No. 12-3841

IN THE
United States Court of Appeals
FOR THE SEVENTH CIRCUIT

CYRIL B. KORTE, et al.

Plaintiffs-Appellants,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellees.

On Appeal from the United States District Court
For the Southern District of Illinois, No. 3:12-cv-01072.
The Honorable **Michael J. Reagan**, Judge Presiding

BRIEF *AMICUS CURIAE* OF BREAST CANCER PREVENTION INSTITUTE, BIOETHICS DEFENSE FUND & LIFE LEGAL DEFENSE FOUNDATION IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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CIRCUIT RULE 26.1
DISCLOSURE STATEMENT/NOTICE OF APPEARANCE

Appellate Court No: 12-3841

Short Caption: Cyril B. Korte, et al. vs. United States Department of Health and Human Services, et al.

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with the Cir. R. 26.1 and Fed. R. App. 26.1

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[**X**] PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.

No. (1) and (3)(i) are new information; Breast Cancer Prevention Institute is a new amicus party.

(1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information requested by Fed. R. App. P. 26.1 by completing item #3:

Breast Cancer Prevention Institute, Bioethics Defense Fund, Life Legal Defense Foundation

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court.

(3) If the party or amicus is a corporation:

i) Identify all its parent corporations, if any; and

The **Breast Cancer Prevention Institute** is a non-profit 501(c)(3) corporation that educates healthcare professionals and the general public through research publications, lectures, and online, on ways to reduce breast cancer incidence. It has no parent corporation.

Bioethics Defense Fund and **Life Legal Defense Foundation** are both non-profit 501(c)(3) corporations that have no parent corporations.

ii) List any publicly held company that owns 10% or more of the party's or amicus' stock: N/A

Attorney's Signature: **/s/ Stephen Robert Clark** Date: February 4, 2013

Attorney's Printed Name: Stephen Robert Clark

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Catherine W. Short, Life Legal Defense Foundation

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Attorney's Signature: **/s/ Catherine W. Short** Date: February 4, 2013

Attorney's Printed Name: Catherine W. Short

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Nikolas T. Nikas, Bioethics Defense Fund

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Attorney's Signature: **/s/ Nikolas T. Nikas** Date: February 4, 2013

Attorney's Printed Name: Nikolas T. Nikas

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Dorinda C. Bordlee, Bioethics Defense Fund

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Attorney's Signature: **/s/ Dorinda C. Bordlee** Date: February 4, 2013

Attorney's Printed Name: Dorinda C Bordlee

Please indicate if you are Counsel of Record for the above listed parties pursuant to Circuit Rule 3(d). **No.**

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INTEREST OF AMICI CURIAE[1]

Breast Cancer Prevention Institute (BCPI) is a non-profit corporation that educates healthcare professionals and the general public through research publications, lectures, and internet resources, about ways to reduce the surge in breast cancer incidence attributable to avoidable risks. BCPI is directed by Angela Lanfranchi, M.D., F.A.C.S., a breast surgeon and graduate of the Georgetown School of Medicine (M.D. 1975). She is the co-author of a publication that puts particular emphasis on dietary and lifestyle factors, such as alternatives to hormone use for contraception and postmenopausal medication. Angela Lanfranchi, MD, FACS & Joel Brind, PhD, *Breast Cancer: Risks and Prevention*, 4th edition (2007), *available at* http:// http://www.bcpinstitute.org/booklet4.htm.

Bioethics Defense Fund (BDF) and **Life Legal Defense Foundation** (LLDF) are two non-profit, public-interest legal and educational organizations whose legal experts and medical advisors address issues at the intersection of law and medical ethics, such as the negative health impact on women of abortion and human egg donation for embryonic stem cell research or in vitro fertilization, protection of vulnerable human beings at the beginning and end of life, healthcare rights of conscience, end of life medical ethics, and the right of individuals to live

[1] Pursuant to Cir. Rule 29, counsel certifies that the parties have consented to the filing of this brief, and further certifies that no party or party's counsel authored this brief in whole or in part, or contributed money to fund the brief.

out their pro-life and religious convictions in the workplace.

Amici have an interest in bringing this Court's attention to objective evidence that the Government entirely disregarded – indeed, never even considered – in promulgating the HHS Mandate; namely, the large body of relevant, widely available, scientifically sound scholarly research documenting serious health risks to women arising from the use of hormonal contraceptives[2], including the classification of combined oral contraceptives by the research arm of the World Health Organization as "Group 1: Carcinogenic to Humans."

[2] The term "contraceptive" as used in this brief reflects terminology used by the Government in the HHS Mandate. *Amici*, however, acknowledge the Plaintiffs' 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://www.scribd.com/doc/97450207/Bioethics-Defense-Fund-Life-Legal-Defense-Foundation-Letter-to-HHS-Regarding-Affordable-Care-Act (last checked November 19, 2012).

SUMMARY OF THE ARGUMENT

In consultation with medical and science advisors,[3] *Amici* bring this Court's attention to the fact that in promulgating the HHS Mandate,[4] the Government entirely failed to consider 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 the acquisition and transmission of human immunodeficiency virus (HIV). These risks have been recognized not only by other agencies of the Government itself, but also by reputable national and international medical authorities, including the research arm of the World Health Organization.

Yet the Government, and the inadequate and defective Institute of Medicine report on which it relied, completely ignored this widely available, peer-reviewed medical research showing significantly increased cancer and other health risks associated with hormonal contraceptives – medical evidence that the Government

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[3] 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 University of North Carolina at Chapel Hill's 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.

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

should have considered to be a highly relevant aspect in determining the drugs and services to be mandated as a no-cost benefit to promote women's health.

In failing to even acknowledge or balance the highly relevant medical evidence presented in this brief, the Mandate is "arbitrary and capricious" under the Administrative Procedures Act because the Government "entirely failed to consider an important aspect of the problem." (Section I)

The disregard of this important medical evidence also shows that the Government cannot meet its burden under the Religious Freedom Restoration Act (RFRA), 42 U.S.C. §2000, of demonstrating that application of the HHS Mandate to a religiously objecting employer "*furthers* a compelling governmental interest" – particularly its asserted interest of promoting women's health. (Section II.A). The Government has also failed to show that the Mandate will further the asserted interest in promoting gender equity. (Section II.B).

ARGUMENT

I. The Mandate is Arbitrary and Capricious under the APA because the Government Entirely Failed to Consider Highly Relevant Evidence Showing that Hormonal Contraceptives Significantly Increase Women's Health Risks, Including Cancers, Cardiovascular Disease, and the Acquisition and Transmission of HIV.

On August 1, 2011, pursuant to the Affordable Care Act,[5] the Government agency known as HRSA (Health Resources and Services Administration) adopted in full the guidelines[6] recommended by a report of the Institute of Medicine (IOM). That 2011 IOM report recommended that "preventive services" for women include all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, injections and implants, emergency contraceptive drugs, and intrauterine devices.[7]

Notably, the IOM report completely failed to consider or address the relevant, widely available, scientific research establishing significant *increased* health risks of hormonal contraceptives, as set forth below. In ignoring this highly relevant medical evidence, it did not even try to establish that on balance the putative health benefits of hormonal contraceptives outweighed the significantly increased health risks. Indeed, the IOM report did not even mention that the World

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[5] 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.

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

[7] 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).

Health Organization classifies combined oral contraceptives as "Group 1: carcinogenic to humans,"[8] or that a substantial body of evidence indicates 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, as set forth below in a brief survey of medical literature.

The widely available studies presented below should have been considered and balanced by the Government against any putative benefits of contraceptives, especially in determining the content of mandated "preventive" health coverage. Yet, the Government and the IOM report on which it relied completely ignored, to the detriment of women's health, the mountain of medical evidence that is partially surveyed below.

Therefore, the Mandate is arbitrary and capricious under the Administrative Procedures Act (APA). The judicial standard for review under the APA "arbitrary and capricious" standard provides:

> An agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, **entirely failed to consider an important aspect of the problem**, offered an explanation for its decision that runs counter to the

[8] 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/?p=2808).

> evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 43 (1983) (emphasis added).

Here, the HHS Mandate is clearly arbitrary and capricious by virtue of the fact that the Government indeed "entirely failed to consider an important aspect of the problem" – namely that the mandated drugs *increase* risk of disease rather than prevent disease.

A non-exhaustive survey of the completely ignored but highly relevant and widely available peer-reviewed medical studies documents the following serious health risks:

A. Serious Health Risks of Oral Contraceptive Pills

1. **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.[9] 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.[10] A meta-analysis of 16 studies found that women who used oral contraceptives

[9] B.C. Tanis et al., *Oral contraceptives and the risk of myocardial infarction*, 345 New England Journal of Medicine 1787 (2001).

[10] *Id.*

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.[11] Hormonal contraceptives also lead to significantly higher incidence of deep venous thrombosis (blood clots in legs)[12] and pulmonary embolism.[13]

2. **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.[14] 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.[15] 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

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[11] L.A. Gillum, *Ischemic stroke risk with oral contraceptives*, 284 JAMA 72 (2000).

[12] A. van Hylckama Vlieg et al.,*Venous thrombotic risk of oral contraceptives, effects of oestrogen does and progestogen type: results of the MEGA case-control study*, 339 BMJ 2921 (2009).

[13] O. Lindegaard et al., *Risk of venous thromboembolism from use of oral contraceptives containing different progestogens and oestrogens. Danish cohort study 2001-9*, 343 BMJ 6423 (2011).

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

[15] 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.

taking oral contraceptives.[16] 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.[17]

3. **Higher risk of cervical cancer.** The Government's own National Cancer Institute (NCI) recognized studies showing a threefold to fourfold increased 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.[18]

4. **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

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

[17] *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).

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

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." [19]

5. **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, as women not taking oral contraceptives.[20] 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.[21] 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

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[19] *Id.*, *citing* C. La Vecchia and A. Tavani, *Female hormones and benign liver tumours*. 38 Digestive and Liver Disease 535 (2006).

[20] S. Franceschi et al., *Genital warts and cervical neoplasia: an epidemiological study*, 48 *Br. J. Cancer* 621 (1983).

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

rate of STIs.[22]

B. 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 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*),[23] 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 organs**.[24]

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

[23] N. Zieman, R.A. Hatcher, 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— R.A. Hatcher et al., *Contraceptive Technology* (20th rev. ed.). Atlanta, GA: Ardent Media, Inc., 2011.

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

(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 resultant loss of pregnancy and a **possible permanent loss of fertility** may result.[25]

(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.[26] 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."[27]

(4) **Depo-Provera©:** This is a popular injectable progestogen intended to last up to three months. A study of breast cancer risk found a **more than doubled risk of breast cancer** in women who used DepoProvera for more than 12 months.[28] Moreover, in addition to this injection's **black box warning on loss of bone mineral density**, Depo-Provera use has been shown to result in a **doubled risk of acquiring and transmitting HIV**, as discussed below.

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[25] 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.

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

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

[28] C. Li et al., *Effect of Depo-Medroxyprogesterone Acetate on Breast Cancer Risk among Women 20 to 44 Years of Age*, 72(8) Cancer Res. 2028 (Apr. 15 2012).

In October 2011, the *New York Times* gave front-page coverage to the rigorous Heffron study[29] that had been published in a prestigious peer-reviewed medical journal after the study's presentation had raised alarm months earlier at an 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 H.I.V.-positive women, their male partners are *twice as likely to become infected* than if the women had used no contraception."[30]

The study focused on Depo-Provera, a drug covered by the HHS Mandate. 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] contraceptions are helping spread the AIDS epidemic, we have a major health crisis on our hands**."[31]

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The 2011 IOM report appears oblivious to the host of adverse health consequences from the contraceptive methods it claims will promote women's

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[29] R. Heffron et al., *Use of hormonal contraceptives and risk of HIV-1 transmission: a prospective cohort study*, 12 Lancet Infect Dis. 19 (2012) (published online October 2011).

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

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

health. The only consequences it discusses are "side effects" (which it says are "generally considered minimal"[32]) and death rates that can be directly linked to contraceptive use.[33] 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.[34]

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 of contraceptives outweighed the significantly increased health risks. By relying exclusively on the defective IOM report, the

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[32] 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.

[33] 2011 IOM at 105-06.

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

Government has "entirely failed to consider an important aspect of the problem" underlying the Mandate, i.e., promoting women's health. For this reason, the Defendants' action in promulgating the Mandate was "arbitrary and capricious," in violation of the APA.

II. Because the Mandate includes Drugs that Significantly Increase Serious Health Risks, the Government Cannot Meet its Burden Under RFRA of Demonstrating that the Mandate "Furthers" its Asserted Interest in Promoting the Health and Well-Being of Women.

Where a government action substantially burdens religious exercise, the Government has the burden of demonstrating that the challenged regulation "furthers a compelling governmental interest."[35] But, as shown above (Section I), far from "furthering" the Government's asserted interests in public health, the HHS Mandate works directly *against* women's health and well-being by incentivizing (with mandated availability of "no-cost" coverage) the use of hormonal contraceptives that are classified as carcinogenic and a source of significantly increased risks of serious diseases.[36]

Because of the large and scientifically sound body of credible peer-reviewed evidence showing significantly increased health risks of hormonal contraceptives, along with the fact that fertility and pregnancy are not disease states, the mandate

[35] *Potter v. District of Columbia*, 558 F.3d 542, 546 (D.C. Cir. 2009) ("The [RFRA] statute makes clear that the term 'demonstrates' means meets the burdens of going forward with the evidence and of persuasion.").

[36] *See* Section I, *supra*.

of hormonal contraceptives "fail[s] the most important test of preventive medicine: they increase risk of disease instead of decreasing it."[37] Thus, the Government's burden of showing that the Mandate furthers its compelling interest in public health is even heavier. The Government must show not merely that contraceptives promote women's health, but that they do so to a degree that outweighs their documented adverse effects on women's health. The IOM Report upon which the Government relied shows that it did not even make an attempt to balance those risks.

A. The IOM Report Does Not Support the Government's Assertion that Increased Use of Contraceptives Will Promote Women's Health.

Unfortunately for the Government, its sole evidence of any health benefits from contraceptives is the 2011 Institute of Medicine Report. Citing this report,[38] 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. In addition to ignoring the large body of medical evidence set forth in the section above showing the significantly increased risks of

[37] 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).

[38] 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.

cancers and other serious diseases,[39] the Government has also failed to show that the Mandate would prevent the negative health consequences allegedly associated with unplanned pregnancy that it seeks to prevent. "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.,* 131 S. Ct. 2729, 2739 (2011) (quotation marks omitted).

The IOM admits that for many negative outcomes from unintended pregnancy, "research is limited."[40] The IOM cites its 1995 report, which similarly emphasizes the fundamental difficulty in defining which pregnancies are "unintended," and in distinguishing between association and causation in assessing the risks of unintended pregnancies.[41]

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

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[39] The medical evidence of the carcinogenic impact of hormonal contraceptives set forth in Section I, *supra*, is in direct contradiction to the IOM report's broad definition of "[p]reventive services for women" as those "that prevent conditions harmful to women's health and well-being." 2011 IOM at 20.

[40] 2011 IOM at 103.

[41] 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).

delay or who have a "support network,"[42] – as do the Plaintiffs' 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.[43] 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 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.[44]

Notably, the 2011 IOM report claims to cite a systematic review on low birth weight, but the citation is incorrect.[45] The IOM then cites three studies showing an association between low birth weight/preterm delivery and shorter

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[42] *Id*. at 68.

[43] 2011 IOM at 103.

[44] 1995 IOM at 70-71.

[45] 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. B.R. Shah, R. Retnakaran, and G. L. Booth, *Increased risk of cardiovascular disease in young women following gestational diabetes mellitus*, 31(8) Diabetes Care 1668 (2008).

pregnancy intervals.[46] 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.[47]

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 itself providing contraceptive services if such services were medically indicated.

In sum, while the Government's general interest in "preventive services" for "women's health and well-being" may be valid, its act of coercing religiously objecting employers to cover drugs that significantly increase risks to women's health, while providing dubious health benefits, certainly fails to further that

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[46] *Id*. at 103.

[47] Chen, et al., *Recent oral contraceptive use and adverse birth outcomes*, 144 *European Journal of Obstetrics & Gynecology and Reproductive Biology* 40–43 (May 2009), *abstract available at* http://www.ejog.org/article/S0301-2115(09)00074-8/.

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).

B. The Government Has Failed to Show that the Mandate Furthers its Asserted Interest of Promoting Gender Equity.

The Government asserts 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 asserts that relieving women of this alleged "disproportionate burden" 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 sections, 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 can not assert a compelling interest in increasing access to and

utilization of contraceptives apart from its interest in promoting women's health. There is no evidence in the legislative record from which the Government 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, the legislative history shows that Congress's intent was to relieve women of the inequitable financial burden they face in maintaining their health. 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 Sections I. and II.A, *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, the evidence presented by the Government to support its premise that women are inequitably burdened by their costs is woefully inadequate.

The Government cites statements of members of Congress, of no evidentiary value. The Government also cites the IOM report for the proposition that women incur more in out-of-pocket costs for preventive care than men do, owing to reproductive and gender-specific conditions.[48] There are two problems with this "evidence."

[48] 2011 IOM at 19.

First, the two sources cited by the IOM do not support the statement. The first study does not discuss out-of-pocket expenses at all. It compared, by gender, rates of primary care office visits, referrals, and hospitalizations. The study noted that the differences between men and women in the utilization of health services "may result from patients' health beliefs and help-seeking behavior. Women have been found to be more predisposed to report their health as poor. They also have a greater willingness and ability to take care of themselves when they are sick and to seek preventive care."[49] Thus, contrary to the Government's argument, this study found that women are more likely than men to seek health care, including preventive care. The second study was focused on "the effect of the lack of health insurance on health care utilization for female-specific conditions." The "female-specific conditions" studied were specific disorders and pathologies, not preventive care. Neither of these studies even identifies contraceptives as a health care cost, much less attempts to quantify to what extent contraceptive coverage contributes to increased health care costs for women.

Finally, 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?

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[49] K.D. Bertakis et al., *Gender differences in the utilization of health care services*, 49(2) Journal of Family Practice 147 (2000).

Three categories of women would receive contraceptives at no cost under the Mandate: Plaintiffs' 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 Plaintiffs' 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 Plaintiffs' 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 Plaintiffs. 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 in 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 Government has failed to carry its burden of proving that the coercive Mandate **in fact**, not in theory, furthers its asserted interest in promoting women's health or gender equity.

CONCLUSION

For the foregoing reasons, *Amici* Breast Cancer Prevention Institute, Bioethics Defense Fund and Life Legal Defense Foundation request that this Court reverse the district court's decision denying Plaintiffs' motion for a preliminary injunction and remand this case with instructions that the district court enter a preliminary injunction as requested by Plaintiffs.

Respectfully submitted this 4th day of February, 2013,

*/s/ Stephen Robert Clark*_____

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure, the undersigned certifies that this brief complies with the type-volume limitations because the brief contains **4,313 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.

DATED: February 4, 2013

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CERTIFICATE OF SERVICE

I certify that on February 4, 2013, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all registered participants in the case will receive service by the CM/ECF system.

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