No. 14-6028

In the United States Court of Appeals for the Tenth Circuit

REACHING SOULS, INC., an Oklahoma non-profit corporation, and TRUETT-MCCONNELL COLLEGE, INC., a Georgia non-profit corporation, by themselves and on behalf of all others similarly situated; GUIDESTONE FINANCIAL RESOURCES OF THE SOUTHERN BAPTIST CONVENTION, a Texas non-profit corporation,

Plaintiff-Appellees.

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, THOMAS PEREZ, Secretary of the United States Department of Labor, UNITED STATES DEPARTMENT OF LABOR, JACOB J. LEW, Secretary of the United States Department of the Treasury, and UNITED STATES DEPARTMENT OF THE TREASURY,

Defendant-Appellants,

On Appeal from the United States District Court for the Western District of Oklahoma
Judge Timothy D. DeGiusti
Civil Action No. 5:13-cv-1092-D

BRIEF OF *AMICI CURIAE* WOMEN SPEAK FOR THEMSELVES & JUDICIAL CRISIS NETWORK IN SUPPORT OF PLAINTIFFS-APPELLANTS

Jonathan S. Keim
Judicial Crisis Network
722 12th St. N.W., Fourth Floor
Washington, D.C. 20005
(202) 470-5346

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1 and 29(c)(1), *amicus* Women Speak for Themselves is a project of the Chiaroscuro Institute, a non-profit corporation under I.R.C. § 501(c)(3) that issues no stock and has no parent corporation. *Amicus* Judicial Crisis Network states that it is a non-profit corporation under I.R.C. § 501(c)(4), issues no stock, and has no parent corporation.

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INTEREST OF AMICUS CURIAE[1]

Amicus curiae Women Speak for Themselves is a project of the Chiaroscuro Institute and a membership organization of more than 41,000 American women who have signed an "open letter" opposing the contraception and emergency contraception mandate ("Mandate") issued by the Department of Health and Human Services ("HHS") under the Affordable Care Act ("ACA") because the Mandate threatens religious freedom and proposes a reductionist and harmful understanding of women's freedom. Members of Women Speak for Themselves bring fact-based and nonpartisan arguments about women's freedom and about religious freedom to their local communities, and to the federal government. The letter's author, Helen Alvaré, is president of the Chiaroscuro Institute. Ms. Alvaré is Professor of Law at George Mason University School of Law, where she teaches Family Law and Law and Religion. She has published extensively on issues of gender, contraception, and religious liberty, including a 2013 article (which research was the basis for this brief) published in the Villanova Law Review

[1] This amicus brief is filed pursuant to Fed. R. App. P. 29(a). All parties have consented to its filing. No counsel for a party authored this brief in whole or in part. No party or party's counsel contributed money intended to fund preparing for or submitting this brief, and no person other than the *amici curiae* contributed money intended to fund preparation or submission of this brief.

regarding the Affordable Care Act and religious freedom. *See* Helen M. Alvaré, *No Compelling Interest: The Birth Control Mandate and Religious Freedom*, 58 Vill. L. Rev. 379 (2013).

Amicus curiae Judicial Crisis Network ("JCN") is dedicated to strengthening liberty and justice in America by defending the Constitution as envisioned by its Framers: a federal government of defined and limited powers, dedicated to the rule of law, and supported by a fair and impartial judiciary. JCN promotes these constitutional principles at every level and branch of government, focusing on legislative and legal efforts opposing attempts to undermine the rule of law, expand the power of government, politicize the enforcement of the law, threaten American sovereignty, supplant American law with foreign or international law, or bias the legal system on behalf of politically-favored groups or individuals. JCN's efforts are conducted through various outlets, including print, broadcast, and internet media, and through educating and organizing citizens to participate in this mission.

SUMMARY OF THE ARGUMENT

As the government correctly recognizes, the Tenth Circuit's decision in *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir.) (*en banc*), *cert. granted*, 134 S. Ct. 678 (2013), controls the Court's compelling-interest analysis in this case. Because the government attempts to preserve its arguments on this point by referring to its Supreme Court briefs in *Hobby Lobby*, this brief provides a

concise analysis of the scientific and medical evidence underlying the government's compelling interest arguments.

At root, the government has not shown a causal relationship between the Mandate and the medical benefits it is said to confer on a population level. The Mandate itself is structured to provide free contraceptives to the women who are least likely to need assistance in obtaining contraceptives. There is ample reason to question the government's contention that the Mandate would increase usage of contraceptives by this population. In addition, the government cannot show that increased contraceptive use would actually reduce unintended pregnancies or abortions at a population level, and has failed to explain how the benefits of contraceptives outweigh the possible harms to the population.

In short, HHS has not demonstrated a "compelling governmental interest" under either the Religious Freedom Restoration Act ("RFRA") or the First Amendment's Free Exercise Clause that would justify forcing Plaintiffs-Appellees to provide certain types of contraception and emergency contraceptives ("EC" or "ECs") against their religious beliefs.

ARGUMENT

To sustain its burden of showing a "compelling governmental interest" under RFRA and the First Amendment, HHS must do more than express "broadly formulated interests." *Gonzales v. O Centro Esprita Beneficente Uniao de Vegetal*,

546 U.S. 418, 431 (2006) As the Supreme Court declared in *Brown v. Entertainment Merchants Association*, where it struck down a California law restricting the sale or rental of violent video games to minors, strict scrutiny requires the government to "specifically identify an 'actual problem' in need of solving," and show that what it does is "actually necessary" to the solution. 131 S. Ct. 2729, 2738 (2011). The government must show more than a "modest gap" (20% in *Brown*) between the government's goal and the current situation, because "the government does not have a compelling interest in each marginal percentage point by which its goals are advanced." *Id.* at 2741, n.9. It may not make a "predictive judgment" about a causal link based upon competing studies. *Id*. at 2738. The government must prove that the matter it regulates is the "cause" of the harm it seeks to prevent. *Id*. at 2739. Evidence of mere "correlation" is insufficient, as are studies with "significant, admitted flaws in methodology" and "ambiguous proof." *Id.*

And even if the government shows some causation, evidence that the claimed effects are "small" and "indistinguishable" from effects produced by things *not* regulated renders the legislation "underinclusive." *Id*. at 2739-40. The government has the burden of production and persuasion and must show that this interest is satisfied by imposing the law on "the particular claimant whose sincere

exercise of religion is being substantially burdened." *O Centro*, 546 U.S. at 428, 430-31 (citation omitted).

This brief primarily addresses empirical claims made by the government in promulgating the Mandate and in subsequent litigation. In particular, the government relies heavily on a 2011 report by the Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gap*, Inst. of Med., (2011) ("IOM Report"), *available at* http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx (last accessed May 23, 2014), which was commissioned to support the creation of a contraceptive and EC Mandate. After the ACA required certain health plans and health insurance issuers to provide (without co-payment) "preventive care and screenings" according to guidelines established by the Health Resources Services Administration ("HRSA"), HRSA commissioned the Institute of Medicine ("IOM") to "develop a set of recommendations" for consideration by HRSA and HHS. IOM Report at 2; 42 U.S.C. § 300gg-13(a)(4). The committee recommended that HRSA and HHS consider covering "the full range of Food and Drug Administration-approved ["FDA"] contraceptive methods," including drugs taken after intercourse, also known as "ECs." IOM Report at 109-10. HRSA adopted the IOM Report's recommendations for contraceptives in full without notice and comment by publishing them on its website. *See* U.S. Dept. of Health & Hum. Svcs., *Women's*

Preventive Services Guidelines, http://www.hrsa.gov/womensguidelines/ (last accessed May 23, 2014).

In its haste to adopt the recommendations of the IOM Report, however, HHS neglected to provide an adequate empirical basis for its claims that the Mandate would improve women's health. One member of the committee dissented on these grounds, objecting that the ACA's compressed timeframe "prevented a serious and systematic review of evidence for preventive services." IOM Report at 232 (dissent of Dr. Anthony Lo Sasso). Consequently, the committee made its recommendations "without high quality, systematic evidence of the preventive nature of the services considered." *Id.* As the dissent put it:

> The view of this dissent is that the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy. An abiding principle in the evaluation of the evidence and the recommendations put forth as a consequence should be transparency and strict objectivity, but the committee failed to demonstrate these principles in the Report. This dissent views the evidence evaluation process as a fatal flaw of the Report particularly in light of the importance of the recommendations for public policy and the number of individuals, both men and women, that will be affected.

IOM Report at 232-33 (dissent of Dr. Anthony Lo Sasso).

The government relies nearly exclusively upon the IOM Report, which offers remarkably few sources supporting HHS' sweeping claims about the links between cost and increased usage of contraception and between increased usage

and reduced unintended pregnancies and abortions, and no studies whatsoever supporting its recommendation respecting ECs. Instead, HHS simply assumes that widespread free contraception and ECs will accomplish on a national level what they are designed to do on an individual level. The evidence is otherwise.

I. HHS HAS NOT SHOWN THAT THE MANDATE WOULD ACTUALLY INCREASE USAGE OF CONTRACEPTIVES OR ACCOMPLISH THE STATED GOAL OF REDUCING UNINTENDED PREGNANCIES.

A. The Mandate's cost incentives are not likely to increase the use of contraceptives in the population.

As a first part of its assertion that the Mandate serves the public health, HHS has argued that cost prevents many women from using contraceptives and ECs, and that insurance coverage without cost-sharing is necessary to increase the use of these services. Br. of Pet'rs at 49-51, *Sebelius v. Hobby Lobby Stores et al.*, No. 13-354 (U.S. Jan. 10, 2014) (citing IOM Report at 19), *available at* http://sblog.s3.amazonaws.com/wp-content/uploads/2014/01/01.12.14_brief_for_petitioners_doj.pdf (last accessed May 24, 2014). There are several problems with this reasoning.

First, the IOM Report and its sources acknowledge that contraceptive usage is already extremely high, having been used by 99% of women who have "ever" had sex, and 89% of currently sexually-active women. IOM Report at103; William D. Mosher & Jo Jones, U.S. Dep't of Health and Human Svcs., *Use of*

Contraception in the U.S.: 1982-2008 5, 9 (2010) [hereinafter "Mosher & Jones"], *available at* http://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf (last accessed May 23, 2014). Any changes in contraceptive usage will therefore be at the margins, and have a correspondingly limited effect on overall population usage.

Second, because the Mandate only requires providing contraceptives to employed women and the daughters of the already-employed, it will largely affect women who already have access to contraception and use it. Women above 150% of the poverty line and more-educated women are more likely to use contraception than less-advantaged women. Mosher & Jones at 25. Also, the IOM Report acknowledges that contraceptive coverage is already "standard practice for most private insurance," with nine of ten employer-based insurance plans already including coverage. IOM Report at 108. Guttmacher Institute testimony before the IOM committee likewise acknowledged that "almost every reversible and permanent contraceptive method available" is covered by nearly 90% of plans. Testimony of Guttmacher Inst., Comm. on Preventive Svcs. for Women (Jan. 12, 2011), *available at* http://www.guttmacher.org/pubs/CPSW-testimony.pdf (last accessed May 23, 2014) (citing Gary Claxton, et al., Kaiser Family Found., *Employer Health Benefits: 2010 Annual Survey*, (2012), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf (last accessed May 23, 2014)). With existing contraceptive use already very high among the

affected demographic, it is difficult to imagine how the Mandate could increase usage by the target audience much, if at all.

Third, because the Mandate is an "employer" mandate, it would not increase usage among the unemployed, who are disproportionately poor, young, and minority women experiencing the highest rates of unintended pregnancy and abortion. IOM Report at 102. Indeed, these groups are already provided free contraception through other federal programs, and have been for more than four decades. Since 1970, the National Family Planning Program ("Title X") has authorized HHS to establish and operate family planning projects. 42 U.S.C. § 300 (2006). In 2010 alone, Title X-funded sites served more than 5 million patients, 69% of whom lived at or below the poverty line and 31% who were above, at 4,389 service sites in all 50 states and the District of Columbia. Christina Fowler et al., *RTI Int'l, Family Planning Annual Report: 2010 National Summary*, 1, 7-8, 21 (2011), http://www.hhs.gov/opa/pdfs/fpar-2010-national-summary.pdf. Both Title XIX of the Social Security Act (Medicaid) and Title XX of the Social Security Act, 42 U.S.C. § 1396r-1c *et seq*. (2010), provide federal funds to states for pregnancy prevention services to adolescents and adults. *See also* Guttmacher Inst. & Kaiser Family Found., *Medicaid: A Critical Source of Support for Family Planning in the United States* (2005), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-a-critical-

source-of-support-for-family-planning-in-the-united-states-issue-brief-update.pdf (last accessed May 23, 2014). Federal Maternal and Child Health Block Grants fund 610 school-based or school-linked health clinics. 42 U.S.C. §§ 701–710, *as amended by* Pub. L. No. 112-240, 126 Stat. 2313 (2012); *see also* U.S. Dept. of Health & Hum. Svcs., Appendix I: HHS Activities, http://aspe.hhs.gov/hsp/teenp/activity.htm (last accessed May 23, 2014). In 2012, Planned Parenthood Federation of America alone received $540 million in government funds directed largely at providing lower-cost contraception. Planned Parenthood Fed'n of Am., *Annual Report: 2012-2013*, 18 (2013), http://www.plannedparenthood.org/files/AR-FY13_111213_vF_rev3_ISSUU.pdf (last accessed May 23, 2014).

The IOM Report suggests that one of the Mandate's goals might be to increase usage of long-acting reversible contraceptives ("LARCs") "especially among poor and low-income women most at risk for unintended pregnancy." IOM Report at 109. The Mandate is not, however, directed at these groups of women; also, the economically more-privileged women at whom it is targeted already use LARCs more. Mosher & Jones at 35. If HHS intended the Mandate to incentivize LARCs among some group of lesser-income women and girls, however, two things should be noted. First, while LARCs may have a higher initial cost, over a longer period they can be cheaper than initially-cheaper barrier methods. *See* Kimberly

Palmer, *The Real Cost of Birth Control*, U.S. News & World Rep. (Mar. 5, 2012), http://money.usnews.com/money/blogs/alpha-consumer/2012/03/05/the-real-cost-of-birth-control (last accessed May 23, 2014). Second, as argued in Section II *infra*, there are possible harms from increasing contraceptive use that the government has not even addressed.

Consequently, for the Mandate to lower unintended pregnancy rates by boosting contraceptive use, the Mandate would need to affect the contraception use of some group of women *other* than the one that it actually affects, *i.e.*, portions of the target audience who are not already using contraception at high rates, not eligible for existing government programs, not opposed to contraception due to its health risks and side effects, price-sensitive, and thereby likely to be influenced by offers of free contraceptives. But on its face, the Mandate is not crafted to reach such a group.

Furthermore, evidence indicates that "cost" plays only a small role in women's decisions about contraception. In Centers for Disease Control ("CDC") data cited in the IOM Report, for instance, cost does not even make the list of "frequently cited reasons for nonuse" among the 11% of sexually-active women not using contraception. Mosher & Jones at 6, 14 (cited in IOM Report at 103). Leading reasons, rather, include everything from "didn't think she could get pregnant" (44%), to "worried about the side effects" (16%). In another study, cost

did not figure into adolescents' "most frequently cited reasons for not using contraceptives." Catherine Stevens-Simon et al., *Why Pregnant Adolescents Say They Did Not Use Contraceptives Prior to Conception*, 19 J. Adolescent Health 48 (1996). In a Guttmacher Institute source that the IOM Report overlooked, only 3.7% of the total sample of women seeking abortions listed cost as a barrier to contraceptive usage. Rachel K. Jones et al., *Contraceptive Use Among U.S. Women Having Abortions in 2000-2001*, 34 Persp. on Sexual & Reprod. Health 294, 297-98 (2002). Some of these women may have been eligible for existing government contraception programs, but the report did not investigate.

The IOM Report never indicates a causal relationship between free contraception and increased contraception usage, although it comes closest on page 19. The sources cited there, however, consider cost as a factor affecting *both* men and women, Henry J. Kaiser Family Found., Focus on Health Reform, *Impact Of Health Reform On Women's Access To Coverage And Care* 3 (2010), or preventive health care *generally*, not contraception or ECs. *See* IOM Report at 19 (citing Sheila D. Rustgi et al., The Commonwealth Fund, *Women at risk: Why many women are forgoing needed health care* (2009), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf (last accessed May 23, 2014)); Geetesh Solanki et al., *The direct and*

indirect effects of cost sharing on the use of preventive services, 34 Health Services Research 1331 (2000); Amal N. Trivedi et al., *Effect of cost sharing on screening mammography in Medicare health plans*, 358 New Eng. J. of Med. 375 (2008) (considering, collectively, cancer screenings, dental exams, mammograms, and Pap smears).

The other sources cited in the IOM Report regarding the nexus between cost and usage are likewise unavailing. IOM Report at 109. The Hudman and O'Malley article does not address contraception, and acknowledges that studies do not consistently find any link between cost-sharing and usage. IOM Report at 109 (citing Julie Hudman & Molly O'Malley, Henry J. Kaiser Family Found., *Health Insurance Premiums and Cost-Sharing: Findings From the Research On Low-Income Populations*, 1 (2003), http://kff.org/medicaid/issue-brief/health-insurance-premiums-and-cost-sharing-findings/ (last accessed May 23, 2014)).

For these reasons, the Mandate fails the *Brown* test of "underinclusivity" because the government might have equalized women's health and health care costs much more effectively. HHS could have devoted more resources, for example, to maternity costs, which are the leading driver of differential health costs between males and females of childbearing ages, or even to children's health care costs, in light of the higher rate of single parenting among women. *See* Ctrs. for Medicare & Medicaid Svcs., *National Health Care Spending by Gender and*

Age, 2004 Highlights (2004), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/2004GenderandAgeHighlights.pdf (last accessed May 23, 2014); Jonathan Vespa, et al., U.S. Census Bureau, *America's Families and Living Arrangements: 2012*, 12 tbl.4 (2013), *available at* http://www.census.gov/prod/2013pubs/p20-570.pdf (last accessed May 23, 2014).

B. HHS has not shown that increased usage of contraceptives would lead to lower rates of unintended pregnancy or abortion in the population.

Evidence also indicates, somewhat counterintuitively, that the provision of free contraceptives and ECs may not actually lead to lower rates of unintended pregnancies and abortions. Concerning contraceptive failure, the CDC estimates that 12.4% of all women using contraception will become pregnant each year. Mosher & Jones at 4. Thus, even if the Mandate could boost contraceptive usage, contraceptive failure will constrain reductions in pregnancy. About half of all unintended pregnancies occur among women who *are already* using contraception; these result from method failure or incorrect use. Guttmacher Institute, *Fact Sheet: Unintended Pregnancy in the United States*, 3 (2013), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.pdf (last accessed May 23, 2014).

This fact shows the limits on the potential for increased contraceptive usage to reduce unintended pregnancies. Such potential is further limited because unintended pregnancies are highly concentrated among women the Mandate does not touch: the poor and the unemployed. Guttmacher reports that poor women have six times the rate of unintended pregnancy of women who earn 200% or more than the poverty line. *Id.* at 1. Yet wealthier women, not the poorer women, are the most likely to be affected by the Mandate.

Furthermore, a significant body of literature suggests that rendering contraception and ECs more accessible can actually drive population-level rates of unintended pregnancy and abortion *up*, not down, because some individuals who believe they are insured against risk will engage in more risky behavior (a behavior called "risk compensation"). One widely-cited study suggests that this effect helps explain why increased access to contraception decreases teen pregnancy in the short run, but increases it in the long run. Peter Arcidiacono et al., *Habit Persistence And Teen Sex: Could Increased Access To Contraception Have Unintended Consequences For Teen Pregnancies?* (2005), *available at* http://public.econ.duke.edu/~psarcidi/addicted13.pdf (last accessed May 23, 2014). Programs promoting ECs (covered by the Mandate) to teens are regularly associated with increases in teen pregnancy and abortion rates. Jose Luis Duenas et al., *Trends in the Use of Contraceptive Methods and Voluntary Interruption of*

Pregnancy in the Spanish Population during 1997-2007, 83 Contraception 82 (2011) (over ten years in Spain, a 63% increase in contraceptive use was accompanied by a 108% increase in the abortion rate); *see also* David Paton, *The Economics of Family Planning and Underage Conceptions*, 21 J. Health Econ. 207 (2002).

In a meta-analysis of 23 studies, Princeton's Dr. James Trussell (upon whom the IOM relied, IOM Report at 108) concluded that "*no* study has shown that increased access to [Plan B, an EC] reduces unintended pregnancy or abortion rates on a population level." Elizabeth G. Raymond, James Trussell, & Chelsea B. Polis, *Population Effect of Increased Access to Emergency Contraceptive Pills: A Systematic Review*, 109 Obstetrics & Gynecology 181 (2007) (emphasis added). A study cited by the IOM Report concludes similarly. IOM Report at 108 (citing Debbie Postlethwaite, et al., *A comparison of contraceptive procurement pre-and post-benefit change*, 76 Contraception 360, 363 (2007)).

For its claims concerning a causal relationship between the Mandate and reduced rates of unintended pregnancies and abortions, the IOM Report cites two studies, neither of which shows a causal relationship for the general population: one by Santelli and Melnikas and the other by the Guttmacher Institute. IOM Report at 105; John S. Santelli & Andrea J. Melnikas, *Teen Fertility in Transition: Recent and Historic Trends in the United States*, 31 Ann. Rev. Pub. Health 371

(2010) [hereinafter "Santelli & Melnikas"]; Heather D. Boonstra et al., Guttmacher Inst., *Abortion In Women's Lives* (2006) [hereinafter "Boonstra"], http://www.guttmacher.org/pubs/2006/05/04/AiWL.pdf (last accessed May 23, 2014). Neither study considers the entire U.S. population for all the years in which access to contraception has expanded, but only portions of the population over selected periods of time. Santelli & Melnikas consider only teens from 1990s to early 2000s, whereas Boonstra considers only unmarried women from 1982-2002. Neither study claims to demonstrate a causal link between contraceptive usage and lowered rates of unintended pregnancy. Santelli & Melnikas claim only an "association," not causation, and concede that they "do *not attempt to resolve this debate*" about the "*causes and consequences of teen pregnancy*." Santelli & Melnikas at 373, 377–78 (emphasis added). They also acknowledge the phenomenon of risk compensation, *id*. at 375, and the many factors that may influence teen pregnancy rates. *Id*. at 377-79 (economy, population composition, family dynamics, social mores, the HIV/AIDS pandemic, and the media). They estimate that abstinence, not contraception, contributed to at least 50% of the reported decline in teen pregnancy rates. *Id*. at 376. (Other scholars believe the figure is higher. Joanna K. Mohn, Lynne R. Tingle & Reginald Finger, *An Analysis of the Causes of the Decline in Non-Marital Birth and Pregnancy Rates for Teens*

from 1991 to 1995, 3 Adolesc. & Fam. Health 39 (2003) (67% of the reduction attributed to abstinence and reduced sexual activity).)

Nor does the Guttmacher study the IOM cited show that increased contraception usage reduced rates of unintended pregnancy. It states, rather, that "the decline in unintended pregnancy in the U.S. seems to have stalled," even with "nearly universal" use of contraceptives. Boonstra at 32. Two other Guttmacher studies ignored by the IOM show unintended pregnancy rates rising from 44.7% in 1994 to 51% by 2001, Stanley K. Henshaw, *Unintended Pregnancy in the United States*, 30 Fam. Plan. Persp. 24 (1998), and remaining flat or edging higher through 2006, during the period when women's contraceptives usage *increased* from 80% to 86%. IOM Report at 105 (citing Boonstra at 18); Mosher & Jones at 376-77; Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Persp. on Sexual Reprod. Health 90 (2006). A Guttmacher journal article also reports that during the period from the 1970s to today—a period during which Guttmacher and the CDC agree that the percentage of women who had "ever used" contraception rose from about 90% to 99%—unintended pregnancy rates nationally rose from 35.4% to 49%. Christopher Tietze, *Unintended Pregnancies in the United States, 1970-1972*, 11 Fam. Plan. Persp. 186, 186 n.* (1979) ("A recent report estimates that in 1972, 35.4% percent of all U.S. pregnancies were 'unwanted' or 'wanted later,' thus

providing, from an independent source, an estimate very close to the one used here.").

A CDC report tracking contraception usage from 1982 to 2008 concluded that "[c]hanges in contraceptive method choice and use have not decreased the *overall* proportion of pregnancies that are unintended between 1995 and 2008." Jo Jones, William Mosher & Kimberly Daniels, *Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995*, Nat'l Health Stat. Rep., 1, 11 (Oct. 2012) (emphasis in original), http://www.cdc.gov/nchs/data/nhsr/nhsr060.pdf (last accessed May 23, 2014). Another Guttmacher report on unintended pregnancy between 2001 and 2006 reached the same conclusion, Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities: 2006*, 84 Contraception 478 (2011), despite CDC data showing that more women in the years between 2002 and 2008 were accessing "more effective" methods of contraception. Mosher & Jones at 5.

It should also be remembered that the rise in unintended pregnancy rates from 44.7% to 51% between 1994 and 2001 — before they settled at about 49% from 2001 to 2006 — occurred during a time period when twenty-eight states passed contraceptive insurance mandates for private insurance coverage. IOM Report at 108. There are also a wide range of influences upon rates of unintended

pregnancy (e.g. poverty, cohabitation, later marriage, and the destigmatizing of nonmarital sex and parenting). Guttmacher Inst., *Fact Sheet: Unintended Pregnancy in the United States* (2013), http://www.guttmacher.org/pubs/FB-Unintended-Pregnancy-US.pdf (last accessed May 23, 2014). HHS never mentions these influences or discusses whether the studies cited by the IOM Report considered them.

Other studies question or contradict the government's claims about the national effects of increased contraception usage. IOM's 1995 report on unintended pregnancy concludes, for example, that it is a "health condition of women for which little progress in prevention has been made despite the availability of safe and effective preventive methods." Institute of Medicine, The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families 104 (1995) [hereinafter "IOM 1995 Report"]. And the 2010 Report states that "there has been no major progress in prevention of unintended pregnancy. . . ." Inst. Of Med., Women's Health Research: Progress, Pitfalls, And Promise 143 (2010).

Still more fundamentally, there is a definitional difficulty of measuring "unintended pregnancies" that is well-recognized in the literature. Jessica D. Gipson, et al., *The effects of unintended pregnancy on infant, child, and parental health: a review of the literature,* 39 Studies in Family Planning 18 (2008)

[hereinafter "Gipson"]; IOM Report 1995 at 21-25. "Unintended" can mean unwanted or it can mean mistimed. Interpretation and memory can change. Partners can disagree. The only study relied upon by the IOM Report to claim a current 49% unintended pregnancy rate suffers precisely this limitation. Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 Persp. on Sexual Reprod. Health 90 (2006), *available at* http://www.guttmacher.org/pubs/journals/3809006.pdf (last accessed May 23, 2014). To reach the sum total of "unintended pregnancies," the authors added together "unwanted" and "mistimed" pregnancies with pregnancies for which the woman was "indifferent." To this figure, the authors added their own abortion estimate.

It should be noted that the IOM's 1995 report on unintended pregnancy acknowledges that "research is limited" on the outcomes from unintended pregnancy, IOM 1995 Report at 103, and that extant studies were *not* able to demonstrate "whether the effect is *caused by* or *merely associated with* unwanted pregnancy."[2] *Id.* at 65. Similarly, the leading meta-analysis cited by the IOM

[2] Although the IOM Report insists that it is not important to resolve the empirical question of causation, this assertion does not comport with the legal standard required to show a compelling governmental interest. Surely the existence of a "compelling" interest can be proven empirically.

Report concluded that "existing evidence on the impact of unintended pregnancy on child and parental health outcomes is mixed and is limited by an insufficient number of studies for some outcomes and by the aforementioned measurement and analytical concerns." *See* Gipson at 20.

The government's contention is typically that free contraception and ECs would reduce abortions. Again, this claim seems intuitively true in the abstract, yet has not succeeded on a national scale. The IOM Report bases its claim upon one Guttmacher study reporting that between 1982 and 2002 there was a 6% rise in the proportion of unmarried women using contraception, and a decline in abortion rates. Boonstra at 18. The study does not address population-level effects but only unmarried women, and only for a 20-year period. It variously claims that increased contraceptive usage "accompanied" or "contributed" to diminished abortion rates. *Id.* It makes no attempt to control for the myriad factors affecting abortion rates at that time such as the economy, changing cultural attitudes and mores, the partial-birth abortion debate, and changes in relationship and family structures, to name just a few. This same study admits that early society-wide adoption of contraception often results in "an increase in both contraceptive use and abortion," but claims that over time abortion rates fall. *Id.* at 19.

The data do not bear this out. The study only considered data from 1983 to 2002. *Id*. at 17. The chart it references omits the years 1970 to 1982, during which

time access to contraception was rising due to the federal Title X program, while abortion rates were *climbing*, not falling, from 14 per 1,000 women in 1973 to 24 per 1,000 in 1982. It was only after this simultaneous *rise* in rates of contraception usage and abortion rates for about 23 years post-Title X, that abortion rates began to fall, although they remained fairly high, fell slowly, and never fell below their earliest 1970s rates. *See* Laurie D. Elam-Evans et al., Ctrs. for Disease Control, *Abortion Surveillance-U.S. 2000*, 52 Morbidity and Mortality Weekly Rep. No. SS-12, 17 (2003), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5212a1.htm (last accessed May 23, 2014). Also, since the falling began in the early 1990s, abortion rates have occasionally ticked up during a few years between 2000 and 2010. Stephanie J. Ventura et al., Ctrs. For Disease Control, *Estimated Rates of Pregnancy Outcomes for the U.S., 1990-2008*, 9 (June 20, 2012), *available at* http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_07.pdf (last accessed May 23, 2014).[3]

[3] There is also reason to doubt that significant public health benefits would accrue even if the Mandate successfully reduced unintended pregnancies. IOM's 1995 report on unintended pregnancy acknowledges that "research is limited" on the outcomes from unintended pregnancy, and that extant studies were not able to demonstrate "whether the effect is caused by or merely associated with unwanted pregnancy." IOM 1995 Report at 65, 103. Similarly, the leading meta-analysis cited by the IOM Report concluded that "existing evidence on the impact of unintended pregnancy on child and parental health outcomes is mixed and is

II. EVEN IF THE MANDATE WOULD INCREASE CONTRACEPTIVE USE, THE GOVERNMENT HAS FAILED TO BALANCE THE POSSIBLE UNINTENDED HARMS OF PROMOTING INCREASED CONTRACEPTIVE USE.

Even if the Mandate were likely to meaningfully increase contraceptive use and reduce unintended pregnancies and abortions at a population level, it would still pose real health hazards, most of which the government has failed to consider or balance against the claimed benefits of promoting contraceptives. The IOM Report says only that "for women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated," IOM Report at 105, and that

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limited by an insufficient number of studies for some outcomes and by the aforementioned measurement and analytical concerns." Gipson at 20.

On the specific matter of a link between unintended pregnancy and domestic violence or depression, it concluded: "causality is *difficult if not impossible to show*." *Id.* (emphasis added). Nor does the 1995 IOM Report assert causation, noting that even figures "associating" unintended pregnancy with mothers' smoking and drinking "drop significantly where studies control for other causes." IOM 1995 Report 68-69, 75. Other studies indicate possible reverse causation or a third factor – risk-taking preferences – that would account both for unintended pregnancy and smoking and drinking during pregnancy. Timothy S. Naimi et al., *Binge Drinking in the Preconception Period and the Risk of Unintended Pregnancy: Implications for Women and Their Children*, 111 Pediatrics 1136 (2003); Carolyn Westhoff et al., *Smoking and Oral Contraceptive Continuation*, 79 Contraception 375 (2009); Gregory J. Colman & Ted Joyce, *Trends in Smoking Before, During, and After Pregnancy in Ten States*, 24 Am. J. Preventive Med. 29, 29-35 (2003) (almost all mothers who smoke during pregnancy smoked before pregnancy).

there are "side effects" which are "generally considered minimal." *Id*. (It excepts "oral contraceptive users who smoke." *Id*.)

But the government overlooks recent literature showing potentially serious health risks posed by certain forms of contraception. Ajeet Singh Bhadoria, et al., *Reproductive factors and breast cancer: A case-control study in tertiary care hospital of North India*, 50 Ind. J. of Cancer 316 (2013); Renee Heffron et al., *Use of Hormonal Contraceptives and Risk of HIV-1 Transmission: A Prospective Cohort Study*, 12 Lancet Infec. Dis. 19 (2012) [hereinafter "Heffron"]. It does not mention that leading cancer associations and the World Health Organization ("WHO") have referred to estrogen-progesterone oral contraceptives as "known carcinogens." Am. Cancer Society, *Known and Probable Human Carcinogens*, http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformationaboutcarcinogens/known-and-probable-human-carcinogens (last accessed May 23, 2014); World Health Organization, *Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment* (Sept. 2005), http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf (last accessed May 23, 2014); Steven A. Narod et al., *Oral Contraceptives and the Risk of Breast Cancer in BRCA1 and BRCA2 Mutation Carriers*, 94 J. Nat'l Cancer Inst. 1773 (2002); *see generally* Int'l Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic Risks to Humans* (1999),

http://monographs.iarc.fr/ENG/Monographs/vol72/index.php (last accessed May 23, 2014).

The government also ignores population-level studies indicating risks associated with increased contraceptive use, such as increased STI rates. Christine Piette Durrance, *The Effects of Increased Access to Emergency Contraception on Sexually Transmitted Disease and Abortion Rates*, Economic Inquiry (Dec. 5, 2012), *available at* http://onlinelibrary.wiley.com/doi/10.1111/j.1465-7295.2012.00498.x/ abstract (last accessed May 26, 2014); *see* Ctrs. for Disease Control, Div. of STD Prevention, *Sexually Transmitted Disease Surveillance 2010*, 93-95, 113, 119-20, 127, 129 (2011) [hereinafter "CDC STDs 2010"], http://www.cdc.gov /StD/stats10/surv2010.pdf (last accessed May 26, 2014). These were highlighted in a study offering free LARCs to mostly poor, minority, post-abortive and less-educated women in St. Louis, Jeffrey F. Peipert et al., *Preventing unintended pregnancies by providing no-cost contraception*, 120 J. Obstet. Gyn. 1291 (2012), *available at* http://www.ncbi.nlm.nih.gov/pubmed/23168752 (last accessed May 23, 2014), which was hailed widely as evidence of the logic of the Mandate. *See*, *e.g.*, Tara Culp-Ressler, *New Study Confirms Obamacare's Birth Control Mandate will Reduce Abortion Rate*, ThinkProgress (Oct. 5, 2012),

http://thinkprogress.org/health/2012/10/05/966121/obamacare-birth-control-abortion/ (last accessed May 23, 2014).

In the study, researchers persuaded a large number of women to adopt LARCs (moving adoption of LARCs from 5% to 75%), and contacted each woman 7 times to monitor continued LARC usage. While the study's empirical methods have been questioned, it appeared to show that persuading women at risk of unintended pregnancy to become virtually sterilized for three to ten years did reduce pregnancy and abortion rates. Michael J. New, *New Study Exaggerates Benefits of No-Cost Contraception,* Nat'l Rev. Online (Oct. 10, 2012), http://www.nationalreview.com/corner/329898/new-study-exaggerates-benefits-no-cost-contraception-michael-j-new (last accessed May 26, 2014). But there are also risks in applying this strategy on a larger scale.

First, LARCs like IUDs and Depo-Provera have been associated with various adverse health outcomes, and the latter has been linked to doubling HIV transmission rate. Tessa Madden, *Risk of Bacterial Vaginosis in Users of the Intrauterine Device: A Longitudinal Study*, 39 Sex. Trans. Diseases 217 (2012); Heffron at 19. Second, LARCs do not protect against sexually transmitted infections ("STIs"), which increased significantly during the St. Louis study. Planned Parenthood, *Should you Choose Long-acting Reversible Contraception?* (2014), https://www.plannedparenthood.org/ppmh/long-acting-reversible-

contraception-right-you-41717.htm (last accessed May 23, 2014); *see also* CDC STDs 2010 at 93-95, 113, 119-20, 127, 129.

Whatever the health benefits HHS sought through increased contraceptive and EC usage and availability, there is a large and growing body of literature suggesting that doing so may pose unforeseen health risks, both on a population and individual level. By adopting the flawed IOM Report's suggestions without serious consideration of its empirical limitations and the numerous countervailing considerations that are already well-recognized in the literature, HHS hastily imposed a policy that may end up hurting women generally more than it helps them.

CONCLUSION

The government has not provided evidence showing that the Mandate will boost contraceptive usage by women who are likely to need cost assistance or that increased usage would reduce rates of unintended pregnancy or abortion. Even if contraceptives had the indirect beneficial effects the government identifies, the government has not indicated the size of these benefits or whether they outweigh the possible harms to women. The "net" health losses or benefits of the Mandate are manifestly uncertain, and HHS has provided no basis for claiming otherwise. In sum, HHS' argument is the kind of "ambiguous proof" of a "compelling

governmental interest" that the Supreme Court rejected in *Brown*. For these reasons, the Court should affirm the preliminary injunction of the district court.

Respectfully submitted,

/s/Jonathan S. Keim
Jonathan S. Keim
Judicial Crisis Network
722 12th St. N.W.,
Fourth Floor
Washington, D.C. 20005
jonathan@judicialnetwork.com
(202) 470-5346
Counsel for Amici Curiae

May 27, 2014

CERTIFICATE OF SERVICE

I certify that on May 27, 2014, I caused the foregoing to be served electronically on the following through the Court's filing system. All other case participants will be served through the Court's electronic filing system:

Daniel Howard Blomberg
Email: dblomberg@becketfund.org
John Dillon Curran
Email: DCurran@cwlaw.com
Jared D. Giddens, Esq.
Email: jgiddens@cwlaw.com
Adele Auxier Keim
Email: akeim@becketfund.org
Mark Rienzi
Email: rienzi@law.edu
Seth Michael Roberts
Email: sroberts@lockelord.com
Carl Christopher Scherz
Email: cscherz@lockelord.com

Counsel for Plaintiffs-Appellees

Adam C. Jed
Email: adam.c.jed@usdoj.gov
Alisa Beth Klein
Email: alisa.klein@usdoj.gov
Patrick Nemeroff
Email: patrick.g.nemeroff@usdoj.gov
Mark B. Stern
Email: mark.stern@usdoj.gov

Counsel for Defendants-Appellants

Respectfully submitted,

/s/Jonathan S. Keim

Jonathan S. Keim
Judicial Crisis Network
722 12th St. N.W.,
Fourth Floor
Washington, D.C. 20005
jonathan@judicialnetwork.com
(202) 470-5346

May 27, 2014

Counsel for Amici Curiae

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Respectfully submitted,

/s/Jonathan S. Keim

Jonathan S. Keim
Judicial Crisis Network
722 12th St. N.W.,
Fourth Floor
Washington, D.C. 20005
jonathan@judicialnetwork.com
(202) 470-5346
Counsel for Amici Curiae

May 27, 2014