No. 13-354

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*.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit

BRIEF OF AMICUS CURIAE THE OVARIAN CANCER NATIONAL ALLIANCE IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

The Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. § 2000BB *et seq.*, provides that the government "shall not substantially burden a person's exercise of religion" unless that burden is the least restrictive means to further a compelling governmental interest. 42 U.S.C. § 2000BB-1(a) and (b). The question presented is whether RFRA allows a for-profit corporation to deny its employees the health coverage of contraceptives to which the employees are otherwise entitled by federal law, based on the religious objections of the corporation's owners.

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STATEMENT OF INTEREST¹

The Ovarian Cancer National Alliance (the Alliance) is the nation's leading organization fighting to save the lives of women with ovarian cancer. Toward that end, the Alliance advocates nationwide for increased research funding for the development of an early detection test, improved health care

¹ *Amicus curiae* provided all parties with timely notice of its intent to file this brief. All parties have consented to the filing of this brief. No party or counsel for a party authored or paid for this brief in whole or in part, or made a monetary contribution to fund the brief's preparation or submission. No one other than *amicus curiae* or its counsel made a monetary contribution to the brief.

practices, and life-saving treatment protocols. In further support of its mission, the Alliance also promotes increased access to medicines and treatments-including preventive treatments-that can help lower the risk of ovarian and other gynecologic cancers. The Alliance has filed amicus briefs in other cases involving the contraceptivecoverage mandate. See Br. of the Ovarian Cancer Nat'l Alliance, et al., as Amici Curiae in Support of Appellees, Eden Foods, Inc. v. Sebelius, No. 13-1677 (6th Cir. July 30, 2013); Br. of the Ovarian Cancer Nat'l Alliance, et al., as Amici Curiae in Support of Appellees, Gilardi v. HHS, No. 13-5069 (D.C. Cir. June 14, 2013).

The contraceptive-coverage mandate takes an important step toward increasing access to treatments that reduce the risk of ovarian and other gynecologic cancers. Research shows that for many women at higher risk of developing ovarian cancer, oral contraceptives can be the difference between developing ovarian cancer and not developing it. The Tenth Circuit's divided en banc opinion permits forprofit corporations across Colorado, Kansas, New Mexico, Oklahoma, Utah, and Wyoming to deny women enrolled in employer-sponsored health insurance the contraceptive coverage to which they are otherwise entitled under federal law. There is no question that this holding undermines women's access to a critical preventive therapy in the fight against ovarian cancer.

That erroneous holding warrants review and reversal. Left undisturbed, the decision could have wide-reaching medical consequences: ovarian cancer kills over half the women diagnosed with the disease within five years, amounting to thousands of American women each year. And because there is currently no way to reliably detect ovarian cancer at an early stage, prevention remains the primary weapon against this devastating disease. Women living in the states of the Tenth Circuit, unlike those living elsewhere in the country, will be forced to pay out of pocket for that protection or forego it entirely. Such important consequences—resulting from an interpretation of federal law in direct conflict with decisions of other circuits—presents precisely the sort of situation in which this Court's review is warranted. The Alliance respectfully requests that this Court grant certiorari.

SUMMARY OF ARGUMENT

The Tenth Circuit's decision to invalidate application of the contraceptive-coverage mandate to for-profit corporations like Hobby Lobby, Inc. and Mardel, Inc. jeopardizes access to critical preventive care. Oral contraceptives and intrauterine devices (IUDs) are widely recognized preventive therapies for reducing the risk of ovarian, endometrial, and other gynecologic cancers. The Tenth Circuit's decision therefore undermines women's ability to afford potentially life-saving treatments, based solely on a for-profit corporation's religious objection.²

That outcome is particularly troubling given the deadly nature of these gynecologic cancers. Ovarian cancer kills thousands of American women each

² Hobby Lobby covered many of these preventive services *before* the contraceptive-coverage mandate took effect; it was only *after* learning about the mandate that the company "re-examined its insurance policies" and at that point determined that certain previously covered contraceptives should be removed from the Hobby Lobby plan based on a religious objection. Pet. 10.

year. More than half of the women diagnosed with the disease will die within five years, and with no effective way to detect ovarian cancer at an early stage, prevention remains the most effective tool to combat the disease. Endometrial cancer—which forms in the tissue lining of the uterus—likewise kills thousands of American women every year, most of whom are post-menopausal women over the age of sixty. For these women too, contraceptives are a potentially life-saving cancer-preventive treatment.

The cancer-preventive potential of oral contraceptives and IUDs has been corroborated by a plethora of scientific research. That research—and the medical practice of prescribing contraceptives to reduce a woman's risk of developing gynecologic cancer—played a key role in the government's decision-making when it implemented the women's preventive-services provision of the Affordable Care Act. Access to the full benefits contemplated by that provision should not turn on the religious convictions of the owners or controlling shareholders of a forprofit corporation.

The Tenth Circuit's decision affects more than just the mothers, wives, sisters, and daughters insured through the Hobby Lobby and Mardel plans. Other for-profit employers have already successfully invoked the decision to enjoin the contraceptivecoverage mandate's application to them. See Newland v. Sebelius, No. 12-1380, 2013 WL 5481997 Cir. Oct. 3, 2013) (manufacturer (10th and distributor of heating and air conditioning units); Armstrong v. Sebelius, No. 13-cv-00563-RBJ, 2013 WL 5213640 (D. Colo. Sept. 17, 2013) (mortgage company). This Court should grant review now to confirm that the contraceptive-coverage mandate

applies to corporations that run craft stores, manufacture heating and air conditioning units, and offer mortgages, just as it does to all other for-profit corporations.

Certiorari is also warranted because of the circuit split on this issue. See Conestoga Wood Specialties Corp. v. HHS, 724 F.3d 377, 388 (3d Cir. 2013); Autocam Corp. v. Sebelius, No. 12-2673, 2013 WL 5182544, at *7 (6th Cir. Sept. 17, 2013). When the health consequences of negative having а contraceptive-coverage mandate that applies differently depending on geography are added to the mix, the case for certiorari becomes even stronger. Congress contemplated, and the Department of Health and Human Services implemented, a statutory and regulatory scheme designed to be uniform throughout the country. Only then could the full benefits of preventive coverage without cost sharing be realized. But so long as the decision below stands, women living within the Tenth Circuit, in contrast to women living elsewhere, will be deprived of the full prophylactic benefits to which they are otherwise entitled under federal law.

For all these reasons, the Court should grant certiorari and reverse the decision below.

ARGUMENT

ACCESS TO CANCER-PREVENTIVE TREATMENTS FOR WOMEN INSURED THROUGH FOR-PROFIT CORPORATIONS SHOULD NOT TURN ON WHERE THE CORPORATION IS LOCATED.

The requirement that health plans provide members with access to contraception is based on the scientific reality that contraceptives provide significant medical benefits for many women, including benefits that are wholly unrelated to preventing pregnancy. The Health Resources and Services Administration (HRSA) took into account the non-contraceptive benefits that contraceptives have, including reducing the risk of cancer and other serious medical conditions. The Institute of Medicine (IOM) report relied upon by HRSA specifically explained that "[1]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer."³ As the IOM report makes clear, the contraceptive-coverage mandate is based, in part, on the government's compelling interest in ensuring that women have cost-free access to this important preventive treatment.

Myriad studies confirm that the use of oral contraceptives and intrauterine devices (IUDs) corresponds to a lower risk of certain deadly cancers in women, including ovarian, endometrial, and other gynecologic cancers. Requiring most health plans to provide coverage for contraceptives thus promotes women's health by ensuring that all women, regardless of their employer, have access to medical treatments that effectively reduce the risk of some of the most lethal cancers.

1. Oral contraceptives offer life-saving preventive health benefits by reducing the risk of ovarian cancer—a disease that kills more American women each year than any other gynecologic malignancy and kills more than half of the women it afflicts within

³ See Inst. of Med., Clinical Preventive Servs. for Women: Closing the Gaps 3 (2011), available at http://www.iom.edu/ Reports/2011/Clinical-Preventive-Services-for-Women-Closingthe-Gaps.aspx.

five years of diagnosis. In 2013 alone, the National Cancer Institute estimates that 22,240 women will be diagnosed with the disease and 14,030 more will die from it.⁴

Because this form of cancer is so lethal and evades early detection, prevention is the best weapon to combat the disease. Oral contraceptives are one of the few effective non-invasive prevention options.⁵ Indeed, study after study has confirmed the significant protective association between oral contraceptive use and the risk of ovarian cancer.⁶ The results are profound for families in the Tenth Circuit and throughout the country: Contraceptive use has saved thousands of lives. A 2008 study, for example, concluded that oral contraceptives have

⁴ Nat'l Cancer Inst., *Ovarian Cancer*, http://www.cancer.gov/ cancertopics/types/ovarian (last visited Oct. 21, 2013).

⁵ Francesmary Modugno *et al.*, Oral Contraceptive Use, Reproductive History, and Risk of Epithelial Ovarian Cancer in Women With and Without Endometriosis, 191 Am. J. Obstet. Gynecol. 733, 738 (2004); see also Roberta B. Ness *et al.*, Risk of Ovarian Cancer in Relation to Estrogen and Progestin Dose and Use Characteristics of Oral Contraceptives, 152 Am. J. Epidemiol. 233, 233 (2000).

⁶ See, e.g., Laura J. Havrilesky et al., Oral Contraceptive Pills as Primary Prevention for Ovarian Cancer, 0 Obstet. & Gynecol. 1 (2013); Valerie Beral et al., Ovarian Cancer and Oral Contraceptives: Collaborative Reanalysis of Data from 45 Epidemiological Studies Including 23,257 Women with Ovarian Cancer and 87,303 Controls, 371 Lancet 303, 307–12 (2008); Julia B. Greer et al., Androgenic Progestins in Oral Contraceptives and the Risk of Epithelial Ovarian Cancer, 105 Obstet. & Gynecol. 731, 735 (2005); Ness et al., supra, at 239; Harvey A. Risch et al., Parity, Contraception, Infertility, and the Risk of Epithelial Ovarian Cancer, 140 Am. J. Epidemiol. 585, 589 (1994).

prevented some 200,000 cases of ovarian cancer worldwide since the drugs were first approved, saving 100,000 women who otherwise would have died from the disease.⁷

2. Oral contraceptives also play a critical role for women at risk of endometrial cancer. A deadly cancer that forms in the tissue lining the uterus, endometrial cancer is the most common invasive gynecologic cancer among U.S. women. Approximately 49,560 new cases are expected in 2013, and more than 8,000 women are expected to die of endometrial cancer this year.⁸ Endometrial cancer typically occurs in post-menopausal women, with an average age of 60 at diagnosis. There are currently no effective screening or detection methods for endometrial cancer.⁹ The use of combination oral contraceptives (containing estrogen and progestin) is an important part of the fight to prevent endometrial cancer.¹⁰

⁷ Beral, Ovarian Cancer and Oral Contraceptives: Collaborative Reanalysis of Data from 45 Epidemiological Studies Including 23,257 Women with Ovarian Cancer and 87,303 Controls, 371 Lancet at 307, 312.

⁸ Nat'l Cancer Inst., *Endometrial Cancer Screening: Significance*, http://www.cancer.gov/cancertopics/pdq/screening/ endometrial/HealthProfessional/page2 (last visited Oct. 21, 2013).

⁹ Nat'l Cancer Inst., *Endometrial Cancer Screening: Evidence* of *Benefit*, http://www.cancer.gov/cancertopics/pdq/screening/ endometrial/HealthProfessional/page3 (last visited Oct. 21, 2013).

¹⁰ The Cancer and Steroid Hormone Study of the Centers for Disease Control and the National Institute of Child Health and Human Development, *Combination Oral Contraceptive Use and the Risk of Endometrial Cancer*, 257 J. Am. Med. Ass'n 796, 796-797 (1987); M.P. Vessey & R. Painter, *Endometrial and*

3. Intrauterine devices are also used to help reduce the risk of gynecologic cancers. In particular, studies have linked IUD use with a reduced risk of endometrial cancer.¹¹ IUDs also may help prevent cervical cancer.¹²

4. As the foregoing research demonstrates, contraceptives provide significant medical benefits that help save women's lives. These medical benefits have nothing to do with the prevention of pregnancy. This preventive-health effect is—beyond dispute—a compelling governmental interest. The contraceptive-coverage mandate furthers that interest by ensuring women covered by most health plans have access to these life-saving treatments without cost sharing.

A woman's decision about whether to use contraceptives to reduce her risk of developing gynecologic cancers should be made in consultation with her physician based on her health profile and

Ovarian Cancer and Oral Contraceptives—Findings in a Large Cohort Study, 71 Br. J. Cancer 1340, 1340 (1995).

¹¹ See, e.g., Abraham Benshushan et al., IUD Use and the Risk of Endometrial Cancer, 105 Euro. J. Obstet. & Gynecol. & Reprod. Biology 166, 167 (2002); Deirdre A. Hill et al., Endometrial Cancer in Relation to Intra-Uterine Device Use, 70 Int'l J. Cancer 278, 279 (1997); Susan Sturgeon et al., Intrauterine Device Use and Endometrial Cancer Risk, 26 Int'l J. Epid. 496, 498 (1997); F. Parazzini et al., Intrauterine Device Use and Risk of Endometrial Cancer, 70 Br. J. Cancer 672, 673 (1994); Xavier Castellsague et al., Intra-uterine Contraception and the Risk of Endometrial Cancer, 54 Int'l J. Cancer 911, 915 (1993).

¹² Xavier Castellsague *et al.*, Intrauterine Device Use, Cervical Infection with Human Papillomavirus, and Risk of Cervical Cancer: A Pooled Analysis of 26 Epidemiological Studies, 12 Lancet Oncol. 1023, 1028 (2011).

risk factors. Under the current rule in the Tenth Circuit, however, that decision can be skewed by the religious views of the for-profit employer providing the woman's health coverage, which may deny coverage for these potentially life-saving treatments. This case presents an ideal vehicle for the Court to reject that conclusion and ensure that the contraceptive-coverage mandate's prophylactic benefits remain uniform nationwide.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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