[ORAL ARGUMENT NOT YET SCHEDULED]
Nos. 12-5273 & 12-5291

IN THE

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

WHEATON COLLEGE and BELMONT ABBEY COLLEGE,

Appellants,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, HILDA SOLIS, Secretary of the United States Department of Labor, UNITED STATES DEPARTMENT OF LABOR, TIMOTHY GEITHNER, Secretary of the United States Department of the Treasury, and UNITED STATES DEPARTMENT OF THE TREASURY,

Appellees.

On Appeal from the United States District Court
For the District of Columbia

BRIEF *AMICUS CURIAE* OF WOMEN SPEAK FOR THEMSELVES IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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Dated: October 12, 2012

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties. All parties before the District Court and in this Court are listed in the Brief for Appellants (Dkt. 1398401) filed on October 5, 2012. Disclosure statements for proposed *amicus* Women Speak for Themselves are provided immediately following this Certificate and incorporated herein.

B. Rulings Under Review.

1. *Wheaton Coll.* v. *Sebelius,* --- F. Supp. 2d ---, 2012 WL 3637162 (D.D.C. Aug. 24, 2012) (Huvelle, J.); JA 264 (order dismissing suit for lack of standing and ripeness and denying motion for preliminary injunction as moot).

2. *Belmont Abbey Coll.* v. *Sebelius,* --- F. Supp. 2d ---, 2012 WL 2914417 (D.D.C. July 18, 2012) (Boasberg, J.); JA 63 (order dismissing suit for lack of standing and ripeness).

3. *Belmont Abbey Coll.* v. *Sebelius,* 2012 WL 3861255 (D.D.C. Sept. 5, 2012) (Boasberg, J.); JA 108 (order denying plaintiff's motion for reconsideration).

C. Related Cases. The twenty-eight (28) related cases challenging the same regulation in federal district courts around the nation are listed in the Brief for Appellants (Dkt. 1398401) filed on October 5, 2012.

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rule 26.1, *Amicus* Women Speak for Themselves makes the following disclosure:

Women Speak for Themselves is a program of the Chiaroscuro Institute, a educational nonprofit organization recognized as tax-exempt under section 501(c)(3) of the Internal Revenue Code. The Chiaroscuro Foundation, a private foundation recognized as tax-exempt under section 501(c)(3) of the Internal Revenue Code is its parent corporation. There is no publicly held corporation with a 10 percent or greater ownership interest in the Chiaroscuro Institute.

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GLOSSARY

FDA: Food and Drug Administration

HHS: U.S. Department of Health & Human Services

HIV: human immunodeficiency virus

HRSA: the Health Resources and Services Administration

IOM: Institute of Medicine

IUD: intrauterine device

NCI: National Cancer Institute

RFRA: Religious Freedom & Restoration Act

STI: sexually transmitted infection

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Appellants (Dkt. 1398401).

INTEREST OF AMICUS CURIAE[1]

Women Speak for Themselves, a program of the non-profit Chiaroscuro Institute, arose out of an open letter signed as of this writing by **more than 36,000 women**. Co-drafted by attorneys Helen Alvaré and Kim Daniels,[2] the open letter provides in part:

> Those currently invoking "women's health" . . . **have never responded to the large body of scholarly research indicating that many forms of contraception have serious side effects**, or that some forms act at some times to destroy embryos, or that government contraceptive programs inevitably change the sex, dating and marriage markets in ways that lead to more empty sex, more non-marital births and more abortions. It is women who suffer disproportionately when these things happen. No one speaks for all women on these issues. Those who purport to do so are simply attempting to deflect attention from the serious religious liberty issues currently at stake . . . .[3]

This amicus brief is submitted in the interest of conveying objective information not addressed in the parties' briefs concerning the HHS Mandate's

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[1] Pursuant to Cir. Rule 29, counsel certifies that the parties have consented to the filing of this brief and that it is impracticable to join with other amici due to the fact bound nature of the brief. Counsel further certifies that no party or party's counsel authored this brief in whole or in part, or contributed money that was intended to fund the brief.

[2] Helen M. Alvaré, president of the Chiaroscuro Institute, is a law professor at George Mason University specializing in the areas of family law, and law and religion. This brief is on behalf of Women Speak for Themselves; it in no way represents the views or opinions of George Mason University or its employees. The open letter was co-drafted by Kim Daniels, Director of Catholic Voices USA.

[3] The full text of the Women Speak for Themselves open letter is available at http://www.womenspeakforthemselves.com.

impact on Belmont Abbey College and Wheaton College ("the Colleges"), both in regard to their rights of conscience and the potential health effects on the women they employ and educate. The Colleges' claims are ripe for review, and such review is urgent in light of the significantly increased risks to women's health ignored by the Government.

In sum, *Amicus* have an interest in bringing this Court's attention to the fact that, in promulgating the HHS Mandate, the Government disregarded – indeed, never considered, the large body of relevant, widely available, scientifically sound scholarly research of serious health risks arising from the use of hormonal contraceptives.[4] For this reason, the Government cannot demonstrate that application of the HHS Mandate to a religiously objecting employer "is in furtherance of a compelling governmental interest" – particularly its asserted interest of promoting women's health by expanding access to "preventive" health services. Indeed, the HHS Mandate fails the most important test of showing a

[4] The term "contraceptive" as used in this brief reflects terminology used by the Government in the HHS Mandate. *Amicus*, however, acknowledge the Colleges' religious objection to the capacity of some of the so-called "contraceptive" drugs and devices to terminate the life of a human being at the embryonic stage of development. For a brief analysis of the underlying embryology and pharmacology, *see* HHS Comment filed on behalf of Dr. Maureen L. Condic, Thomas Berg and James Capretta, *available at* http://bdfund.org/wordpress/wp-content/uploads/2012/06/FINAL.Berg_.Capretta.Condic-HHS-ANPR-Comment.6.15.2012.pdf.

compelling interest in preventive medicine: it increases risk of disease instead of decreasing it.

SUMMARY OF THE ARGUMENT

In consultation with medical and science advisors,[5] *Amicus* emphasize that in promulgating the HHS Mandate,[6] the Government disregarded – indeed, never considered – the robust body of medical evidence indicating that hormonal contraceptives have biological properties that significantly increase women's risks of breast, cervical and liver cancer, stroke, and a host of other diseases including human immunodeficiency virus (HIV). These risks have been recognized not only by other agencies of the Government itself, but also by reputable international

[5] Medical and science advisors who assisted in the compilation of studies presented in this brief include **John M. Thorp, Jr., M.D.**, professor, women's health researcher, and ObGyn director of the UNC Women's Primary Healthcare; **Mary Davenport, M.D.,** obstetrician/gynecologist and president of AAPLOG; **Angela Lanfranchi, M.D., F.A.C.S**., breast surgical oncologist, and co-founder of the Breast Cancer Prevention Institute; **Maureen L. Condic, PhD,** research scientist and embryologist at the University of Utah; and **Joel Brind, PhD**, scientist and professor at Baruch College in the City University of New York system. All universities are listed for purposes of identification only; this brief in no way represents the views of the named universities, nor of any of its employees.

[6] Certain Preventive Services under the Affordable Care Act ("the Mandate"), finalized at 77 Fed. Reg. 8725 (Feb. 15, 2012).

medical authorities including the World Health Organization, which classifies combined oral contraceptives as "Group 1: Carcinogenic to Humans."[7]

Since it completely ignored this widely available, scientifically sound scholarly research, the 2011 IOM report did not even try to establish that on balance the putative health benefits outweighed the significantly increased health risks. Because the Government relied on the defective IOM report to define "preventive" health services, and because the burden is on the Government to prove that its mandated conduct is in *furtherance* of its claimed compelling interest, the Government has failed as a matter of law to establish that it may trample the College's sincere religious objections.

In sum, the Government cannot demonstrate that application of the HHS Mandate to a religiously objecting employer "is in furtherance of a compelling governmental interest" – especially its asserted interests in promoting women's health and gender equity.

In Section I, *Amicus* address how the Government has failed to show that the HHS Mandate furthers its asserted interest of expanding women's preventive health services. Subsection A reveals the flaws and misinformation in the

[7] *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 2007; 91:74–84 (discussed by Kathleen T. Ruddy, M.D. at http://breastcancerbydrruddy.com/?page_id=2).

Government-adopted IOM report. Subsection B presents a survey of peer-reviewed medical studies reporting significant increased health risks.

In Section II, *Amicus* address how the Government has failed to produce evidence showing that the Mandate furthers its asserted interest of promoting gender equity by equalizing health care costs.

ARGUMENT

I. THE GOVERNMENT HAS FAILED TO SHOW THAT THE HHS MANDATE FURTHERS ITS ASSERTED COMPELLING INTEREST IN PROMOTING THE HEALTH AND WELL-BEING OF WOMEN.

On August 1, 2011, pursuant to the Affordable Care Act,[8] the Government agency known as HRSA (Health Resources and Services Administration) adopted in full the guidelines[9] recommended by a report of the Institute of Medicine (IOM).[10] That 2011 IOM report recommended that "preventive services" for

[8] The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) requires all group health plans to provide coverage for certain preventive services without cost-sharing, including "for women, such additional preventive care and screenings . . . as provided in comprehensive guidelines supported by [the Health Resources and Services Administration ('HRSA')]." 42 U.S.C. § 300gg-13.

[9] Health Resources and Services Administration (HRSA), *Women's Preventive Services: Required Health Plan Coverage Guidelines*, available at http://www.hrsa.gov/womensguidelines/

[10] In developing its guidelines, IOM invited a select number of groups to make presentations on the preventive care that should be mandated by all health plans. These included groups that vigorously advocate for abortion, contraceptives and abortifacient drugs including the Guttmacher Institute, the National Women's Law Center, and Planned Parenthood Federation of America. No groups that oppose

women include all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives, and intrauterine devices.[11] Notably, the IOM report completely ignored the relevant, widely available, scientific research establishing significant *increased* health risks of hormonal contraceptives, as set forth below. Consequently, it did not even try to establish that on balance the putative health benefits of hormonal contraceptives outweighed the significantly increased health risks.

The HRSA publication officially adopted this defective IOM report as the basis for including hormonal contraceptives in its definition of women's "preventive" health services. That publication indicated the Government's interest in "coverage for women's health and well-being" by expanding access to "preventive services that have *strong scientific evidence of their health benefits*."[12]

Yet, the Government's reference to "strong scientific evidence" of health benefits is an empty assertion. As summarized below, a large body of peer-

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government-mandated coverage of contraception, sterilization, abortion, and related education and counseling were among the invited presenters.

[11] Institute of Medicine, *Clinical Preventive Services For Women: Closing the Gaps* (2011) ("2011 IOM"), *available at* http://books.nap.edu/openbook.php?record_id=13181 (emphasis added).

[12] Health Resources and Services Administration (HRSA), *Women's Preventive Serivices: Required Health Plan Coverage Guidelines*, available at http://www.hrsa.gov/womensguidelines/ (emphasis added).

reviewed medical evidence establishes that hormonal contraceptives significantly increase a woman's risk of heart attack, blood clots, stroke, breast cancer, cervical cancer, liver tumors, sexually transmitted infections and the contracting and transmission of human immunodeficiency virus (HIV). This evidence is recognized by national and international health agencies, including the World Health Organization, who classifies combined oral contraceptives as "Group 1: carcinogenic to humans."[13]

In fact, many of the surveyed studies were funded by the Government's own National Institutes of Health and recognized on the fact sheets of the National Cancer Institute. Yet, this medical evidence remained wholly unaddressed by the incomplete and poorly sourced 2011 Institute of Medicine (IOM) report relied upon almost exclusively by the Government in finalizing the HHS Mandate.

Because of the large body of evidence regarding serious contraceptive health risks, along with the fact that fertility and pregnancy are not disease states, the mandate of hormonal contraceptives "fail[s] the most important test of preventive

[13] Combined oral contraceptives are classified as a group 1 carcinogen for breast, cervical and liver cancers according to the World Health Organization's International Agency on Research of Cancer (IARC). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 2007; 91:174–84, *available at* http://monographs.iarc.fr/ENG/Monographs/vol91/mono91.pdf. (discussed by Kathleen T. Ruddy, M.D. at http://breastcancerbydrruddy.com/?page_id=2).

medicine: they increase risk of disease instead of decreasing it."[14] Therefore, the Government simply cannot demonstrate that application of the HHS Mandate to objecting employers "is in furtherance of a compelling governmental interest."[15]

While the Government's interest in "preventive services" for "women's health and well-being" may be valid, its act of coercing objecting employers to cover drugs that significantly increase risks to women's health certainly fails to further that interest. As explained by the U.S. Supreme Court, "We do not doubt the validity of these interests, any more than we doubt the general interest in promoting public health and safety. . .but under RFRA **invocation of such general interests, standing alone, is not enough**." *Gonzales v. O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 438 (2006)(emphasis added).

Women in our pluralistic society remain free to face the attendant health risks that come with choosing to use hormonal contraceptives. However, it is a violation of basic tenets of religious liberty for religious institutions or religiously

[14] Rebecca Peck, M.D., C.C.D. and Charles W. Norris, M.D., *Significant Risks of Oral Contraceptives (OCPs)*, 79(1) The Linacre Quarterly 41, 42 (February 2012).

[15] The Religious Freedom Restoration Act (RFRA) prohibits the Federal Government from substantially burdening a person's exercise of religion, "even if the burden results from a rule of general applicability," 42 U.S.C. §2000bb–1(a), except when the Government can "demonstrat[e] that application of the burden to the person (1) [furthers] a compelling government interest; and (2) is the least restrictive means of furthering that . . . interest," 42 U.S.C. § 2000bb-1(b). As set forth herein, the IOM report's failure to consider or balance the evidence of increased risks undermines any Governmental assertion that the Mandate furthers its asserted interests.

observant employers to be coerced by the Government to provide no-cost coverage for drugs that not only violate their rights of conscience, but that also expose women and girls to serious and often life-threatening health risks, all in the name of promoting public health.

A. The IOM report does not support the Government's assertion that increased use of contraceptives will promote the health of women.

Citing the 2011 Institute of Medicine report,[16] the Government asserts that by increasing access to contraceptives, the Mandate will promote public health by decreasing unintended pregnancies, promoting the spacing of births, and preventing pregnancy in women with conditions for which pregnancy is contraindicated. However, the government has failed to show that the Mandate would prevent these negative health consequences. "Nearly all of the research is based on correlation, not evidence of causation, and most of the studies suffer from significant, admitted flaws in methodology." *Brown v. Entm't Merchs. Ass'n.,* 564 U.S. ____, 131 S. Ct. 2729, 2739 (2011) (quotation marks omitted).

The IOM admits that for many negative outcomes from unintended pregnancy, "research is limited."[17] The IOM cites its 1995 report, which similarly

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[16] Institute of Medicine, *Clinical Preventive Services For Women: Closing the Gaps* (2011) ("2011 IOM"), *available at* http://books.nap.edu/openbook.php?record_id=13181.

[17] 2011 IOM at 103.

emphasizes the fundamental difficulty in defining which pregnancies are "unintended," and in distinguishing between association and causation in assessing the risks of unintended pregnancies.[18]

The 1995 IOM report concedes that no causal link has been established for most of its alleged factors. This makes sense, since the intendedness or unintendedness of a pregnancy cannot itself physiologically change its health effect. Thus, a delay in seeking prenatal care for an unintended pregnancy may be "no longer statistically significant" for women who are not already disposed to delay or who have a "support network,"[19] -- as do the Colleges' insured employees, as well as the employees' spouses and dependents.

The IOM report cites to other behavioral risk factors linked with unintended pregnancy, including smoking, drinking, depression, and domestic violence.[20] However, it is impossible to say, and the IOM report does not attempt to prove, that unintended pregnancy leads to these negative behaviors and unhealthy situations. Rather, the linkage between them and unintended pregnancy is in many cases likely to be one of association, not causation.

The IOM's suggestion that increased access to contraceptives will reduce

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[18] Institute of Medicine, *The Best Intentions* (1995) ("1995 IOM"), *available at* http://books.nap.edu/openbook.php?record_id=4903&page=64 (last visited September 20, 2012).

[19] *Id*. at 68.

[20] 2011 IOM at 103.

low birth weight and prematurity overlooks the fact that, like other cited factors, these are merely "associated" with, not caused by, unintended pregnancy (2011 IOM at 103; 1995 IOM at 70); the IOM itself cites studies showing no connection between low birth weight and pregnancy-spacing in the U.S.[21]

Notably, the 2011 IOM report claims to cite a systematic review on low birth weight, but the citation is incorrect.[22] The IOM then cites three studies showing an association between low birth weight/preterm delivery and shorter pregnancy intervals.[23] The IOM report fails to note that all three studies found these same negative outcomes for lengthy pregnancy intervals, a condition likely to follow upon increased contraceptive use.

The IOM also failed to consider the risks of low birth weight that arise from contraceptive use itself: a 2009 Canadian study shows that women who conceive within 30 days of going off contraceptive pills significantly increase the risk of low birth weight and very low birth weight.[24]

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[21] 1995 IOM at 70-71.

[22] 2011 IOM at 103, 166 (citing "Shah, et al., 2008"). The Shah study does not address low birth weight; it was study of cardiovascular disease in young women with gestational diabetes. Shah, B. R., R. Retnakaran, and G. L. Booth. 2008. Increased risk of cardiovascular disease in young women following gestational diabetes mellitus. *Diabetes Care* 31(8):1668–1669.

[23] *Id*. at 103.

[24] Chen, et al., "Recent oral contraceptive use and adverse birth outcomes," 144 *European Journal of Obstetrics & Gynecology and Reproductive Biology* 40–43

Finally, the government's reliance on the special needs of some women, such as those with diabetes, to avoid pregnancy ignores the fact that these women comprise a far smaller group than the Mandate covers, and for that reason, the Mandate as currently structured is not narrowly tailored. Focused care to help women with these conditions could achieve the Mandate's goals, with the government providing contraceptive services itself if such services were medically indicated.

B. The IOM report ignores the substantial evidence showing that hormonal contraceptives pose serious health risks to women including cancers, stroke and the acquisition and transmission of HIV.

By adopting the incomplete and poorly sourced 2011 IOM report, the Government failed to balance any putative benefits of contraceptives against the substantial body of evidence indicating that hormonal contraceptives significantly increase a woman's risk of heart attack, blood clots, stroke, breast cancer, cervical cancer, liver tumors, sexually transmitted infections and the contracting and transmission of HIV.

A non-exhaustive survey of the relevant and widely available peer-reviewed medical studies, none of which were ever addressed in the IOM report, indicate the following serious health risks:

(May 2009), *abstract available at* http://www.ejog.org/article/S0301-2115(09)00074-8/.

1. **Serious Health Risks of Oral Contraceptive Pills**

   a. **Higher risk of heart attack, stroke & cardiovascular complications.** Among women with no conventional risk factors for heart disease, those who take oral contraceptives have twice the risk of heart attack.[25] Those with hypertension had five times the risk; those who smoked, 12 times the risk; those who had diabetes, 16 times the risk; those who had high cholesterol, 23 times the risk.[26] A meta-analysis of 16 studies found that women who used oral contraceptives had nearly three times the risk of ischemic stroke; for those with risk factors such as high blood pressure or migraine headaches, the risk was significantly higher.[27] Hormonal contraceptives also lead to significantly higher incidence of deep venous thrombosis (blood clots in legs)[28] and pulmonary embolism.[29]

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[25] Tanis BC, et al. Oral contraceptives and the risk of myocardial infarction. *New England Journal of Medicine* 2001;345:1787-93.

[26] *Id*.

[27] Gillum, LA. Ischemic stroke risk with oral contraceptives. *JAMA* July 5 2000;284:72-78.

[28] van Hylckama Vlieg A, et al. Venous thrombotic risk of oral contraceptives, effects of oestrogen does and progestogen type: results of the MEGA case-control study. *BMJ* 2009;339 doi: 10.136/bmj.b2921.

[29] Lindegaard O, et al. Risk of venous thromboembolism from use of oral contraceptives containing different progestogens and oestrogens. Danish cohort study 2001-9. *BMJ* 2011;343:d6423.

b. **Higher risk of breast cancer.** A meta-analysis published in 2006 showed a 44% increased risk of breast cancer in women who took oral contraceptives before having a child.[30] In 2007, the World Health Organization's International Agency on Research of Cancer (IARC) reported that estrogen-progestin combination drugs (the Pill) were a Group 1 carcinogen for breast, cervical, and liver cancers.[31] A 2009 study showed a 320% increase risk of triple negative breast cancer, the most difficult and deadly form of breast cancer to treat, in women taking oral contraceptives.[32] Although the risk of uterine and ovarian cancers appears lower for women taking contraceptives, there is four times more breast cancer in women than uterine and ovarian cancers combined.[33]

c. **Higher risk of cervical cancer.** The Government's own National Cancer Institute (NCI) recognized studies showing a threefold to

[30] Kahlenborn C, et al. Oral contraceptive use as a risk factor for premenopausal breast cancer: A meta-analysis. 2006 *Mayo Clinic Proc* 2006;81(10):1290-1302

[31] IARC 2007 Monograph 91. Combined estrogen-progestogen contraceptives and combined estrogen-progestogen menopausal therapy. Available at: http://monographs.iarc.fr/ENG/Monographs/vol91/mono91.pdf

[32] Dolle J, et al. Risk factors for triple negative breast cancer in women under the age of 45. *Cancer Epidemiol Biomarkers Prev* 2009;18(4):1157-65.

[33] *See*, Cancer Statistics by Cancer Type, Centers for Disease Control. Available at: http://www.cdc.gov/cancer/dcpc/data/types.htm (last visited September 20, 2012)

fourfold increase risk of cervical cancer:

> In a 2002 report by the International Agency for Research on Cancer, … data from eight studies were combined to assess the association between oral contraceptive use and cervical cancer risk among women infected with the human papillomavirus (HPV). Researchers found a nearly threefold increase in risk among women who had used oral contraceptives for 5 to 9 years compared with women who had never used oral contraceptives. Among women who had used oral contraceptives for 10 years or longer, the risk of cervical cancer was four times higher.[34]

d. **Higher risk of liver tumors/cancer.** As stated in the Government's own NCI Factsheet, "Oral contraceptive use is associated with an increase in the risk of benign liver tumors [that] have a high risk of bleeding or rupturing." Moreover, "[s]ome studies have found that women who take oral contraceptives for more than 5 years have an increased risk of [malignant liver tumors known as] hepatocellular carcinoma, but others have not." [35]

e. **Greater susceptibility to sexually transmitted infections.** Women taking oral contraceptives are twice as likely to be infected with the genital human papillomavirus (HPV) virus, leading to cervical cancer,

[34] National Cancer Institute: Oral Contraceptives and Cancer Risk (March 21 2012) *citing* Moreno V, Bosch FX, Munoz N, et al. Effect of oral contraceptives on risk of cervical cancer in women with human papillomavirus infection: the IARC multicentric case-control study. *Lancet* 2002; 359(9312):1085–1092.

[35] *Id.*, *citing* La Vecchia C, Tavani A. Female hormones and benign liver tumours. Digestive and Liver Disease 2006; 38(8):535–536.

as women not taking oral contraceptives.[36] While the studies on HIV risk and *oral* contraceptives show mixed results, one well-known study finds that women taking the pill are 60% more likely to be infected with the HIV virus than those who are not.[37] In addition to physiological changes caused by hormonal contraceptives leading to increased susceptibility to sexually transmitted infections (STIs), recent studies indicate that increased access to emergency contraceptives leads to behavioral changes, i.e., increased risk-taking in sexual behavior, that not only cancels out any decrease in the rate of unplanned pregnancy among adolescents, but also drives up the rate of STIs.[38]

2. Serious Health Risks of Long-Acting Contraceptives

As might be predicted by standard microeconomic theory, the "no-cost" element of the HHS Mandate will not only increase use of low-cost pills and emergency contraceptives, it will also increase incentives for women and adolescents to choose the previously cost-prohibitive "long-acting methods," such

[36] Franceschi S, et al. Genital warts and cervical neoplasia: an epidemiological study. *Br J Cancer* 1983;48:621-28.

[37] Wang CC, et al. Risk of HIV infection in oral contraceptive pill users: a meta-analysis *JAIDS* 1999;May 1 21(1):51-58

[38] See Girma, s. et al. The impact of emergency birth control on teen pregnancy and STIs. *Journal of Health Economics* 30 (2011) 373–380.

as injectable contraceptives, implants, and intrauterine devices (IUDs). This decrease in cost results in an increase in exposure of women and teenagers to even more dangerous health consequences as shown below, including an alarming doubled risk of HIV for users of injectable contraceptives.

According to *A Pocket Guide to Managing Contraception* (*MC*)[39], methods of long-acting contraception include:

(1) **ParaGard© Intrauterine Copper IUD:** With a high upfront cost of $475 for the device alone, exclusive of the medical costs of screening and insertion, the copper IUD can result in **uterine perforation** and other malpositioning that can result in **increased bleeding or pain**, and **injury or damage to the surrounding organ**s.[40]

(2) **Mirena© levonorgestrel-releasing IUD:** Unlike ParaGard©, which contains no steroidal hormones, the Mirena© IUD releases levonorgestrel (LNG) into the uterine environment. In addition to risks of **uterine perforation**, which were the subject of a warning letter sent by FDA to the manufacturer Bayer, Mirena has been linked to **ovarian cysts**, a higher profile for **pelvic inflammatory disease** (PID), and irregular bleeding. Also, in the rare case in which a woman conceives while using the Mirena, a

[39] Zieman, N, Hatcher R.A. et al., *A Pocket Guide to Managing Contraception.* Tiger, GA: Bridging the Gap Foundation, 2010, at 37. "*Managing Contraception*" or *MC* is a condensed version of the primary medical textbook on contraception—Hatcher, R.A. et al., *Contraceptive Technology* (20th rev. ed.). Atlanta, GA: Ardent Media, Inc., 2011.

[40] Braaten, K.P. et al., "Malpositioned IUDs: When you should intervene (and when you should not)." *OBG Management* 2012; 24(8):39-46, citing Bernacerraf, B.R. et al. "Three-dimensional ultrasound detection of abnormally located intrauterine contraceptive devices which are a source of pelvic pain and abnormal bleeding." *Ultrasound Obstet Gynecol* 2009; 34(1):110-115.

resultant loss of pregnancy and a **possible permanent loss of fertility** may result.[41]

(3) **Implanon©**: This device is a plastic implant rod containing progestogen etonogestrel which is surgically inserted under the skin of the upper arm; It replaced Norplant© which is no longer marketed in the U.S., after over 50,000 women filed lawsuits—including 70 class actions—over severity of side effects.[42] In addition to **ectopic pregnancy** risks, the manufacturer warning reports "serious thromboembolic events, including cases of **pulmonary emboli (some fatal)** and **strokes**, in patients using IMPLANON."[43]

(4) **Depo-Provera©:** This is a popular injectable progestogen intended to last up to three months. In addition to this injection's **black box warning on loss of bone mineral density**,[44] Depo-Provera use has been shown to result in a **doubled risk of acquiring and transmitting HIV**, as discussed below.

In October 2011, the *New York Times* gave front-page coverage to the rigorous Heffron study[45] reporting that it had been published in a very prestigious peer-reviewed journal after its presentation had raised alarm months earlier at an

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[41] Mirena® Label, Warnings and Precautions; *See also* Uterine Perforation Risk from Mirena, *available at* http://www.womens-health.co.uk/uterine-perforation-risk-from-mirena.html.

[42] CT, *supra* n. 38.

[43] Implanon© Warnings, *available at* http://www.implanon-usa.com/en/HCP/learn-about-it/get-the-facts/warnings/index.asp.

[44] *See* Susan E. Wills, *Depo Provera: What the NYT Did Not See Fit to Print*, National Review Online (Nov. 3, 2011).

[45] Heffron R., et al. Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study. *Lancet Infect Dis* 2012; 12:19-26.

international AIDS conference. The Heffron study resulted in convincing findings that injectable contraceptives have "biological properties" that appear to "*double* the risk that women will become infected with H.I.V," and further finding that "when it is used by HIV-positive women, their male partners are *twice as likely to become infected* than if the women had used no contraception."[46]

The study focused on Depo-Prevera, a drug covered by the HHS Mandate.[47] Of particular note is a statement by the director of the women and foreign policy program at the Council on Foreign Relations: **"If it is now proven that [injectable] contraceptives are helping spread the AIDS epidemic, we have a major health crisis on our hands**."[48]

* * *

The 2011 IOM report appears oblivious to the host of adverse health consequences from the contraceptive methods it claims will promote women's health. The only consequences it discusses are "side effects" (which it says are

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[46] Pam Bellock, *Contraceptive Used in Africa May Double Risk of H.I.V.*, N.Y. Times, October 3, 2011(covering Heffron study, *supra*)(emphasis added).

[47] Other serious health risks of injectable Depo Provera – also ignored by the Government-adopted IOM report – include serious blood clots which can lead to cardiac arrest and stroke; breast cancer and ectopic pregnancy. *See* Susan E. Wills, *Depo Provera: What the NYT Did Not See Fit to Print*, National Review Online (Nov. 3, 2011).

[48] *Id.* (emphasis added).

"generally considered minimal"[49]) and death rates that can be directly linked to contraceptive use.[50] It completely ignores the range of health risks between those extremes, even though the Government itself acknowledges these risks on the National Cancer Institute websites, and indeed funds many of the studies discussed above through the National Institutes of Health.[51]

The IOM report upon which the Government exclusively relied also appears oblivious to the fact that the very conditions it uses to illustrate why some women need to postpone pregnancy (e.g., diabetes, obesity, pulmonary hypertension) and therefore to justify its recommendation to facilitate access to contraception, are the same conditions that put women at greatly increased risk for cardiovascular problems from contraceptive use.

Because it ignored the many serious health risks for women posed by hormonal contraceptives, the 2011 IOM report did not even try to prove that on balance the putative health benefits outweighed the significantly increased health

[49] 2011 IOM cites ACOG informational brochures for its benign judgment on the "side effects" of hormonal contraceptives (2011 IOM at 105,135), neglecting to mention that these brochures additionally contain discussions of the "risks" of oral contraceptives, including, as outlined above, heart attacks, strokes, blood clots, and liver tumors.

[50] 2011 IOM at 105-06.

[51] See, e.g., Heffron, *supra*, which states: "Funding: US National Institutes of Health and the Bill & Melinda Gates Foundation."

risks.[52] Since the Government relied on the defective IOM report, and because the burden is on the Government to prove that its mandated conduct furthers its claimed compelling interest, the Government has failed as a matter of law to establish that it may disregard with impunity the College's sincere religious objections. Without such a balancing, it has not shown that the Mandate, by purportedly increasing access to contraception, furthers the Government's interest in promoting women's health.

II. THE GOVERNMENT HAS FAILED TO SHOW THAT THE MANDATE FURTHERS ITS ASSERTED INTEREST OF PROMOTING GENDER EQUITY.

In other litigation defending the Mandate, the Government has attempted to assert another allegedly compelling governmental interest, namely, promoting gender equity by removing the unequal financial barriers to health care, specifically preventive care, that arise from higher out-of-pocket costs for women's gender-specific conditions. The Government presumes that relieving women of

[52] The Government-adopted IOM report also failed to address or take into account a variety of natural methods of family planning and birth spacing that are as effective as artificial methods of contraception and don't pose any health risks or side effects to the woman. *See, e.g.* Fehring, R, Schneider M, Barron ML. Cohort comparison of two fertility awareness methods of family planning. *J Reprod Med* 2009;54:165–70; *See also,* Frank-Herrmann P. et al., The effectiveness of a fertility awareness based method to avoid pregnancy in relation to a couple's sexual behaviour during the fertile time: a prospective longitudinal study. *Oxford Journals, Human Reproduction* 2007; 22:1310-1319.

these costs will lead to equal access to health care, better health, and therefore equal opportunities to participate in the workplace with men. Underlying this argument are a number of premises for which the Government has provided little or no supporting evidence.

First, as set forth in the preceding section, the Government has failed to show that the Mandate will in fact improve women's health. Indeed, there is substantial evidence that widespread and lengthy use of contraceptives by women has resulted and will result in significant harm to their health. This conclusion in and of itself disposes of the Government's alleged "gender equity" interest. The Government has not asserted a compelling interest in increasing access to and utilization of contraceptives apart from its interest in promoting women's health. It has not argued, and there is no evidence in the legislative record from which it could argue, that Congress intended to increase access to contraceptives for the sake of women being able to avoid pregnancy and childbearing solely as a means of achieving gender equity. Rather, its argument is that, only by being relieved of the inequitable financial burden women face in maintaining their health can they achieve gender equity. Thus, if contraceptives do not promote women's health, they do not promote the government's asserted interest in gender equity. As set forth in Section I. A and B, *supra*, the Government has failed to show that contraceptives promote women's health.

Even assuming *arguendo* that contraceptives in some measure promote women's health, there is a fundamental flaw underlying the Government's argument that providing contraceptive services to women at no cost will eliminate a gender-related burden in the cost of health care. The assertion that women incur greater out-of-pocket expenses for preventive care than men (77 Fed. Reg. 8725, 8728) omits a crucial piece of information: out of whose pocket?

Three categories of women would receive contraceptives at no cost under the Mandate: the Colleges' female employees, the wives of male employees, and the female dependent children of employees.

There is no reason to believe the out-of-pocket health care expenses of the wives of the Colleges' employees are currently being borne solely by them, rather than being a shared household expense, just as the groceries are. Similarly, the out-of-pocket expenses of the female dependents of the Colleges' employees are presumptively being borne by the employees on whom they are *dependent*. Thus, for spouses and dependents, the Mandate does not relieve women of a burden unequally shared with men. Rather, it shifts a burden from the employee's household onto the Colleges. As such, it does nothing to further Government's asserted interest in gender equity.

In the case of a covered employee herself, the Government simply assumes that her out-of-pocket health care expenses are borne by her alone. However,

considering in particular the out-of-pocket expenses for contraceptives, the employee's need for contraceptives indicates some intimate relationship with a man, quite possibly her husband. The Government apparently assumes without proof that men -- whether husbands, roommates, or some other role -- in intimate relationships with women do not contribute to the costs of whatever contraceptive method is used by the couple. But without such proof, there is no reason to believe that women are carrying an inequitable burden when it comes to the costs of contraceptives. And, without such proof, there is no reason to believe that the Mandate does anything but shift the financial burden of contraceptives, not from the woman, but from the couple onto the employer -- again, doing nothing to further the asserted governmental interest in promoting gender equity.

In sum, the facts showing that the Government failed to balance the underlying medical literature can lead to no other conclusion than that the Government has failed to carry its burden of proving that the coercive Mandate furthers its asserted interest in promoting women's health or gender equity.

CONCLUSION

For the foregoing reasons, *Amicus* Women Speak for Themselves respectfully urge this Court to grant an order reversing and remanding the judgments below dismissing the Colleges' cases, and to grant the request of Wheaton College for an order reversing and remanding the trial court's denial of its motion for preliminary injunction, and instructing the court to promptly decide that motion.

Respectfully submitted,

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DATED: October 12, 2012

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7(C) of the Federal Rules of Appellate Procedure, I hereby certify that this brief complies with the type-volume limitations set forth in that rule. This brief contains 3,752 words (exclusive of the cover, table of contents, table of authorities and other front matter). I relied on my word processor, Microsoft Word:mac 2011, to obtain the count.

In addition, this brief complies with the typeface requirements of Fed. R. App. P. 35(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word:mac 2011 in Times New Roman 14 pt.

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CERTIFICATE OF SERVICE

I certify that on October 5, 2012, I caused the foregoing *Brief for Appellants* to be served electronically via the Court's electronic filing system on the following parties who are registered in the system:

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