

**No. 13-13879**

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**In The**  
**United States Court of Appeals for the Eleventh Circuit**

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**BECKWITH ELECTRIC CO., INC., and**  
**THOMAS R. BECKWITH,**

Plaintiffs – Appellees,

v.

**KATHLEEN SEBELIUS**, in her official capacity  
as Secretary of the United States Department of  
Health and Human Services, *et al.*,

Defendants – Appellants.

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On Appeal from the United States District Court  
for the Middle District of Florida (No. 8:13-cv-648)  
(Hon. Elizabeth A. Kovachevich)

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**BRIEF OF THE OVARIAN CANCER NATIONAL ALLIANCE**  
**AND DR. ANIL K. SOOD AS *AMICI CURIAE* IN SUPPORT**  
**OF APPELLANTS AND REVERSAL**

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October 28, 2013

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**CERTIFICATE OF INTERESTED PERSONS AND  
CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1 and 11th Cir. R. 26.1-2, the undersigned certifies that:

1. To the best of my knowledge, those persons listed in Appellants' October 21, 2013 Certificate of Interested Persons and Corporate Disclosure Statement are a complete list of the trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have or may have an interest in the outcome of this case.

2. *Amicus curiae* the Ovarian Cancer National Alliance (the Alliance) is a non-profit organization that advocates for women with ovarian cancer. The Alliance advocates for increases in research funding for the development of an early detection test, improved healthcare practices and life-saving treatment protocols related to ovarian cancer. Relevant to this litigation, the Alliance also advocates for increased access to medicines and treatments that can help lower the risk of ovarian and other gynecological cancers. The Alliance is a tax-exempt corporation under § 501(c)(3) of the Internal Revenue Code and has no parent corporation. The organization issues no stock and thus no publicly held corporation owns ten percent or more of its stock.

3. *Amicus curiae* Dr. Anil K. Sood is an individual.

October 28, 2013

/s/ Mary Helen Wimberly  
Mary Helen Wimberly  
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## **GLOSSARY\***

**AHRQ:** Agency for Healthcare Research and Quality

**Alliance:** Ovarian Cancer National Alliance

**CDC:** Centers for Disease Control and Prevention

**FDA:** Food and Drug Administration

**HHS:** Department of Health and Human Services

**HPV:** human papillomavirus

**HRSA:** Health Resources and Services Administration

**IOM:** Institute of Medicine

**IUD:** intrauterine device

**NCI:** National Cancer Institute

**USPSTF:** United States Preventative Services Task Force

\* Although not required, a glossary is provided for the convenience of the Court.

## STATEMENT OF INTEREST OF *AMICI*<sup>1</sup>

The Ovarian Cancer National Alliance (the Alliance) is a non-profit organization and the foremost advocate for women with ovarian cancer in the United States. To advance the interests of women with ovarian cancer, the Alliance advocates at a national level for increases in research funding for the development of an early detection test, improved health care practices and life-saving treatment protocols. The Alliance also educates healthcare professionals and raises public awareness of the risks and symptoms of ovarian cancer. The Alliance supports the contraception-coverage mandate in the Affordable Care Act because it increases access to medicines and treatments that can help lower the risk of ovarian and other gynecological cancers and thus respectfully requests that this Court reverse the district court's grant of a preliminary injunction in this case.

Dr. Anil K. Sood, MD, Professor and Vice-Chair, Department of Gynecologic Oncology, MD Anderson Cancer Center is an expert in treating gynecologic cancers. As a practicing gynecologic oncologist, Dr. Sood strongly believes that women should have coverage for oral contraceptives since it is one of

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<sup>1</sup> In accordance with Fed. R. App. P. 29, both parties have consented to the filing of this *amicus* brief. No party's counsel has authored the brief in whole or in part. No party or party's counsel has contributed money intended to fund preparing or submitting this brief. No person other than *amici*, their members, or their counsel has contributed money that was intended to fund preparing or submitting this brief.

the few highly effective approaches for reducing the risk of ovarian and uterine cancers.<sup>2</sup>

### **STATEMENT OF THE ISSUE**

Whether the Religious Freedom Restoration Act (“RFRA”) allows a for-profit, secular corporation to deny its employees the health coverage to which they are otherwise entitled by federal law, based on the religious objection asserted by the corporation’s controlling shareholder.

### **SUMMARY OF ARGUMENT**

The Alliance and Dr. Anil K. Sood (*amici*) support reversal of the district court’s injunction and submit this brief to focus on a single consideration that is central to their missions: the government has a compelling interest in ensuring that women have access to oral contraceptives and intrauterine devices (IUDs), without cost sharing, as preventive therapies to reduce the risk of ovarian, endometrial, and other gynecologic cancers. The district court, in adopting an overly narrow view of the government’s interest in the contraceptive-coverage mandate, ignored this consideration entirely. And because the terms of the injunction and the district court’s reasoning are not limited to emergency contraceptives, unless the decision below is reversed, it will broadly prohibit the federal government from enforcing

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<sup>2</sup> Dr. Sood joins this brief in his individual capacity as an expert in gynecological cancers and not as a representative of the MD Anderson Cancer Center. The views expressed here are his personal views, not the official views of the MD Anderson Cancer Center.

the contraceptive-coverage mandate throughout this Circuit when for-profit corporations seek to deny coverage for contraceptives based on religious beliefs attributed to the corporation's owner.

Ovarian cancer is the most common cause of death from a gynecologic malignancy in the United States. The disease is devastating: more than half of the women diagnosed with ovarian cancer will die within five years.<sup>3</sup> Endometrial cancer, meaning cancer that forms in the tissue lining of the uterus, is the most common invasive gynecologic cancer among U.S. women, typically afflicting those over the age of 60.<sup>4</sup> For decades, scientists have studied the apparent positive effects of contraceptive use on the risk factors for women developing these and other gynecologic cancers. As a result, a large body of research evidence exists in support of the significant association between contraceptive use and lowering a woman's risk of developing a gynecologic cancer. The protective effects of contraceptives are particularly notable for women at increased risk for developing a gynecologic cancer because of family history or other factors.

As a result of this extensive body of research, doctors prescribe contraceptive methods as potentially life-saving, preventive therapies that reduce the risk of developing ovarian, endometrial, and other gynecologic cancers. That

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<sup>3</sup> See *infra* note 19 and surrounding text.

<sup>4</sup> See *infra* note 51 and surrounding text.

medical decision, made between a doctor and a woman at risk for these cancers, has nothing to do with preventing unintended pregnancies. Indeed, the research supporting the cancer-preventing properties of oral contraceptives and IUDs and the medical practice of prescribing them for this purpose were key considerations for the government in determining what preventive services the Affordable Care Act should ensure for women in this country.<sup>5</sup> The regulations challenged here provide access to critical preventive therapies—therapies that should be available to all women, regardless of the religious beliefs of the owner of a for-profit corporation. Accordingly, these regulations serve a compelling governmental interest in promoting public health.

## **ARGUMENT**

### **THE MANDATE SERVES A COMPELLING GOVERNMENTAL INTEREST IN ENSURING ACCESS TO LIFE-SAVING CANCER PREVENTIVE THERAPIES**

No one disputes that the promotion of public health is a compelling government interest.<sup>6</sup> The government sought to advance that interest through Section 1001 of the Affordable Care Act. This section of the Act requires group

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<sup>5</sup> See *infra* notes 12, 14 and surrounding text.

<sup>6</sup> See, e.g., *Mead v. Holder*, 766 F. Supp. 2d 16, 43 (D.D.C.), *aff'd*, 661 F.3d 1 (D.C. Cir. 2011) (citing *Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458, 1462 (D.C. Cir. 1989)).

health plans and health insurance issuers that offer non-grandfathered group or individual health plans to cover certain preventive services without cost-sharing.<sup>7</sup>

Congress delegated to the Health Resources and Services Administration (HRSA) the responsibility to identify preventive care and screenings for women.<sup>8</sup> The Department of Health and Human Services (HHS), of which HRSA is a part, tasked the Institute of Medicine (IOM) with developing recommendations as to what preventive services and screenings would be required.<sup>9</sup> The IOM, in consultation with a committee of experts, ultimately recommended that the HRSA guidelines include “[t]he full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.”<sup>10</sup> HRSA adopted the IOM’s recommendations,<sup>11</sup> subject to an exemption for religious employers.<sup>12</sup>

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<sup>7</sup> See Pub. L. No. 111-148, 124 Stat. 119 (2010).

<sup>8</sup> 42 U.S.C. § 300gg-13(a)(4).

<sup>9</sup> See IOM, *Clinical Preventive Services for Women: Closing the Gaps* at 3 (2011), available at <http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx>.

<sup>10</sup> *Id.*

<sup>11</sup> See HRSA, *Women’s Preventative Services: Required Health Plan Coverage Guidelines*, available at <http://www.hrsa.gov/womensguidelines/>.

<sup>12</sup> Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870 (July 2, 2013) (codified at 45 C.F.R. § 147.131).

The district court's decision to invalidate application of this contraceptive-coverage mandate to for-profit corporations like Beckwith Electric Company jeopardizes access to critical preventive care. Moreover, the court's singular focus on "fewer unintended pregnancies, an increased propensity to seek prenatal care, or a lower frequency of risky behavior endangering unborn babies" overlooks the other substantial public health benefits of the mandate.<sup>13</sup>

That analysis wholly ignores the medical benefits of contraceptives, including for women for whom pregnancy does not represent a medical risk, even though those medical benefits were a key reason the government implemented the contraceptive-coverage mandate in the first place. The IOM report specifically discussed the "non-contraceptive benefits" of contraceptives, such as a reduced risk of cancer and other serious medical conditions. For example, the IOM report noted that the "[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer."<sup>14</sup> Moreover, the IOM noted that the Agency for Healthcare Research and Quality (AHRQ) had undertaken a systematic evidence review (completed in June of this year and discussed further below) "to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian

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<sup>13</sup> Beckwith Electric Co., Inc., et al. v. Sebelius, No. 8:13-cv-0648-T-17MAP at 32 (M.D. Fla. June 25, 2013).

<sup>14</sup> See IOM, *Clinical Preventive Services for Women: Closing the Gaps*, at 107 (2011).



cancer.”<sup>15</sup> As the IOM report makes clear, the contraceptive-coverage mandate is based, in part, on the government’s compelling interest in ensuring that women enrolled in most health plans have access to medical treatments that provide significant preventive medical benefits wholly unrelated to preventing pregnancy. The district court’s opinion, if upheld, would undermine the ability of women throughout this Circuit to afford these potentially life-saving treatments, based solely on a religious objection of the individual who owns the for-profit corporation sponsoring an employee health plan.

The multitude of studies described below demonstrate that the use of oral contraceptives and IUDs corresponds to a lower risk of certain deadly cancers in women, including ovarian, endometrial, and other gynecologic cancers.<sup>16</sup> The requirement that most health plans provide coverage for contraceptives thus promotes the compelling governmental interest of promoting the health of women 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.<sup>17</sup>

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<sup>15</sup> *Id.*

<sup>16</sup> For the Court’s convenience, the scientific studies cited in this brief are included in a concurrently filed addendum.

<sup>17</sup> In addition to the *preventive* benefits discussed herein, physicians also prescribe oral contraceptives to *treat* a number of gynecologic conditions such as premenstrual dysphoric disorder, endometriosis, and dysmenorrhea. *See, e.g.,* Paolo Vercellini *et al.*, *Continuous Use of An Oral Contraceptive for*

**A. Oral Contraceptives Can Have Life-Saving Preventive Health Benefits for Women by Reducing the Risk of Ovarian Cancer.**

Ovarian cancer is the most common cause of death from a gynecological malignancy in the United States.<sup>18</sup> Indeed, more than half of the women diagnosed with ovarian cancer will die within five years of diagnosis.<sup>19</sup> While survival is better with localized, early-stage disease, there is currently no way to reliably diagnose ovarian cancer at an early stage.<sup>20</sup> Due to poor results of screening studies, the United States Preventive Services Task Force (USPSTF) does not recommend ovarian cancer screening in the general population.<sup>21</sup> As a result, most

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*Endometriosis-Associated Recurrent Dysmenorrhea That Does Not Respond to a Cyclic Pill Regimen*, 80 *Fertility & Sterility* 560 (2003), ADD. 227. The use of contraceptives as a medical treatment is beyond the scope of this brief, but further indicates the importance of ensuring access to contraception for reasons besides pregnancy prevention.

<sup>18</sup> Am. Cancer Soc’y, *Cancer Facts & Figures 2013*, available at <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-036845.pdf> (last visited Oct. 28, 2013).

<sup>19</sup> NCI, *Surveillance Epidemiology and End Results, Stat Fact Sheet: Ovary*, available at <http://seer.cancer.gov/statfacts/html/ovary.html> (last visited Oct. 28, 2013) (“[t]he overall 5-year relative survival for 2003-2009 from 18 SEER geographic areas was 44.2%. Five-year relative survival by race was: 44.0% for white women; 36.1% for black women”).

<sup>20</sup> NCI, *A Snapshot of Ovarian Cancer*, <http://www.cancer.gov/researchandfunding/snapshots/ovarian> (last visited Oct. 28, 2013).

<sup>21</sup> USPSTF, *Screening for Ovarian Cancer*, <http://www.uspreventiveservicestaskforce.org/uspstf/uspsovar.htm> (last visited Oct. 28, 2013).

women who receive a diagnosis of ovarian cancer do so only after they have reached an advanced stage of the disease.<sup>22</sup> The National Cancer Institute (NCI) estimates that there will be 22,240 new cases of ovarian cancer and 14,030 deaths from the disease in 2013.<sup>23</sup>

Given the high case-fatality rate associated with ovarian cancer and the lack of effective early detection techniques, prevention represents a critical opportunity to reduce morbidity and mortality rates of the disease. Unfortunately, however, women and their physicians have few viable options for reducing the risk of ovarian cancer. Some options, including prophylactic oophorectomy (the preventive removal of the ovaries) and tubal ligation, are invasive surgeries that irreversibly prevent a woman from ever conceiving a child.<sup>24</sup>

A far less invasive option is chemoprevention, generally defined as the prevention or delay of cancer through the use of medicines, vitamins, or other agents. Oral contraceptives are the only chemopreventive medications researchers

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<sup>22</sup> NCI, *A Snapshot of Ovarian Cancer*, <http://www.cancer.gov/researchandfunding/snapshots/ovarian> (last visited Oct. 28, 2013).

<sup>23</sup> NCI, *Ovarian Cancer*, <http://www.cancer.gov/cancertopics/types/ovarian/> (last visited Oct. 28, 2013).

<sup>24</sup> NCI, *Ovarian Cancer Prevention*, <http://www.cancer.gov/cancertopics/pdq/prevention/ovarian/Patient/page3> (last visited Oct. 28, 2013).

have identified for ovarian cancer.<sup>25</sup> Moreover, oral contraceptives are appealing chemopreventive agents because they are well tolerated and their side effects are understood.<sup>26</sup> In addition, a woman can use oral contraceptives as a chemopreventive measure for a certain length of time, and later decide to suspend that use in order to become pregnant.

Researchers first identified an association between oral contraceptive use and a lowered risk of ovarian cancer over thirty-five years ago, in 1977.<sup>27</sup> Since that time, a large body of evidence has accumulated in support of the significant protective association between oral contraceptive use and the risk of ovarian cancer.<sup>28</sup> Indeed, a 1999 review of the published literature concluded: “[t]he

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<sup>25</sup> 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), ADD. 132; *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.”), ADD. 140.

<sup>26</sup> Steven A. Narod *et al.*, *Oral Contraceptives and the Risk of Hereditary Ovarian Cancer*, 339 *N.E. J. Med.* 424, 424 (1998), ADD. 135.

<sup>27</sup> *See* Muriel L. Newhouse *et al.*, *A Case-Control Study of Carcinoma of the Ovary*, 31 *Br. J. Prev. Soc. Med.* 148, 153 (1977), ADD.154.

<sup>28</sup> *See, e.g.*, Laura J. Havrilesky *et al.*, *Oral Contraceptive Pills as Primary Prevention for Ovarian Cancer*, 0 *Am. Coll. of Obstet. & Gynecol.* 1 (2013), ADD. 81; 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–

protection offered by oral contraceptives against ovarian cancer risk is one of the most consistent epidemiological findings . . . .”<sup>29</sup> These epidemiological studies include both case-control studies, which retrospectively compare women diagnosed with ovarian cancer (cases) to women did not develop the disease (control), and cohort studies, which prospectively follow a sample group of women (a cohort) over a period of time and subsequently evaluate whether those women develop ovarian cancer.

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12 (2008), ADD. 20-25; 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), ADD. 63; Ness *et al.*, *Risk of Ovarian Cancer in Relation to Estrogen and Progestin Dose and Use Characteristics of Oral Contraceptives*, 152 *Am. J. Epidemiol.* at 239, ADD. 146; Harvey A. Risch *et al.*, *Parity, Contraception, Infertility, and the Risk of Epithelial Ovarian Cancer*, 140 *Am. J. Epidemiol.* 585, 589 (1994), ADD. 161; Susan E. Hankinson *et al.*, *A Quantitative Assessment of Oral Contraceptive Use and Risk of Ovarian Cancer*, 80 *Obstet. Gynecol.* 708, 712–14 (1992), ADD. 78-80; 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, 1192 (1992), ADD. 242; The Cancer and Steroid Hormone Study of the Centers for Disease Control and the National Institute of Child Health and Human Development, *The Reduction in Risk of Ovarian Cancer Associated with Oral-Contraceptive Use*, 316 *N.E. J. Med.* 650, 654 (1987), ADD. 214. *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), ADD. 193.

<sup>29</sup> Carlo La Vecchia & Silvia Franceschi, *Oral Contraceptives and Ovarian Cancer*, 8 *Eur. J. Cancer Prev.* 297, 297 (1999), ADD. 104.

The repeated corroboration of the protective association between the use of contraceptives and the risk of developing ovarian cancer, from both types of studies, is persuasive evidence that there may be a clinical benefit to using oral contraceptives to help prevent ovarian cancer. Indeed, AHRQ recently completed systematic evaluation of all of the scientific studies related to the use of oral contraceptives for primary prevention of ovarian cancer, which found a consistent decrease in risk for ovarian cancer associated with use of oral contraceptives, including an identifiable decrease in risk for women at high risk of developing ovarian cancer.<sup>30</sup>

A 2008 study, for example, evaluated the public health benefit of the chemopreventive use of oral contraceptives, and concluded that since the Food and Drug Administration (FDA) first approved oral contraceptives nearly 50 years ago, they have prevented some 200,000 cases of ovarian cancer worldwide, saving 100,000 women who otherwise would have died from the disease.<sup>31</sup> The study predicted that “[t]he number of cancers prevented each year is likely to increase

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<sup>30</sup> See AHRQ, *Evidence-Based Practice Center Report, Oral Contraceptive Use for the Primary Prevention of Ovarian Cancer*, <http://www.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html> (last visited Oct. 28, 2013).

<sup>31</sup> 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, *ADD.* 20, 25.

substantially in the future, with the further ageing of past users of oral contraceptives and the increasing numbers of new users . . . .”<sup>32</sup>

While the beneficial effect of oral contraceptive use persists even after women discontinue taking the medications,<sup>33</sup> studies show that the chemopreventive effect is more pronounced during treatment or shortly thereafter.<sup>34</sup> The beneficial effect also increases when women take the medication for a relatively long duration, such as five to ten years.<sup>35</sup> Indeed, a meta-analysis

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<sup>32</sup> *Id.*

<sup>33</sup> Hankinson, *A Quantitative Assessment of Oral Contraceptive Use and Risk of Ovarian Cancer*, 80 Am. J. Obstet. Gynecol. at 713, ADD. 79; Lynn Rosenberg *et al.*, *A Case-Control Study of Oral Contraceptive Use and Invasive Epithelial Ovarian Cancer*, 139 Am. J. Epidemiol. 654, 659–60 (1994), ADD. 175-76.

<sup>34</sup> Greer, *Androgenic Progestins in Oral Contraceptives and the Risk of Epithelial Ovarian Cancer*, 105 Am. Coll. Obstet. & Gynecol. at 735 (2005), ADD. 63; Ness, *Risk of Ovarian Cancer in Relation to Estrogen and Progestin Dose and Use Characteristics of Oral Contraceptives*, 152 Am. J. Epidemiol. at 239, ADD. 146.

<sup>35</sup> Joellen M. Schildkraut *et al.*, *Impact of Progestin and Estrogen Potency in Oral Contraceptives on Ovarian Cancer Risk*, 94 J. Nat’l Cancer Inst. 32, 35 (2002), ADD. 185; Ness, *Risk of Ovarian Cancer in Relation to Estrogen and Progestin Dose and Use Characteristics of Oral Contraceptives*, 152 Am. J. Epidemiol. at 239, ADD. 146; The Cancer and Steroid Hormone Study of the Centers for Disease Control and the National Institute of Child Health and Human Development, *The Reduction in Risk of Ovarian Cancer Associated with Oral-Contraceptive Use*, 316 N.E. J. Med. at 652, ADD. 212. *But see* Whittemore, *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. at 1200 (finding a waning of protection to users for six or more years), ADD. 250.

published in June 2013 found a reduction in incidence of more than 50 percent among women who used oral contraceptives for ten or more years.<sup>36</sup>

Accordingly, it is critical for women—particularly those at a high risk for ovarian cancer—to have access to affordable oral contraceptives over a long period so that they can take full advantage of these preventive benefits in consultation with their physicians. Absent the mandate, the out-of-pocket costs for a ten-year course of oral contraceptives can cost thousands of dollars, even when a woman's health insurance plan covers these drugs.<sup>37</sup> The amounts paid by individuals whose insurance does not cover contraceptives at all are even higher.<sup>38</sup> 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.

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<sup>36</sup> Havrilesky, *Oral Contraceptive Pills as Primary Prevention for Ovarian Cancer*, 0 Am. Coll. Obstet. & Gynecol. at 1, ADD. 81.

<sup>37</sup> See Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing*, 11 Guttmacher Pol. Rev. at 9-10 (providing monthly out-of-pocket costs for contraceptives with insurance coverage), ADD. 197-98; James Trussell *et al.*, *Cost-Effectiveness of Contraceptives in the United States*, 79 Contraception 5, 10 (2009) (citing the portion of the cost contraceptives paid by insurers), ADD. 221.

<sup>38</sup> See Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing*, 11 Guttmacher Pol. Rev. at 9-10 (2011) (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), ADD. 197-98.



As noted above, access to affordable oral contraceptives 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,<sup>39</sup> and a history of ovarian cancer in two or more first-degree relatives is associated with a significant increase in the risk of ovarian cancer.<sup>40</sup> 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 this cancer type.<sup>41</sup> The ovarian cancer risk by age 70 has been estimated to be 16 percent to 66 percent in *BRCA1* mutation carriers and 11 percent to 27 percent in

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<sup>39</sup> Nat'l Cancer Inst., *Genetics of Breast and Ovarian Cancer (PDQ®)*, <http://www.cancer.gov/cancertopics/pdq/genetics/breast-and-ovarian/HealthProfessional/page1> (last visited Oct. 28, 2013).

<sup>40</sup> Nat'l Cancer Inst., *BRCA1 and BRCA2: Cancer Risk and Genetic Testing*, <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (last visited Oct. 28, 2013).

<sup>41</sup> 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), ADD. 95; 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), ADD. 121.

*BRCA2* mutation carriers.<sup>42</sup> Several studies have demonstrated that oral contraceptive use reduces the risk among carriers of these genetic mutations,<sup>43</sup> potentially more so than in the general population.<sup>44</sup>

Women with endometriosis also have a greater risk of developing ovarian cancer.<sup>45</sup> Endometriosis is a condition in which endometrial tissue grows outside

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<sup>42</sup> 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), ADD. 2.

<sup>43</sup> 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), ADD. 117; Narod, *Oral Contraceptives and the Risk of Hereditary Ovarian Cancer*, 339 *N.E. J. Med.* at 426, ADD. 137. *But see* Modan, *Oral Contraceptives, and the Risk of Ovarian Cancer Among Carriers and Noncarriers of a BRCA1 or BRCA2 Mutation*, 345 *N.E. J. Med.* at 238 (finding oral contraceptive use had no protective effect in a study of Israeli women with *BRCA1* and *BRCA2* mutations), ADD. 124.

<sup>44</sup> Iodice, *Oral Contraceptive Use and Breast or Ovarian Cancer Risk in BRCA1/2 Carriers: A Meta-Analysis*, 46 *Euro. J. of Cancer* at 2282 (finding a 50 percent reduction in risk), ADD. 101; 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, 107 (2006) (finding an 80 percent reduction in risk), ADD. 71; 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), ADD. 54. *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), ADD. 256.

of the uterus on other organs in the body, such as the ovaries, the Fallopian tubes, or the lining of the pelvic cavity, sometimes causing severe pain. The disease is a common health problem among women; more than 5 million women in the United States are afflicted with it.<sup>46</sup> The increased risk associated with endometriosis is pronounced: One study observed a 90 percent excess risk of ovarian cancer (compared to the expected risk) among women in Sweden who had been hospitalized with endometriosis and found that the risk of ovarian cancer among such women significantly increased over time.<sup>47</sup> For these women, access to oral contraceptives is critical.

Physicians often prescribe oral contraceptives to treat the symptoms of endometriosis.<sup>48</sup> In addition, studies show that oral contraceptives reduce the risk

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<sup>45</sup> Modugno, *Oral Contraceptive Use, Family History, and Risk of Epithelial Ovarian Cancer in Women With and Without Endometriosis*, 191 *Am. J. Obstet. Gynecol.* at 736, ADD. 130.

<sup>46</sup> Women'sHealth.gov, *Endometriosis Fact Sheet*, <http://womenshealth.gov/publications/our-publications/fact-sheet/endometriosis.cfm> (last visited Oct. 28, 2013).

<sup>47</sup> Louise A. Brinton *et al.*, *Cancer Risk After A Hospital Discharge Diagnosis of Endometriosis*, 176 *Am. J. Obstet. & Gynecol.* 572, 575 (1997), ADD. 31.

<sup>48</sup> *See, e.g.,* Paolo Vercellini *et al.*, *Continuous Use of An Oral Contraceptive for Endometriosis-Associated Recurrent Dysmenorrhea That Does Not Respond to a Cyclic Pill Regimen*, 80 *Fertility & Sterility* 560 (2003), ADD. 227.

of ovarian cancer among women with endometriosis.<sup>49</sup> In contrast, other treatments for endometriosis, such as danazol, have been associated with an increased risk of ovarian cancer.<sup>50</sup>

**B. Use of Oral Contraceptives Is Also Associated with Reduced Risk for Endometrial Cancer.**

Use of oral contraceptives also may help reduce the risk of another type of gynecologic cancer: endometrial cancer. Endometrial cancer—which is cancer that forms in the tissue lining the uterus and includes several different types of tissue abnormalities (known as histologic subtypes)—is the most common invasive gynecologic cancer among U.S. women. Approximately 49,560 new cases are expected in 2013,<sup>51</sup> and more than 8,000 women are expected to die of endometrial cancer this year.<sup>52</sup> Endometrial cancer typically occurs in postmenopausal women, with an average age of 60 at diagnosis. Certain women, including women who have had estrogen hormone replacement therapy or who

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<sup>49</sup> Modugno, *Oral contraceptive use, family history, and risk of epithelial ovarian cancer in women with and without endometriosis*, 191 *Am. J. Obstet. Gynecol.* at 736, ADD. 130.

<sup>50</sup> Greer, *Androgenic Progestins in Oral Contraceptives and the Risk of Epithelial Ovarian Cancer*. 105 *Gynecol Oncol* at 737, ADD. 65.

<sup>51</sup> NCI, *Endometrial Cancer Screening: Significance*, <http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page2> (last visited Oct. 28, 2013).

<sup>52</sup> *Id.*

have been treated with tamoxifen, may also be at increased risk of endometrial cancer.<sup>53</sup> Other risk factors include: never having children, obesity, and early menarche (first menstruation) and late menopause, among others.<sup>54</sup> There are currently no effective screening or detection methods for endometrial cancer;<sup>55</sup> instead, doctors often identify the disease only after a woman experiences its symptoms, such as abnormal vaginal bleeding. In addition, a NCI study suggests that African-American women are diagnosed at later stages of the disease and have a higher mortality rate.<sup>56</sup>

The Centers for Disease Control and Prevention (CDC) and the National Institute of Child Health and Development completed a case-control study of cancers of the breast, endometrium, and ovary in multiple centers across the United

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<sup>53</sup> NCI, *Endometrial Cancer Screening: Special Populations*, <http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page4> (last visited Oct. 28, 2013).

<sup>54</sup> NCI, *Endometrial Cancer Screening: Summary Evidence*, <http://www.cancer.gov/cancertopics/pdq/prevention/endometrial/HealthProfessional> (last visited Oct. 28, 2013).

<sup>55</sup> NCI, *Endometrial Cancer Screening: Evidence of Benefit*, <http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page3> (last visited Oct. 28, 2013).

<sup>56</sup> NCI, *Endometrial Cancer Screening: Significance*, <http://www.cancer.gov/cancertopics/pdq/screening/endometrial/HealthProfessional/page2> (last visited Oct. 28, 2013).

States, called the “Cancer and Steroid Hormone Study.”<sup>57</sup> Analyses of data gathered during the study found that women who had used combination oral contraceptives (containing estrogen and progestin) for at least twelve months had a reduced age-adjusted risk of developing endometrial cancer, and that this protective effect existed for all three major histologic types of endometrial cancer.<sup>58</sup> A cohort study that followed women in England and Scotland over the course of nearly 20 years similarly found a protective effect against endometrial cancer, but the number of women in the study who developed endometrial cancer (15) was too small to allow for a more detailed analysis.<sup>59</sup>

**C. Intrauterine Devices Also May Help Reduce the Risk of Gynecologic Cancers.**

As with oral contraceptives, IUDs have preventive benefits beyond their use for contraception. These devices too are prescribed to some patients to lower the risk of certain types of cancer. In particular, several studies have found a

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<sup>57</sup> 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 (1987), ADD. 205.

<sup>58</sup> *Id.* at 797, ADD. 206.

<sup>59</sup> 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), ADD. 231.

correlation between IUD use and a reduced risk of endometrial cancer.<sup>60</sup> In studies, women who had at some point used an IUD experienced a significant protective effect—i.e., a reduction in risk of developing endometrial cancer by one-third to one-half—compared to women who had never used an IUD, even after controlling for factors such as age, child-bearing, and family history.<sup>61</sup>

In addition, IUDs have a protective association with a lower risk of cervical cancer. A recent analysis of several international studies of human papillomavirus (HPV) and cervical cancer 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

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<sup>60</sup> Abraham Benshushan *et al.*, *IUD Use and the Risk of Endometrial Cancer*, 105 *Euro. J. Obstet. & Gynecol. & Reprod. Biology* 166, 167 (2002), ADD. 13; Deirdre A. Hill *et al.*, *Endometrial cancer in Relation to Intra-Uterine Device Use*, 70 *Int'l J. Cancer* 278, 279 (1997), ADD. 91; Susan Sturgeon *et al.*, *Intrauterine Device Use and Endometrial Cancer Risk*, 26 *Int'l J. Epid.* 496, 498 (1997), ADD. 202; F. Parazzini *et al.*, *Intrauterine Device Use and Risk of Endometrial Cancer*, 70 *Br. J. Cancer* 672, 673 (1994), ADD. 156; Xavier Castellsagué *et al.*, *Intra-uterine Contraception and the Risk of Endometrial Cancer*, 54 *Int'l J. Cancer* 911, 915 (1993), ADD. 40. *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), ADD. 179-80; Risch, *Parity, Contraception, Infertility, and the risk of Epithelial Ovarian Cancer*, 140 *Am. J. Epidemiol.* at 591 (observing “essentially no” association with use of an IUD), ADD. 163.

<sup>61</sup> Benshushan, *IUD Use and the Risk of Endometrial Cancer*, 105 *Eur. J. Obstet. & Gynecol. & Reprod. Biology* at 167, ADD. 13; Castellsagué, *Intra-uterine Contraception and the Risk of Endometrial Cancer*, 54 *Int'l J. Cancer* at 912, ADD. 37.

never used an IUD.<sup>62</sup> The results were consistent across women who had different numbers of screening Pap smears (used to detect cervical cancer) and across women who tested positive or negative for HPV (known to cause certain types of cervical cancers).<sup>63</sup>

Like oral contraceptives, an IUD can be expensive,<sup>64</sup> and without health insurance coverage (or even with health insurance coverage that imposes cost sharing), women who cannot afford those costs are likely to forego that care.

**D. The Government Has a Compelling Interest in Protecting Public Health.**

The promotion of public health is a compelling government interest.<sup>65</sup> More specifically, the government has a compelling interest in ensuring broad access to contraceptives as a means to promote public health. Indeed, aside from the benefits associated with delaying or preventing pregnancy, the studies cited herein demonstrate that contraceptives are one of the few evidence-based methods for the

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<sup>62</sup> Xavier Castellsagué *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), ADD. 47.

<sup>63</sup> *Id.*

<sup>64</sup> See James Trussell *et al.*, *Update on and Correction to the Cost-Effectiveness of Contraceptives in the United States*, 85 *Contraception* 218, 218 (2012) (updating the study results to reflect an increase in the average wholesale price for brand IUD products), ADD. 226.

<sup>65</sup> See *supra* at note 6.



prevention of certain deadly gynecological cancers, even in women who are not at increased risk of negative medical consequences of pregnancy. Indeed, beyond preventing pregnancy, the extensive research cited herein shows that FDA-approved contraceptives can serve as an important preventive tool to protect women's health. The government therefore had ample basis, and a compelling interest, in classifying contraceptives as preventive therapies to reduce the risk of these cancers. As with any medical intervention, each woman who elects to use contraceptive treatments—whether to lower her risk of gynecological cancers or for any other reason—should do so only after consultation with her physician. The contraceptive mandate ensures that women will have the opportunity to elect to use these potentially life-saving preventive therapies, regardless of their employers' religious views.

### CONCLUSION

The Ovarian Cancer National Alliance and Dr. Anil K. Sood urge the Court to reverse the district court's decision.

October 28, 2013

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

I hereby certify that in reliance on the word count feature of the software used to prepare this brief – Microsoft Word 2010 – this brief complies with the type-volume limitations of Fed. R. App. P. 29(b) and 32(a)(7)(B) because it contains 5,495 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I further certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), as it has been prepared in a 14-point, proportionally spaced typeface, Times New Roman.

October 28, 2013.

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**CERTIFICATE OF SERVICE**

I hereby certify that, on this 28th day of October, 2013, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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