

IN THE
Supreme Court of the United States

LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

Petitioner,

v.

COMMONWEALTH OF PENNSYLVANIA
AND STATE OF NEW JERSEY,

Respondents.

DONALD J. TRUMP, PRESIDENT
OF THE UNITED STATES, *et al.*,

Petitioners,

v.

COMMONWEALTH OF PENNSYLVANIA
AND STATE OF NEW JERSEY,

Respondents.

ON WRITS OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE THIRD CIRCUIT

**BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF
OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN
NURSES ASSOCIATION, AMERICAN ACADEMY OF
NURSING, PHYSICIANS FOR REPRODUCTIVE HEALTH,
AND NURSES FOR SEXUAL AND REPRODUCTIVE HEALTH
IN SUPPORT OF RESPONDENTS AND AFFIRMANCE**

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INTEREST OF AMICI CURIAE¹

Amici, listed below, are leading health professional organizations that are directly involved in the provision of health care to women. *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. 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.²

American College of Obstetricians and Gynecologists (ACOG) is a non-profit educational

1. Petitioners and Respondents have granted blanket consent to the filing of amicus briefs in this case in letters on file with the Court. Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part and no person other than *amici*, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief.

2. This Court has relied 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 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).

and professional organization. With more than 60,000 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 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.

The American Academy of Nursing (Academy) serves the public by advancing health policy through the generation, synthesis, and dissemination of nursing knowledge. Academy Fellows are inducted into the organization for their extraordinary contributions to improve health locally and globally. With more than 2,800 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia.

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.

Nurses for Sexual and Reproductive Health (NSRH) provides students, nurses and midwives with education and resources to become skilled care providers and social change agents in sexual and reproductive health and justice.

SUMMARY OF ARGUMENT

The current health-care crisis this nation is facing demonstrates the importance of ensuring that the country's health care policy not be compromised by political or private interests. The Final Religious Exemption Rule and Final Moral Exemption Rule at issue (the "Final Rules") are not only capricious and contrary to the contraception coverage requirement of the Patient Protection and Affordable Care Act (ACA), but they also jeopardize the health and well-being of countless women and their families by depriving them of an important component of women's health care.

The ACA made prevention a priority in the nation's health care policy by requiring private health insurance plans to cover various essential preventive care services with no additional cost sharing for the patient. Among the preventive services that the ACA requires be covered, without deductible or co-pay, are screenings for various conditions, such as cholesterol tests and colonoscopy screenings; pediatric and adult vaccinations; as well as women's preventive health services, including FDA-approved contraceptives prescribed by a health care provider.

Contraception not only helps to prevent unintended pregnancy, but also helps to protect the health and

well-being of women and their children. The benefits of contraception are widely recognized and include improved health and well-being, reduced maternal mortality, health benefits of pregnancy spacing for maternal and child health, female engagement in the work force, and economic self-sufficiency for women. Conversely, as recognized by the Circuit Court, “removing cost free contraceptive coverage can have ramifications on women’s health beyond birth control and unplanned pregnancies.” Pet. App. at 24a. The contraception coverage requirement recognizes that women of childbearing age have unique health needs and that contraception counseling and services are essential components of women’s routine preventive health care.

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 women. However, the Final Rules threaten to deprive countless women nationwide of the no-cost contraceptive coverage that must be provided under the ACA’s preventive care requirement. The breadth of the Final Rules, which allow any employer or health insurance provider itself to exclude contraception from coverage by invoking religious or moral objections, expands impermissibly the category of persons who may deprive their employees of contraceptive coverage. The Final Rules threaten the health of women and families throughout the United States, undermining Congress’s very objective in making comprehensive preventive women’s health care widely accessible, and disrupting the seamless provision of health care within the existing patient-provider relationship. The overly-broad self-exemptions made available by the Final Rules effectively downgrade contraceptive coverage from a legal

entitlement under the ACA to a voluntary employment benefit at the discretion of the employer. If allowed to take effect, the Final Rules will compromise access to a critical component of women's preventive health care for countless American women.

A religious accommodation to the contraceptive coverage requirement already exists, allowing certain qualifying employers to exclude contraceptive coverage from the health insurance they arrange for their employees. Because an employer's opt-out creates a gap in coverage, the existing accommodation ensures that the gap is filled seamlessly by third parties (the group plan insurer or administrator) without any coverage interruption or change in services for the covered individual. The Final Rules, by contrast, fail to ensure this vital and seamless continuity of care. Similarly, other proposed alternatives to the contraceptive coverage requirement and the existing accommodation require an up-front payment or separate enrollment, or impose administrative hurdles to obtaining contraception coverage that do not exist for other health care services and are not equally effective at accomplishing the compelling national interest in making comprehensive preventive women's health care widely accessible.

ARGUMENT

I. THE FINAL RULES CONTRAVENE THE ACA'S MANDATE THAT WOMEN BE ENTITLED TO CONTRACEPTIVE COVERAGE AT NO ADDITIONAL COST

A. Contraception is an Essential Component of Women's Preventive Health Care³

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. 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");

3. Petitioners mischaracterize FDA-approved contraceptives as "abortifacients." *See* Pet. Little Sisters' Br. at 8. However, none of the FDA-approved contraceptive drugs or devices causes abortion; rather, they prevent pregnancy. Medically speaking, pregnancy begins only upon implantation of a fertilized egg in the uterine lining. *See, e.g.,* Rachel Benson Gold, *The Implications of Defining When a Woman is Pregnant*, 8:2 GUTTMACHER POL'Y REV. 7 (2005); Am. Coll. of Obstetricians & Gynecologists, *Long-Acting Reversible Contraception: Implants and Intrauterine Devices*, Practice Bulletin 186, 130 OBSTET. & GYNECOL. e251, e252-253 (2017) (available evidence supports that mechanism of action for intrauterine devices is preventing fertilization and not disrupting pregnancy). Regardless of one's personal or religious beliefs, the medical terms "abortion" and "abortifacient" refer to – and should only be used in connection with – the termination of a pregnancy, not the prevention of it.

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).

Many women and their families 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. The Circuit Court correctly recognized that the Final Rules pose financial harm to the States, as States will have to fill

the coverage gaps created by the Final Rules as well as bear the continuing costs of unintended pregnancies and associated health care costs resulting from the loss of contraceptive coverage. Pet. App. at 25a (“ . . . some women who lose contraceptive coverage may either fail to qualify for state services or elect to forego the use of contraceptives altogether. Women who stop using contraception are more likely to have unplanned pregnancies and to require additional medical attention. The costs of such unintended pregnancies are often shouldered by the states, costing hundreds of millions of dollars.”) (internal quotation marks and citations omitted).

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 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 have been shown to be less likely to breastfeed, which has demonstrated 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

The Circuit Court’s determination that, “[w]ithout insurance to defray or eliminate the cost for the more-effective contraceptive methods, women will use less expensive and less effective methods” (Pet. App. at 24a) (internal quotation marks and citation omitted), is consistent with the scientific research.

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”). Relatedly, 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 higher-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 \$1,000.⁴ 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](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 ISSUES S26, S26 (3d Suppl. 2011)

4. 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.

(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 higher-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 the 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 participants 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 more 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. There is a strong national 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.

II. THE FINAL RULES RESTRICT ACCESS TO CARE AND COMPROMISE THE PATIENT PROVIDER RELATIONSHIP BY DIVORCING REPRODUCTIVE HEALTH FROM OTHER PREVENTIVE HEALTH CARE SERVICES

By establishing additional exemptions that allow individual employers to opt out of contraceptive coverage,

including on the basis of moral convictions not based in any particular religious belief, the Final Rules will undeniably reduce the availability of contraceptive coverage for women who want it. An employer's decision to opt out of contraceptive coverage under the Final Rules would jeopardize access to contraception for all covered adult and adolescent family members. Additionally, because the Final Rules make the existing accommodation a mere voluntary alternative to outright exemption, they not only limit access to contraceptive coverage under a woman's existing health plan, but may also limit access to contraception coverage entirely. The Final Rules themselves provide no solution for women who seek access to contraception, but whose employers claim a moral objection, aside from suggesting that they might avail themselves of other governmental programs or obtain contraceptive coverage elsewhere. *See, e.g.*, 83 Fed. Reg. 57,536 (Nov.15, 2018) at 57,548 (asserting the availability of contraceptive coverage from other sources, including governmental programs for low-income women). The Final Rules, thus, threaten access to seamless care for countless women, resulting in grave harm to the public health.

A. The Final Rules Undermine the Patient-Provider Relationship

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 an 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 prepared 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 surrogate health care provider may have more limited information about the patient, whose care 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 health care provider between visits are more likely to use contraception inconsistently. *See* Frost & Darroch, 40 PERSPS. ON SEXUAL & REPROD. HEALTH at 100.

As currently implemented, the contraceptive coverage requirement ensures seamless, no-cost coverage and

continuity of care within the existing patient-physician relationship. Women should be able to make these personal decisions regarding their reproductive health —decisions that often require sharing intimate details of their sexual history and private family planning—in collaboration with their trusted health care providers. The patient’s employer should not be part of that decision-making process, no matter his particular beliefs.

B. The Final Rules Undermine Seamless and Equal Access to Care for Many Women

The Final Rules could remove contraceptive coverage under the health plan that covers a woman’s other routine health services, or could remove coverage for the form of contraception that is most appropriate for her. Upon self-exemption by her employer, a woman would be pushed into a two-tiered system of insurance coverage—one for her overall health needs and one limited to contraceptive care (if such option is even available)—or be forced to pay out of pocket for these services. *See* 83 Fed. Reg. at 57,549 (acknowledging that some women may not receive contraceptive coverage, but contending that “Congress did not create a right to receive contraceptive coverage” in the ACA), By requiring women to seek out alternative coverage (or forego coverage entirely) for what is and should be a routine health care service, the Final Rules contravene the Supreme Court’s express directive that women covered by insurance plans of any employer objecting to contraceptive coverage still “receive full and equal health coverage, including contraceptive coverage.” *Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016). As Justice Sotomayor aptly recognized in her concurring opinion in that case:

Requiring standalone contraceptive-only coverage would leave in limbo all of the women now guaranteed seamless preventive-care coverage under the Affordable Care Act. And requiring that women affirmatively opt into such coverage would ‘impose precisely the kind of barrier to the delivery of preventive services that Congress sought to eliminate.’

Id. at 1561 (noting that lower courts could “consider only whether existing or modified regulations could provide *seamless contraceptive coverage* to petitioners’ employees, through petitioners’ insurance companies . . .”) (emphasis added) (internal quotation marks and citation omitted). The Final Rules expressly reject the principle that seamless coverage serves a compelling national interest and, thus, impermissibly deny women access to the full range of preventive services to which they are entitled under the ACA. *See, e.g.*, 83 Fed. Reg. at 57,548.

Petitioners claim that “no compelling government interest will be undermined by allowing additional religious objectors to opt out,” and point to “the alternative avenues available for obtaining contraceptive coverage.” Pet. Donald J. Trump’s Br. at 26-27 (internal quotation marks and citations omitted). Among the alternatives Petitioners propose are “existing federal, state, and local programs” and “paying out of pocket.” *Id.* at 27, 47. Petitioners ignore the fact that, while women who lose contraceptive insurance coverage “will seek out . . . state-funded programs and services,” many of those programs are income-based and “women who do not seek or qualify for state-funded contraceptives may have unintended pregnancies.” Pet. App. at 19a. Further, as the Circuit

Court noted, other alternatives, such as Title X clinics, are facing decreased federal funding and are ill-equipped to handle the increased demand that would result from implementation of the Final Rules. *Id.* at 18a. The Final Rules, thus, represent a significant and impermissible step backwards in achieving the ACA's goals of, among other things, expanding access to and improving preventive care services for women and reducing the gender disparities with respect to the cost of health care services.

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. 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.

“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 And 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., *Number of Oral Contraceptive Pill Packages Dispensed and*

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).

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 seamless no-cost coverage and therefore all would compromise the ACA’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 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.

CONCLUSION

Amici respectfully urge that the judgment of the court of appeals be affirmed.

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Respectfully submitted,

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