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.

CONESTOGA WOOD SPECIALTIES CORP., ET AL.,
Petitioners,

v.

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

Respondents.

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

BRIEF OF AMICI CURIAE THE OVARIAN CANCER NATIONAL ALLIANCE AND ITS PARTNER MEMBERS IN SUPPORT OF THE GOVERNMENT

JESSICA L. ELLSWORTH
Counsel of Record
MICHELLE A. KISLOFF
R. CRAIG KITCHEN*
ANDREW S. FURLOW
MARGIA K. CORNER
HOGAN LOVELLS US LLP
555 Thirteenth St., N.W.
Washington, D.C. 20004
(202) 637-5886

jessica.ellsworth@hoganlovells.com

Counsel for Amici Curiae

^{*} Not admitted in D.C.; supervised by members of the firm

QUESTIONS PRESENTED

- 1. Whether the Religious Freedom Restoration Act of 1993, 42 U.S.C. § 2000bb *et seq.*, 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.
- 2. Whether the requirement that non-exempted, non-grandfathered group health plans include coverage of contraceptives violates the Free Exercise Clause of the First Amendment.

TABLE OF CONTENTS

Page
QUESTIONS PRESENTEDi
TABLE OF AUTHORITIESii
STATEMENT OF INTEREST1
SUMMARY OF ARGUMENT3
ARGUMENT6
I. THE CONTRACEPTIVE-COVERAGE PROVISION FURTHERS A COMPELLING GOVERNMENTAL INTEREST IN EXPANDING ACCESS TO TREATMENTS THAT REDUCE THE RISK OF OVARIAN AND OTHER GYNECOLOGIC CANCERS
II. BECAUSE CONTRACEPTIVES ARE TAKEN FOR NON- CONTRACEPTIVE REASONS— INCLUDING FOR THEIR CANCER- PREVENTIVE EFFECT—ANY BURDEN ON THE INDIVIDUAL- PLAINTIFFS' EXERCISE OF RELIGION IS TOO ATTENUATED TO BE SUBSTANTIAL WITHIN THE MEANING OF RFRA
CONCLUSION20
LIST OF AMICI1a

TABLE OF AUTHORITIES

Page
CASES:
Civil Liberties for Urban Believers v. City of Chicago, 342 F.3d 752 (7th Cir. 2003)18
Eden Foods, Inc. v. Sebelius, No. 13-591 (U.S. Nov. 12, 2013)
Gilardi v. Dep't of Health & Human Servs., 733 F.3d 1208 (D.C. Cir. 2013)3, 15, 17, 19
Gilardi v. Dep't of Health & Human Servs., No. 13-567 (U.S. Nov. 5, 2013)3
Grote v. Sebelius, 708 F.3d 850 (7th Cir. 2013)
Hobby Lobby Stores, Inc. v. Sebelius, 870 F. Supp. 2d 1278 (W.D. Okla. 2012)16
Kammerling v. Lappin, 553 F.3d 669 (D.C. Cir. 2008)18
Korte v. Sebelius, 735 F.3d 654 (7th Cir. 2013)3, 19
United States v. Lee, 455 U.S. 252 (1982)18
STATUTES:
42 U.S.C. § 2000bb-1(a)16
42 U.S.C. § 2000bb-1(b)16

Page	•
REGULATIONS:	
45 C.F.R. § 164.508	7
45 C.F.R. § 164.510	7
Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013)6	;
LEGISLATIVE MATERIALS:	
S. Rep. No. 103-111 (1993)19)
139 Cong. Rec. S14,352 (daily ed. Oct. 26, 1993)	3
OTHER AUTHORITIES:	
Abraham Benshushan et al., IUD Use and the Risk of Endometrial Cancer, 105 Euro. J. Obstet. & Gynecol. & Reprod. Biology 166 (2002)	1
Adam Sonfield, The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing, 14 Guttmacher Pol. Rev. 7 (2011)	1
Alice S. Whittemore et al., Characteristics Relating to Ovarian Cancer Risk: Collaborative Analysis of 12 US Case- Control Studies – II. Invasive Epithelial Ovarian Cancers in White Women, 136 Am. J. Epidemiol. 1184 (1992)	9

	Page
Alice S. Whittemore et al., Oral Contraceptive Use and Ovarian Cancer Risk Among Carriers of BRCA1 or BRCA2 Mutations, 91 Br. J. Cancer 1911 (2004)	13
American Cancer Soc'y, Cancer Facts & Figures 2013	7
Antonis C. Antoniou et al., Reproductive and Hormonal Factors, and Ovarian Cancer Risk for BRCA1 and BRCA2 Mutation Carriers: Results from the International BRCA1/2 Carrier Cohort Study, 18 Cancer Epidemiol. Markers 601 (2009)	12
Baruch Modan et al., Parity, Oral Contraceptives, and the Risk of Ovarian Cancer Among Carriers and Noncarriers of a BRCA1 or BRCA2 Mutation, 345 N.E. J. Med. 235 (2001)	12
Beatrice Godard et al., Risk Factors for Familial and Sporadic Ovarian Cancer Among French Canadians: A Case-Control Study, 170 Am. J. Obstet. Gynecol. 403 (1998)	13
Brief 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)	2
Brief of the Ovarian Cancer Nat'l Alliance, et al., as Amici Curiae in Support of	

	Page
Appellees, Gilardi v. Dep't of Health & Human Servs., No. 13-5069 (D.C. Cir. June 14, 2013)	2
Carlo La Vecchia & Silvia Franceschi, Oral Contraceptives and Ovarian Cancer, 8 Eur. J. Cancer Prev. 297 (1999)	9
Deirdre A. Hill et al., Endometrial Cancer in Relation to Intra-Uterine Device Use, 70 Int'l J. Cancer 278 (1997)	14
F. Parazzini et al., Intrauterine Device Use and Risk of Endometrial Cancer, 70 Br. J. Cancer 672 (1994)	14
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 (2004)	8, 13
Harvey A. Risch et al., Parity, Contraception, Infertility, and the Risk of Epithelial Ovarian Cancer, 140 Am. J. Epidemiol. 585 (1994)	9, 14
Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps (2011)	6
Jacek Gronwald et al., Influence of Selected Lifestyle Factors on Breast and Ovarian Cancer Risk in BRCA1 Mutation Carriers from Poland, 95 Breast Cancer Res. & Treatment 105 (2006)	12

	Page
James Trussell et al., Cost-Effectiveness of Contraceptives in the United States, 79 Contraception 5 (2009)	11
John R. McLaughlin et al., Reproductive Risk Factors for Ovarian Cancer in Carriers of BRCA1 and BRCA1 Mutations: A Case-Control Study, 8 Lancet 26 (2007)	12
Julia B. Greer et al., Androgenic Progestins in Oral Contraceptives and the Risk of Epithelial Ovarian Cancer, 105 Am. Coll. Obstet. & Gynecol. 731 (2005)	9
Karin A. Rosenblatt et al., Intrauterine Devices and Endometrial Cancer, 54 Contraception 329 (1996)	14
Laura J. Havrilesky et al., Oral Contraceptive Pills as Primary Prevention for Ovarian Cancer, Am. Coll. of Obstet. & Gynecol. 1 (2013)	9
Mette Tuxin Faber et al., Oral Contraceptive Use and Impact of Cumulative Intake of Estrogen and Progestin on Risk of Ovarian Cancer, 24 Cancer Causes and Control 2197 (2013)	9
M.P. Vessey & R. Painter, Endometrial and Ovarian Cancer and Oral Contraceptives—Findings in a Large Cohort Study, 71 Br. J. Cancer 1340 (1995)	14

	Page
National Cancer Inst., Surveillance Epidemiology and End Results, Stat Fact Sheet: Ovary Cancer	7
National Cancer Inst., A Snapshot of Ovarian Cancer	8
National Cancer Inst., BRCA1 and BRCA2: Cancer Risk and Genetic Testing	11
National Cancer Inst., Endometrial Cancer Screening: Evidence of Benefit	13
National Cancer Inst., Endometrial Cancer Screening: Significance	13
National Cancer Inst., Genetics of Breast and Ovarian Cancer (PDQ®)	11
National Cancer Inst., Ovarian Cancer	8
National Cancer Inst., Ovarian Cancer Prevention	8
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 (2000)	8, 9
S. Iodice et al., Oral Contraceptive Use and Breast or Ovarian Cancer Risk in BRCA1/2 Carriers: A Meta-Analysis, 46 Euro. J. of Cancer 2275 (2010)	11, 12

	Page
Steven A. Narod, Oral Contraceptives and the Risk of Hereditary Ovarian Cancer, 339 N.E. J. Med. 424 (1998)	Ü
Susan E. Hankinson et al., A Quantitative Assessment of Oral Contraceptive Use and Risk of Ovarian Cancer, 80 Am. J. Obstet. Gynecol. 708 (1992)	9
Susan Sturgeon <i>et al.</i> , <i>Intrauterine Device Use and Endometrial Cancer Risk</i> , 26 Int'l J. Epid. 496 (1997)	14
The Cancer and Steroid Hormone Study of the Ctrs. for Disease Control and the Nat'l Inst. of Child Health and Human Dev., Combination Oral Contraceptive Use and the Risk of Endometrial Cancer, 257 J. Am. Med. Ass'n 796 (1987)	14
The Cancer and Steroid Hormone Study of the Ctrs. for Disease Control and the Nat'l Inst. of Child Health and Human Dev., The Reduction in Risk of Ovarian Cancer Associated with Oral-Contraceptive Use, 316 N.E. J. Med. 650 (1987)	10
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 (2008)	. 9. 10

Pag	ge
Xavier Castellsague et al., Intra-uterine Contraception and the Risk of Endometrial Cancer, 54 Int'l J. Cancer 911 (1993)	15
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 (2011)	15
Xiao Ou Shu et al., Population-Based Case- Control Study of Ovarian Cancer in Shanghai, 49 Cancer Res. 3670 (1989)1	10

IN THE

Supreme Court of the United States

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

Petitioners,

v.

Hobby Lobby Stores, Inc., $\it ETAL.$, $\it Respondents.$

CONESTOGA WOOD SPECIALTIES CORP., ET AL.,

Petitioners.

v.

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

Respondents.

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

BRIEF OF AMICI CURIAE THE OVARIAN CANCER NATIONAL ALLIANCE AND ITS PARTNER MEMBERS IN SUPPORT OF THE GOVERNMENT

STATEMENT OF INTEREST¹

The Ovarian Cancer National Alliance and its partner members (collectively, the "Alliance") are

¹ 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 the *amici curiae* or their counsel made a monetary contribution to the brief. All parties have consented to the filing of this brief in letters lodged with the Clerk.

leading the nationwide effort to save the lives of women with ovarian cancer. Toward that end, the Alliance advocates for increased research funding for the development of an early detection test, improved health care practices, and life-saving treatment protocols. The Alliance has filed amicus briefs in other cases involving the Affordable Care Act's contraceptive-coverage provision in the courts of See Br. of the Ovarian Cancer Nat'l appeals. 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. Dep't of Health & Human Servs., No. 13-5069 (D.C. Cir. June 14, 2013). It is participating here because $ext{the}$ contraceptivecoverage provision takes an important step toward increasing access to treatments that reduce the risk of ovarian and other deadly gynecologic cancers, but the position of the companies and shareholders challenging that provision jeopardizes that access for thousands of women nationwide.

Research shows that for many women at higher risk of developing ovarian cancer, oral contraceptive use can be the difference between developing ovarian cancer and not developing it. Although Plaintiffs in these two cases do not expressly object to most oral contraceptives (as opposed to certain contraceptives), a decision by this Court in Plaintiffs' favor would allow employers to claim entitlement to exemption from the contraceptive-coverage provision as to all FDA-approved contraceptives, including oral contraceptives. That is the conclusion at least two courts of appeals have already reached in cases involving plaintiffs similar to the ones here. See Gilardi v. Dep't of Health & Human Servs., 733 F.3d 1208, 1224 (D.C. Cir. 2013); Korte v. Sebelius, 735 F.3d 654, 687 (7th Cir. 2013). And at least two petitions for certiorari addressing that broader question remain pending in this Court. See Eden Foods, Inc. v. Sebelius, No. 13-591 (Nov. 12, 2013); Gilardi v. Dep't of Health & Human Servs., No. 13-567 (Nov. 5, 2013). The Alliance accordingly believes that its unique insight into the cancer-preventive benefit of oral and other contraceptives may aid this Court in addressing the far-reaching implications of the questions presented.

Ovarian cancer is deadly; it kills over half the women diagnosed with it within five years. amounting to thousands of American women each 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. The contraceptive-coverage provision ensures that women nationwide have access, without cost-sharing, to this important preventive treatment in the battle against ovarian and other gynecologic cancers. Under Plaintiffs' interpretation of the Religious Freedom Restoration Act (RFRA), that access would be subject to veto based solely on the religious views of the owners or controlling shareholders of a woman's for-profit employer. That outcome is neither sound as a matter of health policy nor compelled by RFRA.

SUMMARY OF ARGUMENT

1. The medical practice of prescribing contraceptives to reduce a woman's risk of developing ovarian and other gynecologic cancers played a key role in the government's decision-

making when it implemented the women's preventive-services provision of the Affordable Care Act. The contraceptive-coverage provision is thus based, in part, on the government's compelling interest in ensuring that women have cost-free access to this important medical treatment.

Plaintiffs' RFRA theory jeopardizes access to this 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. These cancers are particularly deadly. Ovarian cancer kills thousands of American women each 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. For these women contraceptives are a potentially life-saving cancerpreventive treatment. Affordable access to such treatment—to which employees in most employersponsored health plans are entitled under federal law—should not be subject to veto by a for-profit corporation's owners or controlling shareholders. The claims of entitlement to a religious exemption from the contraceptive-coverage provision made by Hobby Lobby Stores, Inc., Mardel, Inc., and Conestoga Wood Specialties Corp. (collectively the "Corporate-Plaintiffs")—as well as by the individual owners of these for-profit corporations (collectively the "Individual-Plaintiffs")—should accordingly be rejected.

2. The RFRA claims in these cases require the Individual-Plaintiffs to prove that their exercise of religion is "substantially burdened." In addition to the reasons explained by the government, see Hobby Lobby Petrs' Br. 31-37, there is an independent reason why any burden on the Individual-Plaintiffs' exercise of religion—allegedly caused by owning a business that complies with federal law requiring employee health coverage for the full range of preventive care—is too attenuated to be "substantial" within the meaning of RFRA. The individual owners of a for-profit company are "separated by multiple steps from both the coverage that the company health plan provides and from the decisions that individual employees make in consultation with their physicians as to what covered services they will use." Grote v. Sebelius, 708 F.3d 850, 858 (7th Cir. 2013) (Rovner, J., dissenting). And because contraceptives are often prescribed and taken for non-contraceptive purposes—including to reduce the risk of ovarian, endometrial, and other deadly gynecologic cancers their use in many situations will not result in the socalled "abortifacient" effect that individuals who own for-profit corporations like Hobby Lobby, Mardel, and Conestoga Wood object to on religious grounds. In those circumstances, the companies' coverage of the drug in their employee health plans would not facilitate a practice to which the individual owners religiously object, further attenuating any burden on any individual's exercise of religion. Indeed, under patient privacy laws, an employer is barred from knowing what medical treatment its employees undertake, let alone the purpose for any course of treatment. These additional layers of attenuation mean that any burden on any individual's religious exercise is a hypothetical one, which dooms the RFRA claims in these cases.

ARGUMENT

I. THE CONTRACEPTIVE-COVERAGE
PROVISION FURTHERS A COMPELLING
GOVERNMENTAL INTEREST IN
EXPANDING ACCESS TO TREATMENTS
THAT REDUCE THE RISK OF OVARIAN
AND OTHER GYNECOLOGIC CANCERS

The requirement that most health plans provide their female members with access to contraception is based, in part, on the scientific reality that, for many women, contraceptives provide significant medical benefits wholly unrelated to preventing pregnancy. The Health Resources and Services Administration (HRSA) took into account these "non-contraceptive" benefits that contraceptives have for many women, including reducing their risk of cancer and other serious medical conditions. See Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,872 (July 2, 2013) (noting that "there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy"). Indeed, the Institute of Medicine (IOM) report relied upon by HRSA specifically explained that the "[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer."2 As the IOM report makes clear, the contraceptive-coverage

 $^{^2}$ See IOM, Clinical Preventive Services for Women: Closing the Gaps at 107 (2011), available at http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx.

provision 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. That access—to which women are entitled as a matter of federal law should not be subject to a religion-based veto by the owners or controlling shareholders of the arts-andcrafts store, kitchen-cabinet manufacturer, or other for-profit corporation for which a woman works.

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 malignancy³ and kills more than half of the women it afflicts within five years of diagnosis.⁴ In 2013 alone, the National Cancer Institute (NCI) estimates that 22,240 women will be diagnosed with the disease and

³ American Cancer Soc'y, Cancer Facts & Figures 2013, available at http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-036845.pdf.

⁴ National Cancer Inst., Surveillance Epidemiology and End Results, Stat Fact Sheet: Ovary Cancer, http://seer.cancer.gov/statfacts/html/ovary.html (last visited Jan. 27, 2014).

14,030 more will die from it.⁵ And since there is presently no reliable way to detect ovarian cancer at an early stage, most women learn they have the disease only once it is far too late for treatment to have a high probability of success.⁶

Because this form of cancer is so lethal and evades early detection, prevention is the best weapon to combat the disease. Yet few preventive treatments exist. And among those that do exist, some have drastic consequences. Prophylactic oophorectomy (the preventive removal of the ovaries) and tubal ligation, for example, are invasive surgeries that irreversibly prevent a woman from ever conceiving a child.⁷

A far less invasive option is the use of oral contraceptives, which remain one of the few effective non-invasive preventive options.⁸ Indeed, study after

⁵ NCI, *Ovarian Cancer*, http://www.cancer.gov/cancertopics/types/ovarian (last visited Jan. 27, 2014).

⁶ NCI, A Snapshot of Ovarian Cancer, http://www.cancer.gov/researchandfunding/snapshots/ovarian (last visited Jan. 27, 2014).

⁷ NCI, *Ovarian Cancer Prevention*, http://www.cancer.gov/cancertopics/pdq/prevention/ovarian/Patient/page3 (last visited Jan. 27, 2014).

⁸ 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) ("Oral contraceptives are thought to be the most powerful known chemopreventive agents for ovarian cancer.").

study has confirmed the significant protective association between oral contraceptive use and the risk of ovarian cancer. As a 1999 literature survey concluded, the scientific consensus is that "[t]he protection offered by oral contraceptives against ovarian cancer risk is one of the most consistent epidemiological findings * * * *."9 That significant protective association between oral contraceptive use and the risk of ovarian cancer has been replicated in both retrospective "case-control" studies (which compare women diagnosed with ovarian cancer to women who did not develop the disease) and prospective "cohort" studies (which follow a sample group of women over time and later evaluate whether they develop ovarian cancer).¹⁰

⁹ Carlo La Vecchia & Silvia Franceschi, *Oral Contraceptives* and *Ovarian Cancer*, 8 Eur. J. Cancer Prev. 297, 297 (1999).

¹⁰ See, e.g., Mette Tuxin Faber et al., Oral Contraceptive Use and Impact of Cumulative Intake of Estrogen and Progestin on Risk of Ovarian Cancer, 24 Cancer Causes Control 2197 (2013); Laura J. Havrilesky et al., Oral Contraceptive Pills as Primary Prevention for Ovarian Cancer, Am. Coll. of 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 Am. Coll. 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); Susan E. Hankinson et al., A Quantitative Assessment of Oral Contraceptive Use and Risk of Ovarian Cancer, 80 Am. J. Obstet. Gynecol. 708, 712-14 (1992); Alice S. Whittemore et al., Characteristics Relating to Ovarian Cancer Risk: Collaborative Analysis of 12 US Case-Control

This research demonstrates that oral contraceptives play an important role in medical treatment wholly apart from preventing pregnancy. The real-world results are profound for families throughout the country: Contraceptive use has saved thousands of lives. A 2008 study, for example, concluded that oral contraceptives have 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.11 That number is "likely to increase substantially in the future, with the further ageing of past users of oral contraceptives and the increasing numbers of new users * * * ."12

Accordingly, it is critical that women—particularly those at a high risk for ovarian cancer—have access to affordable oral contraceptives. Absent the contraceptive-coverage provision, the out-of-pocket costs for a ten-year course of oral contraceptives can reach thousands of dollars, even when a woman's

Studies – II. Invasive Epithelial Ovarian Cancers in White Women, 136 Am. J. Epidemiol. 1184, 1192 (1992); The Cancer and Steroid Hormone Study of the Ctrs. for Disease Control and the Nat'l Inst. of Child Health and Human Dev., The Reduction in Risk of Ovarian Cancer Associated with Oral-Contraceptive Use, 316 N.E. J. Med. 650, 654 (1987). But see Xiao Ou Shu et al., Population-Based Case-Control Study of Ovarian Cancer in Shanghai, 49 Cancer Res. 3670, 3673 (1989) (finding a slight increase in ovarian cancer risk associated with oral contraceptive use, although the increase was not significant).

¹¹ Beral *et al.*, *supra*, at 307, 312.

¹² *Id.*

health insurance plan covers these drugs.¹³ The amounts paid by individuals whose insurance does not cover contraceptives at all are even higher.¹⁴ Such substantial out-of-pocket costs may prevent women from maintaining a course of oral contraceptive use, denying these women access to an effective, minimally invasive, chemopreventive agent to reduce their risk of ovarian cancer.

That access is even more important for women at higher risk for ovarian cancer, including women with a family history of the disease and women with endometriosis. Like some breast cancers, some ovarian cancers are caused in part by a familial component, ¹⁵ and a history of ovarian cancer in two or more first-degree relatives is associated with a significant increase in the risk of the disease. ¹⁶

¹³ See Adam Sonfield, The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing, 14 Guttmacher Pol. Rev 7, 9-10 (2011) (providing monthly out-of-pocket costs for contraceptives with insurance coverage); James Trussell et al., Cost-Effectiveness of Contraceptives in the United States, 79 Contraception 5, 10 (2009) (noting the portion of the cost of contraceptives paid by insurers).

¹⁴ See Sonfield, supra, at 9-10 (noting that the out-of-pocket costs for individuals with insurance coverage of contraceptives averages \$14 per month, whereas the out-of-pocket costs for individuals without such coverage averages \$60 per month, not including the cost of the visit to the healthcare provider).

¹⁵ NCI, Genetics of Breast and Ovarian Cancer (PDQ®), http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page1 (last visited Jan. 27, 2014).

¹⁶ NCI, *BRCA1* and *BRCA2*: Cancer Risk and Genetic Testing, http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA (last visited Jan. 27, 2014).

Moreover, there is clear evidence that mutations in the *BRCA1* and *BRCA2* genes account for a large proportion of familial ovarian cancer, conferring a very high lifetime risk of developing the disease. ¹⁷ By age 70, *BRCA1* mutation carriers face a 16 to 66 percent chance of developing ovarian cancer, and BRCA2 mutation carriers face an 11 to 27 percent chance of developing the disease. ¹⁸ Several studies demonstrate that oral contraceptive use reduces the risk among women with these genetic mutations, ¹⁹ potentially more so than in the general population. ²⁰

¹⁷ See S. Iodice et al., Oral Contraceptive Use and Breast or Ovarian Cancer Risk in BRCA1/2 Carriers: A Meta-Analysis, 46 Euro. J. of Cancer 2275, 2276 (2010) (discussing strong evidence supporting association between BRCA1 and BRCA2 mutations and an increased risk for ovarian cancer); Baruch Modan et al., Parity, Oral Contraceptives, and the Risk of Ovarian Cancer Among Carriers and Noncarriers of a BRCA1 or BRCA2 Mutation, 345 N.E. J. Med. 235, 235 (2001) (same).

¹⁸ Antonis C. Antoniou et al., Reproductive and Hormonal Factors, and Ovarian Cancer Risk for BRCA1 and BRCA2 Mutation Carriers: Results from the International BRCA1/2 Carrier Cohort Study, 18 Cancer Epidemiol. Markers 601, 601 (2009).

¹⁹ John R. McLaughlin *et al.*, *Reproductive Risk Factors for Ovarian Cancer in Carriers of BRCA1 and BRCA1 Mutations: A Case-Control Study*, 8 Lancet 26, 31 (2007); Steven A. Narod, *Oral Contraceptives and the Risk of Hereditary Ovarian Cancer*, 339 N.E. J. Med. 424, 426 (1998). *But see* Modan *et al.*, *supra*, at 238 (finding oral contraceptive use had no protective effect in a study of Israeli women with *BRCA1* and *BRCA2* mutations).

²⁰ Iodice et al., supra, at 2282 (finding a 50 percent reduction in risk); Jacek Gronwald et al., Influence of Selected Lifestyle Factors on Breast and Ovarian Cancer Risk in BRCA1 Mutation Carriers from Poland, 95 Breast Cancer Res. &

For these women, oral contraceptives may be the only viable option to reduce their risk of ovarian cancer while still allowing them to someday conceive.

2. Oral contraceptives also play a critical role for women at risk of endometrial cancer. 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 2013,²¹ and more than 8,000 women are expected to die of endometrial cancer this year.²² 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.²³ Use of combination oral

Treatment 105, 107 (2006) (finding an 80 percent reduction in risk); Beatrice Godard et al., Risk Factors for Familial and Sporadic Ovarian Cancer Among French Canadians: A Case-Control Study, 170 Am. J. Obstet. Gynecol. 403, 406 (1998). But see Alice S. Whittemore et al., Oral Contraceptive Use and Ovarian Cancer Risk Among Carriers of BRCA1 or BRCA2 Mutations, 91 Br. J. Cancer 1911, 1913 (2004) (finding the reduction in risk among carriers to be consistent with, but somewhat weaker than, reductions observed in the general population).

²⁰ Modugno et al., supra, at 736.

²¹ NCI, Endometrial Cancer Screening: Significance, http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page2 (last visited Jan. 27, 2014).

NCI, Surveillance Epidemiology and End Results, Stat Fact Sheet: Endometrial Cancer, http://seer.cancer.gov/statfacts/html/corp.html (last visited Jan. 27, 2014).

²³ NCI, Endometrial Cancer Screening: Evidence of Benefit, http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page3 (last visited Jan. 27, 2014).

contraceptives (containing estrogen and progestin) is thus an important part of the fight against endometrial cancer.²⁴

3. Intrauterine devices (IUDs) are also used to help reduce the risk of deadly gynecologic cancers. In particular, several studies have linked IUD use with a reduced risk of endometrial cancer.²⁵ Other studies show that women who have at some point used an IUD experience a significant protective effect—i.e., a reduction in risk of developing endometrial cancer by one-third to one-half—compared to women who have never used an IUD,

²⁴ The Cancer and Steroid Hormone Study of the Ctrs. for Disease Control and the Nat'l Inst. of Child Health and Human Dev., *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 Ovarian Cancer and Oral Contraceptives—Findings in a Large Cohort Study*, 71 Br. J. Cancer 1340, 1340 (1995).

²⁵ 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). But see Karin A. Rosenblatt et al., Intrauterine Devices and Endometrial Cancer, 54 Contraception 329, 330-31 (1996) (finding an association between IUD use and reduced risk of endometrial cancer that was not statistically significant, but that was stronger for copper IUDs than other types of IUDs); Risch et al., supra, at 591 (observing "essentially no" association with use of an IUD).

even after controlling for factors such as age, child-bearing, and family history.²⁶

In addition, IUDs may help prevent cervical cancer. A recent analysis of several international studies, for example, consistently found that women who used an IUD for at least one year reduced their risk of cervical cancer by one half, compared to women who had never used an IUD.²⁷

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. See Gilardi, 733 F.3d at 1240 (Edwards, J., concurring in part and dissenting in part). The contraceptive-coverage provision furthers that interest by ensuring women covered by most health plans have access to these life-saving treatments without cost sharing. under Plaintiffs' interpretation of RFRA, women (and their families) may lose this access basely solely on the religious objections of the owners or controlling shareholders of their for-profit employers. This Court should reject that interpretation and ensure that access to life-saving preventive medical care turns on the health risks of the patient, not the

 $^{^{26}\,}$ Benshushan et al., supra, at 167; Castellsague et al., supra, at 912.

²⁷ 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).

religious views of the owner or controlling shareholder of the patient's employer.

II. **BECAUSE CONTRACEPTIVES** ARE **TAKEN FOR** NON-CONTRACEPTIVE REASONS—INCLUDING **FOR** THEIR **CANCER-PREVENTIVE EFFECT—ANY** BURDEN \mathbf{ON} THE INDIVIDUAL-PLAINTIFFS' EXERCISE OF RELIGION IS TOO ATTENUATED TO BE SUBSTANTIAL WITHIN THE MEANING OF RFRA

To the extent this Court perceives any burden on the Individual-Plaintiffs' exercise of religion, that burden does not constitute a "substantial[] burden" within the meaning of RFRA. 42 U.S.C. § 2000bb-1(a); see id. § 2000bb-1(b). At bottom, the Individual-Plaintiffs' complaint "is that funds, which [the companies they own] will contribute to a group health plan, might, after a series of independent decisions by health care providers and patients covered by [the] plan, subsidize someone else's participation in an activity that is condemned by [the Individual-Plaintiffs'] religion." Hobby Lobby Stores, Inc. v. Sebelius, 870 F. Supp. 2d 1278, 1294 (W.D. Okla. 2012) (internal quotation marks omitted). The health plan "covers many medical services, not just contraception," and the Individual-Plaintiffs are "separated by multiple steps from both the coverage that the company health plan provides and from the decisions that individual employees make consultation with their physicians as to what covered services they will use." Grote, 708 F.3d at 858, 865 (Rovner, J., dissenting). Indeed, federal privacy regulations prohibit employers from learning "whether individual employees purchase

other contraceptive products, orabout anv information regarding employees' health care decisions." Gilardi, 733 F.3d at 1238 (Edwards, J., concurring in part and dissenting in part) (citing 45 §§ 164.508 & 164.510). The Alliance anaccordingly agrees any impact on Individual-Plaintiffs is too indirect and attenuated to qualify as a "substantial burden" on their exercise of religion. See Hobby Lobby Petrs' Br. 31-37.

Yet the incidental burden on the Individualexercise of religion is even more attenuated than the government points out. Because contraceptives are used for preventive and medical reasons aside from pregnancy-prevention, burden entirely hypothetical. When contraceptives to which the Individual-Plaintiffs object are prescribed and taken for non-contraceptive purposes—including, as discussed, to reduce the risk of ovarian, endometrial, and other deadly gynecologic cancers—their use often does not result in the socalled "abortifacient" effect forbidden Individual-Plaintiffs' religious beliefs. Put another way, when a woman, in consultation with her doctor, decides take a contraceptive chemopreventive or other non-contraceptive benefit. the coverage of the drug in the Corporate-Plaintiffs' emplovee health plans does not facilitate "abortifacient" or contraception in any fashion, otherwise. In those circumstances, the Individual-Plaintiffs are not complicit, through the corporations they own, with activity their religion deems wrong, so the Individual-Plaintiffs' exercise of religion is not burdened at all, let alone substantially. additional layer of attenuation dooms their RFRA claims.

A contrary holding would strip he"substantial" of any meaning, "because the slightest obstacle to religious exercise * * * —however minor the burden it were to impose—could then constitute a burden sufficient to trigger [the] requirement that the regulation advance a compelling governmental interest by the least restrictive means." Liberties for Urban Believers v. City of Chicago, 342 F.3d 752, 761 (7th Cir. 2003). Accordingly, the Court need not accept the Individual-Plaintiffs' "legal conclusion, cast as a factual allegation, that [their] religious exercise is substantially burdened." Kammerling v. Lappin, 553 F.3d 669, 679 (D.C. Cir. 2008). Doing so would lead to countless RFRA claims, with the potential for "myriad exceptions flowing from a wide variety of religious beliefs." United States v. Lee, 455 U.S. 252, 260 (1982). And in this context, such exceptions would allow private employers to veto women's affordable access to an important medical benefit to which they otherwise entitled under federal law. Congress could not have intended for RFRA to sweep so far.

Indeed, an examination of RFRA's drafting history demonstrates that Congress intended to circumscribe RFRA's reach. As Senator Kennedy explained when he introduced the amendment adding "substantially" to what originally was only "burden": "this amendment * * * is intended to make it clear that the compelling interest standards set forth in the act provides only to Government actions to place a substantial burden on the [exercise of religion]." 139 Cong. Rec. S14,352 (daily ed. Oct. 26, 1993) (statement of Sen. Kennedy). Senator Hatch, a sponsor of RFRA, further added that RFRA "does not require the Government to justify every action that

has some effect on religious exercise." Id. (statement Sen. Hatch). Congress's inclusion "substantially" thus reflects its expectation that RFRA "would not require [justification pursuant to the compelling-interest test] for every government action that may have some incidental effect on [religion]." S. Rep. No. 103-111, at 9 (1993); see also Gilardi, 733 F.3d at 1235-36 (Edwards, J., concurring in part and dissenting in part) (discussing RFRA's drafting history). To give "substantially" some independent meaning beyond what "burden" already conveys, this Court should conduct "a qualitative assessment of the burden that a challenged statute orother government action imposes individual's exercise of religion." Korte, 735 F.3d at 705 (Rovner, J., dissenting). Conducting that inquiry here, it is plain that the burden on the Individual-Plaintiffs' exercise of religion is, at most, incidental. And an incidental burden is, as a matter of law, insufficient to trigger a RFRA claim.

CONCLUSION

The judgment of the court of appeals in No. 13-354 should be reversed, and the judgment of the court appeals in No. 13-356 should be affirmed.

Respectfully submitted,

JESSICA L. ELLSWORTH

Counsel of Record

MICHELLE A. KISLOFF
R. CRAIG KITCHEN*

ANDREW S. FURLOW

MARGIA K. CORNER

HOGAN LOVELLS US LLP

555 Thirteenth St., N.W.

Washington, D.C. 20004

(202) 637-5886

jessica.ellsworth@hoganlovells.com

January 2014

* Not admitted in D.C.; supervised by members of the firm

Counsel for Amici Curiae

LIST OF AMICI PARTNER MEMBERS OF THE OVARIAN CANCER NATIONAL ALLIANCE

4th Angel Mentoring Program: The Scott Hamilton CARES Initiative

Arkansas Ovarian Cancer Coalition

Betty Allen Ovarian Cancer Foundation

Bluegrass Ovarian Cancer Support Inc.

Bright Pink

Cancer Support Community

CancerDancer

Capital Ovarian Cancer Organization

Caring Together, Inc.

CCare Lynch Syndrome

Celma Mastry Foundation for Ovarian Cancer Research Inc.

Colorado Ovarian Cancer Alliance

Dancing for a Cure

Diane's Voice

Feel Teal Club

FORCE: Facing Our Risk of Cancer Empowered

Georgia Ovarian Cancer Alliance

GRACE'S

HERA Women's Cancer Foundation

Hope for Heather

J's Hope-Ovarian Cancer Awareness, Julianne Guidry Benefit Inc.

JLR Foundation

Kaleidoscope of Hope Foundation

Karene C Pace Ovarian Cancer Foundation Inc.

Michigan Ovarian Cancer Alliance

Midwest Ovarian Cancer Association

Minnesota Ovarian Cancer Alliance, Inc.

Nine Girls Ask for a Cure for Ovarian Cancer

No To O

Norma Leah Foundation

Norma Livingston Ovarian Cancer Foundation

OASIS of Southern California

Ovacome Ovarian Cancer Support and Advocacy of Tampa Bay

Ovar'Coming Together

Ovarcome

Ovarian and Breast Cancer Alliance

Ovarian Awareness of Kentucky

Ovarian Cancer Advocacy Alliance of San Diego

Ovarian Cancer Alliance of Arizona

Ovarian Cancer Alliance of California

Ovarian Cancer Alliance of Florida

Ovarian Cancer Alliance of Greater Cincinnati

Ovarian Cancer Alliance of Ohio

Ovarian Cancer Alliance of Oregon and Southwest Washington

Ovarian Cancer Awareness Foundation of the MidSouth

Ovarian Cancer Circle (Inspired by Robin Babbini)

Ovarian Cancer Coalition of Greater California

Ovarian Cancer Education and Research Network, Inc. (OCERN)

Ovarian Cancer Orange County Alliance

Ovarian Cancer TOGETHER!

Perspectives

Promises of Hope

Ribbons to Remember Foundation, Inc.

Rose Mary Flanagan Ovarian Cancer Foundation

Sandy Rollman Ovarian Cancer Foundation, Inc.

SHARE: Self-Help for Women with Breast or Ovarian Cancer

Sherie Hildreth Ovarian Cancer (SHOC)

Small Cell Ovarian Cancer Foundation

South Carolina Ovarian Cancer Foundation

Space Coast Ovarian/Gynecologic Cancer Alliance

St. Louis Ovarian Cancer Awareness

Stop GCT

Teal Divas

Teal Tea Foundation

Teal Toes

The Sacred Sisterhood of Wonderful Wacky Women Redneck Riviera Chapter, Inc.

The University of Texas MD Anderson Cancer Center

Turn the Towns Teal

Western New York Ovarian Cancer Project

Wisconsin Ovarian Cancer Alliance

You'll Never Walk Alone