions for draft recommendations. A "yes" vote from two thirds of the current Task Force membership is needed to pass the motion.

After the meeting, the topic leads draft the full recommendation statement, and it is posted for public comment.

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

Civil Action No. 4:20-cv-00283-O

JOHN KELLEY, ET AL., PLAINTIFFS

v.

XAVIER BECERRA, ET AL., DEFENDANTS

Filed: Aug. 2, 2022

DEFENDANTS' SUPPLEMENTAL FILING REGARDING CROSS-MOTIONS FOR SUMMARY JUDGMENT

At the July 26, 2022 hearing on the parties' cross-motions for summary judgment, the Court asked the undersigned whether the Secretary of Health and Human Services (the "Secretary") can "override a nonrecommendation" of or, in other words, impose a coverage requirement under 42 U.S.C. § 300gg-13 absent a prior recommendation of, any of the three entities referenced in subsection (a) of that statute.[1] The undersigned agreed to respond in writing after confirming with Defendant agencies. Defendants hereby respond as follows:

[1] The three entities are the United States Preventive Services Task Force ("PSTF"), the Advisory Committee on Immunization Practices ("ACIP"), and the Health Resources and Services Administration ("HRSA").

1. **HRSA:** Yes, the Secretary is empowered to direct HRSA to include particular care and screenings in the guidelines they support under 42 U.S.C. § 300gg-13(a)(3) and (a)(4), pursuant to his authority over the Public Health Service of the United States, see, for example, 42 U.S.C. § 202 and Reorganization Plan No. 3 of 1966, 31 Fed. Reg. 8855 (June 25, 1966), 5 U.S.C. app. 1. See also Defs.' Br. in Supp. of Resp. ("Cross-Mot.") at 5-6, 29, ECF No. 64; Defs.' Reply at 23-25, ECF No. 83.

2. **ACIP:** Yes, the Secretary is empowered to direct ACIP's recommendation of specific vaccines such that those recommendations directed by the Secretary take "effect" pursuant to 42 U.S.C. § 300gg-13(a)(2). Moreover, unlike with respect to the preventive services considered by the PSTF and HRSA, federal law does not permit ACIP to decline to issue a recommendation regarding any licensed vaccine or indication for a vaccine. ACIP is required by law to consider the use of any vaccine at ACIP's next scheduled meeting after "the licensure of [that] vaccine or any new indication for [that] vaccine [if the vaccine was previously licensed for a different indication]," and at a minimum provide a report on the status of its review if there is not sufficient time to make a recommendation between licensure and that meeting. 21st Century Cures Act, Pub. L. No. 114-255, § 3091, 130 Stat. 1033, 1149-50 (Dec. 13, 2016) (attached as Exhibit A hereto). Accordingly, there should be no licensed vaccines or vaccine uses as to which ACIP declines to issue a recommendation. However, if for some reason ACIP were to decline to issue a recommendation for a particular licensed vaccine or use of a vaccine, ACIP's Designated Federal Officer, a federal em-

ployee selected by the CDC, could add consideration of that vaccine to the agency's next meeting agenda. *See* App'x to Defs' Br. ("App'x"), ECF No. 65 at APP 150.

At the conclusion of the meeting, the CDC Director (who acts under the Secretary's supervision and direction pursuant to his authority over the Public Health Service) is empowered to adopt or otherwise amend any recommendation or "nonrecommendation" made at ACIP's meeting. (Defendants provided an example of the CDC Director making a broader recommendation than ACIP's initial recommendation at footnote 26 on page 38 of their cross-motion.) It is this final "recommendation" adopted by the CDC Director that takes "effect" for purposes of 42 U.S.C. § 300gg-13(a)(2)'s coverage requirement. *See* App'x at APP 149 ("[U]nder provisions of the Affordable Care Act . . . immunization recommendations of [ACIP] that have been adopted by the [CDC Director] must be covered by applicable health plans."); *see also* 45 C.F.R. § 147.130(a)(1)(ii). The Secretary or CDC Director could also exercise their removal authority over recalcitrant ACIP members. *See* Cross-Mot. at 5 (noting that ACIP "[m]embers are selected by the Secretary . . . and . . . are removable at will").

3. **PSTF:** The Secretary may not, consistent with 42 U.S.C. § 299b-4(a)(6), direct that the PSTF give a specific preventive service an "A" or "B" rating, such that it would be covered pursuant to 42 U.S.C. § 300gg-13(a)(1). *See* 42 U.S.C. § 299b-4(a)(6) ("All members of the [PSTF], and any recommendations made by such members, shall be independent and, to

the extent practicable, not subject to political pressure."). The Secretary could, however, remove members of the PSTF who were unwilling to provide an "A" or "B" rating to a particular service pursuant to his authority over the Public Health Service, in general, and the Agency for Healthcare Research and Quality ("AHRQ"), in particular. *See* 42 U.S.C. § 299(a) ("There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this subchapter acting through the Director."); 42 U.S.C. § 299b-4(a)(1) ("The [AHRQ] Director shall convene an independent Preventive Services Task Force . . . to be composed of individuals with appropriate expertise."); *see also* App'x at APP 067, § 1.5.1. As Defendants argued in their briefing, to the extent that the Court concludes that this restriction creates a problem under the Appointments Clause or Vesting Clause, the appropriate remedy is to hold 42 U.S.C. § 299b-4(a)(6)'s restriction on the Secretary's control over the PSTF unconstitutional in the context of the Preventive Services Provision, but otherwise uphold the Preventive Services Provision and the PSTF's recommendations. *See* Cross-Mot. at 47; Defs.' Reply at 27.

Respectfully submitted,

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

Civil Action No. 4:20-cv-00283-O

BRAIDWOOD MANAGEMENT INC., ET AL., PLAINTIFFS

v.

XAVIER BECERRA, ET AL., DEFENDANTS

Filed: July 20, 2020

FINAL JUDGMENT

This Judgment is issued pursuant to Fed. R. Civ. P. 58(a).

This action came on for consideration by the Court, and the issues having been duly considered and a decision duly rendered in the Court's orders partially granting and partially denying the parties' motions for summary judgment.

It is therefore **ORDERED**, **ADJUDGED**, and **DECREED** that:

1) All claims of Joel Miller and Gregory Scheideman in the above-entitled and numbered cause are hereby **DISMISSED without prejudice** for lack of subject matter jurisdiction.

2) The Advisory Committee on Immunization Practices (ACIP) and the Health Resources and Services Administration (HRSA) do not, on the rec-

ord in this case, violate Article II's Appointments clause. Therefore, Braidwood Management Inc., Kelley Orthodontics, John Kelley, Joel Starnes, Zach Maxwell, and Ashley Maxwell's (remaining Plaintiffs) **Claim No. 1** as it pertains to ACIP and HRSA is **DISMISSED with prejudice** to the re-filing of same or any part thereof.

3) The U.S. Preventive Services Task Force's (PSTF) recommendations operating in conjunction with 42 U.S.C. § 300gg-13(a)(1) violate Article II's Appointments Clause and are therefore unlawful. Therefore, any and all agency actions taken to implement or enforce the preventive care coverage requirements in response to an "A" or "B" recommendation by the PSTF on or after March 23, 2010 are **VACATED** and Defendants and their officers, agents, servants, and employees are **ENJOINED** from implementing or enforcing 42 U.S.C. § 300gg-13(a)(1)'s compulsory coverage requirements in response to an "A" or "B" rating from PSTF in the future.

   Further, any and all agency action taken to implement or enforce the preventive care mandates in response to an "A" or "B" recommendation by PSTF on or after March 23, 2010 and made compulsory under 42 U.S.C. § 300gg-13(a)(1) are **DECLARED** unlawful as violative of the Appointments Clause. Therefore, Braidwood Management Inc. and Kelley Orthodontics, and to the extent applicable, individual Plaintiffs need not comply with the preventive care coverage recommendations of PSTF issued on or after March 23, 2010, because the members of the Task Force

have not been appointed in a manner consistent with Article II's Appointments Clause. Accordingly, the Court **ENJOINS** Defendants and their officers, agents, servants, and employees from implementing or enforcing the same against these Plaintiffs.

4) 42 U.S.C. § 300gg-13(a)(1)-(a)(4) do not violate the nondelegation doctrine. Therefore, remaining Plaintiffs' **Claim No. 2** is **DISMISSED with prejudice** to the re-filing of same or any part thereof.

5) The operation of 42 U.S.C. § 300gg-13(a)(1) does not violate Article II's Vesting Clause. Therefore, remaining Plaintiffs' **Claim No. 3** is **DISMISSED with prejudice** to the re-filing of same or any part thereof.

6) Remaining Plaintiffs' Claim No. 4 is **DISMISSED with prejudice** to the re-filing of same or any part thereof for failure to state a claim upon which relief may be granted.

7) The PrEP mandate violates remaining Plaintiffs' rights under the Religious Freedom Restoration Act and is therefore **DECLARED** unlawful. As such, remaining Plaintiffs need not comply with the preventive care coverage recommendations of PSTF issued on or after March 23, 2010 and the Court **ENJOINS** Defendants and their officers, agents, servants, and employees from implementing or enforcing the PrEP mandate as against these Plaintiffs.

8) All costs shall be paid by the party incurring the same.

9) All relief not expressly granted herein is denied.

The Clerk of Court is **DIRECTED** to close the above-captioned case.

SO ORDERED on this **30th day** of **March, 2023**.

/s/ REED O'CONNOR
REED O'CONNOR
UNITED STATES DISTRICT JUDGE

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

Civil Action No. 4:20-cv-00283-O

BRAIDWOOD MANAGEMENT INC., ET AL., PLAINTIFFS

v.

XAVIER BECERRA, ET AL., DEFENDANTS

DECLARATION OF JEFF WU

I, Jeff Wu, pursuant to 28 U.S.C. § 1746, and based upon my personal knowledge and information made known to me in the course of my employment, hereby make the following declaration with respect to the above-captioned matter:

1. I currently serve as the Deputy Director for Policy in the Center for Consumer Information & Insurance Oversight (CCIIO) at the Centers for Medicare & Medicaid Services (CMS). In my role as the Deputy Director, I oversee policy for the commercial health insurance market, including the Health Insurance Exchanges (exchanges).

2. On March 30, 2023, the United States District Court for the Northern District of Texas issued a decision in the case of *Braidwood Management Inc. v. Becerra,* 4:20-cv-00283-0, vacating any and all actions taken by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) to implement or enforce the Affordable Care Act's preventive service coverage requirements in re-

sponse to an "A" or "B" rating by the United States Preventive Services Task Force (USPSTF) on or after March 23, 2010, and enjoining the Departments from implementing or enforcing the preventive service coverage requirements in response to an "A" or "B" rating from USPSTF in the future (the "'*Braidwood* decision,'). On March 31, 2023, the U.S. Department of Justice filed a notice of appeal.

3. More than 150 million people with private insurance currently can receive preventive services without cost-sharing under the ACA. *See* Access to Preventive Services without Cost-sharing: Evidence from the Affordable Care Act, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, Issue Brief No. HP-2022-01 (January 2022), https://perma.cc/UH32-KX6D.

4. The *Braidwood* decision will likely lead to individuals losing access to services, either because their plans or issuers drop coverage of certain preventive services or because the plans or issuers impose cost sharing on such services, leading to individuals forgoing preventive care out of concern about paying for these services. Indeed, the *Braidwood* decision could generate enough confusion that consumers may be concerned they will face cost sharing even when they will not, which could further lead to a decrease in utilization of preventive services. These losses or changes in coverage may result in adverse health outcomes.

5. Most group health plans and group and individual market health insurance policies operate on a calendar year basis, but a significant minority operate on different cycles. For example, universities may offer health insurance policies tied to their academic years and local

and state governments may offer group health plans using state fiscal years. Group health plans start in a variety of months throughout the year based on what makes sense for their coverage needs (for example, if a business launched in September, they likely would have started coverage in September and will continue starting their plan years in September moving forward).

6. Plans and issuers do not typically make changes to coverage or cost sharing mid-year because they price their insurance premiums or premium contributions and design their health plans based on coverage for a full year, and issuers have signed contracts with enrollees and with employers stating that they will cover certain services at certain costs through the end of the plan year. However, certain mid-year changes might be permissible under these contracts, and at least some plans or issuers are expected either to drop coverage or impose cost sharing for certain preventive services because of the *Braidwood* decision. Because not all plans and policies operate on the calendar year cycle, and because certain mid-year changes might be permissible, some of this expected coverage loss could occur in the near future.

7. The *Braidwood* decision affects dozens of preventive services that were added or modified after March 23, 2010, including PrEP for people at high-risk of HIV, colorectal cancer screening for people ages 45-49, lung cancer screenings, and statins for adults at increased risk for cardiovascular disease, just to name a few.

8. Indeed, in light of the *Braidwood* decision, CMS expects that some employers will drop some of the more costly preventive services or impose cost sharing on such services. CMS also expects that some enrollees

will choose to forgo preventive services due to plans or issuers imposing cost sharing on such services. For example, employers may decide to drop PrEP coverage (and related ancillary services) because it is a relatively expensive service to cover, it is a newer recommendation, and individuals eligible for PrEP may not be a risk profile that plans and issuers want to attract. It is also possibl that some employers may decide to drop coverage of colonoscopies for adults age 45 to 49 due to the cost of such procedures.

9. A number of studies on the effects of cost sharing on health care services have shown a reduction in the use of services after cost sharing increased, regardless of income. *See* Kaiser Commission on Medicaid and the Uninsured, *Premiums and Cost-Sharing in Medicaid: A Review of Research Findings* (2013), https://penna.cc/U5S6-74KP. More recent research on the effects of cost sharing on low-income individuals also found reductions in the use of health care services, and even small increases in cost sharing can create insurmountable financial barriers for people with low incomes. *See id.* at 6.

10. Research has also shown significant declines specifically in the utilization of preventive services after the introduction of or increase in cost sharing. *See id.* at 6-7. For example, one study analyzed the effect of cost sharing on mammogram utilization among Medicare beneficiaries, comparing the use of mammography services for individuals in plans that had increased or instituted new copays to individuals in plans that had not. *See id.* at 9. The results showed that biennial screening rates were 8.3 percentage points lower in cost sharing plans than in those with full coverage, and that the effect

was magnified for women residing in lower income areas. *See id.* (citing Amal N. Trivedi et al., *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans,* 358(4) NEW ENG. J. MED. 375,375 (2008)); *see also id.* at 8-10 (compiling other studies showing a decrease in utilization of preventive services after the introduction of or increase in cost sharing).

11. In addition to studies demonstrating that cost sharing leads to a decrease in utilization of services, a recent poll indicates that a similar result can be expected here. The Morning Consult (a business intelligence company) polled a sample of 2,199 U.S. adults in January 2023 to better understand if preventive service utilization would be affected by the potential *Braidwood* decision. *See* Jay Asser, HealthLeaders, *Patients Likely to Skip Preventive Care if ACA Rulings Holds* (Mar. 17, 2023), https://perma.cc/RK.S3-EXXM. At least two in five respondents said that cost sharing barriers would prevent them from obtaining most of the preventive services currently covered by the Affordable Care Act. *See id.*

12. A decrease in the utilization of preventive services is likely to lead to adverse health outcomes. For example, according to one recent study of men who have sex with men (MSM), for every 10% decrease in PrEP coverage resulting from the anticipated *Braidwood* decision (i.e. for every 10% decrease in PrEP-indicated MSM receiving PrEP), the authors estimate an additional 1,140 HIV infections in the following year in that population. *See* A. David Paltiel et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis* (2023), https://perma.cc/ED2W-X7KL. The authors call this a "conservative" es-

timate, as they only considered primary HIV transmission effects in the year after the ruling, ignoring both infections occurring beyond one year and all secondary transmissions. *Id.* Additionally, PrEP is used by other populations and can help prevent maternal HIV infection and therefore the risk of transmitting HIV to a child through childbirth or breast feeding.

13. Younger people could also lose coverage for colorectal cancer screening, as the 2021 recommendation from USPSTF lowered the minimum age of screening from 50 to 45. Colorectal cancer is the third leading cause of cancer death in the nation with cases increasing in younger ages. *See* American Cancer Society, *Key Statistics for Colorectal Cancer* (2023), https://perma.cc/Y7G6-NPST. During a colonoscopy, physicians remove pre-cancerous polyps as they find them to avoid such polyps becoming cancerous in subsequent years. The American Cancer Society notes that "observational studies suggest that colonoscopy can help reduce [colorectal cancer] incidence by about 40% and mortality by about 60%." *See* American Cancer Society, *Colorectal Cancer: Facts and Figures 2020-2022* at 19, https://perma.cc/PFS2-6L64. The rate of people being diagnosed with colon or rectal cancer each year has dropped overall since the mid-1980s, mainly because more people are getting screened and changing their lifestyle-related risk factors. *See supra, Key Statistics for Colorectal Cancer,* https://perma.cc/Y7G6-NPST.. From 2011 to 2019, colorectal cancer incidence rates dropped by about 1% each year, but this downward trend is mostly in older adults. *Id.* In people younger than 50, rates have been increasing by 1% to 2% a year since the mid-1990s. *Id.* These percentages are significant given the number of new cases each year-the American Cancer

Society estimates that there will be 106,970 new cases of colon cancer and 46,050 new cases of rectal cancer in the United States in 2023. *See id.*

14. People could also lose coverage for lung cancer screening, as the USPSTF issued its initial recommendation for lung cancer screening in 2014, and then later expanded it. Lung cancer is the leading cause of cancer deaths among both women and men. *See* American Lung Association, *Lung Cancer Key Findings* (2022), https://perma.cc/6BJZ-AN87. Screening with annual low-dose CT scans can reduce the lung cancer death rate by up to 20% by detecting tumors at early stages when the cancer is more likely to be curable. *Id.* Lung cancer five-year survival rates are significantly higher when cases are diagnosed at an early stage (61%), compared to when they are not caught until a late stage (7%). *Id.* Early diagnosis rates for lung cancer increased by 33% between 2015 and 2020. *See* American Lung Association, *State of Lung Cancer 2020 Report* at 4, https://perma.cc/T8QU-WFRH. Some estimates indicate that the USPSTF recommendations will reduce lung cancer mortality by an estimated 20% to 33% for high-risk individuals, saving approximately 10,000 to 20,000 additional lives each year. *See* American Society of Clinical Oncology Daily News, *Lung Cancer Screening Remains Poor. Here's How to Increase Rates and Save Lives* (Mar. 20, 2022), https://dailynews.ascopubs.org/do/lung-cancer-screening-remains-poor-here-s-increase-rates-and-save-lives.

15. Statins are yet another example of coverage people could lose with potentially devastating health outcomes. Cardiovascular disease is the leading cause of morbidity and death in the United States. While the

USPSTF had earlier recommended screening for people at increased risk for cardiovascular disease, in 2016 USPSTF recommended (and later updated) that clinicians prescribe a statin for the prevention of cardiovascular disease in certain adults with risk factors, as statin use reduces the probability of cardiovascular events, such as heart attacks and strokes. *See* U.S. Preventative Services Task Force, *Stalin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventative Medication* (Aug. 23, 2022), https://perma.cc/82AC-NHYU. Lower copayments for statin medications have been associated with higher levels of adherence, with a $10 increase in copayments resulting in a 1.8 percentage point reduction in the likelihood of adherence for new users and a 3 percentage point reduction in the likelihood of adherence for continuing users. *See* Teresa B. Gibson & Tami L. Mark, *Impact of Statin Copayments on Adherence and Medical Care Utilization and Expenditures,* AMERICAN JOURNAL OF MANAGED CARE (2006), https://perma.cc/MYC8-G4R5. Studies find that poor adherence to statins is associated with increased risks of cardiovascular disease and death. *See* Mary A. De Vera et al., *Impact of Statin Adherence on Cardiovascular Disease and Mortality Outcomes: A Systematic Review,* BRITISH JOURNAL OF CLINICAL PHARMACOLOGY (2014), https://perma.cc/9LMV-M4XT.

16. In addition to the expected losses of coverage, the *Braidwood* decision will also lead to uncertainty in the health insurance market during the pendency of the appeal and will create confusion for a variety of entities, particularly enrollees and providers. For example, enrollees in plans that make mid-year coverage changes may suddenly be billed for services that they thought

would be free, creating confusion and significant frustration. Also, providers may be conflicted if current best practices and standards of care suggest they prescribe preventive services that are now no longer covered.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on April 12, 2022

/s/ JEFF WU
JEFF WU
Deputy Director for Policy
Center for Consumer Information & Insurance Oversight (CCIIO)
Centers for Medicare & Medicaid Services (CMS)