STROOCK & STROOCK & LAVAN LLP
JOHN R. LOFTUS (State Bar No. 126841)
2029 Century Park East
Los Angeles, CA 90067-3086
Telephone: 310-556-5800
Facsimile: 310-556-5959
Email: lacalendar@stroock.com

STROOCK & STROOCK & LAVAN LLP
BRUCE H. SCHNEIDER*
MICHELE L. PAHMER*
GILANA R. KELLER*
180 Maiden Lane
New York, NY 10038-4982
Telephone: 212-806-5400
Facsimile: 212-806-6006
Email: docketing@stroock.com
**Not admitted in this jurisdiction*

Attorneys for Amici Curiae
AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICIANS, PHYSICIANS FOR REPRODUCTIVE HEALTH AND CALIFORNIA MEDICAL ASSOCIATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STATE OF CALIFORNIA, et al., Plaintiffs v. HEALTH AND HUMAN SERVICES, et al., Defendants.	Case No. 17-CV-05783-HSG **CONSENT MOTION FOR LEAVE TO APPEAR AS AMICI CURIAE AND TO FILE AN AMICUS BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION** Hon. Haywood S. Gilliam, Jr.

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

American Nurses Association, American College of Obstetricians and Gynecologists, American Academy of Nursing, American Academy of Pediatricians, Physicians for Reproductive Health, and California Medical Association (collectively, "the Health Professional Organization *Amici*") respectfully move the Court for leave to file the attached proposed amicus curiae brief in support of Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction. Plaintiffs and Defendants consent to this Motion.

In support of this Motion, the Health Professional Organization *Amici* state as follows:

1. *Amici curiae* are leading health professional organizations that share the common goal of improving health for all by, among other things, ensuring that women have access to high quality healthcare that is comprehensive and evidence-based. *Amici* believe that the overwhelming weight of the evidence establishes that access to the full range of FDA-approved prescription contraceptives is an essential component of effective health care for women and their families. *Amici* seek leave to file a brief in support of Plaintiffs' motion for a preliminary injunction to provide the Court with their unique perspective as health professional organizations on the importance of safeguarding the availability of no-cost contraceptive coverage in the interest of women's preventive health care.[1] *Amici's* proposed brief is annexed hereto as Exhibit A.

[1] Courts, including the U.S. Supreme Court, frequently rely on submissions by *amici* as authoritative sources of medical information on issues concerning women's healthcare. *See, e.g., Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315, 195 L. Ed. 2d 665 (2016) (citing *amicus* brief submitted by ACOG, AAP, ANA,AAN and other health professional organizations in reviewing clinical and privileging requirements); *Stenberg v. Carhart*, 530 U.S. 914, 932-36 (2000) (quoting ACOG's *amicus* brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the healthcare procedure at issue); *Hodgson v. Minnesota*, 497 U.S. 417, 454 n.38 (1990) (citing *amicus* brief submitted by ACOG, AAP and other health professional organizations in assessing law concerning medical notification); *Simopoulos v. Virginia*, 462 U.S. 506, 517 (1983) (citing ACOG publication in discussing "accepted medical standards" for the provision of obstetric-gynecologic services); *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2799, 189 L. Ed. 2d 675 (2014) (Ginsburg, J. dissenting) (citing *amicus* brief submitted by ACOG, PRH, ANA and other health professional organizations in its discussion of how contraceptive coverage helps safeguard the health of women for whom pregnancy may be hazardous); *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 916-17 (9th Cir. 2014) (citing brief submitted by *amici* ACOG and other medical organizations in further support of a particular medical regimen), cert. denied, 135 S. Ct. 870, 190 L. Ed. 2d 702 (2014); *Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 790 (7th Cir. 2013) (citing ACOG's *amicus* brief in evaluating the relative safety of abortion and other outpatient procedures); *Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 168 (4th Cir. 2000) (extensively discussing ACOG's guidelines and describing those guidelines as "commonly used and relied upon by obstetricians and gynecologists nationwide to determine the standard and the appropriate level of

2. Briefs by this group of *amici* were received by Courts of Appeals for the First and Ninth Circuits in appeals from the promulgation of the Interim Final Rules that preceded these Final Rules. Other briefs by various of these *amici* have been received by the United States Supreme Court and other Courts of Appeals regarding the contraceptive mandate of the Affordable Care Act.

3. The proposed amicus brief will provide the Court with the specialized perspective and expertise of leading health professional organizations who collectively represent providers of women's healthcare, including reproductive healthcare. Well-established and evidence-based standards of healthcare services recommend access to contraception and contraception counseling as essential components of health care for women of childbearing age. *Amici* are directly involved in the provision of healthcare for women and adolescents and, as such, have unique insight into the critical importance of access to no-cost seamless contraceptive coverage, as well as the risks posed by the loss of such coverage. Given their specialized knowledge and perspective, *amici* believe that their brief will be helpful to the Court on this motion for a preliminary injunction.

4. For these reasons, the proposed Health Professional Organization *Amici* respectfully request that their motion be granted and that their brief be filed.

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Los Angeles, California 90067-3086

care for their patients"); *Stuart v. Camnitz*, 774 F.3d 238, 251-52, 254-55 (4th Cir. 2014) (citing ACOG's *amicus* brief and committee opinion in its discussion of informed consent). In addition, ANA and AAN have published position statements on religious and moral exemptions to the ACA's contraceptive mandate that are at issue in the Final Rules. *See* Ellen Olshansky, et al,, *Sexual and Reproductive Health Rights, Access & Justice: Where Nursing Stands*,66 Nursing Outlook 345-424 (July-August 2018), available at https://doi.org/10.1016/j.outlook.2018.07.001.

Dated: January 7, 2019

Respectfully submitted,

STROOCK & STROOCK & LAVAN LLP
JOHN R. LOFTUS
BRUCE H. SCHNEIDER*
MICHELE L. PAHMER*
GILANA R. KELLER*
** Not admitted in this jurisdiction*

By: */s/ John R. Loftus*
John R. Loftus

Attorneys for Amici Curiae
AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICIANS, PHYSICIANS FOR REPRODUCTIVE HEALTH, AND CALIFORNIA MEDICAL ASSOCIATION

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

CERTIFICATE OF SERVICE

I hereby certify that on January 7, 2019, a copy of the foregoing **CONSENT MOTION FOR LEAVE TO APPEAR AS AMICI CURIAE AND TO FILE AN AMICUS BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**, the proposed amicus curiae brief, and proposed order were filed and served pursuant to the Court's electronic filing procedures using CM/ECF.

/s/ John R. Loftus
JOHN R. LOFTUS

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

EXHIBIT A

STROOCK & STROOCK & LAVAN LLP
JOHN R. LOFTUS (State Bar No. 126841)
2029 Century Park East
Los Angeles, CA 90067-3086
Telephone: 310-556-5800
Facsimile: 310-556-5959
Email: lacalendar@stroock.com

STROOCK & STROOCK & LAVAN LLP
BRUCE H. SCHNEIDER*
MICHELE L. PAHMER*
GILANA R. KELLER*
180 Maiden Lane
New York, NY 10038-4982
Telephone: 212-806-5400
Facsimile: 212-806-6006
Email: docketing@stroock.com
**Not admitted in this jurisdiction*

Attorneys for Amici Curiae
AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICIANS, PHYSICIANS FOR REPRODUCTIVE HEALTH, AND CALIFORNIA MEDICAL ASSOCIATION

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STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

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Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

INTRODUCTION[1]

Amici curiae are leading health professional organizations directly involved in the provision of healthcare to women and adolescents. *Amici* have a particular interest in the outcome of this case because well-established and evidence-based standards of care recommend access to contraception and contraception counseling as essential components of health care for women and adolescents of childbearing age. The overwhelming weight of the evidence establishes that access to the full range of FDA-approved prescription contraceptives is an essential component of effective health care for women and their families and that even small increases in cost decrease access.

The Patient Protection and Affordable Care Act (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; and women's preventive health services, including FDA-approved contraceptives prescribed by a health care provider.

Contraception not only helps to prevent unintended pregnancy, but it 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, the existence of cost and other barriers to access have been shown to reduce the consistent use of appropriate contraception, thereby increasing the risk of unintended pregnancies and all of the attendant consequences. The contraception coverage requirement recognizes that women of childbearing age have unique health

[1] No counsel for a party authored this brief in whole or in part; no counsel, party, or other person made a monetary contribution intended to fund the preparation or submission of this brief, other than amici, their members, or their counsel. A description of each amicus organization is included in the accompanying motion for leave.

needs and that contraception counseling and services are essential components of women's routine preventive health care.

However, the Final Religious Exemption Rule and Final Moral Exemption Rule at issue (the "Final Rules") threaten to strip from countless women in California and nationwide the no-cost contraceptive coverage required under the ACA. The breadth of the Final Rules, which allow any employer or health insurance provider to exclude contraceptive coverage by invoking religious or moral objections, greatly expands 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' very objective in making comprehensive preventive women's healthcare widely accessible and disrupting the seamless provision of health care within the existing patient-provider relationship. Because the Final Rules greatly expand the availability of the exemption, they effectively demote contraceptive coverage from a legal entitlement under the ACA to a voluntary employment benefit at the discretion of the employer. This Court's prior decision similarly recognized with respect to the interim final rules, which are indistinguishable from the Final Rules in this respect, that:

> more employers than ever before are eligible for the exemption and the accommodation, the latter of which is now entirely optional for organizations asserting a religious or moral objection. Put another way, for a substantial number of women, the 2017 IFRs transform contraceptive coverage from a legal entitlement to an essentially gratuitous benefit wholly subject to their employer's discretion.

Order Granting Plaintiffs' Motion for a Preliminary Injunction 25-26, ECF No. 105. The Ninth Circuit similarly recognized that the new rules "dramatically expanded" the category of employers who could deny women contraceptive coverage to which they are entitled under the ACA. *California v. Azar*, No. 18-15144, 2018 WL 6566752, at *13 (9th Cir. Dec. 13, 2018).

Amici submit this brief to highlight for the Court, with citation to scientific literature and research, the importance of contraception to women's preventive health care and the grave harms to women's health and public health generally presented by the two Final Rules now at issue. Absent a preliminary injunction, those Final Rules will compromise access to a critical component of women's preventive healthcare for countless American women. *Amici*, who include the leading

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

health professionals providing women's health care, therefore urge this Court to grant the States' Motion for a Preliminary Injunction.

INTEREST OF AMICI CURIAE

The 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 College of Obstetricians and Gynecologists (ACOG) is a non-profit educational and professional organization with more than 58,000 members nationwide, including more than 6,000 in the State of California. ACOG's members represent approximately 90% of all board-certified obstetricians and gynecologists practicing in the United States. As the leading professional association for physicians who specialize in the healthcare of women, ACOG supports access to comprehensive contraceptive care and contraceptive methods as an integral component of women's health care and is committed to encouraging and upholding policies and actions that ensure the availability of affordable and accessible contraceptive care and contraceptive methods.

The American Academy of Nursing (the "Academy") serves the public and the nursing profession by advancing health policy, practice, and science through organizational excellence and effective nursing leadership. The Academy influences the development and implementation of policy that improves the health of populations and achieves health equity including advancing policies that improve ethical and evidence-based standards of care and women's access to safe, quality sexual/reproductive health care without interference with the patient-provider relationship.

The American Academy of Pediatrics (AAP) was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since the AAP's inception, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 88 years, the AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. The AAP has worked with the

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

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 contraceptives.

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.

California Medical Association (CMA) is a non-profit, incorporated professional association for physicians with approximately 43,000 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 comprehensive reproductive health services.

Briefs by this group of *amici* were received by Courts of Appeals for the First and Ninth Circuits in appeals from the promulgation of the Interim Final Rules that preceded these Final Rules. Other briefs by various of these *amici* have been received by the United States Supreme Court and other Courts of Appeals regarding the contraceptive mandate of the Affordable Care Act.

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

ARGUMENT

I. THE FINAL RULES THREATEN THE IMPORTANT PUBLIC INTEREST IN ENSURING THAT WOMEN HAVE SEAMLESS ACCESS TO CONTRACEPTIVE COVERAGE AT NO ADDITIONAL COST

A. Contraception is an Essential Component of Women's Preventive Health Care[2]

The ACA's coverage requirement for FDA-approved contraceptives and counseling comports with prevailing standards of care for healthcare providers. *See, e.g.*, Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* 104 (2011) ("IOM Report") (noting recommendation of the use of family planning services as part of preventive care for women by numerous health professional organizations). 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 poses a significant impact on health. IOM Report at 8. Unintended pregnancies have long been established to 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). Reducing the unintended pregnancy rate is a national public health goal. The U.S. Department of Health and Human Services' Healthy People 2020 campaign aims to increase the proportion of pregnancies that are intended by 10% between 2010 and 2020. *See* Guttmacher Inst., *Unintended*

[2] FDA-approved contraceptives are often mischaracterized as "abortifacients." However, none of the FDA-approved 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.

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2029 Century Park East
Los Angeles, California 90067-3086

Pregnancy in the United States, 2 (2016), https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us_0.pdf

The human cost of unintended pregnancy is high: women must either carry an unplanned pregnancy to term and either raise the baby or elect adoption, or choose abortion. Women and their families may struggle with this challenge for medical, ethical, social, legal, and financial reasons. Am. Coll. of Obstetricians & Gynecologists, *Access to Contraception,* Comm. Op. 615, Jan. 2015 (reaffirmed 2017).

Unintended pregnancies impose significant financial costs 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 Institute (2015), https://www.guttmacher.org/sites/default/files/report_pdf/public-costs-of-up-2010.pdf. The Ninth Circuit already recognized the financial harm posed by the interim rules. *Azar*, 2018 WL 6566752 at *7. Nothing about the Final Rules warrants a different conclusion.

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 may experience 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*

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

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. Am. Coll. of Obstetricians & Gynecologists, GUIDELINES FOR WOMEN'S HEALTH CARE 343 (4th ed. 2014) ("ACOG GUIDELINES"). Given their unique reproductive health needs, access to contraception is a basic and essential preventive service for women.

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 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); 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. In 2011, 34% of all unintended pregnancies ended with abortions. Guttmacher Institute, *Memo on Estimation of Unintended Pregnancies Prevented* (2017), https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.

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

and respiratory and gastrointestinal illnesses, fewer allergies, and lower rate of obesity and diabetes).

A woman's unintended pregnancy may also have lasting effect 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 the year, account for 54% of all unintended pregnancies. Guttmacher Inst., *Unintended Pregnancy in the United States* 2 (September 2016), https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us_0.pdf.

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).

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

Inadequate spacing between pregnancies can also be detrimental to the child. 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 Service, 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, particularly when the birth is unwanted, 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 Centers for Disease Control and Prevention 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. <u>For Women with Certain Medical Conditions or Risks, Contraception Is Medically Necessary to Prevent Other Serious Health Complications</u>

Contraception also helps protect the health of those women for whom pregnancy can be hazardous, or even life-threatening. Ctrs. for Disease Control & Prevention, *U.S. Medical*

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

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 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."). Contraception allows women with these and other conditions to care for their own health and avoid complications for themselves or their fetuses because of an unintended pregnancy. *See* ACOG GUIDELINES at 187.

3. Contraception Is An Effective Treatment For Many Conditions

In addition to preventing pregnancy, contraception has other scientifically recognized 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 Ninth Circuit correctly recognized that "[e]vidence supports that, with reasonable probability, some women residing in the plaintiff states will lose coverage due to the IFRs." *Azar*, 2018 WL 6566752 at *6. Cost is a significant consideration for many women in their choice of contraception, as well as its proper and consistent use. 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). 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* Am. Coll. of Obstetricians & Gynecologists, *Access to Emergency Contraception*, Comm. Op. 542 (2012), 120 Obstet. & Gynecol. 1250, 1251 (2012) (citing 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). By 2013, most women had no out-of-pocket costs for their contraception, as median expenses for most contraceptive methods, including the IUD and the pill, dropped to zero. 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/.

The rate of unintended pregnancies are 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%). Guttmacher Inst., *Unintended Pregnancy in the United States*, 2 (September 2016), https://www.guttmacher.org/sites/default/files/factsheet/fb-unintended-pregnancy-us_0.pdf. However, among high-income women (those with incomes of at least 200% of the federal poverty level), the unintended pregnancy rate dropped to 20 per 1,000, or 2%. Among poor women, by contrast (those with incomes below the federal poverty level) the rate of unintended pregnancy was more than five times that, with 112 unintended pregnancies per 1,000 women (11.2%).

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: The Effect of Insurance Status*, 110 OBSTET. & GYN. 1371, 1378 (2007). *See also* Guttmacher Inst., *Testimony of Guttmacher Institute Submitted to the Committee on Preventive Services for Women Institute of*

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

Medicine, 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."); Jeffrey Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception,* 120 OBSTET. & GYNECOL. 1291, 1291 (2012) (when over 9,000 study participants were offered the choice of any contraceptive method at no cost, 75% chose long-acting methods, such as the intrauterine device ("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 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).

Women regularly identify insurance coverage as having an impact on their choice of a method of contraception. Approximately one-third of women using contraception report that they would change their contraceptive method if cost were not an issue. 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). Lack of insurance coverage deters many women from choosing a high-cost contraceptive, even if that method is best for her, and may result in her resorting to an alternative method that places her more at risk for medical complications or improper or inconsistent use, with the attendant risk of unintended pregnancy.

The link between no-cost insurance coverage and health outcomes is substantial because the most effective contraception is also the most expensive. The out-of-pocket cost for a woman to initiate long acting reversible contraceptive methods ("LARC") 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). The IUD, for example, a 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

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2029 Century Park East
Los Angeles, California 90067-3086

$1,000.[3] David Eisenberg et al., *Cost as a Barrier to Long-Acting Reversible Contraceptive (LARC) Use in Adolescents*, J. of Adolescent Health, 52(4):S59–S63 (2013), http://www.jahonline.org/article/S1054-139X(13)00054-2/fulltext; *see also* Brooke Winner et. al, *Effectiveness of Long-Acting Reversible Contraception*, 366 New Eng. J. Med. 1998, 2004-05 (2012) (a study of 7,486 participants found that participants who used oral contraceptive pills, the patch or vaginal ring had a risk of contraceptive failure that was 20 times as high as the risk among those using LARC, and a failure rate of 4.55 per 100 participants, as compared with a failure rate of .27 for those using LARC and that study participants who were younger than 21, using oral contraception, the patch or ring, had almost twice the risk of unintended pregnancy as older women using the same methods); 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) (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).

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 right time of 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).

A study of nearly 30,000 women and girls showed that compliance with the ACA's requirement of contraceptive 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

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

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). Indeed, a recent study confirmed that LARC insertions increased by three percent following the implementation of the ACA's coverage requirement, through 2014. 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 are given their contraceptive method of choice. 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). A national survey conducted in 2004 found that one-third of women using contraception would switch methods if cost were not a factor. *Id*. A more 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." Peipert et al., 120 OBSTET. & GYNECOL. at 1291. When relieved of cost-sharing, women choose these methods more often, with favorable implications for the rate of unintended pregnancy and associated costs of childbirth. Sobel et al., *supra*. Data compiled over several decades demonstrate the significant health benefits to women and children when a woman can delay the birth of her first child and plan the spacing of any subsequent children. Plaintiffs have a substantial interest in reducing unintended pregnancies by 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.

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

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, by making the existing accommodation a mere voluntary alternative to outright exemption, the Final Rules may 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 whose employers claim a moral objection to enable them to access contraception, aside from suggesting that they might avail themselves of governmental programs or obtain contraceptive coverage elsewhere. *See, e.g.,* Religious Exemptions and Accommodations for Coverage of Certain Preventative Services Under the Affordable Care Act, 83 Fed. Reg. 57,536, 57,548 (Nov. 15, 2018) (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. 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, *Patient Rights,* AMA Code of Medical Ethics Op. 1.1.3, https://www.ama-assn.org/delivering-care/patient-rights/. *See also* Am. Coll. of Obstetricians & Gynecologists, *Elective Surgery and Patient Choice,* Comm. Op. 578, 122 OBSTET. & GYNECOL. 1134, 1135 (2013) ("The goal should be decisions reached in partnership between patient and physician."); Am. Nurses Ass'n, *Code of Ethics for Nurses with Interpretive Statements,* Statement, 1.4 at 2-3 (2015) (Patients are to "be given necessary support throughout the decision-making and treatment process, …[including] the opportunity to make decisions with

family and significant others and to obtain advice from expert, knowledgeable … health professionals.").

Within the patient-provider relationship, the provider's obligation to patient 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." Am. Coll. of Obstetricians & Gynecologists, *Ethical Decision Making in Obstetrics and Gynecology,* Comm. Op. 390, 110 OBSTET. & GYNECOL. 1479, 1481 (2007). *Cf. 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 . . ."); *Cruzan by Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 289 (1990) (O'Connor, J., concurring) (recognizing "patient's liberty, dignity, and freedom to determine the course of her own treatment"); Am. Nurses Ass'n, Revised Position Statement, *Protecting and Promoting Individual Worth, Dignity, and Human Rights In Practice Settings* (2016), https://www.nursingworld.org/~4ad4a8/globalassets/docs/ana/nursesrole-ethicshumanrights-positionstatement.pdf (emphasizing the patient's right to self-determination, "including the right to choose or decline care").

The decision whether to use contraception, and if so, in what form, should take place within this established relationship. This is particularly true given the intimate nature of the reproductive health and family planning services that are at issue here. CDC Guidelines, health professional organizations and women's health experts have recommended tools and guidelines for effective education and counselling for reproductive life planning and unintended pregnancy prevention. *See, e.g.*, Ctrs. for Disease Control & Prevention, *Recommendations to Improve Preconception Health and Health Care – United States: A Report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care* (Apr. 21, 2006), http://www.cdc.gov/mmwr/pdf/rr/rr5506.pdf; *see also* Diana Taylor & Evelyn Angel James, *An Evidence-Based Guideline for Unintended Pregnancy Prevention*, 40:6 J. OF OBSTETRIC, GYNECOLOGIC, & NEONATAL NURSING 782-793 (2011). An evidence-based report issued by the

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2029 Century Park East
Los Angeles, California 90067-3086

CDC in 2014 and updated in 2017 demonstrates the importance of effective patient-provider communication about reproductive life planning. *See* Loretta Gavin et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, Morbidity & Mortality Wkly. Rep. (Apr. 25, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm?s_cid=rr6304a1_w, *updated by* Loretta Gavin et al., Update: *Providing Quality Family Planning Services — Recommendations from CDC and the U.S. Office of Population Affairs, 2017*, Morbidity & Mortality Wkly. Rep. (Dec. 22, 2017), http://dx.doi.org/10.15585/mmwr.mm6650a4.

Prescribing birth control is typically far more intimate and intrusive than simply signing a prescription pad; in addition to medical screening to ensure that a particular birth control method is not contraindicated, a pelvic exam is required when prescribing a diaphragm or cervical cap or inserting an IUD. A pelvic exam may also be warranted before prescribing other types of contraceptives, based on the woman's medical history. Am. Coll. of Obstetricians & Gynecologists, *Well-Woman Visit*, Committee Op. 534, 120 OBSTET. & GYNECOL. 421, 422 (2012). Women should be able to make these personal decisions – decisions that often require sharing intimate details of their sexual history and family planning – in collaboration with their trusted healthcare providers. The patient's employer should not be part of that decision-making process, no matter his particular moral beliefs.

B. At Best, the Final Rules Create a Two-Tiered System that Undermines Seamless and Equal Access to Care for Many Women

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. Yet, absent a preliminary injunction, the Final Rules could remove contraceptive coverage under the health plan that covers a woman's other routine health services, or remove coverage for the form of contraception that is most appropriate for her. Upon an exemption claimed by her employer, a woman would be pushed into a two-tiered system of coverage – one for her overall health needs and one limited to contraceptive care (if such coverage is even available) – or be forced to pay out of pocket for these services. By requiring women to seek out alternative coverage (or forego

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2029 Century Park East
Los Angeles, California 90067-3086

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, 194 L. Ed. 2d 696 (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). The Final Rules expressly reject the principle that seamless coverage is a compelling government 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. The Final Rules represent a significant 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.

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STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

CONCLUSION

Amici respectfully urge that the States' Motion for a Preliminary Injunction be granted.

Dated: January 7, 2019

Respectfully submitted,

STROOCK & STROOCK & LAVAN LLP
JOHN R. LOFTUS
BRUCE H. SCHNEIDER*
MICHELE L. PAHMER*
GILANA R. KELLER*
* *Not admitted in this jurisdiction*

By: */s/ John R. Loftus*
John R. Loftus

Attorneys for Amici Curiae
AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICIANS, PHYSICIANS FOR REPRODUCTIVE HEALTH AND CALIFORNIA MEDICAL ASSOCIATION

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086

STROOCK & STROOCK & LAVAN LLP
JOHN R. LOFTUS (State Bar No. 126841)
2029 Century Park East
Los Angeles, CA 90067-3086
Telephone: 310-556-5800
Facsimile: 310-556-5959
Email: lacalendar@stroock.com

STROOCK & STROOCK & LAVAN LLP
BRUCE H. SCHNEIDER*
MICHELE L. PAHMER*
GILANA R. KELLER*
180 Maiden Lane
New York, NY 10038-4982
Telephone: 212-806-5400
Facsimile: 212-806-6006
Email: docketing@stroock.com
**Not admitted in this jurisdiction*

Attorneys for Amici Curiae
AMERICAN NURSES ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN ACADEMY OF NURSING, AMERICAN ACADEMY OF PEDIATRICIANS, PHYSICIANS FOR REPRODUCTIVE HEALTH, AND CALIFORNIA MEDICAL ASSOCIATION

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STATE OF CALIFORNIA, et al., Plaintiffs v. HEALTH AND HUMAN SERVICES, et al., Defendants.	Case No. 17-CV-05783-HSG **[PROPOSED] ORDER GRANTING CONSENT MOTION FOR LEAVE TO APPEAR AS AMICI CURIAE AND TO FILE AN AMICUS BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION** Hon. Haywood S. Gilliam, Jr.

On January 7, 2018, American Nurses Association, American College of Obstetricians and Gynecologists, American Academy of Nursing, American Academy of Pediatricians, Physicians for Reproductive Health, and California Medical Association (collectively, "the Health Professional Organization *Amici*") filed a Consent Motion for Leave to Appear as *Amici Curiae* and to File an *Amicus* Brief in Support of Plaintiffs' Motion for a Preliminary Injunction. Having considered the pleadings and papers filed in connection therewith and all other matters presented to the Court, and good cause having been shown:

It is hereby **ORDERED** that the Motion is **GRANTED.** The *Amicus* Brief is deemed filed and served as of this date.

IT IS SO ORDERED.

Dated: _____

_____
Honorable Haywood S. Gilliam, Jr.
United States District Judge

STROOCK & STROOCK & LAVAN LLP
2029 Century Park East
Los Angeles, California 90067-3086