Nos. 13-354 and 13-356

IN THE

Supreme Court of the United States

KATHLEEN SEBELIUS,
SECRETARY OF HEALTH AND HUMAN SERVICES, *ET AL.*,

Petitioners,

v.

HOBBY LOBBY STORES, INC., *ET AL.*,

Respondents.

(Additional Caption on the Reverse)

On Writs of Certiorari to the United States Court of Appeals for the Tenth and Third Circuits

BRIEF OF *AMICI CURIAE* AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, PHYSICIANS FOR REPRODUCTIVE HEALTH, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN NURSES ASSOCIATION, *ET AL.* IN SUPPORT OF THE GOVERNMENT

Bruce H. Schneider
Counsel of Record
Michele L. Pahmer
Darya Bril
STROOCK & STROOCK & LAVAN LLP
180 Maiden Lane
New York, New York 10038
212-806-5400
bschneider@stroock.com

Counsel for Amici Curiae

(Additional Counsel on the Reverse)

January 28, 2014

CONESTOGA WOOD SPECIALTIES CORPORATION,

Petitioners,

v.

KATHLEEN SEBELIUS,
SECRETARY OF HEALTH AND HUMAN SERVICES, *ET AL.*,

Respondents.

B. Robert Piller
Jennifer Blasdell
PHYSICIANS FOR
REPRODUCTIVE HEALTH
55 West 39th Street, Suite 1001
New York, New York 10018
646-366-1897

Sara Needleman Kline
AMERICAN COLLEGE OF
OBSTETRICIANS AND GYNECOLOGISTS
409 12th Street SW
Washington, D.C. 20024
202-863-2581

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INTEREST OF AMICI CURIAE[1]

Amici curiae are organizations of physicians, registered nurses and other health care professionals that share the common goal of ensuring access to high quality medical care for women and families that is comprehensive and evidence-based. Such medical care should include reproductive health care and services. Amici believe that increased access to the full range of FDA-approved prescription contraceptives is an essential component of effective health care for women and their families.

The American College of Obstetricians and Gynecologists (ACOG) is a non-profit educational and professional organization founded in 1951. With more than 57,000 members, ACOG is the leading professional association of physicians who specialize in the health care of women. ACOG's members represent approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States.

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.

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[1] 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. Letters of consent to this filing have been filed with the Clerk of the Court.

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.

The American Academy of Pediatrics (AAP) was founded in 1930 and is a national, not-for-profit organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 pediatricians to over 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 84 years, AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children and adolescents to ensure the availability of safe and effective childhood vaccines and contraceptives.

The American Nurses Association (ANA) represents the interests of the nation's 3.1 million registered nurses. Founded over a century ago and with members in every state across the nation, ANA is comprised of state nurses associations and individual nurses. Collectively, ANA and its organizational affiliates represent more than 300,000 nurses who practice across the continuum of care and in all health care settings.

American College of Nurse-Midwives (ACNM) is the professional organization for certified nurse-midwives and certified midwives. ACNM leads the profession through education, clinical practice, research and advocacy. ACNM advocates on behalf of women and families, its members, and the midwifery profession to eliminate health disparities and increase access to evidence-based, quality care.

The American College of Osteopathic Obstetricians and Gynecologists (ACOOG), which traces its origins to 1934, is passionately committed to excellence in women's health. ACOOG educates and supports osteopathic health care professionals to improve the quality of life for women.

The American Medical Student Association (AMSA) is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training.

The American Medical Women's Association (AMWA) is a multispecialty organization comprised of physicians, residents, medical students, and health care professionals. AMWA functions at the local, national, and international level by providing and developing leadership, advocacy, education, expertise, mentoring, and

strategic alliances to advance women in medicine and improve women's health.

The American Society for Emergency Contraception (ASEC) is a national organization which holds as its primary mission the promotion of access to and education about emergency contraception. ASEC supports collaboration among and represents a diverse group of stakeholders in the reproductive health community whose work includes a focus on emergency contraception.

The American Society for Reproductive Medicine (ASRM) is a non-profit, multidisciplinary organization with members in all 50 states and more than 100 countries worldwide. Founded in 1944, ASRM is dedicated to the advancement of the art, science, and practice of reproductive medicine.

The Association of Reproductive Health Professionals (ARHP) is a non-profit membership organization that was founded by Alan Guttmacher in 1963 as the education arm of Planned Parenthood. ARHP translates good science into practice by producing accredited, evidence-based programs for health care professionals across a broad range of sexual and reproductive health topics.

The California Medical Association (CMA) is a non-profit, incorporated professional association for physicians with approximately 39,000 members throughout the state of California. For more than 150 years, CMA has promoted the science and art

of medicine, the care and well-being of patients, the protection of public health, and the betterment of the medical profession. CMA's physician members practice medicine in all specialties and settings, including providing reproductive health services.

International Association of Forensic Nurses (IAFN) is a non-profit membership organization comprised of forensic nurses working around the world and other professionals who support and complement the work of forensic nursing. IAFN is dedicated to the use of evidence-based forensic nursing practices and advocates for the availability of emergency contraception to victims of sexual assault who choose to use it as a means of preventing pregnancy.

Jacobs Institute for Women's Health (JIWH) is an organization that works to improve health care for women across their lifespan and in all populations. The mission of JIWH is to identify and study issues involving the interaction of medical and social systems, facilitate informed dialogue and foster awareness among consumers and providers, and promote problem resolution, interdisciplinary coordination and information dissemination.

The Maine Medical Association (MMA), founded in 1853, is a non-profit membership organization headquartered in Manchester, Maine representing the interests of over 4000 physicians, medical students and residents in training. MMA's mission is to support Maine physicians, advance

the quality of medicine in Maine and promote the health of all Maine citizens.

The Massachusetts Medical Society (MMS) was founded in 1781 as a statewide professional association committed to advancing medical knowledge, developing and maintaining the highest professional and ethical standards of medical practice and health care, and promoting medical institutions. MMS is the oldest continuously operating medical society in the United States; its nearly 25,000 members include physicians practicing in all areas of medicine throughout the Commonwealth.

The National Association of Nurse Practitioners in Women's Health (NPWH) is a non-profit educational and professional organization that was established over 30 years ago and is the leading professional association of nurse practitioners who specialize in the health care of women. The mission of NPWH is to ensure the provision of quality health care to women of all ages by nurse practitioners and to protect and promote women's rights to make their own health care choices.

The National Physicians Alliance (NPA) creates research and education programs that promote health and foster active engagement of health care providers with their communities to achieve high quality, affordable health care for all. NPA offers a professional home to physicians who

share a commitment to professional integrity and health justice.

The Society for Adolescent Health and Medicine was founded in 1968 and is a multidisciplinary organization committed to improving the physical and psychosocial health and well-being of all adolescents through advocacy, clinical care, health promotion, health service delivery, professional development and research.

The Society of Family Planning (SFP) is an academic society of researchers, clinicians and educators dedicated to improving sexual and reproductive health. Among its other activities, SFP promotes scientifically sound research by funding studies on family planning and fosters the advancement of clinical care through the development of evidence-based clinical guidelines. SFP also advances the creation of family planning knowledge to inform public policy.

The Society for Maternal-Fetal Medicine was established in 1977 and is the membership organization for obstetricians/ gynecologists who have additional formal education and training in maternal-fetal medicine. With approximately 2,000 members the Society works to improve maternal and child health through clinical guideline development, scientific research, continuing medical education, health policy leadership, and advocacy.

The Washington State Medical Association (WSMA) represents physicians and physician

assistants throughout Washington state. The WSMA delivers strong advocacy that is patient focused and physician driven, working to help physicians deliver complete care patients can trust and to make Washington the best place to practice medicine and to receive care.

SUMMARY OF ARGUMENT

One of the major goals of the Affordable Care Act (ACA) is to provide access to certain forms of preventive care without additional cost to the patient, among them, contraceptives for women. Widespread access to contraception is an essential component of health care for women of childbearing age. Contraception helps to prevent unintended pregnancy and protects the health and well-being of women and their children. Cost is often an impediment to widespread use of appropriate contraceptives. The Government has a compelling interest in addressing the medical and social consequences of unintended pregnancy and ensuring the availability of medically appropriate contraception for all women, regardless of their financial status and ability to pay.

Recognizing an exemption to the contraception mandate for for-profit corporate employers based on their owners' personal religious beliefs would deny the ACA's promise of better preventive care coverage to female plan beneficiaries.[2] Employers'

[2] In both cases before the Court, the religious exemptions sought under RFRA and/or the Free Exercise

refusal to provide insurance coverage for contraceptives would increase the cost of health care to women. Some women, particularly lower income women, would be unable to access the most medically appropriate method because of the additional expense. As a result, a private, medical decision that should be made by a woman in consultation with her health care provider would be unduly influenced by the employer. Employers should not be allowed to interfere in the provider-patient relationship in this way. Contraceptive access is critical to the health of women and women should not be denied coverage to which they are otherwise entitled by law based on the religious beliefs of their employer-corporation's owners.

Moreover, allowing an employer a religious exemption to the ACA's mandated coverage requirements would have consequences that extend far beyond contraception. Employers who object to any medical treatment, device, or procedure on personal religious grounds could similarly exclude such services from the coverage they provide—with potentially disastrous results. Employers could, for example, seek to exclude vaccinations that they

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Clause of the First Amendment are asserted on behalf of the individual owners of the corporate employers as well as the corporations themselves. Amici do not agree that corporations can have religious beliefs or that the personal beliefs of the owners are attributable to the corporations. References herein to the employer's beliefs are intended solely to enhance the readability of the brief and are not an acknowledgment that the corporate employer has religious beliefs.

deem offensive to their religious beliefs, forcing individuals to pay for objected-to vaccinations out-of-pocket or worse, forgo the medically-recommended vaccinations entirely. The public health implications of allowing a for-profit corporation to assert a religious exemption to the ACA's mandated coverages are self-evident.

In short, health care decisions should be made by patients in consultation with their health care providers based on the best interests of the patient. This is possible only when health care providers have the full range of options available to recommend or prescribe in accordance with the individual circumstances of each patient. To allow the personal view of a remote party—the employer of a patient (or the patient's spouse or guardian)—to play a role in a patient's medical treatment would undermine the very nature of the patient-provider relationship and would cause wide ranging harms to public health.

ARGUMENT

POINT I.

EMPLOYERS SHOULD NOT BE ALLOWED TO INTERFERE IN THE PROVIDER-PATIENT RELATIONSHIP BY OPTING OUT OF PROVIDING INSURANCE COVERAGE FOR CONTRACEPTION

Decisions regarding contraception have a profound impact on a woman's health as well as on

the health of her children. These important, private, medical decisions should be made by a patient in consultation with her health care provider. There is no role for a woman's employer in these decisions. Yet, if the requested religious exemption were to be recognized, corporate employers could deny access to prescription drugs and devices recommended by a woman's health care provider and thus inappropriately interfere in the provider-patient relationship.

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

Access to contraception is a medical necessity for women during approximately thirty years of their life—from adolescence to menopause. *See* Guttmacher Inst., *Next Steps for America's Family Planning Program: Leveraging the Potential of Medicaid and Title X in an Evolving Health Care System* (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*, National Health Statistics Reports (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 risks becoming pregnant approximately twelve times. Guttmacher Inst., *Sharing Responsibility: Women, Society and Abortion Worldwide,* 18 (1999), https://www.guttmacher.org/pubs/sharing. pdf.

Contraception helps women plan their pregnancies and determine the timing and spacing of them, which improves their own health and the well-being of their children. Women with unintended pregnancies are less likely to breastfeed, and more likely to receive delayed prenatal care, to be anxious or depressed, and experience domestic violence during pregnancy. Jessica D. Gipson, Michael A. Koenig, Michelle J. Hindin, *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 STUD. IN FAM. PLANNING 18, 18-38 (2008). The fact that a woman did not intend to become pregnant may have a lasting effect on her child's health; low birth weight and preterm birth, which have long term sequela, 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).

Unintended pregnancy remains a significant public health concern in the United States. Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006,* 84 CONTRACEPTION 478, 478-485 (2011). Approximately 50% of all pregnancies in the United States are unintended. *Increasing Use of Contraceptive Implants and Intrauterine Devices to Reduce Unintended Pregnancy,* ACOG Comm. Op. 450, 114 OBSTET. & GYNECOL. 1434, 1434-1438 (2009); *see also* Lawrence B. Finer & Mia R. Zolna, *Shifts in Intended and Unintended Pregnancies in*

the United States, 2001-2008, 104 AM. J. PUB. HEALTH S43, S43-S48 (2014). Many unintended pregnancies end in abortion. *See* Guttmacher Inst., *Unintended Pregnancy in the United States* (Dec. 2013), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.html ("In 2008, 40% of unintended pregnancies (excluding miscarriages) ended in abortion").

Pregnancies that are too frequent and too closely spaced, which are more likely when those pregnancies are unintended, 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), 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. Augustin Conde-Agudelo & Jose M. Belizan, *Maternal Morbidity and Mortality Associated with Interpregnancy Interval: Cross Sectional Study*, 321 BRITISH MED. J. 1255, 1257 (2000). It is generally not possible to predict, in advance, which women will suffer these complications in pregnancy.

Inadequate spacing between pregnancies can increase the risk of low birth weight, preterm birth, and small size for gestational age. Augustin Conde-Agudelo, Anyeli Rosas-Bermúdez and Anna Cecilia

Kafury-Goeta, *Birthspacing and Risk of Adverse Perinatal Outcomes: a Meta-Analysis,* 295 J. AM. MED. ASS'N 1809, 1809-1823 (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, S25–S33 (2005); AM. ACAD. OF PEDIATRICS & AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES FOR PERINATAL CARE 202 (7th ed., 2013). Infants conceived 18 to 23 months after a previous live birth had the lowest risks of these adverse perinatal outcomes. Bao Ping Zhu et al., *Effect of the Interval Between Pregnancies on Perinatal Outcomes*, 340 NEW ENG. J. MED. 589, 590 (1999).

Because of these recognized benefits of contraceptives, the Centers for Disease Control and Prevention identified family planning as one of the greatest public health achievements of the twentieth century, finding that smaller families and longer birth intervals contribute to the better health of infants, children, and women, as well as improving the social and economic roles of women. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999*, (Dec. 3, 1999), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.

Contraception also helps to protect 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*

(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 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); AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, GUIDELINES FOR WOMEN'S HEALTH CARE 187 (3rd ed. 2007) ("ACOG GUIDELINES FOR WOMEN'S HEALTH"); *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.").

Contraception has other scientifically recognized health benefits for many women. Hormonal birth control, in addition to preventing unintended pregnancies, 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, S5-S22 (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* Inst. of Medicine*, Clinical Preventive Services for Women: Closing the Gaps* 107 (2011) ("IOM Report"), http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx.

Virtually all American women who are or have been sexually active have used contraceptives 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. At any given time, approximately two-thirds of American women of reproductive age wish to avoid or postpone pregnancy. ACOG GUIDELINES FOR WOMEN'S HEALTH at 182. Access to contraception is a medical necessity for all women, regardless of their economic means.

B. Allowing the Exemption Sought Would Impose Financial Barriers to Medically Appropriate Contraception for Many Women

If employers are permitted to exclude contraceptive methods from the insurance coverage they provide to their employees, contraception will become cost prohibitive for many women. As a

result, many will use no contraception or will use an imperfect form of contraception inconsistently or improperly, with a concomitant increase in unintended pregnancies with all their consequences. Numerous studies have demonstrated that the cost of treatment or prescriptions generally, and the out-of-pocket costs associated with contraceptives in particular, creates a barrier for many women to obtain and consistently use the particular contraceptive best suited for their needs.

1. Insurance Coverage Promotes Contraception Use

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 that method. Kelly R. Culwell & Joe Feinglass, *Changes in Prescription Contraceptive Use, 1995-2002*, 110 OBSTET. & GYNECOL. 1371, 1378 (2007). *See also* Guttmacher Inst., *Testimony of Guttmacher Institute Submitted to the Committee on Preventive Services for Women,* 8 (Jan. 12, 2011), http://www.guttmacher.org/pubs/CPSW-testimony.pdf ("Guttmacher Testimony") ("Several studies indicate that costs play a key role in the contraceptive behavior of substantial numbers of U.S. women."); Gina M. Secura et al., *The Contraceptive CHOICE Project: Reducing Barriers to Long-Acting Reversible Contraception*, 203 AM. J. OBSTET. &. GYNECOL. 115, 115 (2010) (when 10,000 study participants were offered the choice of any contraceptive method at no cost, two-

thirds of participants chose long-acting methods, such as the IUD or implant); 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 PERSPS. 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).

A 1998 poll commissioned by the Kaiser Family Foundation reported that 75% of adult women identified insurance coverage as having an impact on their choice of a method of contraception. Adam Sonfield & Rachel Benson Gold, *New Study Documents Major Strides in Drive for Contraceptive Coverage*, 7 GUTTMACHER REP. ON PUB. POL'Y 4, 5 (2004) ("Sonfield & Gold"). Lack of insurance coverage deters many women from choosing a high-cost contraceptive, even if that method is best for her health and lifestyle, and may result in her resorting to a method that places her more at risk for medical complications or improper or inconsistent use. The intrauterine device ("IUD"), for example, a long-acting reversible contraceptive ("LARC") that does not require regular action by the user, is among the most effective forms of contraception, but it has up-front costs of between

$500 and $1000.[3] IOM Report at 108; *see also* Megan L. Kavanaugh et al., *Perceived and Insurance-Related Barriers to the Provision of Contraceptive Services in U.S. Abortion Care Settings*, 21-3S WOMEN'S HEALTH ISSUES S26, S26 (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). 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, e69-e71 (2013). Women and couples are more likely to use contraception successfully when they are given their contraceptive method of choice, be it a birth control pill, a vaginal ring, or an IUD. Jennifer J. Frost & Jacqueline E. Darroch, *Factors Associated with Contraceptive Choice and Inconsistent Method Use, United States, 2004*, 40 PERSPS. ON SEXUAL & REPROD. HEALTH 94, 94 (2008). A national survey conducted in 2004 found that one-third of women using contraception would switch methods if cost was not a factor. *Id*.

Even seemingly insubstantial additional cost requirements can dramatically reduce the use of

[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, due to some women skipping or delaying an injection or pill. Guttmacher Testimony at 2.

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). *See also* Sonfield & Gold at 14 ("coverage, in and of itself, may not be enough for many women. Insurance plans typically require co-payments that may effectively render service use unaffordable"); *Access to Emergency Contraception,* ACOG Comm. Op. 542, 120 OBSTET. & GYNECOL. 1250, 1251 (2012) ("ACOG Opinion 542") (citing Jodi Nearns, *Health Insurance Coverage and Prescription Contraceptive Use Among Young Women at Risk for Unintended Pregnancy*, 79 CONTRACEPTION 105, 105-110 (2009)) (financial barriers, including lack of insurance, or substantial co-payments or deductibles, may deprive women of access to contraception).

The Department of Health and Human Services recognized that mandated preventive services had been underutilized, and anticipated that eliminating cost sharing would result in greater utilization. This, in turn, would improve health for individuals by *inter alia*, preventing and reducing transmission of disease and enabling earlier treatment of disease, and would result in savings due to lower health care costs. 75 C.F.R. at 41731, 41733 (July 19, 2010); IOM Report at 1-2.[4]

[4] Public Health Service Act Section 2713 as added by the ACA requires non-grandfathered group health plans to cover certain preventive-health services without cost sharing. These include services with Grade A and B recommendations made by the United States Preventive Services Task Force,

Similarly, in studying the issue of contraceptive coverage under the ACA, the Institute of Medicine ("IOM") found that imposing additional costs like deductibles and co-payments can pose barriers and result in reduced use of services. IOM Report at 109. The IOM concluded that the elimination of cost-sharing for contraceptive care could greatly increase contraceptive use, including use of LARCs, especially for low-income women at greater risk of unintended pregnancy. IOM Report at 109. Many women are so cost-sensitive that even small increments in cost-sharing have been shown to reduce the use of beneficial preventive services. IOM Report at 109.

2. The Requested Exemption Would Deny Women Access to Medically Appropriate Contraception

The consequences of lack of coverage for contraceptives fall more heavily on women and families with the fewest resources. IOM Report at 109. Specifically, unintended pregnancy is more likely amongst unmarried women aged 18-24, women who are low-income, who are not high school graduates, and who are members of certain

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preventive care and screenings for children provided for in guidelines supported by the Health Resources and Services Administration (HRSA), vaccinations specified by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, and preventive services for women as recommended by the HRSA and the Institute of Medicine. *See* 42 U.S.C. 300gg-13; 75 C.F.R. at 41731 (July 19, 2010).

racial or ethnic minority groups. IOM Report at 2. Moreover, approximately 750,000 adolescents get pregnant each year, and 80% of those pregnancies are unintended. *US Teenage Pregnancies, Births and Abortions: National and State Trends and Trends By Race and Ethnicity* (2010), http://www.guttmacher.org/pubs/USTPtrends.pdf; Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006,* 84 CONTRACEPTION 478, 478-85 (2011). 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 right time of day), and therefore more passive contraceptive methods like IUDs and other LARCS are often preferable, but they have greater up-front costs. Am. Acad. of Pediatrics, *Policy Statement: Contraception and Adolescents*, 120 PEDIATRICS 1135, 1135-1148 (2007). A recent study of over 9,000 adolescents and women desiring reversible contraception, for which all participants received their choice of contraceptive at no cost, resulted in a significant reduction in abortion rates and teenage birth rates. The study concluded that "unintended pregnancies may be reduced by providing no-cost contraception and promoting the most effective contraceptive methods." Jeffrey Peipert et al. *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120 OBSTET. & GYNECOL. 1291, 1291 (2012). Excluding contraception from insurance coverage, and thereby creating barriers to access to suitable

contraceptives for adolescents, could increase rates of unintended teenage pregnancies.

The ACA mandate represents the Government's determination that ensuring a woman's access to the full range of FDA-approved contraceptives is sufficiently essential to warrant mandatory coverage without cost-sharing. IOM Report at 109-10. Allowing employers to exclude all or certain contraception methods from their employees' insurance coverage would make appropriate contraceptives cost-prohibitive to many women. Because expense is such a high barrier for many women, the availability of contraceptives without cost sharing makes a crucial difference in women's access to this essential element of their health care.

C. Decisions About Contraception Should be Made in the Context of the Provider-Patient Relationship, Without Interference by the Employer

The provider-patient relationship is essential to all health care. The health care professional and the patient share responsibility for the patient's health, and the well-being of the patient depends upon their collaborative efforts. Am. Med. Ass'n, *Opinon 10.01*, http://www.ama-assn.org//ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1001.page. *See also, Elective Surgery and Patient Choice,* ACOG Comm. Op. 578, 122 OBSTET. & GYNECOL. 1134, 1135 (2013) ("The goal should be decisions reached in partnership between

patient and physician."). Within the provider-patient relationship, the provider's respect for the patient's autonomy is fundamental. Am. Coll. Of Obstetricians & Gynecologists, *Code of Professional Ethics,* http://www.acog.org/About_ACOG/~/media/Departments/National%20Officer%20Nominations%20Process/ACOGcode.pdf. "In medical practice, the principle of respect for autonomy implies personal rule of the self that is free . . . from controlling interferences by others." *Ethical Decision Making in Obstetrics and Gynecology,* ACOG Comm. Op. 390, 110 OBSTET. & GYNECOL. 1479, 1481 (2007).

Deciding on the best form of contraceptive for any specific patient should take place within the shared responsibility of the provider-patient relationship. Like other decisions, the welfare of the patient should receive the highest priority in the consideration of appropriate contraceptive use. Not all contraceptives are clinically appropriate for every woman. Rachel A. Bonnema, Megan C. McNamara, Abby L. Spencer, *Contraception Choices in Women with Underlying Medical Conditions,* 82 AM. FAM. PHYSICIAN 612, 612-628 (2010). A variety of individualized factors must be considered, including, for example, a patient's current health and medical conditions, potential drug interactions, medical history, stage of life, and religious and personal preferences.

More particularly, LARCS, such as implants and IUDs, may be preferable for women who require highly effective methods, who wish to postpone

pregnancy for an extended length of time, and who desire or need a method that is effective without the user taking regular action once it is initiated. Emergency contraception pills or devices are used by women to prevent pregnancy after rape, unprotected sex or the failure of some other contraceptive. ACOG Opinion 542 at 1250.[5]

Hormonal birth control pills or a hormonal IUD may not be suitable for women with certain medical conditions such as heart or liver disease, women who have certain blood-clotting disorders, or who have had or are at a higher risk of certain types of cancer. Ctrs. for Disease Control & Prevention, *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*, (June 18, 2010), http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf. Oral contraceptives may be inappropriate for women who smoke. *Id.* Similarly, use of a copper IUD may be inappropriate for women with uterine abnormalities, pelvic infections, or women with disorders resulting in accumulation of copper in their organs, such as Wilson's disease. *Id.* Use of certain contraceptives may be contraindicated based on adverse interactions with other medications a woman is taking, or based on certain

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[5] None of the FDA-approved emergency contraceptives or IUDs cause abortion; rather, they prevent unintended pregnancy from occurring and thereby prevent situations in which a woman may 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 *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354.

lifestyle factors that could make certain forms of contraception inadvisable. *Id.* All of these factors concerning a woman's medical and personal circumstances, and the patient's *own* personal beliefs, should be weighed by health care providers when advising her about her contraception choices.

To best serve the particular medical needs of their patients, physicians must have available to them an array of contraceptive options from which to recommend in order to ensure that the particular method prescribed optimally meets the particular medical and personal circumstances of the patient. *See* Adam Sonfield et al., *U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, 2002*, 36 PERSPS. ON SEXUAL & REPROD. HEALTH 72, 78 (2004) ("By covering a wide range of contraceptive methods, plans may enable women to choose the method that is best suited to their needs; by doing so, plans may help them to use contraceptives correctly and more consistently; and hence reduce unintended pregnancy.").

This Court has also repeatedly recognized the importance of safeguarding the relationship between individual and health care provider, as well as the independence of medical judgment. *See, e.g., Doe v. Bolton*, 410 U.S. 179, 197 (1973) (recognizing a "woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it"); *Planned Parenthood of Cent. Missouri v. Danforth*, 428 U.S. 52, 67 (1976)

(avoiding "confin[ing] the attending physician in an undesired and uncomfortable straitjacket in the practice of his profession"). As noted in *Colautti v. Franklin, Doe v. Bolton* "underscored the importance of affording the physician adequate discretion in the exercise of his medical judgment." 439 U.S. 379, 387 (1979). *See Doe v. Bolton*, 410 U.S. at 192 (recognizing that "medical judgment may be exercised in the light of all factors—physical, emotional, psychological, familial, and the woman's age—relevant to the well-being of the patient").

An employer's personal religious beliefs should not intrude into private medical decisions made between a health care provider and patient by controlling the available medical options, and should not be permitted to compel a woman to accept lesser preventive health care services or to pay for services to which she is entitled to at no additional cost under the ACA. *Cf. Estate of Thornton v. Caldor, Inc.,* 472 U.S. 703, 710 (1985) ("The First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities.") (*quoting Otten v. Baltimore & Ohio R. Co*, 205 F.2d 58, 61 (2d Cir. 1953).[6]

[6] Although it is the employer that selects and purchases the health insurance plan available for employees, employees themselves are frequently expected to contribute to the cost of the premium and pay significant deductibles and co-payments which are increasingly significant features of health plan design. In 2013, on average, covered workers

POINT II.

ALLOWING EMPLOYERS TO VETO MANDATED COVERAGE BASED ON THEIR OWNERS' RELIGIOUS BELIEFS HAS PUBLIC HEALTH RAMIFICATIONS FAR BROADER THAN CONTRACEPTIVES

The issues presented in these cases can have far-reaching effects. Recognizing a for-profit employer's right to a religious belief exemption to mandated insurance coverage can have dangerous health implications that extend beyond the ACA and far beyond contraceptive use. The ability of medical professionals to provide comprehensive health care to their patients could be significantly impaired if corporate employers (or their owners) are permitted to veto objected-to medications, treatments, or other mandated health services from their employees' health plans.

Our diverse society holds a wide variety of religious beliefs. And, the Constitution's protection of religious beliefs "is not limited to beliefs which

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contributed 18% of the cost of single coverage, and 29% of the cost of family coverage. Kaiser Fam. Found., *Employer Health Benefits 2013 Annual Survey* 67 ("Kaiser Survey"). Among small firms (fewer than 200 employees), 31% of workers paid more than half of the cost of premiums. *Id*. at 68. Notwithstanding the employees' contribution to the cost of their insurance, the religious exemption sought would allow the employer to deprive the company's employees of mandated coverage to which they are entitled in exchange for the premium to which the employee contributed.

are shared by all of the members of a religious sect." *Thomas v. Review Bd. of Indiana Employment Sec. Div.*, 450 U.S. 707, 716 (1981). "[R]eligious beliefs need not be acceptable, logical, consistent, or comprehensible to others in order to merit First Amendment protection," *id.* at 714; all that is required is that the individual have an "honest conviction" that the act in question violates his religious beliefs. *Id.* at 716. Consequently, employers' religious objections to providing insurance coverage can be as broad and wide-ranging as the diverse beliefs of the American population.[7]

Sincerely held religious beliefs prompt some adherents to object to a variety of medical services that are an essential part of mainstream health care, such as, for example, vaccines and mental

[7] The diversity of employers' personal religious beliefs is evident in these cases alone. Respondents in *Hobby Lobby* object to covering IUDs and emergency contraception, but not to contraceptives generally. *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1125 (10th Cir. 2013), *cert. granted*, 134 S. Ct. 678 (2013). Petitioners in *Conestoga Wood* object to various contraceptives that "prevent implantation." *Conestoga Wood Specialties Corp. v. Sec'y of U.S. Dep't of Health & Human Servs.*, 724 F.3d 377, 381-82 (3d Cir. 2013), *cert. granted*, 134 S. Ct. 678 (2013). Plaintiffs in other cases awaiting this Court's decision object to covering all contraceptives. *See*, *e.g. Gilardi v. U.S. Dep't of Health & Human Servs.,* 733 F.3d 1208, 1210 (D.C. Cir. 2013), *pet. for cert. pending*, No. 13-567 (filed Nov. 5, 2013) (plaintiffs oppose contraception); *Korte v. Sebelius*, 735 F.3d 654, 663-664 (7th Cir. 2013) (same); *Autocam Corp. v. Sebelius,* 730 F.3d 618, 621 (6th Cir. 2013), *pet. for cert. pending*, No. 13-482 (filed Oct. 15, 2013) (plaintiffs "accept their church's teaching that artificial contraception [is] immoral").

health services. Giving corporate employers a religious exemption to mandated insurance coverage for these health services creates significant barriers to access to health care that pose a serious risk to patients' health.

A. Allowing Religious Objections to Coverage of Vaccinations Would Pose a Threat to the Provision of Comprehensive Health Care

Vaccines have been hailed as the single greatest improvement in the history of medicine and have long been recognized as a public health imperative, particularly for children. According to the National Center for Immunization and Respiratory Diseases "vaccination with 7 of the 12 routinely recommended childhood vaccines prevents an estimated 33,000 deaths and 14 million cases of disease in every birth cohort." Sandra W. Roush & Trudy V. Murphy, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 J. AM. MED. ASS'N 2155, 2160 (2007). They also found that "the number of cases of most vaccine-preventable diseases is at an all-time low; hospitalizations and deaths have also shown striking decreases . . . due to reaching and maintaining high vaccine coverage levels from infancy throughout childhood." *Id.* All 50 states require certain vaccinations for children entering public schools and most mandate insurance

coverage for certain vaccinations.[8] Recognizing the vital role vaccinations play in preventive care, the ACA also mandates coverage, without cost sharing, of numerous immunization services for both children and adults. *See* 42 U.S.C. 300gg-13(a)(2); 75 Fed. Reg. 41728 (July 19, 2010). At the same time, vaccines are often the object of religious objections, across various religious groups and for differing reasons.[9]

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[8] Most states allow religious exemptions to mandatory vaccinations. These exemptions allow an individual to refuse vaccination for himself (or his child) based on his own religious beliefs. These types of exceptions, and the mandates to which they apply, are entirely different from those at issue in this case and would be unaffected by a denial of the exemptions sought here. Unlike state mandates which require individuals to be vaccinated prior to school entry, the mandate in this case does not require individuals to undergo a medical intervention—rather it requires that insurance coverage for that intervention be part of a package of employee benefits. Moreover, the exemptions to state vaccine mandates are given to individuals based on their own beliefs; in contrast, the exemption sought here would impose one individual's religious beliefs onto others.

[9] Religious objections to vaccinations are very real. By way of example only, in 1994, significant measles outbreaks occurred in two religious communities originating from an unvaccinated teenager who lived in Illinois and attended boarding school in Missouri. *Outbreak of Measles Among Christian Science Students—Missouri and Illinois, 1994* (July 1, 1994), http://www.cdc.gov/mmwr/preview/mmwrhtml/00031788.htm. In 2005, a measles outbreak occurred in Indiana among a religious community that opposed vaccinations when an unvaccinated teenager passed the disease to others at a church gathering. Amy A. Parker et al., *Implications of a 2005 Measles Outbreak in Indiana for*

Certain religious adherents object to vaccines derived from fetal tissue, including vaccinations for chicken pox, Hepatitis A and B, MMR (Measles, Mumps, and Rubella), and Polio. Richard K. Zimmerman, *Ethical Analyses of Vaccines Grown in Human Cell Strains Derived From Abortion: Arguments and Internet Search*, 22 VACCINE 4238, 4238-4244 (2004). Others object to vaccines containing bovine or porcine extracts, or blood fragments, and some object to vaccines more generally as defiling the body by introducing foreign or virulent substances.[10] Tara M. Hoesli et al., *Effects of Religious and Personal Beliefs on Medication Regimen Design*, 34 ORTHOPEDICS 292, 292-295 (2011).

Vaccinations against the Human Papillomavirus (HPV) prevent serious health conditions such as cancer and genital warts.[11] The vaccine offers the best protection to individuals who receive all three

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Sustained Elimination of Measles in the United States, 355 NEW ENG. J. MED. 447-455 (2006). And in 2010, an outbreak of whooping cough was similarly linked to vaccination refusals. Jessica E. Altwell et al., *Nonmedical Vaccine Exemptions and Pertussis in California*, 132 PEDIATRICS 624, 624-630 (2010).

[10] Certain vaccines contain a low dose of the live virus against which the vaccine inoculates.

[11] HPV causes most forms of cervical cancers, with which approximately 12,000 women are diagnosed annually and from which 4,000 women die each year. Ctrs. for Disease Control & Prevention, *HPV and HPV Vaccine*, http://www.cdc.gov/std/hpv/stdfact-hpv-vaccine-hcp.htm.

doses of the vaccine before beginning sexual activity, thus giving their bodies time to develop an immune response to the vaccine before possible exposure to the virus. Therefore, the HPV vaccine is recommended for preteens at 11 or 12 years of age. Ctrs. for Disease Control & Prevention, *Human Papillomavirus (HPV),* http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf. However, there are religious objections to the HPV vaccine in that these diseases can and should best be reduced by abstinence outside of marriage. Surveys have shown a definite correlation between those who have rejected the HPV vaccine and attendance at religious services. Rachel Shelton et al., *HPV Vaccine Decision-Making and Acceptance: Does Religion Play a Role?*, 52 J. RELIGIOUS HEALTH 1120, 1120-30 (2013); Debra Bernat et al., *Characteristics Associated with Initiation of the Human Papillomavirus Vaccine Among a National Sample of Male and Female Young Adults*, 53 J. ADOLESCENT HEALTH 630, 630-636 (2013).

By logical extension, if a religious exemption to providing mandated coverage were recognized, corporate employers holding any of these views could similarly decline to cover any or all of the vaccines deemed to violate the corporation owners' religious beliefs.

B. Recognizing a Religious Exemption to Providing Mandated Health Insurance Coverage Would Deprive Patients of Access to Other Essential Health Services

Certain religious adherents object to other specific health services, or to medical interventions at all. Corporate owners whose religion renounces medical treatment on the belief that disease is prevented or cured by prayer may assert a religious objection to the provision of health insurance in its entirety as being contrary to their religious beliefs. *See* Park Ridge Ctr. for the Study of Health, Faith, and Ethics, *The Christian Science Tradition: Religious Beliefs and Healthcare Decisions,* http://www.che.org/members/ethics/ docs/1276/Christian%20Science.pdf (noting religious belief that illness and disease results from an underlying condition of spiritual distance from God; healing is sought primarily from prayer, rather than medical intervention). Similarly, certain religious interpretations hold that insurance generally is forbidden as a form of gambling. Mubbsher M. Khan & Hassan M. Alam, *Comparative Analysis of Islamic and Prevailing Insurance Practices,* 2 INT'L J. BUS. & SCIENCE 282, 283 (2011). Thus, owners of a corporation adhering to this belief could assert a religious objection to providing any health insurance to its employees. Followers of a religion which eschews mainstream mental health care in favor of that religion's own mental health therapies, may assert a religious objection to coverage of mandated depression screening,

treatment, and psychiatric pharmaceuticals. *See* Steven A. Kent & Terra A. Manca, *A War Over Mental Health Professionalism: Scientology Versus Psychiatry,* MENTAL HEALTH, RELIGION & CULTURE 1, 1 (2012).

Moreover, the ACA further requires coverage of essential benefits that have been mandated by the respective states. *See* 42 U.S.C. 300gg-13. Certain medical treatments required to be covered under the ACA through state mandates may also be vulnerable to religious objections. Coverage for fertility treatments, including in-vitro fertilization, embryo transfer and artificial insemination, is presently mandated by some states. *See* National Conference of State Legislatures, *State Laws Related to Insurance Coverage for Infertility Treatment* (Mar. 2012), http://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx.[12] Religious objections to in-vitro fertilization and other fertility treatments are well documented. For example, in 1987, the Vatican's Congregation for the Doctrine of the Faith expressed the Vatican's opposition to certain fertility treatments, including in vitro fertilization and artificial insemination by donor. *Instruction* Donum Vitae *on Respect for Human Life at its Origins and for the Dignity of Procreation* (1988), http://www.vatican.va/roman_curia/ congregations/

[12] Although some states allow religious exemptions to coverage, as does the contraception mandate under the ACA, these exemptions do not apply to for-profit corporate employers.

cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html. In 2008, the Vatican reaffirmed its objection to in vitro fertilization. *Instruction* Dignitas Personae *on Certain Bioethical Questions* (2008), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_20081208_dignitas-personae_en.html. If a religious exemption is permitted, a corporate employer in an in-vitro mandated state may nevertheless object to covering such treatment if its owners have a religious objection to such treatment.

Hospice care is similarly mandated by the ACA through mandates in at least 11 states. *See* National Conference of State Legislatures, *Cancer Insurance Mandates and Exceptions,* (Aug. 2009), http://www.ncsl.org/portals/1/documents/health/CancerMandatesExcept09.pdf. Palliative care, which may incorporate features such as Do Not Resuscitate orders or large dosage narcotics, is objected to by some as hastening the patient's death in violation of religious prohibitions. *See, e.g.,* Nigel Sykes & Andrew Thorns, *Sedative Use in the Last Week of Life and the Implications for End-of-Life Decision Making*, 163 ARCH. INTERN. MED. 341, 341 (2003) (noting that "[t]he use of sedation at the end of life has aroused ethical controversy, attracting accusations of hastening death by gradually increasing sedative doses.").

Though framed as issues of religious exercise under the First Amendment and RFRA, these cases also raise the concern that owners of a for-profit corporate employer, based upon their personal

religious beliefs, can deny a plan beneficiary insurance coverage for the treatment that she, in consultation with her health care provider and taking into account *her own* religious beliefs, believes to be appropriate and that has been determined to have a public health interest. *Amici* respectfully urge the Court to recognize the impact its decision will have, not only on the specific challenges to coverage of contraception, but also on employees' rights to other evidence-based essential health care services and the impact that denial of those rights will have on public health.

CONCLUSION

For the foregoing reasons, as well as those in the Government's brief, the judgment of the Court of Appeals for the Third Circuit should be *affirmed* and the judgment of the Tenth Circuit should be *reversed*.

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January 28, 2014

STROOCK & STROOCK & LAVAN LLP

By: /s/ Bruce H. Schneider

Bruce H. Schneider
Counsel of Record
Michele L. Pahmer
Darya Bril
180 Maiden Lane
New York, New York 10038
212-806-5400

Attorneys for Amici Curiae American College of Obstetricians and Gynecologists, Physicians for Reproductive Health, American Academy of Pediatrics, American Nurses Association, American College of Nurse-Midwives, American College of Osteopathic Obstetricians and Gynecologists, American Medical Student Association, American Medical Women's Association,

American Society for Emergency Contraception, American Society for Reproductive Medicine, Association of Reproductive Health Professionals, California Medical Association, International Association of Forensic Nurses, Jacobs Institute for Women's Health, Maine Medical Association, Massachusetts Medical Society, National Association of Nurse Practitioners in Women's Health, National Physicians Alliance, Society for Adolescent Health and Medicine, Society of Family Planning, Society for Maternal-Fetal Medicine, and Washington State Medical Association

LIST OF ADDITIONAL *AMICI*

American College of Nurse-Midwives

American College of Osteopathic Obstetricians and Gynecologists

American Medical Student Association

American Medical Women's Association

American Society for Emergency Contraception

American Society for Reproductive Medicine

Association of Reproductive Health Professionals

California Medical Association

International Association of Forensic Nurses

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Maine Medical Association

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Society for Adolescent Health and Medicine

Society of Family Planning

Society for Maternal-Fetal Medicine

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