

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA**

IRISH 4 REPRODUCTIVE HEALTH;)
)
 NATASHA REIFENBERG;)
)
 JANE DOES 1-3;)
)
 Plaintiffs,)
)
 v.)
)
 UNITED STATES DEPARTMENT OF)
 HEALTH AND HUMAN SERVICES;)
)
 UNITED STATES DEPARTMENT OF)
 LABOR;)
)
 UNITED STATES DEPARTMENT OF THE)
 TREASURY;)
)
 ALEX M. AZAR II, in his official capacity as)
 Secretary of Health and Human Services;)
)
 R. ALEXANDER ACOSTA, in his official)
 capacity as Secretary of Labor;)
)
 STEVEN MNUCHIN, in his official capacity as)
 Secretary of the Treasury;)
)
 and)
)
 UNIVERSITY OF NOTRE DAME,)
)
 Defendants.)

Case No. 3:18-cv-491

AMENDED COMPLAINT

INTRODUCTION

1. This case is a challenge to actions by the United States Departments of Health and Human Services, Labor, and the Treasury (the “Departments”), and the University of Notre Dame that will harm at least tens of thousands of people nationwide, including at Notre Dame. If Defendants’ conduct is not enjoined, these people—including the four individual Plaintiffs and members of Plaintiff Irish 4 Reproductive Health—will lose meaningful access to contraceptive

services, in violation of the Administrative Procedure Act, the Patient Protection and Affordable Care Act of 2010, and the First and Fifth Amendments to the U.S. Constitution.

2. The ACA requires group health plans and health-insurance issuers to cover, without cost-sharing, a range of preventive health services. Recognizing that women historically have been required to pay more money out-of-pocket than men for health care, including for contraception and related services, Congress expressly required the inclusion of women’s preventive services among the benefits that health plans must cover without copays or other cost-sharing. Since 2011, the Departments’ controlling regulations have clarified that these services must include contraception and related patient education and counseling, without cost-sharing.

3. The regulations currently in effect contain an exemption from the ACA’s contraceptive coverage requirement for houses of worship. The regulations also contain an “accommodation” for certain employers and universities that have religious objections to contraceptive coverage and meet certain criteria. Through the accommodation process, an objecting employer or university may inform the government, or the entity’s insurer or third-party administrator, that it has religious objections to providing coverage for contraceptive services. The entity’s insurance issuer then fulfills its legal obligation by separately providing payments for contraceptive services. The long-standing regulations thus ensure that women¹ covered by health plans at objecting employers or universities obtain the full range of U.S. Food and Drug Administration-approved contraceptives guaranteed to them by law, while at the same time

¹ This Complaint uses the term “women” because the individual Plaintiffs are women and because the Rules and settlements at issue target women. The denial of reproductive health care and insurance coverage for that care, however, also affects individuals who may not identify as women, including some gender-nonconforming individuals and transgender men.

relieving employers and universities with religious objections of their obligation to cover contraception in their health insurance plans.

4. Now the Departments seek to eviscerate the ACA’s contraceptive coverage requirement, to the detriment of Plaintiffs and countless others nationwide. There is no legitimate basis for these actions. Indeed, Defendants’ unlawful actions come on the heels of failed attempts by Defendant Notre Dame and others to challenge the accommodation process in court: Eight of the nine federal courts of appeals to consider such challenges flatly rejected them—including the Seventh Circuit, twice, in a case brought by Notre Dame. And the United States Supreme Court remanded all the cases to be resolved in a manner that “ensur[es] that women covered by [the entities’] health plans receive full and equal health coverage, including contraceptive coverage.” *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016); *see also, e.g., Univ. of Notre Dame v. Burwell*, 136 S. Ct. 2007 (Mem.).

5. By their actions, the Departments have embarked on a two-tiered effort to do by fiat what the courts had refused to allow: give employers and universities a veto over the legal rights of countless women to obtain coverage for necessary health care.

6. First, on October 6, 2017, with total disregard for the Administrative Procedure Act’s procedural requirements, the Departments issued two Interim Final Rules that allowed all nongovernmental entities—including for-profit businesses, non-profits, and universities—to declare themselves exempt from the ACA contraceptive coverage requirement based on religious beliefs, and allowed most such entities to exempt themselves based on so-called “moral convictions.”² The Interim Final Rules also made the accommodation process optional. In other

² These Interim Final Rules were issued and went into effect on October 6, 2017, and were published in the Federal Register on October 13. Religious Exemptions and Accommodations

words, the Interim Final Rules allowed such entities to impose their religious and moral beliefs on countless women by preventing employees, students, and their dependents from receiving contraceptive coverage.

7. Second, on October 13, 2017, just one week after issuing the Interim Final Rules, the Departments executed a private settlement agreement with more than 70 entities, including Notre Dame, resolving the signatories' pending legal challenges to the ACA accommodation process, with terms that echoed the Interim Final Rules' unlawful religious and moral exemptions and then extended the scope of those exemptions even further. *See* Exhibit A. In direct contravention of legal requirements and long-standing Department of Justice policy, the Settlement Agreement impermissibly negotiates away the rights of third parties by purporting *permanently* to exempt the signatories from all contraceptive coverage requirements, both past *and future*. Even though the University admits that “most of [the 17,000 people] covered [by its health plans] have no financially feasible alternative but to rely on the University for such coverage,”³ the Settlement Agreement allows Notre Dame to deny them contraceptive coverage in their regular health plan. The Settlement Agreement also awards the signatories millions of taxpayer dollars in attorneys' fees.

8. In December 2017, two federal courts preliminarily enjoined the Interim Final Rules nationwide. *See Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (2017); *California v. HHS*, 281 F. Supp. 3d 806 (2017). Nevertheless, on February 7, 2018, Notre Dame announced that it

for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017); Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (collectively, the “Interim Final Rules” or “IFRs”).

³ Letter to Faculty and Staff by President Rev. John I. Jenkins, C.S.C. (Feb. 7, 2018).

would no longer abide by the ACA's contraceptive coverage requirement. Citing the Settlement Agreement as support, the University declared that it would change its faculty and student insurance policies to decline to cover the full range of FDA-approved contraceptives and related services as required by the ACA. Still further, the University would subject the limited remaining covered contraceptives to co-pays and deductibles, also in contravention of the ACA. In other words, the University announced that it would impose its own views about contraception on the 17,000 people covered by its health plans, and would do so in ways that are prohibited by the ACA and were already enjoined by two federal courts. By excluding some methods of contraceptives altogether and imposing cost-sharing on other methods, the University's new policy strips women of the contraceptive coverage guaranteed to them by law and erects financial, administrative, and logistical barriers to contraception.

9. On November 7, 2018, the Departments issued two Final Rules, which purport to make final the Interim Final Rules in all material respects, and which are as substantively unlawful and, as detailed in ¶¶ 104-05, *infra*, as procedurally deficient as the Interim Final Rules.⁴

10. The Rules and the Settlement Agreement thus harm Plaintiffs and other women, who will be discriminated against, incur greater costs, and be deterred or prevented from using the most appropriate method of contraception for them. Some women will be unable to obtain contraception altogether. The Rules and the Settlement Agreement thereby deprive Plaintiffs and other women of their constitutional right to make fundamental reproductive decisions consistent

⁴ These Final Rules were issued on November 7, 2018, and were published in the Federal Register on November 15, 2018. Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (collectively, the "Final Rules" or "Rules").

with their own values and beliefs. Instead of respecting that right, the Rules and the Settlement Agreement impose the religious beliefs of a select few on individuals who may not share those beliefs, and reinstate the discrimination against women that the ACA's contraceptive coverage requirement addressed.

11. Allowing employers and universities to deny women access to contraceptive coverage violates federal law, the U.S. Constitution, and the directive of the U.S. Supreme Court.

12. For these reasons and others described below, this Court should invalidate and enjoin the Rules, enjoin Defendants from enforcing or relying on the Rules, declare the Settlement Agreement between Notre Dame and the Departments void, and enjoin Defendants from enforcing or relying on the Settlement Agreement with respect to Notre Dame and the health plans it sponsors.

PARTIES

13. Plaintiff Irish 4 Reproductive Health ("I4RH") is an unincorporated association of undergraduate and graduate students in South Bend, Indiana, who attend Notre Dame. The organization's mission is to advocate for reproductive justice on campus and in the surrounding community, including by securing access to insurance coverage for the full range of FDA-approved contraceptive methods and related services, education, and counseling, with no out-of-pocket costs. I4RH promotes human dignity by affording respect to all people to make moral choices about their own lives, including whether and when to have children. I4RH recognizes that sexual health is essential for overall well-being, and that access to reproductive health care, education, and resources is necessary for realizing social, political, and gender equality—both at the University and around the globe. The students who would eventually form I4RH began

organizing in the wake of the upheaval and uncertainty over the future of contraceptive coverage at the University. Initially, the founding student members of I4RH came together to protest the University's October 2017 decision to terminate contraceptive coverage. After the University temporarily reversed that decision in early November 2017, the students continued to work to improve and expand access to reproductive health care at the University and in the surrounding community. The students formed I4RH on February 7, 2018, in response to the University's letter of that date announcing its plan to terminate coverage for certain methods of contraception. Obtaining relief from Defendants' unlawful Settlement Agreement and Rules is essential to realizing I4RH's animating purpose and to further its broader mission of promoting and protecting reproductive health at the University and beyond. Several members of I4RH will be personally harmed by the Settlement Agreement and the Rules. For example:

a. I4RH Member 1 is a graduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. I4RH Member 1 uses an oral contraceptive that she refills every three months to prevent pregnancy. During the 2017-18 school year, I4RH Member 1 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health. Through the accommodation process, Aetna covered the full cost of I4RH Member 1's oral contraceptive. Since the changes to the University's student health plan went into effect on August 15, 2018, I4RH Member 1 has paid coinsurance for her oral contraceptive out of pocket.

b. I4RH Member 2 is a graduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives.

From 2010 until June 2018, Member 2 used the NuvaRing, a hormonal contraceptive with no generic alternative, both to prevent pregnancy and to reduce pain during menstruation, which she has experienced since suffering complications from a surgery. During the 2017-18 school year, I4RH Member 2 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health. Through the accommodation process, Aetna covered the full cost of I4RH Member 2's NuvaRing. Beginning August 15, 2018, Member 2 has had to pay coinsurance for her NuvaRing. To avoid this added cost, Member 2 had to switch to a hormonal long-acting intrauterine device while she still had coverage through the accommodation. Since August 15, 2018, Member 2 is subject to cost-sharing for removal or replacement of the IUD and for help with complications should any occur, including the cost of office visits related to her IUD.

c. All members of I4RH who rely on University-sponsored health insurance for their contraceptive needs are subject to the University's new contraceptive coverage policy. Although the ACA requires the University to cover all FDA-approved contraceptive methods for women without cost-sharing, all members of I4RH who rely on University health insurance for their contraceptive needs are subject to cost-sharing for some contraceptive methods and are being deprived of coverage for other methods. As all members of I4RH enrolled in University-sponsored health insurance are subject to the same illegal University policy and seek the same form of relief, neither the claims asserted nor the relief requested requires the participation of individual members in this lawsuit.

14. Plaintiff Natasha Reifenberg is a recent graduate of the University and lives in

Chicago, Illinois.⁵ She is a woman of child-bearing age who is enrolled as a dependent in the University's faculty and staff health plan administered by the University's third-party administrator, Meritain Health, and the University's prescription-benefit manager, OptumRx. Ms. Reifenberg relies on that plan for all her medical needs. Although the University objects to contraceptive coverage, Ms. Reifenberg previously received it without cost-sharing through the accommodation process administered by Meritain Health and OptumRx. Ms. Reifenberg has used hormonal birth control in the past and plans to use her health plan to obtain a long-acting, reversible form of contraception going forward. Ms. Reifenberg was unable to obtain a long-acting form of contraception before the University's revised employee plan went into effect on July 1, 2018 because her OB-GYN had relocated, and she had to undertake the process of finding a new doctor to provide this service. Ms. Reifenberg has since chosen an OB-GYN, and arranged for insertion of a long-acting intrauterine device. Meritain has confirmed that both the cost of the device and the cost of the office visit for the insertion procedure are only 85% covered through Ms. Reifenberg's health plan, and that both are subject to a deductible.

15. Plaintiff Jane Doe 1 is a graduate student at the University and lives in Granger, Indiana. She is a woman of child-bearing age who is enrolled in the University's student health-insurance plan and relies on that plan for all her medical needs, including contraceptives. Doe 1 uses an oral contraceptive that she refills every three months to prevent pregnancy. During the 2017-18 school year, Doe 1 received contraceptive coverage without cost-sharing through the accommodation process from Aetna Student Health even though the University objected to that coverage. Through the accommodation process, Aetna previously covered the full cost of

⁵ Ms. Reifenberg expects to be living in Chile from February 2019 to December 2019, to conduct research through a grant program.

Doe 1's oral contraception. Since the changes to the University's student health plan went into effect on August 15, 2018, Doe 1 has paid coinsurance for her oral contraceptive out of pocket.

16. Plaintiff Jane Doe 2 is an undergraduate student at the University and lives in South Bend, Indiana. She is a woman of child-bearing age who is enrolled as a dependent in the University's faculty and staff health plan administered by Meritain Health and OptumRx, and relies on that plan for all her medical needs, including contraceptives. Although the University objects to contraceptive coverage, prior to July 1, 2018, Doe 2 received it without cost-sharing through the accommodation process administered by Meritain Health and OptumRx. Doe 2 uses an oral contraceptive both for non-contraceptive medical purposes and to prevent pregnancy. Through the accommodation process, OptumRx previously covered the full cost of Doe 2's prescription. Since the changes to the University's employee plan went into effect on July 1, 2018, Doe 2 has paid a copayment for her oral contraceptive out of pocket.

17. Plaintiff Jane Doe 3 is a graduate student at another university and lives in Massachusetts. She is a woman of child-bearing age who is enrolled as a dependent in Notre Dame's faculty and staff health plan administered by Meritain Health and OptumRx, and relies on that plan for all her medical needs, including contraceptives. Although the University objects to contraceptive coverage, prior to July 1, 2018, Doe 3 received it without cost-sharing through the accommodation process administered by Meritain Health and OptumRx. Doe 3 has been relying on oral contraception since 2013 to prevent pregnancy, to control acne, and to regulate her menstrual cycle. Through the accommodation process, OptumRx previously covered the full cost of Doe 3's oral contraception. Since the changes to the University's employee plan went into effect on July 1, 2018, Doe 2 has paid a copayment for her oral contraceptive out of pocket.

18. The Government Defendants are agencies and appointed officials of the Executive

Branch of the United States who are responsible for issuing and enforcing the contraceptive coverage requirement under the ACA and the Rules and are parties to the Settlement Agreement.

- a. Defendant HHS is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.
- b. Defendant Department of Labor is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.
- c. Defendant Department of Treasury is an executive agency of the United States and promulgated the Rules and executed the Settlement Agreement at issue in this action.
- d. Defendant Alex M. Azar II is the Secretary of Health and Human Services and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of Health and Human Services.
- e. Defendant R. Alexander Acosta is the Secretary of Labor and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of Labor.
- f. Defendant Steven Mnuchin is the Secretary of the Treasury and is sued in his official capacity. He is responsible for the operation and management of the U.S. Department of the Treasury.

19. Defendant University of Notre Dame is a private university located in Notre Dame, Indiana, and executed the Settlement Agreement at issue in this action. The University's health plans cover more than 17,000 people, including employees, students, and dependents.

JURISDICTION AND VENUE

20. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1361, as this action arises under the Constitution and laws of the United States. This Court has jurisdiction to render

declaratory and injunctive relief under 28 U.S.C. §§ 2201 and 2202, 5 U.S.C. § 702, and Fed. R. Civ. P. 57 and 65.

21. Venue is proper in this district under 28 U.S.C. § 1391(e). The University is located in this judicial district, and a substantial part of the events, actions, or omissions giving rise to these claims are occurring in this judicial district. The Government Defendants are United States agencies and officers sued in their official capacities. I4RH and Does 1 and 2 reside in this judicial district, and all the Plaintiffs get their health coverage through the University student and faculty plans.

FACTUAL BACKGROUND

The Importance of Contraception

22. Regardless of their religious affiliation, 99% of women of reproductive age who have had sexual intercourse report using at least one form of contraception at some point in their lives. K. Daniels, W.D. Mosher & J. Jones, *Contraceptive Methods Women Have Ever Used: United States, 1982–2010*, National Health Statistics Reports, 2013, No. 62.

23. Contraception is critical to women’s and children’s health.

24. Research has also shown that access to contraception improves the social and economic status of women.

25. Contraception reduces unintended pregnancies, the need for abortion, adverse pregnancy outcomes, and negative health consequences to women and children. Inst. of Med., *Clinical Preventive Services for Women, Closing the Gaps*, (“IOM Report”) at 102-109 (July 19, 2011).⁶

⁶ As of July 1, 2015, IOM changed its name to the National Academy of Medicine. It is part of the National Academies of Sciences, Engineering, and Medicine, which advise the nation on matters of science, technology, and health.

26. Contraception prevents unintended pregnancy, which can have severe negative consequences for both women and their children.

27. During an unintended pregnancy, a woman is more likely to receive delayed or no prenatal care, to be depressed, and to suffer from domestic violence. *Id.* at 103.

28. An unintended pregnancy may result in preterm birth and low birth weight. *Id.*

29. Contraception allows women to postpone pregnancy and optimally space their children to avoid adverse consequences (*e.g.*, low birth weight, premature birth) associated with more than one pregnancy in 18 months. *Id.* at 103.

30. Contraception is highly effective in treating and preventing certain health conditions.

31. Contraception decreases the risk of certain cancers (such as endometrial and ovarian cancer), manages menstrual disorders, and protects against pelvic inflammatory disease and some breast diseases. *Id.* at 107.

32. In addition, pregnancy may be dangerous to some women with certain chronic medical conditions, such as diabetes, obesity, pulmonary hypertension, or heart disease. *Id.* at 103.

33. When pregnancy is contraindicated, women may need contraception to delay pregnancy until their medical conditions are under control or to prevent pregnancy throughout their lives. *Id.* at 103-4.

34. In a national study conducted in 2017, 22% of women age 18-44 who use contraception said that they used contraceptives to manage a medical condition and prevent pregnancy; 13% used contraceptives solely to manage a medical condition. Caroline Rosenzweig et al., Kaiser Family Found., *Women's Sexual and Reproductive Health Services: Key Findings*

from the 2017 Kaiser Women's Health Survey 3 (2018), <http://files.kff.org/attachment/Issue-Brief-Womens-Sexual-and-Reproductive-Health-Services-Key-Findings-from-the-2017-Kaiser-Womens-Health-Survey>.

35. Women also rely on contraception to prevent pregnancy following a sexual assault and to prevent or delay pregnancy during public-health crises, such as the outbreak of the Zika virus.

36. Access to contraception has been proven to advance women's equality and participation in the social and economic life of this country.

37. Studies show that contraception is directly linked to women's increased educational and professional opportunities and increased lifetime earnings. See, e.g., Jennifer J. Frost & Laura Duberstein Lindberg, *Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics*, 87 *Contraception* 465, 467 (2013); Adam Sonfield, et al., Guttmacher Inst., *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children* (2013), <http://www.guttmacher.org/pubs/social-economic-benefits.pdf>.

38. There are 18 methods of contraception for women approved by the FDA. Contraceptives vary in effectiveness, duration, side effects, methods of action, and ease of use.

39. Not all women can tolerate all forms of contraception, and as the FDA has said: "No one product is best for everyone." U.S. Food & Drug Admin., *Birth Control Guide*, <https://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM517406.pdf>.

40. Thus, women need insurance coverage of all FDA-approved methods, contraceptive counseling, and education to find the most appropriate method for them.

41. Women using contraception also need insurance coverage for associated services that assist them in understanding their contraceptive options, such as counseling with a health-care provider, and to ensure the effectiveness and safety of their chosen form of contraception.

Cost Barriers Impede Access to Contraception

42. Cost is often an impediment to women's obtaining contraception.

43. Cost may influence women to avoid more effective but more expensive methods of contraception or to forgo contraceptives altogether.

44. Without insurance coverage, the most effective methods of contraception carry large up-front costs that make them unaffordable for many women.

45. For example, without coverage, an IUD can cost up to \$1,300.

46. Studies show that the costs associated with contraception, even when small, lead women to forgo it completely, to choose less effective methods, or to use it inconsistently. *See, e.g.,* Guttmacher Inst., *A Real-Time Look at the Impact of the Recession on Women's Family Planning and Pregnancy Decisions 5* (Sept. 2009), <http://www.guttmacher.org/pubs/RecessionFP.pdf>.

47. When costs lead women to forgo contraception completely, to choose less effective methods, or to use it inconsistently, there is an increased risk of unintended pregnancy. *See, e.g.,* Rachel Benson Gold, *The Need for and Cost of Mandating Private Insurance Coverage for Contraception*, 1 Guttmacher Rep. on Pub. Pol'y 5, 6 (1998).

48. Cost barriers to contraception in and of themselves not only threaten the economic security of women and their families, but in undermining access to contraception, they also threaten women's long-term financial well-being, job security, workforce participation, and educational attainment.

The ACA and the Contraceptive Coverage Requirement

49. Since the ACA was passed by Congress and signed by the President in March 2010, it has extended accessible and affordable health-insurance coverage to millions of Americans and reduced sex discrimination in health care.

50. To ensure that health insurance remains accessible and affordable, the ACA contains a number of critical provisions.

51. Among these provisions is the requirement that group health plans include insurance coverage for preventive health services with no cost-sharing. 42 U.S.C. § 300gg-13(a).

52. To protect women's health, to ensure that women do not pay more for insurance coverage than men, and to advance women's equality and well-being, Congress included the Women's Health Amendment in the ACA.

53. The Women's Health Amendment requires insurance plans to cover certain women's preventive health services without cost-sharing. 42 U.S.C. § 300gg-13(a)(4).

54. Before the ACA was enacted, insurers had not consistently covered women's preventive health services.

55. Women had historically paid much more in out-of-pocket health costs than men had, based largely on significant costs for basic and necessary preventive care; and in some instances, women were unable to obtain this care at all because of cost barriers.

56. Congress included the Women's Health Amendment in the ACA to help alleviate the "punitive practices of insurance companies that charge women more and give [them] less in a benefit" and to combat other forms of widespread sex discrimination in the health-insurance market. 155 Cong. Rec. S12,021, S12,026 (daily ed. Dec. 1, 2009) (statement of Sen. Mikulski).

57. Congress specifically intended for the Women's Health Amendment to improve

women’s health by providing “affordable family planning services” to “enable women and families to make informed decisions about when and how they become parents.” 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken).

58. Under the Women’s Health Amendment, Congress required the Health Resources and Services Administration (“HRSA”), a component of HHS, to adopt guidelines on the women’s preventive-care services that must be covered under the ACA without cost-sharing.

59. Before issuing the Guidelines, HRSA commissioned the Institute of Medicine (now the National Academy of Medicine) to convene a committee of experts on women’s health, adolescent health, disease prevention, and evidence-based guidelines, to conduct a comprehensive review of women’s preventive-health needs and to produce a report. *See* IOM Report (2011).

60. Based on detailed findings—including findings that access to contraception reduces unintended pregnancies, abortions, adverse pregnancy outcomes, and negative health consequences to women and children, and that even small cost-sharing requirements significantly reduce the use of contraception—this expert committee of the Institute of Medicine recommended that HRSA include the “full range of Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity” as one of eight critical preventive services for women. *Id.* at 109-110.

61. In August 2011, HRSA adopted the required Guidelines, which accepted and implemented in full the Institute of Medicine’s recommendation on contraception and seven other preventive services for women. *See* HRSA, *Women’s Preventive Services Guidelines*, <http://hrsa.gov/womens-guidelines>.

62. To date, HRSA has not removed any services from the list set forth in the Guidelines regarding which women’s preventive services must be covered for a group or

individual health plan to comply with the ACA: Contraceptive methods and counseling remain required benefits. See HRSA, *Women's Preventive Services Guidelines*, <http://hrsa.gov/womens-guidelines>.⁷

63. As recently as December 2016, a panel of experts convened by the American College of Obstetricians and Gynecologists, through a cooperative agreement with HRSA, reaffirmed the importance of the ACA's contraceptive coverage requirement. Women's Preventive Services Initiative, *Recommendations for Preventive Services for Women* (2016), <https://www.womenspreventivehealth.org/final-report/>.

64. After the IOM Report and years of comments, the three departments primarily responsible for implementing the Women's Health Amendment—the Departments of Health and Human Services, Labor, and Treasury—finalized the preventive-services regulations, which required coverage of all the women's preventive-care services outlined in the Guidelines, including all FDA-approved methods of contraception and related education and counseling for women. See 45 C.F.R. § 147.130(a)(1)(iv) (HHS); 29 C.F.R. § 2590.715-2713(a)(1)(iv) (Labor); 26 C.F.R. § 54.9815-2713(a)(1)(iv) (Treasury).

65. The Departments have stated that contraceptive services were included in these regulations based on the regulatory findings that “cost sharing can be a significant barrier to effective contraception” and that “[c]ontraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating [the gender]

⁷ Following issuance of the Interim Final Rules, language was added in a footnote to the “contraceptive methods and counseling” line of the Guidelines with the text of the Religious and Moral Exemption language. *Id.* The Guidelines on HRSA's website have continued to include this footnote, and thereby impermissibly tell entities that they may unilaterally opt out of providing contraceptive coverage, even though the enabling Interim Final Rules currently are subject to two nationwide preliminary injunctions.

disparity [in health coverage] by allowing women to achieve equal status as healthy and productive members of the job force.” 77 Fed. Reg. 8,725, 8,728 (Feb. 15, 2012).

Religious Objections to Contraceptive Coverage and the Accommodation Process

66. Houses of worship were and continue to be exempt from the ACA’s contraceptive coverage requirement.

67. Certain religiously affiliated employers and universities that did not qualify for the house-of-worship exemption objected to providing health-insurance coverage for contraception to their employees and students and their dependents.

68. To accommodate these entities’ objections while still ensuring that women at the entities receive access to seamless, affordable contraceptive coverage, the Departments developed and made available an “accommodation” process for certain religiously affiliated nonprofit institutions. *See* 78 Fed. Reg. 39,870, 39,871 (July 2, 2013).⁸

69. The Departments made the accommodation final only after reviewing a total of 600,000 comments on the Advance Notice of Proposed Rulemaking and Notice of Proposed Rulemaking.

70. The accommodation was later extended to certain closely held, for-profit entities with religious objections to contraception, in response to the U.S. Supreme Court’s decision in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). *See* 80 Fed. Reg. 41,318 (July 14,

⁸ While the term “accommodation” has been used as a shorthand in this context to mean the ability of certain qualifying employers and universities to refuse to provide the contraceptive coverage on giving notice (so that the government may ensure that separate payments for contraception will be made by the entity’s insurer or third-party administrator), and the term “exemption” has been used to mean the ability to opt out of providing the coverage without giving notice (leaving employees and students without coverage through their regular insurance plan), a “religious accommodation” is merely an exemption from a general legal requirement on religious grounds. *See generally Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327 (1987).

2015).

71. The federal government made the extension of the accommodation final only after reviewing 75,000 comments in response to the related Notice of Proposed Rulemaking.

72. The accommodation allows an objecting entity either to sign a form (the EBSA Form 700) stating its objection to providing contraceptive coverage and submit that form to the entity's insurance company or otherwise to notify the federal government of its objection. 26 C.F.R. § 54.9815-2713A (2015).

73. After this notification, the insurance company or third-party administrator provides or arranges for separate payments for contraceptive services, without cost-sharing, directly to the affected women. *Id.*

74. Thus, under the accommodation, an objecting entity is entirely relieved of “contracting, arranging, paying, or referring for contraceptive coverage,” while the women who are employees or students, and their dependents, receive the required coverage without cost-sharing from their regular insurance company.

75. A number of entities that were eligible for the accommodation nevertheless challenged it, contending that merely filling out the accommodation form or notifying the government of their objection violated the Religious Freedom Restoration Act (“RFRA”) and the U.S. Constitution.

76. The objecting employers and universities argued that providing notification in order to opt out of the ACA's contraceptive coverage requirement is a “trigger” to women's receiving contraceptive coverage, even though the objecting entities are not required to provide the coverage in their health plan.

77. Several of these entities filed lawsuits.

78. Eight of the nine federal courts of appeals to consider these cases flatly rejected these challenges. *See, e.g., Little Sisters of Poor House v. Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll. v. Sec’y U.S. Dep’t of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015); *Priests for Life v. U.S. Dep’t of Health & Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014); *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449, 459–63 (5th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 611–15 (7th Cir. 2015); *Catholic Health Care Sys. v. Burwell*, 796 F.3d 207, 218–26 (2d Cir. 2015); *Mich. Catholic Conference & Catholic Family Servs. v. Burwell*, 807 F.3d 738, 749–50 (6th Cir. 2015); *Eternal Word Television Network, Inc. v. Sec’y of U.S. Dep’t Health & Human Servs.*, 818 F.3d 1122, 1148–51 (11th Cir. 2016); *but see Dordt Coll. v. Burwell*, 801 F.3d 946 (8th Cir. 2015).

79. The U.S. Court of Appeals for the Seventh Circuit held that the accommodation process does not substantially burden Notre Dame’s exercise of religion and therefore does not violate RFRA. *See Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 607 (7th Cir. 2015), *vacated on other grounds*, 136 S. Ct. 2007 (2016); *Univ. of Notre Dame v. Sebelius*, 743 F.3d. 547, 554 (7th Cir. 2014), *vacated on other grounds*, 135 S. Ct. 1528 (2015); *see also Grace Sch. v. Burwell*, 801 F.3d 788, 791 (7th Cir. 2015), *vacated on other grounds*, 136 S. Ct. 2011 (2016); *Wheaton Coll. v. Burwell*, 791 F.3d 792, 795 (7th Cir. 2015).

80. The U.S. Supreme Court granted certiorari in seven of the cases and ultimately vacated and remanded *all* the cases with the instruction that the parties “should be afforded an opportunity to arrive at an approach going forward that “accommodates [the entities’] religious exercise *while at the same time ensuring that women covered by [the entities’] health plans receive full and equal health coverage, including contraceptive coverage.*” *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016) (citation and internal quotation marks omitted) (emphasis added).

81. On July 22, 2016, in light of the Supreme Court’s decision in *Zubik*, the Departments issued a Request for Information (“RFI”) to solicit from interested parties comments on “whether there are alternative ways (other than those offered in current regulations) for eligible organizations that object to providing coverage for contraceptive services on religious grounds to obtain an accommodation, while still ensuring that women enrolled in the organizations’ health plans have access to seamless coverage of the full range of Food and Drug Administration-approved contraceptives without cost sharing.” 81 Fed. Reg. 47,741 (July 22, 2016).

82. On January 9, 2017, in response to 54,000 comments received in response to the RFI, the federal government concluded: “the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that affected women receive full and equal health coverage, including contraceptive coverage,” so “the Departments continue to believe that the existing accommodation regulations are consistent with RFRA” Dept. of Labor, FAQs About Affordable Care Act Implementation Part 36, at 4-5 (Jan. 9, 2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf>.

83. Meanwhile, the various *Zubik* cases were held in abeyance while the parties attempted to work out a resolution.

84. According to court filings in those cases, the federal government met numerous times with entities challenging the coverage requirement to discuss a resolution of the accommodation process.

85. Although Notre Dame students had intervened in the University’s challenge to the contraceptive coverage requirement, they were not permitted to participate in that process (*see*

Status Report of Intervenors-Appellees at 2, *Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir. Oct. 2, 2017)).

The Interim Final Rules and Final Rules

86. Despite the Supreme Court’s clear order in *Zubik* to find an approach that “ensur[es] that women covered by [the employers’] health plans receive full and equal health coverage, including contraceptive coverage,” President Trump issued an Executive Order on May 4, 2017, titled “Promoting Free Speech and Religious Liberty,” directing issuance of the type of Rules challenged here. Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017).

87. The Order states that, regarding the “Conscience Protections with Respect to Preventive-Care Mandate,” “[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code.”

88. Without any public notice and comment or other pre-promulgation mechanism for receiving input from the public, the Departments issued the Interim Final Rules on October 6, 2017.

89. The Interim Final Rules took effect immediately on October 6, 2017.

90. Only after the Interim Final Rules went into effect did the Departments solicit comments from the public.

91. In the midst of the post-promulgation comment period, Defendant HHS began the process of implementing the Interim Final Rules, including by preparing revised forms to be used for the “optional accommodation” under the Interim Final Rules and seeking public comments on these forms. Specifically, HHS sought comments on a model notice of a “religious or moral

objection” to be given to HHS, as well as a new EBSA Form 700—the form previously used by entities to certify an objection to the contraceptive coverage requirement to the entities’ health insurance issuers or third party administrators (which had been revised as of “September 2017” to conform to the Interim Final Rules).

92. On December 15, 2017, the U.S. District Court for the Eastern District of Pennsylvania entered a nationwide preliminary injunction temporarily blocking the Interim Final Rules from taking effect. *Pennsylvania v. Trump*, -- F. Supp. 3d --, No. CV 17-4540, 2017 WL 6398465, at *15 (E.D. Pa. Dec. 15, 2017).

93. The court concluded that the plaintiff—the Commonwealth of Pennsylvania—would likely succeed on the merits of its claim that the Government Defendants promulgated the Interim Final Rules without following the requisite procedures under the Administrative Procedure Act. *Id.* at *11-14.

94. The court further concluded that Pennsylvania was likely to succeed on its claim that the Interim Final Rules are substantively illegal because they were promulgated without statutory authority. *Id.* at *15-17.

95. A few days later, the U.S. District Court for the Northern District of California issued a second nationwide preliminary injunction against the Interim Final Rules, similarly concluding that the plaintiff States in that action would likely succeed on their claim that the Government Defendants issued the Interim Final Rules without following the procedures required by the Administrative Procedure Act. *California v. Health & Human Servs.*, -- F. Supp. 3d --, No. 17-CV-05783-HSG, 2017 WL 6524627 (N.D. Cal. Dec. 21, 2017).

96. Both decisions are on appeal.

97. Despite two federal court injunctions prohibiting the Interim Final Rules from

taking effect, the Departments issued Final Rules on November 7, 2018, with an effective date of January 14, 2019. The Final Rules finalize the Interim Final Rules in all material respects and are as substantively unlawful and procedurally deficient as the Interim Final Rules.

98. The Final Rules, like the IFRs, dramatically expand the scope of the exemption and the types of entities that can claim it, allowing the covered entities to choose whether they will participate in the accommodation process or whether they will instead affirmatively prevent employees and students from receiving contraceptive coverage.

99. The latter approach has the effect of denying Plaintiffs and other women coverage to which they are otherwise legally entitled.

100. The Final Rules, like the IFRs, broaden the entities eligible for an exemption so that almost any university, nonprofit, for-profit business (whether publicly or privately held), or other nongovernmental employer may refuse to cover contraception in its group health plans without notifying the government.

101. Through the Final Rules, like the IFRs, the Departments also impermissibly attempt to broaden the permissible bases for seeking the exemption, from sincerely held religious beliefs to sincerely held religious beliefs or sincerely held moral convictions.

102. The Final Rules, like the IFRs, make optional the previously-required accommodation process for objecting entities, which was designed to ensure that employees and students would continue to receive seamless contraceptive coverage.

103. Under the Final Rules, like the IFRs, an employer, university, or insurance issuer may claim an exemption and deny coverage, so that the insureds will no longer have seamless contraceptive coverage.

104. The Final Rules, like the IFRs, are also procedurally deficient. The Departments'

complete failure to follow the required notice-and-comment procedure prior to promulgation of the Interim Final Rules was not cured by the Departments' acceptance of comments post-promulgation.

105. Not only does solicitation of post-promulgation comments fail to cure the procedural infirmity, but also the Departments failed to keep an open mind in evaluating post-promulgation comments. This failure is evident from, among other things,

a. The Departments' decision to issue Final Rules that are functionally the same in all material respects as the unlawful Interim Final Rules.

b. The Departments' decision to issue those Final Rules without regard to the fact that they were already preliminarily enjoined from implementing the IFRs on substantive as well as procedural grounds that apply equally to the Final Rules.

c. The Departments' preparation of, and solicitation of comments on, forms intended to implement the IFRs, including a revised EBSA Form 700 and a model notice to HHS, a month before the post-promulgation comment period had even closed.

d. The Departments' failure to address substantial empirical and scientific data regarding the benefits and effectiveness of contraception and contraceptive coverage and other significant concerns submitted in comments opposing the IFRs' expansive exemptions.

e. The Departments' failure to address the directive of the United States Supreme Court to resolve legal challenges in a manner that "ensur[es] that women covered by [the objecting entities'] health plans receive full and equal health coverage, including contraceptive coverage." *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016); *see also, e.g., Univ. of Notre Dame v. Burwell*, 136 S. Ct. 2007 (Mem.), and decisions of eight federal courts of appeals

rejecting the Departments' contention that the existing accommodation process substantially burdens religion.

f. The Departments' decision to execute dozens of settlement agreements immediately after promulgating the IFRs that expressly rely on the IFRs; that entrench, by contract, the exemptions in the IFRs; and that even purport to bind future administrations to these exemptions. *See, e.g., infra* ¶¶ 108, 112.

The Settlement Agreement

106. On October 13, 2017, just one week after the Departments issued the Interim Final Rules, and the same day that the Interim Final Rules were published in the Federal Register, the Government Defendants executed the Settlement Agreement, which purported to resolve several pending cases challenging the ACA contraceptive coverage requirement.

107. The Government Defendants executed the Settlement Agreement with Notre Dame in order to dispose of the University's ongoing legal dispute. The Settlement Agreement also resolved separate legal challenges with more than 70 other private entities.

108. Among other terms, the Settlement Agreement purports to exempt Notre Dame and the health plans that it sponsors from complying with either the existing contraceptive coverage requirement or any "materially similar regulation or agency policy." (Exhibit A at 4).

109. The Settlement Agreement states that "[n]o person may receive [contraceptive coverage] as an automatic consequence of enrollment in any health plan sponsored by Plaintiffs." (Exhibit A at 4).

110. The Settlement Agreement also retroactively rescinds penalties for noncompliance with the contraceptive coverage requirement, providing that no fines should have been assessed. (Exhibit A at 6).

111. By these provisions, the Government Defendants purport to grant private entities, including the Defendant University, a contractual right to deny contraceptive coverage to women who rely on their health plans, in direct violation of the ACA and the Supreme Court’s directive in *Zubik* that any resolution of legal challenges to the contraceptive coverage requirement must “ensur[e] that women covered by [the entities’] health plans receive full and equal health coverage, including contraceptive coverage.” *Zubik*, 136 S. Ct. at 1560.

112. As a justification for this unlawful action, the Settlement Agreement relied on “the new regulations,” notwithstanding that those Interim Final Rules were themselves unlawful and accordingly would be preliminarily enjoined by two district courts. (Exhibit A at 2).

113. The Settlement Agreement further awards the private entities \$3 million to cover the costs and fees for their legal counsel, the law firm Jones Day. (Exhibit A at 7).

114. Despite repeated requests by the students who intervened in the University’s lawsuit to be included in settlement negotiations, the student-intervenors were excluded from all settlement discussions and were never informed by either the Defendant University or the Government Defendants that a settlement agreement had been negotiated or executed. *See, e.g., Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir.), Status Report of Intervenors-Appellees at 2, (filed Oct. 2, 2017), Status Report of Intervenors-Appellees, Dkt. 152 (filed Aug. 31, 2017).

115. No court was informed of, reviewed, or judicially confirmed the Settlement Agreement.

116. Neither the U.S. Department of Justice nor any of the Defendant agencies issued a public press release announcing the Settlement Agreement.⁹

⁹ *See* U.S. Dep’t of Justice, Justice News, <https://www.justice.gov/news> (listing all press releases and revealing that no release was issued about the Settlement Agreement); U.S. Dep’t of Health

117. Notre Dame voluntarily dismissed its lawsuit concerning the contraceptive coverage requirement on October 19, 2017, less than two weeks after the Interim Final Rules were issued, and just days after execution of the secret Settlement Agreement, although neither Plaintiffs here nor the student-intervenors in the Notre Dame action were informed about or aware of the Settlement Agreement at that time, and notwithstanding that their rights under the ACA were directly affected thereby. *See Univ. of Notre Dame v. Sebelius*, No. 13-cv-1276 (N.D. Ind.); *Univ. of Notre Dame v. Price*, No. 13-3853 (7th Cir.) (appeal dismissed October 17, 2017).

Notre Dame's Changes to Contraceptive Coverage

118. On October 27, 2017, Notre Dame announced in e-mails to students, faculty, and staff its intention to withdraw contraceptive coverage from its health plans beginning in the new plan years.

119. After the University's October 27 announcement, students began to organize in response to the University's decision to withdraw contraceptive coverage.

120. Students who would soon form Plaintiff I4RH collected 516 signatures from undergraduate students, graduate students, faculty, and alumni on a statement condemning the University's decision to withdraw contraceptive coverage.

121. During this same period, individuals covered by Notre Dame's health plans—including some of the Plaintiffs in this case¹⁰—filed lawsuits against the Departments, challenging the Interim Final Rules that had given rise to the University's announced policy

& Human Servs., 2017 News Releases, <https://www.hhs.gov/about/news/2017-news-releases/index.html#October> (same); U.S. Dep't of Labor, Newsroom, <https://www.dol.gov/newsroom/releases/date/2017/October> (same); U.S. Dep't of Treasury, Press Releases, <https://home.treasury.gov/news/press-releases> (same).

¹⁰ The plaintiffs in these prior suits included Plaintiff Natasha Reifenberg and Jane Doe 2.

changes.

122. Several Notre Dame students filed a lawsuit in this Court. *Shiraef v. Hargan*, 3:17-cv-817 (N.D. Ind.) (filed October 31, 2017).

123. Two other Notre Dame students, along with a national student association, filed a lawsuit in the U.S. District Court for the District of Columbia. *Medical Students for Choice v. Wright*, 1:17-cv-02096, (D.D.C.) (filed on October 10, 2017).

124. Following public expression of serious concerns from students, alumni, and faculty, the University soon reversed course on its decision to terminate contraceptive coverage.

125. In early November 2017, the University sent e-mails to students, faculty, and staff announcing that it would “not interfere” with the provision of contraceptive coverage to students by Aetna or to faculty and staff by Meritain and OptumRx.

126. In reliance on Notre Dame’s statements that it would “not interfere” with the provision of contraceptive coverage by the insurance companies, the plaintiffs in the cases identified in Paragraphs 122 and 123 filed notices of voluntary dismissal.

127. The Courts granted voluntary dismissal of the District of Columbia and Northern District of Indiana cases without prejudice on February 6 and 7, 2018.

128. Also on February 7, immediately after the dismissal orders were entered, the University again reversed course, announcing that it would, in fact, be terminating insurance coverage for certain FDA-approved methods of contraception for employees in the middle of the plan year on July 1, 2018, and for students beginning with the new plan year in August 2018.

129. In justifying this change in coverage, the University publicly invoked the

Settlement Agreement as independent authority.¹¹

130. As explained in two letters sent on February 7, 2018, by Notre Dame's President, John Jenkins, to "Aetna Student Health Enrollees" and to "Faculty and Staff," a "favorable" settlement with the U.S. government purportedly gave "the University, its insurers and third party administrators the option of an exemption from providing" coverage for all FDA-approved methods of contraception. Jenkins's letters did not state which contraceptive methods would continue to be covered and which would not.

131. Following the February 7 announcements, students, faculty, and staff were left guessing whether their method of contraception would remain covered.

132. On March 25, 2018, University Health Services circulated a "Health Care Coverage Update" to students, which directed students to review a "Frequently Asked Questions about Contraceptive Coverage" ("FAQ") webpage for more information about the changes to contraceptive coverage in the student health plan.

133. The FAQ explains that the University will provide no coverage for copper IUDs or emergency contraceptives.

134. The FAQ also explains that even though the University said that it will "cover" certain methods of contraception, it will require students to pay sums out-of-pocket for any covered contraceptive method, in direct contravention of the Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4), and implementing regulations.

135. According to the FAQ, students must pay the same out-of-pocket costs for contraception covered by the plan as for other prescription drugs.

¹¹ The University has subsequently also stated that it considers itself "fully exempt from the [contraceptive coverage] mandate" pursuant to "current regulations." ECF No. 35-1 at 8.

136. On April 30, 2018, Plaintiff I4RH sent Notre Dame President Jenkins an “insurance clarity petition” with more than 100 signatures from Notre Dame undergraduates, graduate students, alumni, faculty, and staff demanding additional details about the University’s announced changes to contraceptive coverage.

137. The petition also expressed disapproval over the change in policy and the “lack of transparency that has characterized the [university] administration’s every move on this issue since October 2017.”

138. On May 4, 2018, Ann Firth, Chief of Staff in the Notre Dame Office of the President, responded to I4RH that the University would not issue any more details about the Aetna student health plan until July 1, which was after matriculating and returning students already had to commit to their programs.

139. The 2018-19 Aetna Student Health plan went into effect for annual enrollees on August 15, 2018.

140. The 2018-19 Aetna Student Health plan documents show that for certain contraceptive methods, including hormonal IUDs (but not copper IUDs, which are not covered at all), injections, implants, and related services, and for office visits related to covered contraceptives, students must first meet a \$500 annual deductible before receiving any coverage from Aetna, and then students must pay coinsurance of either 20 percent of the negotiated charge for in-network coverage or 40 percent of the recognized charge for out-of-network coverage.¹²

141. The 2018-19 Aetna Student Health plan documents show that for other

¹² Aetna Student Health Plan Design and Benefits Summary 2018-19, University of Notre Dame at 16, 24, https://uhs.nd.edu/assets/282390/aetna_student_health_plan_design_and_benefits_summary_notre_dame_2018_19_7_24_18.pdf.

prescription contraception, including oral contraception, students will have to pay coinsurance of either 20 or 40 percent of the negotiated charge, depending on whether a generic alternative is available.

142. Although the FAQ and publicly available 2018-19 Aetna Student Health plan documents show that “certain IUDs and contraceptive implants” will remain covered, neither specifies which, if any, forms of hormonal IUDs or implants will receive coverage or what related services other than insertion and removal, if any, will be covered.

143. IUDs and implants are among the most effective forms of contraception but carry the largest up-front costs.

144. Under the 2018-19 Aetna Student Health plan, the deductible is waived for expenses incurred at the University Health Services, but because Notre Dame will not allow the University Health Services to provide most contraceptives, at least for undergraduates, students may be forced to incur additional out-of-pocket expenses in order to obtain contraception from off-campus physicians and pharmacies.

145. On April 27, 2018, Notre Dame Human Resources sent an e-mail to faculty and students with a link to revised medical and prescription plan documents and summaries of material modifications to those plans related to the changes to contraceptive coverage effective July 1, 2018.

146. In this correspondence, the University notified faculty and staff that, as with students, they must pay out-of-pocket for any covered contraceptive method, in direct contravention of the Women’s Health Amendment, 42 U.S.C. § 300gg-13(a)(4), and implementing regulations. The e-mail also states that, as for students, the revised Employee plan provides no coverage for copper IUDs or emergency contraceptives, and that “instructional and

counseling appointments related to natural family planning will be covered” but counseling and education related to other contraceptive methods and services will not.

147. The e-mail correspondence states that certain “hormonal contraceptives” included on the University’s contraceptive-drug formulary are covered by OptumRx under the revised Employee plan but are subject to co-payments.

148. The e-mail correspondence further states that IUDs and implants (as well as their insertion and removal) and contraceptive injections are covered by Meritain as “medical services” under the revised Employee plan, but the e-mail does not specify which, if any, hormonal IUDs or implants are covered or whether any related services other than insertion and removal are covered.

149. The revised Employee plan went into effect on July 1, 2018, and remains in effect. The revised plan does not cover copper IUDs or emergency contraception. The Employee Plan requires copays for oral contraceptives, which are treated as prescription benefits. And to the limited extent that some hormonal IUDs and implants (as well as their insertion and removal) and contraceptive injections are covered, the Employee Plan treats them as “medical services,” not preventive care, which means that they are still subject to annual deductibles and copays.

Effect of the Rules and Settlement Agreement

150. The expanded exemptions in the Rules effectively nullify the ACA’s contraceptive coverage requirement, including regulations that took over six years to promulgate and involved multiple consultations with expert committees as well as six rounds of notice-and-comment rulemaking in the form of Advanced Notices of Proposed Rulemaking, Notices of Proposed Rulemaking, Interim Final Rules with comment periods, and Requests for Information that together involved more than 725,000 comments.

151. The Settlement Agreement and any other similar settlements, separate and apart from the Rules, also effectively nullify the ACA's contraceptive coverage requirement as to its signatories and unknown related entities offering coverage through the health plan of a signatory.

152. The expanded exemptions in the Rules allow virtually any employer or university to evade the contraceptive coverage requirement and thereby to harm women by imposing their religious and moral views on employees and students.

153. The Rules, the Settlement Agreement, and any other similar settlements create a major change in law.

154. The Government Defendants issued both the Interim Final Rules and the Final Rules and Defendants executed the Settlement Agreement without constitutional or statutory authority, and in violation of Supreme Court orders.

155. The Government Defendants further issued the Interim Final Rules without following the statutorily mandated notice-and-comment procedure, a procedural deficiency that was not remedied by the post-promulgation notice-and-comment process and issuance of the functionally-identical Final Rules.

156. The Rules, the Settlement Agreement, and any other similar settlements establish and impose one subset of religious views while denying health care to those with different beliefs.

157. The result is that Plaintiffs and other women are denied coverage for contraception and related services and thus are harmed.

158. The expanded exemptions jeopardize the health, economic security, and equality of more than 62 million women who currently have coverage for all FDA-approved contraceptive methods and related education and counseling without out-of-pocket costs. *See Nat'l Women's Law Center, New Data Estimate 62.4 Million Women Have Coverage of Birth Control without*

Out-of-Pocket Costs (Sept. 2017), available at <https://nwlc.org/resources/new-data-estimate-62-4-million-women-have-coverage-of-birth-control-without-out-of-pocket-costs/>.

159. The Rules, the Settlement Agreement, and any other similar settlements reinstate the cost barriers to contraceptive care.

160. Additionally, the Rules, the Settlement Agreement, and any other similar settlements impose other significant informational, administrative, and logistical burdens on Plaintiffs and other women, who will need to navigate finding other sources of contraceptive care.

161. Some women will not have access to contraception at all because of the Rules, the Settlement Agreement, and any other similar settlements.

162. Congress included the Women's Health Amendment in the ACA to improve women's health by removing cost and access barriers, to protect women's economic security, and to remedy systemic sex discrimination in the insurance market.

163. Yet the Rules, the Settlement Agreement, and other similar settlements, by allowing employers, universities, and insurance issuers to exempt themselves from the contraceptive coverage requirement, target women for adverse treatment, directly undermining those legislative purposes.

164. The Rules, the Settlement Agreement, and other similar settlements create unreasonable barriers to critical health care services for Plaintiffs and countless other women.

FIRST CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Settlement Agreement Violates the Administrative Procedure Act)

165. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

166. Plaintiffs are entitled to relief under the Administrative Procedure Act because the Settlement Agreement is illegal under and contrary to controlling orders and precedential

decisions of the federal courts, federal statutes, and the U.S. Constitution.

167. HHS, the Department of Labor, and the Department of the Treasury are “agencies” under the Administrative Procedure Act. *See* 5 U.S.C. § 551(1).

168. The Government Defendants’ decision to enter into the Settlement Agreement is a final agency action subject to judicial review under 5 U.S.C. § 551(13) and 5 U.S.C. § 704.

169. The Administrative Procedure Act requires courts to “hold unlawful and set aside” any agency action, finding, or conclusion that is “arbitrary,” “capricious,” “an abuse of discretion,” “not in accordance with the law,” “contrary to constitutional right, power, privilege, or immunity,” or “in excess of statutory . . . authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A)-(C).

170. The Settlement Agreement is not in accordance with the U.S. Supreme Court’s Orders in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), and *Univ. of Notre Dame v. Burwell*, 136 S. Ct. 2007 (2016).

171. *Zubik* required the Government Defendants to resolve legal challenges to the ACA contraceptive coverage requirement in a manner that “accommodates [the entities’] religious exercise *while at the same time ensuring that women covered by [the entities’] health plans receive full and equal health coverage, including contraceptive coverage.*” *Zubik*, 136 S. Ct. at 1560 (citation and internal quotation marks omitted) (emphasis added); *see also Univ. of Notre Dame*, 136 S. Ct. 2007 (“Nothing in the *Zubik* opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by petitioners’ health plans obtain, without cost, the full range of FDA approved contraceptives.” (internal quotation marks omitted)).

172. The Settlement Agreement violates these orders by authorizing the University to

withdraw, block, or impose cost-sharing on contraceptive coverage for its students and employees, with no provision for ensuring that plan beneficiaries, including the Plaintiffs, continue to receive the full, equal, and comprehensive contraceptive coverage to which they are entitled by law.

173. The Settlement Agreement is not in accordance with the ACA requirement that group health plans or individual health insurance cover the preventive care services identified in HRSA's Women's Preventive Service Guidelines without cost-sharing, because the Settlement Agreement permits the University to withdraw or impose cost-sharing under the student and employee health plans on coverage for contraceptive services specified in the Guidelines. Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4).

174. The Government Defendants exceeded their statutory authority by executing a Settlement Agreement that is not in accordance with the ACA requirement that group health plans and individual health insurance cover without cost-sharing the contraceptive services identified in HRSA's Women's Preventive Service Guidelines. Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4).

175. Thus, the Government Defendants violated 5 U.S.C. § 706(2)(C).

176. The Settlement Agreement is contrary to the Establishment Clause of the First Amendment because, among other constitutional defects, it prefers some religious beliefs and denominations over others and imposes costs, burdens, and harms on Plaintiffs to favor the religious beliefs of the University.

177. The Settlement Agreement is contrary to the Due Process Clause of the Fifth Amendment because it erects unnecessary barriers to exercising the fundamental liberty right to make personal decisions regarding use of contraception without government intrusion.

178. The Settlement Agreement is contrary to the equal-protection guarantees of the Due Process Clause of the Fifth Amendment because it discriminates based on sex, religion, and the exercise of fundamental rights.

179. The Settlement Agreement is contrary to the Due Process Clause of the Fifth Amendment because it deprives Plaintiffs of their rights without notice or an opportunity to be heard.

180. By entering an illegal Settlement Agreement, the Government Defendants abused their discretion in violation of 5 U.S.C. § 706(2)(A).

181. Because the Government Defendants' actions are "not in accordance with law," are in excess of statutory authority and short of statutory right, are "contrary to constitutional right," are "arbitrary," are "capricious," and are "an abuse of discretion," the Government Defendants have violated the Administrative Procedure Act.

182. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

SECOND CAUSE OF ACTION—ALL DEFENDANTS

(Settlement Agreement is Void for Illegality)

183. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

184. Under federal common law, contracts that are illegal are void *ab initio* and unenforceable. *See, e.g., U.S. Nursing Corp. v. Saint Joseph Med. Ctr.*, 39 F.3d 790, 792 (7th Cir. 1994); *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 863 (N.D. Ind. 1999).

185. The Settlement Agreement is illegal under and contrary to controlling orders and precedential decisions of federal courts, federal statutes, and the U.S. Constitution.

186. For example, the Settlement Agreement violates:

a. The U.S. Supreme Court’s Orders in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), and *Univ. of Notre Dame v. Burwell*, 136 S. Ct. 2007 (2016).

b. The Women’s Health Amendment, 42 U.S.C. § 300gg-13(a)(4), and the HRSA *Women’s Preventive Services Guidelines*, <http://hrsa.gov/womens-guidelines>.

c. The Establishment Clause of the First Amendment to the U.S. Constitution.

d. The Due Process Clause of the Fifth Amendment to the U.S. Constitution.

187. The Settlement Agreement is null and void *ab initio* because it is illegal.

188. Absent declaratory and injunctive relief voiding the Settlement Agreement and enjoining its enforcement, Defendants’ violations will cause ongoing harm to Plaintiffs.

THIRD CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Administrative Procedure Act—Final Rules are Procedurally Arbitrary and Capricious)

189. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

190. Plaintiffs are entitled to relief under the Administrative Procedure Act because the Departments did not follow procedures required by law for agency rulemaking.

191. The Administrative Procedure Act requires courts to “hold unlawful and set aside” agency action taken “without observance of procedure required by law.” 5 U.S.C. § 706(2)(D).

192. HHS, the Department of Labor, and the Department of the Treasury are “agencies” under the Administrative Procedure Act. *See* 5 U.S.C. § 551(1).

193. The challenged Rules qualify as rules under the Administrative Procedure Act. *See* 5 U.S.C. § 551(4).

194. With exceptions not applicable here, a federal agency must provide the public with pre-promulgation notice of and an opportunity to comment on a proposed rulemaking. 5 U.S.C. § 553. Post-promulgation opportunities for notice and comment do not satisfy this requirement.

195. Defendants promulgated the Interim Final Rules in violation of 5 U.S.C. § 553.

196. Defendants' promulgation of the Interim Final Rules was unlawful because they did not have good cause or statutory authority to forgo notice-and-comment rulemaking or to waive the 30-day waiting period between publication and effective date for new rules.

197. Defendants' post-promulgation notice and comment, followed by issuance of the Final Rules, did not cure their violation of 5 U.S.C. § 553, and Defendants' failure to keep an open mind in evaluating post-promulgation comments is evident from, among other things,

a. The Departments' decision to issue Final Rules that are functionally and materially the same as the unlawful Interim Final Rules.

b. The Departments' decision to issue those Final Rules even though they were already preliminarily enjoined from implementing the IFRs on substantive as well as procedural grounds that apply equally to the Final Rules.

c. The Departments' preparation of, and solicitation of comments on, revised forms to implement the IFRs before the post-promulgation comment period had even closed.

d. The Departments' failure to address substantial empirical and scientific data regarding the benefits and effectiveness of contraception and contraceptive coverage and other significant concerns submitted in comments opposing the IFRs' expansive exemptions.

e. The Departments' failure to address controlling orders and precedential decisions of the federal courts rejecting the Departments' legal justification for the Rules.

f. The Departments' decision to execute dozens of settlement agreements immediately after promulgating the IFRs that expressly rely on the IFRs; that entrench, by contract, the exemptions in the IFRs; and that even purport to bind future administrations to these exemptions.

198. Absent declaratory and injunctive relief, Plaintiffs have been and will continue to be harmed.

FOURTH CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Administrative Procedure Act—The Final Rules Violate the Substantive Requirements of the Administrative Procedure Act)

199. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

200. Plaintiffs are entitled to relief under the Administrative Procedure Act because the Rules are illegal under the Constitution and federal statutes.

201. The Administrative Procedure Act requires courts to “hold unlawful and set aside” any agency action, finding, or conclusion that is “arbitrary,” “capricious,” “an abuse of discretion,” “not in accordance with the law,” “contrary to constitutional right, power, privilege, or immunity,” or “in excess of statutory . . . authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(A)-(C).

202. The Rules are contrary to the Establishment Clause of the First Amendment.

203. The Rules are contrary to the Due Process Clause of the Fifth Amendment because they erect unnecessary barriers to exercising the fundamental liberty right to make personal decisions regarding use of contraception without government intrusion.

204. The Rules are contrary to the equal-protection guarantees of the Due Process Clause of the Fifth Amendment because they discriminate based on sex, religion, and the exercise

of fundamental rights.

205. The Rules are contrary to the Due Process Clause of the Fifth Amendment because they deprive Plaintiffs of their rights without notice or an opportunity to be heard.

206. The Rules are not in accordance with the ACA requirement that group health plans and individual health insurance cover the preventive-care services identified in HRSA's Women's Preventive Service Guidelines, because the Rules exempt coverage of services specified in the Guidelines. Women's Health Amendment, 42 U.S.C. § 300gg-13(a)(4).

207. The Government Defendants exceeded their statutory authority by issuing Rules that do away with the requirement for coverage of contraceptives without cost-sharing for Plaintiffs and at least tens of thousands of other women under 42 U.S.C. § 300gg-13(a)(4), thus violating 5 U.S.C. § 706(2)(C).

208. The Rules are inconsistent with the weight of the hundreds of thousands of comments that were submitted for each of the previous rules relating to the contraceptive coverage requirement, and the post-promulgation comments submitted following the Interim Final Rules, and thus are arbitrary, capricious, and in violation of 5 U.S.C. § 706(2)(A).

209. The Rules were adopted with no valid justification. Thus, the Government Defendants' issuance of the Rules was arbitrary and capricious and violates 5 U.S.C. § 706(2)(A).

210. By issuing illegal Rules, the Government Defendants abused their discretion in violation of 5 U.S.C. § 706(2)(A).

211. Because the Government Defendants' actions are "not in accordance with law," "contrary to constitutional right," "arbitrary and capricious," "an abuse of discretion," and in excess of statutory authority and short of statutory right, the Government Defendants have violated the Administrative Procedure Act.

212. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

FIFTH CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(First Amendment—Violation of the Establishment Clause)

213. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

214. Plaintiffs are entitled to relief because the Settlement Agreement and the Rules subject, and will continue to subject, Plaintiffs to deprivations of their rights under the Establishment Clause of the First Amendment to the U.S. Constitution.

215. The Establishment Clause provides that “Congress shall make no law respecting an establishment of religion.”

216. The Government Defendants have violated, and will continue to violate, Plaintiffs' rights under the Establishment Clause, including in the following ways:

a. The Settlement Agreement and the Rules provide religious exemptions from the ACA that will harm Plaintiffs and others by depriving them of, or limiting their access to, contraceptive services, a critical preventive health service.

b. The Settlement Agreement and the Rules are governmental conduct that has and will continue to have the primary purpose and principal effect of promoting, advancing, and endorsing religion.

c. The Settlement Agreement and the Rules coercively impose religious beliefs and practices to which Plaintiffs and other affected persons do not subscribe.

d. The Settlement Agreement and the Rules excessively entangle the government with religion.

e. The Settlement Agreement and Rules impermissibly impose on Plaintiffs and other innocent third parties undue costs, burdens, and harms arising from the granting of religious exemptions from the ACA.

f. The Settlement Agreement and the Rules impermissibly favor and prefer some denominations and religious beliefs over others.

217. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

SIXTH CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Fifth Amendment—Due Process) (Right to Liberty)

218. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

219. The Due Process Clause of the Fifth Amendment prohibits the government from denying fundamental rights such as the right to liberty.

220. By impairing women's ability to gain access to contraception and forcing women either to incur significant costs or to forgo contraception altogether, the Rules and the Settlement Agreement infringe the fundamental right to liberty, in violation of Plaintiffs' rights under the Fifth Amendment to the U.S. Constitution.

221. The Settlement Agreement and the Rules deny Plaintiffs due process by depriving Plaintiffs of their rights without notice or an opportunity to be heard.

222. The Settlement Agreement and the Rules do not further a compelling governmental interest and are not tailored to achieve any such interest.

223. The Government Defendants cannot proffer any legitimate justification for the Settlement Agreement or the Rules, let alone an exceedingly persuasive or compelling

justification.

224. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

SEVENTH CAUSE OF ACTION—GOVERNMENT DEFENDANTS

(Fifth Amendment—Equal Protection)

225. The foregoing allegations are re-alleged and incorporated by reference as if restated fully here.

226. The Due Process Clause of the Fifth Amendment prohibits the government from denying equal protection of the laws, including on the basis of sex and religion.

227. The Settlement Agreement and the Rules deny Plaintiffs the equal protection of the laws because the expansive exemptions that they create impermissibly target women for adverse treatment.

228. The Settlement Agreement and the Rules deny Plaintiffs the equal protection of the laws by endorsing one set of religious beliefs to the exclusion of others.

229. The Settlement Agreement and the Rules deny Plaintiffs the equal protection of the laws because they discriminate against individuals who seek to exercise their fundamental right to make personal decisions regarding the use of contraception.

230. The Settlement Agreement and the Rules do not further a compelling governmental interest and are not tailored to achieve any such interest.

231. The Government Defendants cannot proffer any legitimate justification for the Settlement Agreement or the Rules, let alone an exceedingly persuasive or compelling justification.

232. Absent declaratory and injunctive relief, the Government Defendants' violations will cause ongoing harm to Plaintiffs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests that the Court:

- a. Declare the Settlement Agreement between the Departments and Notre Dame void because it violates the Administrative Procedure Act, the ACA, orders and precedential decisions of federal courts, and the First and Fifth Amendments to the U.S. Constitution;
- b. Enter a permanent injunction prohibiting Notre Dame from implementing, enforcing, or relying on the Settlement Agreement or any provision thereof;
- c. Enter a permanent injunction prohibiting the Departments from implementing, enforcing, or relying on the Settlement Agreement, or any provision thereof, with respect to Notre Dame and any of the health plans that it sponsors;
- d. Enjoin the Defendant University from sponsoring any student or employee health plan that fails to comply with the Women’s Health Amendment, 42 U.S.C. § 300gg-13(a)(4);
- e. Declare that the Final Rules were issued in violation of, and violate, the Administrative Procedure Act, the ACA, and the First and Fifth Amendments to the U.S. Constitution;
- f. Enter a permanent injunction prohibiting the Government Defendants from implementing or enforcing the Final Rules;
- g. Retain jurisdiction until Defendants have fully satisfied their court-ordered obligations;
- h. Award nominal damages in the sum of \$1.00;
- i. Award Plaintiffs attorneys’ fees and costs, as provided by any applicable

statute or regulation or the inherent powers of the Court;

j. Grant all further and additional relief that the Court may determine is just and proper.

Dated: December 4, 2018

Respectfully submitted,

/s/ Jeffrey A. Macey

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* Motion for *pro hac vice* forthcoming.

** Admitted *pro hac vice*.