No. 12-6294

IN THE

United States Court of Appeals

FOR THE TENTH CIRCUIT

HOBBY LOBBY STORES, INC., MARDEL, INC., DAVID GREEN, BARBARA GREEN, STEVE GREEN, MART GREEN, AND DARSEE LETT,

Plaintiffs-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

Defendants-Appellees.

On Appeal from the United States District Court
For the Western District of Oklahoma, No. 5:12-cv-01000
Judge Joe Heaton, Presiding

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

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CORPORATE DISCLOSURE STATEMENT

In accordance with Rule 26.1 of the Federal Rules of Appellate Procedure, *Amici* make the following disclosures:

Breast Cancer Prevention Institute, Bioethics Defense Fund and **Life Legal Defense Foundation** are each nonprofit organizations organized under Section 501(c)(3) of the Internal Revenue Code. They have no parent corporations, and no publicly held corporations hold 10 percent or more of their stock.

DATED: February 18, 2013

/s/*Dorinda C. Bordlee*
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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).

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 such as the negative health impact on women of abortion and human egg donation for embryonic stem cell research or in vitro fertilization, healthcare rights of conscience, end of life medical ethics, and the right of individuals to live out their pro-life and religious convictions in the workplace.

Amici have an interest in bringing this Court's attention to objective evidence the Government entirely disregarded in promulgating the HHS Mandate, namely, (1) studies that debunk the unsupported claims regarding the impact of the

[1] Pursuant to Cir. Rule 29, counsel certifies that all 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 that was intended to fund the brief.

Mandate on unintended pregnancies, and (2) the large body of research documenting significantly increased health risks to women arising from the use of hormonal contraceptives.[2]

SUMMARY OF THE ARGUMENT

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[3] to a religiously objecting employer "*furthers* a compelling governmental interest" – particularly its asserted interests of promoting access to preventive health care and promoting gender equity. In Section I, *Amici* address the logical gaps and misinformation in the Institute of Medicine Report that formed the flawed basis for the Government's decision to impose the Mandate. Amici demonstrate that the purported benefits of the mandated drugs rest entirely on the combined false premises that "unintended" pregnancy is a disease state and that providing free contraceptives will decrease unintended pregnancies and promote gender equity.

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[2] The term "contraceptive" as used in this brief reflects terminology used by the Government in the HHS Mandate. *Amici*, however, affirm the scientific basis of 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.

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

In Section II, *Amici* present a survey of the robust body of medical evidence completely ignored by the Government, 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 increased 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 which classifies combined oral contraceptives as "Group 1: Carcinogenic to Humans."

In failing to even acknowledge or balance the highly relevant increased risks presented in this brief, the Mandate both fails the RFRA requirement to "further" the asserted Government interest in "preventive" health, and is also "arbitrary and capricious" under the Administrative Procedures Act because the Government "entirely failed to consider an important aspect of the problem."

ARGUMENT

I. 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.

On August 1, 2011, pursuant to the Affordable Care Act, the Government agency known as HRSA (Health Resources and Services Administration) adopted in full the guidelines recommended by a report of the Institute of Medicine (IOM).

That 2011 IOM report recommended that no-cost "preventive services" for women include drugs, devices and services that Plaintiffs object to as gravely immoral under the teachings of their faith, namely all FDA-approved contraceptive methods including diaphragms, oral contraceptive pills, injections and implants, emergency contraceptive drugs, and intrauterine devices.[4]

Where a government action substantially burdens religious exercise, the Government has the burden of demonstrating that the challenged regulation "furthers a compelling governmental interest." 42 U.S.C. § 2000bb-1(b) Under RFRA, "the term 'demonstrates' means meets the burden of going forward with the evidence and of persuasion." 42 U.S.C. §2000bb-2(3). The Government's burden is not met by showing hypothetical or insignificant advances in the service of its interests: "The government does not have a compelling interest in each marginal percentage point by which its goals are advanced." *Brown v. Entm't Merchs. Ass'n.,* 131 S.Ct. 2729, 2749 n.9 (2011).

The Government's evidence that the Mandate will further its asserted compelling interests falls far short of meeting its burden under RFRA.

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[4] 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).

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

Relying entirely on the 2011 IOM Report, the Government asserts that by increasing access to contraceptives, the Mandate will promote public health by decreasing unintended pregnancies.[5] Beyond the implication that "unintended pregnancy" is a disease state, "[r]esearchers have long-abandoned the false dichotomy of intended versus unintended pregnancy." Some women welcome "unintended" yet healthy pregnancies, and some "intended" pregnancies end in abortion due to complications or a change in a woman's social situation.[6]

In addition to ignoring the large body of medical evidence set forth in the section below showing the significantly increased risks of cancers and other

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[5] The Government also asserts that increased contraceptive use will promote birth spacing. Assuming that the Government does not intend to employ coercive measures to achieve "healthy" birth spacing, this goal can be subsumed under the more general goal of reducing unintended pregnancies. Similarly, its goal of preventing pregnancy in women for whom pregnancy is contraindicated is also a subcategory of preventing unintended pregnancies; as discussed *infra*, the promotion of contraceptives to avoid pregnancy in women with medical conditions such as heart disease and obesity ignores the fact that hormonal contraceptives are contraindicated for these women.

[6] Jacqueline C. Harvey, *Outdated Lexicons and obsolete solutions: A response to the editorial in the February 2013 issue of Contraception,* Reproductive Research Audit (February 12, 2013), *available at* http://reproductiveresearchaudit.com/wp-content/uploads/2013/02/Pregnancy-Ambivilence-1.pdf (citing Trussell, J., Vaughn, B. & Stanford, J. 1999. *Are All Contraceptive Failures Unintended Pregnancies? Evidence from the 1995 National Survey of Family Growth.* Family Planning Perspectives, 31(5)).

serious diseases,[7] the Government has also failed to 1) demonstrate that lowering the costs of contraceptives (to zero) for those covered by insurance will lead to any appreciable increased usage among those currently at risk of unintended pregnancy within that population and to a decrease in unintended pregnancies within that population, and 2) demonstrate that unintended pregnancies have negative health consequences for women. Rather, the Government's argument is based on a chain of presumed causes and effects, and the evidence supporting each link is attenuated, ambiguous, disputed, or non-existent. Indeed, "[n]early 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, supra,* 131 S.Ct. at 2739 (quotation marks omitted).

1. The Government has failed to show that the Mandate will lead to increased usage among those at risk of unintended pregnancy or to a decrease in unintended pregnancies among those covered by the Mandate.

The Government hypothesizes that women are deterred from obtaining contraceptives because of the cost, and that therefore the Mandate will increase utilization of contraceptives. However, its evidence is based on supposition, dubious analogies, and assumed but unproven correlations.

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[7] The medical evidence of the carcinogenic impact of hormonal contraceptives set forth in Section II, *infra*, 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.

The IOM report cites a Kaiser Family Foundation report as evidence that women are more likely than men to report cost-related barriers to receiving medical care. The study in question asked men and women whether they *or a family member* had delayed or foregone certain health care in the past year because of the cost.[8] Thus, the fact that more women than men, by a factor of a few percentage points, reported they *or a family member* had done so says little about which gender is actually foregoing medical care because of the cost.

The IOM also cites studies showing that the costs of cancer screening, dental services, mammograms and pap smears may deter women from receiving those services. 2011 IOM at 19. Yet, even if these studies in fact supported the IOM's statement,[9] none of them makes the necessary connection between women deferring or foregoing this type of care, i.e., screening tests, and women failing to buy contraceptives because of the cost. It is far from a logical corollary that a woman who delays getting her annual pap smear because of the cost will also decide to stop using contraceptives because of the cost.

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[8] *Impact of health reform on women's access to coverage and care*. Focus on Health Reform. Washington, DC: Henry J. Kaiser Family Foundation (2010), *available at* http://www.kff.org/womenshealth/upload/7987.pdf.

[9] One of the two studies cited for the proposition that women forego mammograms and pap smears because of the cost (2011 IOM at 19) has nothing to do with that topic. Trivedi, A. N., H. Moloo, and V. Mor. 2010. *Increased ambulatory care copayments and hospitalizations among the elderly*. New England Journal of Medicine 362(4):320–328.

Regarding contraceptives in particular, the IOM's own sources show that 89% of women avoiding pregnancy are already practicing contraception,[10] and that among the other 11%, lack of access is not a statistically significant reason why they do not contracept.[11]

Undeterred, the IOM report concludes, "The elimination of cost-sharing for contraception therefore could greatly increase its use, including use of the more effective and long-acting methods, especially among poor and low-income women most at risk for unintended pregnancy."[12] The final logical lapse in the IOM's treatment of this topic is that poor and low-income women are already eligible to receive no-cost contraceptives under myriad state and federal programs.[13] Yet, as the Report itself notes, they have significantly higher rates of unintended pregnancy than that part of the female population not guaranteed free contraceptives.

The IOM report, and similarly the Government, seems oblivious to the lessons learned over the five decades since the advent of hormonal contraceptives,

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[10] The Guttmacher Institute, *Facts on Contraceptive Use in the United States* (June 2010), *available at* http://www.guttmacher.org/pubs/fb_contr_use.html (last visited September 20, 2012).

[11] Mosher WD and Jones J, *Use of contraception in the United States: 1982–2008, Vital and Health Statistics* (2010) Series 23, No. 29, at 14 and Table E, *available at* http://www.cdc.gov/NCHS/data/series/sr_23/sr23_029.pdf.

[12] 2011 IOM at 109.

[13] 2011 IOM at 108.

namely, that while for the individual, **a** contraceptive drug or device may prevent **a** pregnancy, this result cannot be extrapolated to a societal scale. Increasing access to contraceptives does not affect only those who were already at risk for unintended pregnancy. Rather, it changes behaviors and expectations across society.

For example, Duke University Professor Peter Arcidiacono found that data from the 1997 National Longitudinal survey of Youth suggested that while access to contraception decreases teen pregnancy in the short run, it increases teen pregnancy in the long run by encouraging sexual activity.[14] Multiple studies have analyzed the effect of access to emergency contraception (EC) on pregnancy and abortion rates. Not only have ECs failed to lower teen pregnancy rates according to every relevant study in myriad countries, but they are disturbingly and regularly associated with increases in teen pregnancy and abortion rates.[15] In two studies

[14] P. Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* Working Paper, Duke Univ. Dept. of Economics (Oct. 3, 2005), *available at* http://public.econ.duke.edu/~psarcidi/teensex.pdf.

[15] J. Duenas, et al., *Trends in the Use of Contraceptive Methods and voluntary Interrruption of Pregnancy in the Spanish Population during 1997-2007*, 83 Contraception 82 (2011)(over ten year period, 63% increase in contraceptive use accompanied by a 108% increase in the abortion rate); D. Paton, *The Economics of Family Planning and Underage Conceptions*, 21 J. of Health Economics, 207 (2002).

conducted in 2000 and 2005, teens admitted to researchers that they "had been more careless about birth control and more likely to have had unprotected sex."[16]

EC appears similarly ineffective at reducing unintended pregnancies for the general population. A meta-analysis of 23 studies evaluating the effectiveness of Plan B concluded that "*no study* has shown that increased access to [Plan B] reduces unintended pregnancy or abortion rates on a population level."[17]

A Guttmacher Institute report on unintended pregnancy between 2001 and 2006, concluded that changes in contraceptive method and use did not decrease the overall proportion of pregnancies that were unintended, despite CDC data showing that more women in the years between 2002 and 2008 were accessing methods of contraception deemed "more effective" by the IOM, the CDC and Guttmacher.[18]

Considering a broader perspective, in 1972 an estimated 35.4% of pregnancies in the United States were unintended.[19] Since 1972, Medicaid has required coverage for contraceptives in all state programs and has exempted them

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[16] Roni Caryn Rabin, *Teenagers and the Morning After Pill*, The New York Times, Dec 3, 2012, *available at* http://well.blogs.nytimes.com/2012/12/03/teenagers-and-the-morning-after-pill/?ref=ronicarynrabin.

[17] Elizabeth G. Raymond, James Trussel & Chelsea B. Polis, *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review*, 109 Obstetrics & Gynecology 181 (2007).

[18] Lawrence Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: incidence and disparities, 2006*, 84 Contraception 478 (2011).

[19] Christopher Tietze, *Unintended Pregnancies in the United States, 1970-1972*, 11 Fam. Planning Perspectives 186 (1979).

from cost-sharing requirements. Over half the states also operate Medicaid-funded contraceptive programs for low-income women who exceed Medicaid's income guidelines. Following suit, most private employers now include contraceptive coverage in their plans, and 28 states require private employers to cover contraceptives.[20]

The IOM places the current rate of unintended pregnancy at 49%. This 40% increase since 1972 has occurred despite – or possibly because of – multiple programs and policies operating on the same premise as the HHS Mandate does, that lowering or erasing the cost of contraceptives will decrease unintended pregnancies.

The Government has signally failed to show that the Mandate, by forcing employers to provide contraceptives at no cost, will further the asserted governmental interest in promoting women's health through decreasing unintended pregnancies.

2. The Government has failed to show that unintended pregnancies have negative health consequences for women.

The IOM admits that for many negative outcomes from unintended pregnancy, "research is limited."[21] The IOM cites its 1995 report, which similarly emphasizes the fundamental difficulty in defining which pregnancies are

[20] 2011 IOM at 108.

[21] 2011 IOM at 103.

"unintended," and in distinguishing between association and causation in assessing the risks of unintended pregnancies.[22]

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,"[23] – 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.[24] 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.

For example, on the topic of depression, the IOM report cites a 2008 meta-analysis, but fails to reveal that the study's authors concluded there that, due to the

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[22] 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).

[23] *Id*. at 68.

[24] 2011 IOM at 103.

"paucity of studies investigating the impact of unintended pregnancy on psychosocial health and well being, and their limitations in terms of establishing causality, the existing research should only be considered to be suggestive of such an impact." This study also states that all research regarding the "effects" of unintended pregnancies on mothers' health is "plague[d] by the problem of establishing causality between unintended pregnancy and subsequent health outcomes," and that "*causality is difficult if not impossible to show*."[25]

Further, the preventive services recommended by the U.S. Preventive Services Task Force, already required by the ACA to be provided without a co-pay, include counseling for pregnant women concerning smoking and drinking, while domestic violence prevention is a separately recommended preventive service for women within the 2011 IOM Report itself.[26]

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

[25] Gipson, J. D., M. A. Koenig, and M. J. Hindin, *The effects of unintended pregnancy on infant, child, and parental health: A review of the literature*, 39 *Studies in Family Planning* 18 (2008).

[26] 2011 IOM at 117.

between low birth weight and pregnancy-spacing in the U.S.[27]

Notably, the 2011 IOM report claims to cite a systematic review on low birth weight, but the citation is incorrect.[28] The IOM then cites three studies showing an association between low birth weight/preterm delivery and shorter pregnancy intervals.[29] 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.[30]

Also absent from the IOM's discussion of low birth weight and prematurity is any measure of how detrimental these conditions are for newborns in terms of immediate or long-term health effects. Assuming arguendo some (unstated) percentage of unplanned pregnancies were shown to result in premature or low-birth weight babies, the IOM report provides no information as what percentage of

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[27] 1995 IOM at 70-71.

[28] 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).

[29] *Id*. at 103.

[30] 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 contraceptives significantly increase the risk of low birth weight and very low birth weight. 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/.

these babies will require significant medical intervention or suffer long-term consequences. "The government does not have a compelling interest in each marginal percentage point by which its goals are advanced." *Brown*, *supra*, 131 S.Ct.at 2749 n.9.

More importantly, however, the IOM makes no attempt to link these alleged negative outcomes of unplanned pregnancy with women's health. The IOM was tasked with making recommendations for women's health, not children's health.[31] "The Institute of Medicine will convene an expert committee to review *what preventive services are necessary for women's health and well-being* and should be considered in the development of comprehensive guidelines for preventive services for women."[32] Thus, unless the Government can point to evidence in the record that caring for children is detrimental to women's health and well-being, the IOM report's discussion of the purported negative effects of unintended pregnancy on the health of children born of such pregnancies is irrelevant to the Government's

[31] One court has noted the "somewhat odd implication by the Government that the *use* of contraception could somehow have a beneficial impact on a 'developing fetus' that contraceptive use is itself designed to avoid. . . ." *Legatus v. Sebelius*, 2012 U.S. Dist. LEXIS 156144, 2012 WL 5359630 (E.D.Mich., Oct. 31, 2012) (emphasis added).

[32] Office of Secretary, Statement of Task to the Committee on Preventive Services for Women, reprinted at 2011 IOM at 2 (emphasis added).

case that the Mandate promotes women's health.[33]

Finally, the Government's reliance on the special needs of some women, such as those with Marfan syndrome, 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.[34] Moreover, the IOM 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

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[33] If the Government intends to broaden the definition of "women's health and well-being," and thus the goal of the Mandate, to include non-health related concepts such as emotional well-being and economic prosperity, then it should likewise have considered the documented negative effects the widespread availability of contraceptives has on women's ability to enter into and maintain desired marital relationships. This in turn leads to decreased emotional well-being and economic stability (out-of-wedlock childbearing being a chief predictor of female poverty), as well as deleterious physical health consequences arising from, *inter alia*, sexually transmitted infections and domestic violence. *See, e.g.*, George A. Akerlof, Janet L. Yellen & Michael L. Katz, *An Analysis of Out-of-Wedlock Childbearing in the United States*, 111 The Quarterly J. of Econ. 277 (1996); Timothy Reichert, *Bitter Pill*, First Things (May 2010) 25; Jonathan Klick & Thomas Stratmann, *The Effect of Abortion Legalization on Sexual Behavior: Evidence from Sexually Transmitted Diseases*, 32 J. of Legal Studies 407, 431-32 (2003) (citations omitted); Jackson, Nicky Ali, *Observational Experiences of Intrapersonal Conflict and Teenage Victimization: A Comparative Study among Spouses and Cohabitors*, 11:3 Journal of Family Violence at 191-203 (1996)("regardless of methodology . . . cohabitors engage in more violence than spouses").

[34] About one in 6,000 to 10,000 women have Marfan Syndrome. Keane MG, Pyeritz RE, *Medical management of Marfan syndrome*, 117 (21) Circulation 2802–13. (May 2008). The percentage would be even smaller for sexually active women in their childbearing years.

contraception, are the same conditions that put women at greatly increased risk for cardiovascular problems from contraceptive use (see Section II, *infra*). Focused care to help women with these conditions could achieve the Mandate's goals, with the Government itself providing pregnancy prevention 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 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 cannot 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.A, *supra*, and II, *infra*, 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.[35] There are two problems with this "evidence."

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 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.

[35] 2011 IOM at 19.

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?

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 nor, consequently, 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.

II. Because The Mandate Includes Hormonal Contraceptives that Significantly Increase Risks of Serious Disease, It Cannot "Further" a Compelling Interest in "Preventive" Women's Health Under RFRA, and It Is "arbitrary and capricious" Under the APA

In this Section, *Amici* present a survey of the large body of peer-reviewed scientific research – completely absent from the IOM report – that show the significantly increased health risks associated with the mandated drugs. In light of these studies, the hormonal contraceptives required under the Mandate "fail the most important test of preventive medicine: they increase risk of disease instead of

decreasing it."[36] Therefore, the Government has not demonstrated and cannot demonstrate that application of the HHS Mandate to religious objectors "furthers a compelling governmental interest."

Women in our pluralistic society remain free to face the attendant health risks that come with choosing to use hormonal contraceptives that are FDA-approved as effective for the intended use of avoiding pregnancy. However, more than a dozen drugs have been taken off the market since 1997 due to severe side-effects, injuries or deaths.[37] Thus, FDA-approval is not the final word on safety, nor is FDA-approval dispositive in the HHS inquiry of whether a drug should be mandated as "preventive" healthcare, much less of whether mandating coverage of such drugs "furthers a compelling governmental interest."

In addition to the Government's not having met its burden under RFRA, the failure of the IOM report to consider or even balance the putative benefits with the increased health risks reveals that 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,

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[36] 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).

[37] PBS Frontline, *Dangerous Prescription* (November 2003), available at http://www.pbs.org/wgbh/pages/frontline/shows/prescrption/etc/synopsis.html.

> **entirely failed to consider an important aspect of the problem**, offered an explanation for its decision that runs counter to the 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 "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.[38] 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.[39] A

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

[39] *Id.*

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.[40] Hormonal contraceptives also lead to significantly higher incidence of deep venous thrombosis[41] and pulmonary embolism.[42]

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.[43] 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.[44] A 2009

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

[41] 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).

[42] 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).

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

[44] 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.

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.[45] 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.[46]

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.[47]

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[45] 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).

[46] *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).

[47] 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).

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 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." [48]

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.[49] 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.[50] In addition to physiological changes caused by hormonal contraceptives leading to increased susceptibility to sexually transmitted infections (STIs),

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

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

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

> 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.[51]

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).

According to *A Pocket Guide to Managing Contraception* (*MC*),[52] methods of long-acting contraception include:

(1) **ParaGard© Intrauterine Copper IUD:** 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**.[53]

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

[52] 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.

[53] 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

(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.[54]

(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.[55] 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."[56]

(4) **Depo-Provera©:** This is an 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

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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).

[54] 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.

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

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

> months.[57] 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.

In October 2011, the *New York Times* gave front-page coverage to the rigorous Heffron study[58] 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."[59]

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**

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[57] 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).

[58] 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).

[59] 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).

major health crisis on our hands."[60]

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 "generally considered minimal"[61]) and death rates that can be directly linked to contraceptive use.[62] 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.[63]

Because it ignored the many serious health risks for women posed by hormonal contraceptives, the 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.

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

[61] 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.

[62] 2011 IOM at 105-06.

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

CONCLUSION

For the foregoing reasons, *Amici* request that this Court reverse the district court's decision and remand with instructions that the district court enter a preliminary injunction.

Respectfully submitted this 18th day of February, 2013,

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CERTIFICATES OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,930 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. 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) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word:mac 2011 in Times New Roman 14-point font.

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a. all required privacy redactions have been made;

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DATED: February 18, 2013

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CERTIFICATE OF SERVICE

I certify that on February 18, 2013, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Sixth 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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