No. 19-10754

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

RICHARD W. DeOTTE, *et al.*,

Plaintiffs-Appellees,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al*.,

Defendants,

and

STATE OF NEVADA,

Movant-Appellant.

On Appeal from the United States District Court
for the Northern District of Texas
Case No. 4:18-CV-825

AMICUS CURIAE BRIEF OF HEALTH PROFESSIONAL ORGANIZATIONS AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN NURSES ASSOCIATION, AMERICAN ACADEMY OF NURSING, and PHYSICIANS FOR REPRODUCTIVE HEALTH IN SUPPORT OF MOVANT-APPELLANT AND REVERSAL

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 29.2, the undersigned hereby certifies that the following parties, none of which has corporate parents or stockholders, have an interest in this amicus brief:

Amici Curiae:

American College of Obstetricians and Gynecologists
American Academy of Pediatrics
American Nurses Association
American Academy of Nursing
Physicians for Reproductive Health

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INTEREST OF AMICI CURIAE[1]

Amici, listed below, are leading health professional organizations that are directly involved in the provision of health care to women and adolescents. *Amici* share the common goal of improving health for all by, among other things, ensuring that women have access to high quality medical care that is comprehensive and evidence-based. *Amici* have a particular interest in the outcome of this case because well-established and evidence-based standards of care recommend access to contraception and contraception counseling as essential components of effective health care for women and adolescents of childbearing age, and even small increases in the cost of contraceptives or added hurdles to obtain it, reduce access.

Amici submit this brief to highlight for the Court the importance of contraception to women's preventive health care and the grave harms to women's health and public health generally presented by the District Court's order enjoining enforcement of the Contraceptive Mandate. Among other things, the injunction

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), *amici* state that no counsel for a party authored this brief in whole or in part and no counsel, party, or other person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this brief.

could have the effect of restricting access to appropriate contraception and seamless health care for the many women affected.[2]

American College of Obstetricians and Gynecologists (ACOG) is a non-profit educational and professional organization. With more than 58,000 members, ACOG is the leading professional association of physicians who specialize in the health care of women. ACOG's members represent more than 90% of all board-certified obstetricians and gynecologists practicing in the United States.

American Academy of Pediatrics ("AAP") was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since 1930, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. The AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. The AAP has worked with the federal and state

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[2] Courts frequently rely on submissions by *amici* as authoritative sources of medical information on issues concerning women's health care. *See, e.g., Whole Woman's Health v. Hellerstedt,* 136 S. Ct. 2292, 2312, 2315 (2016) (citing *amici* brief submitted by ACOG, AAP, and other health professional organizations in reviewing clinical and privileging requirements); *Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG's amicus brief extensively and recognizing ACOG as a "significant medical authority"); *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 761 (2014) (Ginsburg, J., dissenting) (citing *amici* brief submitted by ACOG, PRH, and other health professional organizations in its discussion of how contraceptive coverage helps safeguard the health of women for whom pregnancy may be hazardous).

governments, health care providers, and parents on behalf of America's children and adolescents to ensure the availability of safe and effective contraceptives.

American Nurses Association ("ANA") represents the interests of the nation's four million registered nurses. With members in every state, ANA is comprised of state nurses associations and individual nurses. ANA is an advocate for social justice with particular attention to preserving the human rights of vulnerable groups, such as the poor, homeless, elderly, mentally ill, prisoners, refugees, women, children, and socially stigmatized groups.

American Academy of Nursing (the "Academy") serves the public and the nursing profession by advancing health policy, practice, and science through organizational excellence and effective nursing leadership. The Academy's more than 2,800 Fellows are nursing's most accomplished leaders in education, management, practice, research, and policy. They have been recognized for their extraordinary contributions to nursing and health care.

Physicians for Reproductive Health (PRH) is a doctor-led national not-for-profit organization that relies upon evidence-based medicine to promote sound reproductive health care policies. Comprised of physicians, PRH brings medical expertise to discussions of public policy on issues affecting reproductive health care and advocates for the provision of comprehensive reproductive health services as part of mainstream medical care.

SUMMARY OF ARGUMENT

The Patient Protection and Affordable Care Act (ACA) plays a vital role in ensuring that women have access to preventive health services, including FDA-approved contraceptives prescribed by a health care professional (the "Contraceptive Mandate"). By requiring private health insurance plans to cover various essential preventive care services with no additional cost sharing for the patient, the ACA advances its objective of improving public health by increasing access to comprehensive preventive health services.

Well-established and evidence-based standards of medical care recommend access to contraception and contraception counseling as essential components of health care for women of childbearing age. Contraception not only helps to prevent unintended pregnancy, but it also protects the health and well-being of women and their children. There is a compelling national interest in addressing the medical and social consequences of unintended pregnancy and promoting the widespread availability of medically appropriate contraception for all health insurance plan beneficiaries who want it.

As currently implemented, the Contraceptive Mandate ensures that, even when an employer is entitled to a religious accommodation to opt out of contraceptive coverage, that coverage is provided by the group plan insurer or administrator, without any coverage interruption or change in services for the

covered individual. The accommodation process is, thus, vital to ensuring that contraceptive coverage is provided to the patient seamlessly, alongside her other covered health services. Alternatives to the accommodation that de-link contraceptive care from an insured's covered preventive services, or that impose additional cost or administrative barriers to obtaining comprehensive care, reduce the likelihood of her consistent use of appropriate contraception. The accommodation, thus, represents the least restrictive *effective* means of making comprehensive preventive women's health care widely accessible.

ARGUMENT

POINT I.

INCREASING ACCESS TO THE FULL RANGE OF FDA-APPROVED CONTRACEPTIVES SERVES A COMPELLING NATIONAL INTEREST

A. Contraception is an Essential Component of Women's Preventive Health Care

The ACA's coverage requirement for FDA-approved contraceptives and counseling comports with guidance for good clinical practice for health care professionals. *See, e.g.*, Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) ("IOM Report"); Am. Coll. Of Obstetricians & Gynecologists, *Access to Contraception*, Comm. Op. 615, Jan. 2015 (reaffirmed 2017) ("ACOG Comm. Op. 615"). Indeed, in recommending that contraceptive methods and counseling be included within the preventive services required by the ACA, the Institute of Medicine ("IOM") recognized that the risk of unintended pregnancy affects a broad population and significantly impacts health. IOM Report at 8. It has long been established that unintended pregnancies have negative health consequences for women and children and contraception services are, therefore, critically important public health measures. *See, e.g.*, Jeffrey P. Mayer, *Unintended Childbearing, Maternal Beliefs, and Delay of Prenatal Care*, 24 BIRTH 247, 250-51 (1997); Suezanne T. Orr et al., *Unintended Pregnancy and Preterm Birth*, 14 PAEDIATRIC AND PERINATAL EPIDEMIOLOGY 309, 312 (2000);

Jennifer S. Barber et al., *Unwanted Childbearing, Health, and Mother-Child Relationships*, 40 J. HEALTH AND SOCIAL BEHAVIOR 231, 252 (1999).

Women and their families may struggle with the medical, ethical, financial, or other challenges presented by unintended pregnancy. ACOG Comm. Op. 615. Unintended pregnancies impose significant financial costs to the government as well. Unplanned pregnancies cost approximately $21 billion in government expenditures in 2010. Adam Sonfield & Kathryn Kost, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, Guttmacher Inst. (2015), https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf.

Access to contraception is a medical necessity for women during approximately thirty years of their lives—from adolescence to menopause. *See* Rachel Benson Gold et al., *Next Steps for America's Family Planning Program: Leveraging the Potential of Medicaid and Title X in an Evolving Health Care System*, Guttmacher Inst. (February 2009), http://www.guttmacher.org/pubs /NextSteps.pdf; *see also* Gladys Martinez et al., *Use of Family Planning and Related Medical Services Among Women Aged 15-44 in the United States: National Survey of Family Growth, 2006-2010*, Nat'l Health Stat. Rep. (Sept. 5, 2013), http://www.cdc.gov/nchs/data/nhsr/nhsr068.pdf. Without the ability to

control her fertility during her childbearing years, a woman is potentially capable of experiencing approximately twelve pregnancies during her lifetime. Guttmacher Inst., *Sharing Responsibility: Women, Society and Abortion Worldwide,* 18 (1999), https://www.guttmacher.org/pubs/sharing.pdf.

Virtually all American women who have had heterosexual sex have used contraception at some point during their lifetimes, irrespective of their religious affiliation. Rachel K. Jones & Joerg Dreweke, *Countering Conventional Wisdom: New Evidence on Religion and Contraceptive Use*, Guttmacher Inst. (April 2011), http://www.guttmacher.org/pubs/Religion-and-Contraceptive-Use.pdf; Megan L. Kavanaugh & Jenna Jerman, *Contraceptive Method Use In The United States: Trends and Characteristics Between 2008, 2012 and 2014*, Guttmacher Inst. (Oct. 2017), https://www.guttmacher.org/article/2017/10/contraceptive-method-use-united-states-trends-and-characteristics-between-2008-2012. Given women's unique reproductive health needs, there is certainly a compelling interest in ensuring, for as many women as possible, access to effective contraception that is medically appropriate for them.

1. Unintended Pregnancy and Short Interpregnancy Intervals Pose Health Risks to Women and Children

Unintended pregnancy remains a significant public health concern in the United States; the unintended pregnancy rate in the United States is substantially higher than that in other highly industrialized regions of the world. Lawrence B.

Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006,* 84 CONTRACEPTION 478, 478, 482 (2011); Am. Coll. of Obstetricians & Gynecologists, GUIDELINES FOR WOMEN'S HEALTH CARE 343 (4th ed. 2014) ("ACOG GUIDELINES") at 343. Approximately 45% of all pregnancies in the United States are unintended. Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008–2011*, 374:9 NEW ENG. J. MED. 843-852 (2016), http://nejm.org/doi/full/10.1056/NEJMsa1506575; *see also* ACOG GUIDELINES at 343.

Women with unintended pregnancies are more likely to receive delayed prenatal care and to be anxious or depressed during pregnancy. Jessica D. Gipson et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 STUD. IN FAM. PLANNING 18, 22, 28-29 (2008). Women with unintended pregnancies are also less likely to breastfeed, which has been shown to have health benefits for the mother and her child. *See* Am. Acad. of Pediatrics, *Policy Statement: Breastfeeding and the Use of Human Milk*, 129 PEDIATRICS 827, 831 (2012) (noting maternal benefits of breastfeeding, including less postpartum blood loss and fewer incidents of postpartum depression and child benefits).

A woman's unintended pregnancy may also have lasting effects on her child's health; low birth weight and preterm birth, which have long term sequelae,

are associated with unintended pregnancies. Prakesh S. Shah et al., *Intention to Become Pregnant and Low Birth Weight and Preterm Birth: A Systematic Review*, 15 MATERNAL & CHILD HEALTH J. 205, 205-206 (2011).

Contraception is undeniably effective at reducing unintended pregnancy. The approximately 68% of U.S. women at risk for unintended pregnancies who use contraceptives consistently and correctly throughout the course of any given year account for only 5% of all unintended pregnancies. By contrast, the 18% of women at risk who use contraceptives inconsistently or incorrectly account for 41% of all unintended pregnancies. The remaining 14% of women at risk who do not practice contraception at all, or who have gaps in usage of a month or more during each year, account for 54% of all unintended pregnancies. Guttmacher Inst., *Moving Forward: Family Planning in the Era of Health Reform*, 8-9 (Mar. 2014), https://www.guttmacher.org/report/moving-forward-family-planning-era-health-reform.

Contraception not only helps to avoid unwanted pregnancies, but it also helps women plan their pregnancies and determine the optimal timing and spacing of them, which improves their own health and the well-being of their children. Pregnancies that are too frequent and too closely spaced, which are more likely when contraception is more difficult to obtain, put women at significantly greater risk for permanent physical health damage. Such damage can include: uterine

prolapse (downward displacement of the uterus), rectocele (hernial protrusion of the rectum into the vagina), cystocele (hernial protrusion of the urinary bladder through the vaginal wall), rectus muscle diastasis (separation of the abdominal wall) and pelvic floor disorders. Additionally, women with short interpregnancy intervals are at greater risk for third trimester bleeding, premature rupture of membranes, puerperal endometritis, anemia, and maternal death. Agustin Conde-Agudelo & Jose M. Belizan, *Maternal Morbidity and Mortality Associated with Interpregnancy Interval: Cross Sectional Study*, 321 BRITISH MED. J. 1255, 1257 (2000).

Studies have linked unintended childbearing with a number of adverse prenatal and perinatal outcomes, including inadequate or delayed initiation of prenatal care, prematurity, low birth weight, absence of breastfeeding, poor maternal mental health, and reduced mother-child relationship quality. U.S. Department of Health and Human Services, Health Resources and Services Administration, & Maternal and Child Health Bureau, *Unintended Pregnancy and Contraception* (2011), http://www.mchb.hrsa.gov/whusa11/hstat/hsrmh /pages/227upc.html; Gipson, *supra;* Agustin Conde-Agudelo et al., *Birth Spacing and Risk of Adverse Perinatal Outcomes: A Meta -Analysis,* 295 J. AM. MED. ASS'N 1809, 1821 (2006); Bao-Ping Zhu, *Effect of Interpregnancy Interval on Birth Outcomes: Findings From Three Recent U.S. Studies*, 89 INT'L J. GYNECOL.

& OBSTET. S25, S26, S31 (2005); Am. Acad. Of Pediatrics & Am. Coll. of Obstetricians & Gynecologists, GUIDELINES FOR PERINATAL CARE, 205-206 (8th ed. 2017). Some studies find that children born as a result of unintended pregnancies have poorer physical and mental health and have impaired mother-child relationships as compared with children from pregnancies that were intended. Gipson, *supra*; Lina Guzman et al., *Unintended Births: Patterns by Race and Ethnicity and Relationship Type*, 42:3 PERSP. ON SEXUAL & REPROD. HEALTH 176-185 (2010).

These recognized benefits of contraceptives have led the CDC to identify family planning as one of the greatest public health achievements of the twentieth century. The CDC has found that smaller families and longer birth intervals contribute to the better health of infants, children, and women, and improve the social and economic status of women. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Family Planning*, (Dec. 3, 1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.

2. Contraception is Beneficial for Women with Certain Health Conditions or Risks

Contraception protects the health of those women for whom pregnancy can be hazardous, or even life-threatening. Ctrs. for Disease Control & Prevention, *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010* Vol. 59 (June 18, 2010), http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf. Women with certain chronic

conditions such as heart disease, diabetes mellitus, hypertension, and renal disease are at increased risk for complications during pregnancy. Other chronic conditions complicated by pregnancy include sickle-cell disease, cancer, epilepsy, lupus, rheumatoid arthritis, hypertension, asthma, pneumonia and HIV. *See generally*, F. Gary Cunningham et al., WILLIAMS OBSTETRICS 958-1338 (23d ed. 2010); ACOG GUIDELINES at 187; *see also Harris v. McRae*, 448 U.S. 297, 339 (1980) (Marshall, J., dissenting) ("Numerous conditions—such as cancer, rheumatic fever, diabetes, malnutrition, phlebitis, sickle cell anemia, and heart disease—substantially increase the risks associated with pregnancy or are themselves aggravated by pregnancy.").

In addition to preventing pregnancy, contraception has other scientifically recognized uses and health benefits. Hormonal birth control helps address several menstrual disorders, helps prevent menstrual migraines, treats pelvic pain from endometriosis, and treats bleeding from uterine fibroids. Ronald Burkman et al., *Safety Concerns and Health Benefits Associated With Oral Contraception*, 190 AM. J. OF OBSTET. & GYNECOL. S5, S12 (2004). Oral contraceptives have been shown to have long-term benefits in reducing a woman's risk of developing endometrial and ovarian cancer, protecting against pelvic inflammatory disease and certain benign breast disease, and short-term benefits in protecting against colorectal cancer. *Id.* *See also* IOM Report at 107.

B. Providing Contraceptive Coverage At No Additional Cost Promotes Use of Effective and Appropriate Contraception

Numerous studies confirm that cost is a significant consideration for many women in their choice of contraception, as well as its proper and consistent use. *See* Guttmacher Inst., *Testimony of Guttmacher Institute Submitted to the Committee on Preventive Services for Women Institute of Medicine,* 8 (Jan. 12, 2011), http://www.guttmacher.org/pubs/CPSW-testimony.pdf ("Guttmacher Testimony"). Consequently, insurance coverage has been shown to be a "major factor" for a woman when choosing a contraceptive method and determines whether she will continue using it. Kelly R. Culwell & Joe Feinglass, *Changes in Prescription Contraceptive Use, 1995-2002: The Effect of Insurance Status*, 110 OBSTET. & GYN. 1371, 1378 (2007); Debbie Postlethwaite et al., *A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change*, 76 CONTRACEPTION 360, 360 (2007) (elimination of cost-sharing for contraceptives at Kaiser Permanente Northern California resulted in significant increases in the use of the most effective forms of contraceptives); Kelly R. Culwell & Joe Feinglass, *The Association of Health Insurance with Use of Prescription Contraceptives,* 39 PERSP. ON SEXUAL & REPROD. HEALTH 226, 226 (2007) (study reveals that uninsured women were 30% less likely to use prescription contraceptives than women with some form of health insurance).

Lack of insurance coverage deters many women from choosing a high-cost contraceptive, even if that method is best for her, and may result in her resorting to an alternative method that places her more at risk for medical complications or improper or inconsistent use, with the attendant risk of unintended pregnancy. This link between no-cost insurance coverage and health outcomes is substantial because the most effective contraception is also the most expensive option. The intrauterine device ("IUD"), a long-acting reversible contraceptive method ("LARC") that does not require regular action by the user, is among the most effective forms of contraception, but it has substantial up-front costs that can exceed $1,000.[3] David Eisenberg et al., *Cost as a Barrier to Long-Acting Reversible Contraceptive (LARC) Use in Adolescents,* J. OF ADOLESCENT HEALTH, 52(4):S59–S63 (2013), http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext; *see also* Brooke Winner et al., *Effectiveness of Long-Acting Reversible Contraception*, 366 NEW ENG. J. MED. 1998, 2004-05 (2012) (finding a failure rate of 4.55 per 100 participants among those who used oral contraceptive pills, the patch or vaginal ring, compared to 0.27 for those using LARCs); Megan L. Kavanaugh et al., *Perceived and Insurance-Related Barriers to the Provision of Contraceptive Services in U.S. Abortion Care Settings*, 21 WOMEN'S HEALTH

[3] The IUD, as well as sterilization and the implant, have failure rates of 1% or less. Failure rates for injectable or oral contraceptives are 7% and 9% respectively, because some women skip or delay an injection or pill. Guttmacher Testimony at 2.

ISSUES S26, S26 (3d Suppl. 2011) (finding that cost can be a barrier to the selection and use of LARCs and other effective forms of contraceptives, such as the patch, pills, and the ring); E.A. Aztlan-James et al., *Multiple Unintended Pregnancies in U.S. Women: A Systematic Review*, 27 WOMEN'S HEALTH ISSUES 407 (2017) (finding that the use of IUDs decreases the risk of multiple unintended pregnancies). The out-of-pocket cost for a woman to initiate LARC methods was 10 times higher than a 1-month supply of generic oral contraceptives. Stacie B. Dusetzina et al., *Cost of Contraceptive Methods to Privately Insured Women in the United States*, 23 Women's Health Issues e69, e70 (2013).

A national survey conducted in 2004 found that one-third of women using contraception would switch methods if cost were not a factor. Jennifer J. Frost & Jacqueline E. Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004*, 40:2 PERSP. ON SEXUAL & REPROD. HEALTH 94, 103 (2008). *See also* Su-Ying Liang et al., *Women's Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills Between 1996 and 2006*, 83 CONTRACEPTION 528, 531 (2011) (approximately one-third of women using contraception report that they would change their contraceptive method if cost were not an issue). In a study in which 9,000 participants were offered the choice of any contraceptive method at no cost, 75% chose long-acting methods, such as the IUD or implant. Jeffrey Peipert et al., *Preventing Unintended*

Pregnancies by Providing No-Cost Contraception, 120 OBSTET. & GYNECOL. 1291, 1291 (2012).

The rate of unintended pregnancies is highest among poor and low-income women—those least able to absorb the added financial burden of contraception. For example, in 2011, the national rate of unintended pregnancy was 45 for every 1,000 women aged 18-44 (4.5%). However, among high-income women (those with incomes of at least 200% of the federal poverty level), the unintended pregnancy rate dropped to 20 per 1,000, or 2%. By contrast, the rate of unintended pregnancy among poor women (those with incomes below the federal poverty level) was more than five times that, with 112 unintended pregnancies per 1,000 women (11.2%). Guttmacher Inst., *Unintended Pregnancy in the United States*, 2 (Jan. 2019), https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us_0.pdf.

A study of women at high risk of unintended pregnancy who had free access to and used highly effective methods of contraception showed that they had much lower rates of unintended pregnancy than did those who used other methods, including less expensive methods such as the oral contraceptive pill. Among adolescents, oral contraceptives have been found to be less effective due to faulty compliance (*e.g.*, not taking the pill every day or at the same time each day), and therefore more passive contraceptive methods like IUDs and other LARCs are

often preferable, but they have forbidding up-front costs. Am. Acad. of Pediatrics, *Policy Statement: Contraception and Adolescents*, 120 PEDIATRICS 1135, 1136 (2007); Am. Coll. of Obstetricians & Gynecologists, *Increasing Access to Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy*, Comm. Op. 642, Oct. 2015 (reaffirmed 2018).

Even seemingly insubstantial additional cost requirements can dramatically reduce women's use of health care services. Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing,* 14 GUTTMACHER POL'Y REV. 7, 10 (2011). For this reason, pre-ACA conventional coverage alone has been shown to be insufficient, as co-pays and deductibles required by insurance plans may still render the most effective contraception unaffordable. *See* Jodi Nearns, *Health Insurance Coverage and Prescription Contraceptive Use Among Young Women at Risk for Unintended Pregnancy*, 79 CONTRACEPTION 105 (2009) (financial barriers, including lack of insurance, or substantial co-payments or deductibles, may deprive women of access to contraception).

Studies of this period after the ACA's contraceptive mandate went into effect confirm that it is having a "positive impact" on reducing inconsistent use of contraceptives and increasing use of prescription—and more effective—forms of contraception. Adam Sonfield, *What is at Stake with the Federal Contraceptive*

Coverage Guarantee?, 20 GUTTMACHER POL'Y REV. 8, 10 (2017), https://www.guttmacher.org/gpr/2017/01/what-stake-federal-contraceptive-coverage-guarantee. When relieved of cost-sharing, women choose the most effective methods more often, with favorable implications for the rate of unintended pregnancy. Laurie Sobel et al., *The Future of Contraceptive Coverage*, Kaiser Family Foundation Issue Brief (2017), https://www.kff.org/womens-health-policy/issue-brief/the-future-of-contraceptive-coverage/.

A study of nearly 30,000 women and girls found that compliance with the ACA's requirement of contraception coverage with no cost-sharing significantly increased the probability that a woman would choose a long-term contraceptive. The study predicts that eliminating out of pocket spending on contraception increases the overall rate of choosing prescription contraceptives, and long-term options in particular. Caroline S. Carlin et al., *Affordable Care Act's Mandate Eliminating Contraceptive Cost Sharing Influenced Choices of Women With Employer Coverage*, 35:9 HEALTH AFFAIRS 1608-1615 (2016). A recent study has confirmed this prediction. Ashley H. Snyder et al., *The Impact of the Affordable Care Act on Contraceptive Use and Costs among Privately Insured Women*, 28 Women's Health Issues 219-223 (2018).

Women and couples are more likely to use contraception successfully when they can choose the contraceptive method that is personally best for them. Frost &

Darroch, *supra*. And data compiled over several decades demonstrate the significant health benefits to women and families when a woman can choose to delay the birth of her first child and can plan the spacing of any subsequent children. The Government has a substantial interest in reducing unintended pregnancies and in ensuring that women retain access to the full range of FDA-approved contraceptives so that those who choose to use contraception can make their decisions based on evidence-based policies and standards of care, rather than ability to pay.

POINT II.

THE ACCOMMODATION IS THE LEAST RESTRICTIVE *EFFECTIVE* MEANS OF PROVIDING CONTRACEPTIVE COVERAGE TO PLAN BENEFICIARIES

The Religious Freedom Restoration Act ("RFRA") permits regulations that further compelling government interests to substantially burden a person's religious exercise if the regulation is "the least restrictive means of furthering that compelling government interest." 42 U.S.C. § 2000bb-1(b).[4] As framed by each

[4] As health professionals, *amici* do not address the first prong of the RFRA analysis, whether the accommodation constitutes a substantial burden on Plaintiffs-Appellees' religious objection to the Contraceptive Mandate. *See* Religious Freedom Restoration Act of 1993, 42 U.S.C. § 2000bb *et seq*. However, while acknowledging Plaintiffs-Appellees' theological beliefs that some or all forms of contraception are sinful, *amici* note that there is no scientific evidence for their belief and erroneous assertion that any of the FDA-approved forms of contraception are "abortifacients." *See, e.g.*, First Am. Compl. at 41, 44-45 (summarizing objection to providing coverage for certain contraceptive services

of the separate opinions in *Hobby Lobby*, this prong of the RFRA analysis addresses whether proposed alternatives are as effective as the challenged regulation at accomplishing the Government's objectives. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 692 (2014) (there are "other ways in which Congress or HHS could *equally ensure* that every woman has cost-free access . . .") (plurality opinion) (emphasis added); *id.* ("HHS has already devised and implemented a system that . . . ensur[es] that the employees of these entities have *precisely the same access* to all FDA-approved contraceptives as employees of companies whose owners have no religious objections . . .") (emphasis added); *id*. at 731 (the accommodation "serves HHS's stated interests *equally well*")

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described as "abortifacient contraception"). The medical and scientific communities have long defined pregnancy as beginning upon implantation. *See, e.g.*, OBSTETRIC-GYNECOLOGIC TERMINOLOGY: WITH SECTION ON NEONATOLOGY AND GLOSSARY OF CONGENITAL ABNORMALITIES 299, 327 (E.G. Hughes, ed., F.A. Davis Co. 1972). An "abortifacient," therefore, refers only to drugs or devices that work after implantation to end a pregnancy, not those that prevent it. As many of these same *amici* noted in briefing in the *Hobby Lobby* case, none of the FDA-approved contraceptives are abortifacients; rather, they prevent unintended pregnancy from occurring and thereby prevent situations in which a woman might otherwise consider abortion. *See* Brief of *Amici Curiae* Physicians for Reproductive Health et al. in Support of the Government's Petition for a Writ of Certiorari in *Burwell* v. *Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014) (No. 13-354) (citing authorities). Studies since the briefing in *Hobby Lobby* reinforce this conclusion, confirming for example, with respect to ella's ulipristal acetate (UPA), that in the dose used for contraception, UPA does not affect human embryo viability or implantation. Cecilia Berger et al., *Effects Of Ulipristal Acetate On Human Embryo Attachment And Endometrial Cell Gene Expression In An In Vitro Co-Culture System*, 30 HUMAN REPRODUCTION 4, 6 (2015). While Plaintiffs-Appellees' sincere religious beliefs must be accepted, their beliefs as to matters of science need not be.

(emphasis added); *id*. at 732 (no reason why "this accommodation would fail to protect the asserted needs of women *as effectively* as the contraceptive mandate . . . ."") (emphasis added); *id*. at 738 (the "accommodation *equally furthers* the Government's interest . . .") (Kennedy, J., concurring) (emphasis added); *id*. at 765 (finding "no less restrictive, *equally effective* means . . .")(Ginsburg, J., dissenting, with Sotomayor, J., Breyer, J., and Kagan, J., joining) (emphasis added). *See also Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006) (challenged regulation stands if "proposed less restrictive alternatives are less effective . . ") (citing *Ashcroft v. Am. Civil Liberties Union*, 542 U. S. 656, 666 (2004) (considering efficacy of alternatives and finding that proposed less restrictive means were not shown to be "less effective than the [challenged] restrictions . . ."")); *Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997) (challenged regulation does not survive strict scrutiny "if less restrictive alternatives would be *at least as effective* in achieving the legitimate purpose that the statute was enacted to serve.") (emphasis added); *F.C.C. v. League of Women Voters of California*, 468 U.S. 364, 395 (1984) (observing that the Government's interest can be "*fully satisfied* by less restrictive means that are readily available") (emphasis added).

The ACA reflects the public interest in providing more women with access to the full range of FDA-approved contraceptives along with their other routine

preventive health services. As demonstrated above, this interest is compelling—a determination that Plaintiffs-Appellees did not dispute below. Barriers to either access, or to the range of available contraceptives necessarily undermine this interest. Here, there are no alternatives to the accommodation that are as effective at meeting the ACA's objectives of increasing access to the full range of contraceptives available for a greater number of women.

A. There Are No Alternatives to the Accommodation that Would Ensure the Seamless No-Cost Coverage That the Accommodation Provides

Just as direct cost barriers deter women from using appropriate contraception, or from using appropriate contraception consistently, administrative or logistical barriers are also likely to result in lower or less consistent utilization rates. Any alternative that removes contraceptive care from a woman's routine health services and requires her to use a two-tiered system of access and coverage—one for her overall health needs and one limited to contraceptive care—is not an effective alternative to the accommodation, which ensures seamless coverage, with no out-of-pocket costs, for women whose plan sponsor opts out. Similarly, de-linking contraceptive services from routine health care negatively affects continuity of care within the patient-physician relationship and creates additional hurdles to contraceptive coverage that will likely reduce women's use of contraceptives.

Under the accommodation, prescription contraceptives continue to be available to the patient seamlessly and automatically. If access to appropriate, cost-free contraception is removed from women's routine health care services or is made more difficult, or costly, to obtain, the likely result is that many women will simply not use contraception, will use an imperfect form of contraception, or will use contraception inconsistently or improperly. Any of these scenarios portend an increase in unintended pregnancies with all their consequences. Any alternative that imposes added layers of coverage eligibility (or a separate insurance mechanism altogether) is not simply less effective than the accommodation, but actually thwarts the ACA's objective of increasing access to cost-free contraceptive services.

"Considerable research shows that modest procedural requirements—completing a simple form or even checking a box—can greatly lower participation levels in public and private benefit programs." Frederic Blavin et al., *Using Behavioral Economics to Inform the Integration of Human Services and Health Programs under the Affordable Care* Act, Urban Inst., ii (July 2014), https://www.urban.org/sites/default/files/publication/22956/413230-Using-Behavioral-Economics-to-Inform-the-Integration-of-Human-Services-and-Health-Programs-under-the-Affordable-Care-Act.PDF; *see also* Dahlia K. Remler & Sherry A. Glied, *What Other Programs Can Teach Us: Increasing Participation in*

Health Insurance Programs, 93 AMERICAN J. PUB. HEALTH 67, 67 (2003) (recognizing impact of nonfinancial features, such as administrative complexity, on enrollment); Cass R. Sunstein, *Nudges.gov: Behavioral Economics and Regulation* 3 (Feb. 2013), http://tinyurl.com/nudgesgov (reducing paperwork burdens results in greater participation in public programs).

The most effective means of ensuring high utilization rates is when benefits are provided automatically. Remler & Glied, *supra* (observing, as a "striking pattern," that programs where "no 'extra action' is required" have the highest "take up" or participation rates). In Louisiana, when a child's enrollment in Medicaid was de-linked from the Supplemental Nutrition Assistance Program (SNAP) in 2011, thus requiring parents to check a box on the SNAP application form, enrollment in Medicaid through SNAP dropped off by an average of 62% per month. Blavin, *supra* at 8 (noting that de-linking programs caused decline notwithstanding that "the check-box was highlighted, bolded, prominently placed" and written in clear language).[5] Similarly, even the seemingly minor burden of having to renew or refill prescriptions more frequently results in reduced compliance and an increased risk of pregnancy. *See* Diana Greene Foster et al.,

[5] Numerous other studies demonstrate the impact of requiring prospective participants to affirmatively opt-in on participation rates, including with respect to organ donation, car insurance preferences, and online privacy settings and information sharing. *See* Cass R. Sunstein, *Deciding by Default,* 162 U. Pa. L. Rev. 1 (2013) (summarizing studies).

Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies, 117 OBSTET. & GYNECOL. 566, 570-71 (2011).

Alternative arrangements, including safety net health programs and providers, require a woman to take additional steps for contraceptive coverage beyond what is required for other covered services—by enrolling in a separate plan on an exchange, making a separate visit for contraceptive services, and/or paying out of pocket for covered services and seeking a tax credit. None of these proposed alternatives provide the seamless no-cost coverage effectuated by the accommodation, and therefore all would compromise the Government's objective of facilitating access to contraception for all women who want it. As the government itself argued when addressing similar proposed alternatives in *Zubik,* these proposals "would undermine the government's compelling interest by imposing on tens of thousands of women seeking contraceptive coverage the very sort of obstacles the Women's Health Amendment was designed to eliminate." Brief for the Respondents, *Zubik v. Burwell*, 2016 WL 537623, at *73 (U.S. Feb. 10, 2016). *See also id*., at *29 (asserting that added burdens for women to obtain contraceptive coverage "would thwart the basic purposes of the Women's Health Amendment, which was enacted to ensure that women receive *equal* health coverage and to remove barriers to the use of preventive services.").

Additionally, when women face informational gaps on obtaining coverage for contraceptives outside of their employer-provided plan, this further exacerbates any administrative barriers discussed above. Any alternative to the accommodation would have to require that plan beneficiaries be notified that they are entitled to receive coverage for contraceptives elsewhere and be given clear, timely and easily followed information as to how to obtain it. Yet the same employers that object to informing the government or their health plan administrators that they opt out of the coverage requirement, are also likely to object to providing necessary information about obtaining coverage to plan beneficiaries. Any failure to adequately inform plan beneficiaries how no-cost contraceptive coverage can be obtained (or even that it is available at all) necessarily impedes the government's objective of promoting contraceptive coverage and deprives plan beneficiaries of the rights secured by the ACA coverage requirement.

B. Alternatives that Do Not Allow For Continuity of Care Compromise Women's Health

The patient-provider relationship is essential to all health care. For many women of reproductive age, their well-woman visits are their primary, if not exclusive, contact with the health care system. ACOG GUIDELINES at 201. Deciding on the best form of contraception for any specific patient should take place within this established patient-provider relationship. This is particularly true

given the highly personal nature of the reproductive health and family planning services that are at issue here. Based on a recent evidence-based report issued by the CDC, ACOG stresses the importance of "effective and efficient patient-practitioner communication about reproductive life planning . . . ."). Am. Coll. of Obstetricians & Gynecologists, *Reproductive Life Planning to Reduce Unintended Pregnancy*, Comm. Op. 654, 127 OBSTET. & GYNECOL. 66, 67 (Feb. 2016). Prescribing birth control is typically far more intimate and extensive than signing a prescription pad; in addition, it involves medical screening to ensure that a particular birth control method is not contraindicated, as well as patient counseling. Women should be able to make these personal decisions—decisions that often require sharing intimate details of their sexual history and family planning—with health care professionals they have sought out and trust.

Even if a woman is inclined to obtain contraceptive coverage outside of her regular health system, she may not be able to choose her health care professional, or see the same practitioner for follow-up visits. In either case, the care she receives may be compromised as a result. Continuity of care has been shown to affect continuity and consistency of contraceptive use and women who are not satisfied with their health care professional, who do not see the same professional at visits, or who feel they cannot call their provider between visits are more likely

to use contraception inconsistently. *See* Frost & Darroch, 40 PERSPS. ON SEXUAL & REPROD. HEALTH at 100.

There are no alternatives to the accommodation that would ensure seamless, no-cost coverage and continuity of care within the existing patient-physician relationship, and Plaintiffs-Appellees have identified none. The accommodation does this and is the most effective means of making important preventive health services more widely attainable.

CONCLUSION

For the foregoing reasons, as well as those in Movant-Appellant's Brief, the judgment of the District Court should be *reversed*.

Dated: December 26, 2019

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CERTIFICATE OF COMPLIANCE

This amicus brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(a)(7)(B) because this brief contains 6,060 words as determined by the word count of Microsoft Word, excluding the parts of the brief exempted. This document complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and (6) because this document has been prepared in a 14-point, proportionally-spaced typeface, Times New Roman.

Dated: December 26, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on December 26, 2019, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the CM/ECF system. Participants in this case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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