**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF NEW YORK**

PRIESTS FOR LIFE,

Plaintiff,

vs.

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

Defendants.

Case No. 12-00753-FB-RER

**MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

# TABLE OF CONTENTS


TABLE OF AUTHORITIES .......... ii

INTRODUCTION .......... 1

BACKGROUND .......... 3

I. STATUTORY BACKGROUND .......... 3

II. CURRENT PROCEEDINGS .......... 11

STANDARD OF REVIEW .......... 11

ARGUMENT .......... 12

I. PLAINTIFF'S CLAIMS MUST BE DISMISSED IN THEIR ENTIRETY FOR LACK OF STANDING AND RIPENESS .......... 12

II. PLAINTIFF HAS NOT ESTABLISHED IMMINENT IRREPARABLE HARM RESULTING FROM THE CHALLENGED REGULATIONS OR THAT AN INJUNCTION WOULD BE IN THE PUBLIC INTEREST .......... 13

III. PLAINTIFF HAS NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS .......... 14

A. Plaintiff's Religious Freedom Restoration Act Claim Should Be Rejected .......... 14

B. Plaintiff's Free Exercise Claim is Without Merit .......... 23

CONCLUSION .......... 25

# TABLE OF AUTHORITIES

## FEDERAL CASES

*Adams v. Comm'r of Internal Revenue*,
170 F.3d 173 (3d Cir. 1999)....................22

*Am. Family Ass'n v. FCC*,
365 F.3d 1156 (D.C. Cir. 2004)....................24

*Am. Friends Serv. Comm. Corp. v. Thornburgh*,
951 F.2d 957 (9th Cir. 1991)....................24, 25

*Axson-Flynn v. Johnson*,
356 F.3d 1277 (10th Cir. 2004)....................24

*Belmont Abbey Coll. v. Sebelius*,
Civil Action No. 11-1989 (JEB),
2012 WL 2914417 (D.D.C. July 18, 2012)....................1, 13

*Church of the Lukumi Babalu Aye v. City of Hialeah*,
508 U.S. 520 (1993)....................23, 24

*Emp't Div., Dep't of Human Res. of Or. v. Smith*,
494 U.S. 872 (1990)....................3, 23

*Ex parte McCardle*,
74 U.S. (7 Wall) 506 (1869)....................2

*Fraternal Order of Police v. City of Newark*,
170 F.3d 359 (3d Cir. 1999)....................24

*Fullilove v. Klutznick*,
448 U.S. 448 (1980)....................21

*Gooden v. Crain*,
353 F. App'x 885, 888 (5th Cir. 2009)....................22

*Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*,
546 U.S. 418 (2006)....................14, 15, 18

*Graham v. Comm'r*,
822 F.2d 844 (9th Cir. 1987)....................22

*Ill. State Bd. of Elections v. Socialist Workers Party*,
440 U.S. 173 (1979)....................21

*Intercommunity Ctr. for Justice & Peace v. INS*,
910 F.2d 42 (2d Cir. 1990)....................................................................................25

*Jolly v. Coughlin*,
76 F.3d 468 (2d Cir. 1996)....................................................................................12

*Kaplan v. Bd. of Educ. of City Sch. Dist. of City of N.Y.*,
759 F.2d 256 (2d Cir. 1985)..................................................................................13

*Legatus v. Sebelius*,
No. 12-cv-12061, 2012 WL 5359630 (E.D. Mich. Oct. 31, 2012)..........................1, 13, 14, 23

*Mead v. Holder*,
766 F. Supp. 2d 16 (D.D.C. 2011) .........................................................................17

*Nebraska v. U.S. Dep't of Health & Human Servs.*,
No. 4:12CV3035, 2012 WL 2913402 (D. Neb. July 17, 2012)..........................................1, 13

*New Life Baptist Church Acad. v. Town of E. Longmeadow*,
885 F.2d 940 (1st Cir. 1989)........................................................................20, 21, 22

*Newland v. Sebelius*,
Civil Action No. 1:12-cv-1123-JLK,
2012 WL 3069154 (D. Colo. July 27, 2012) .................................................................1

*O'Brien v. U.S. Dep't of Health & Human Servs.*,
No. 4:12-CV-476 (CEJ), 2012 WL 4481208
(E.D. Mo. Sept. 28, 2012)..................................................................2, 15, 16, 24, 25

*Olsen v. Mukasey*,
541 F.3d 827 (8th Cir. 2008) ....................................................................................24

*Roberts v. U.S. Jaycees*,
468 U.S. 609 (1984).................................................................................................18

*S. Ridge Baptist Church v. Indus. Comm'n of Ohio*,
911 F.2d 1203 (6th Cir. 1990) ..................................................................................20

*Sherbert v. Verner*,
374 U.S. 398 (1963)...........................................................................................15, 16

*Steel Co. v. Citizens for a Better Env't*,
523 U.S. 83 (1998)...............................................................................................2, 12

*Ungar v. N.Y.C. Hous. Auth.*,
363 F. App'x 53, 56 (2d Cir. 2010) ........................................................................1

*United States v. Amer*,
110 F.3d 873 (2d Cir. 1997) ........................................................................1

*United States v. Friday*,
525 F.3d 938 (10th Cir. 2008) ........................................................................18

*United States v. Indianapolis Baptist Temple*,
224 F.3d 627 (7th Cir. 2000) ........................................................................25

*United States v. Lafley*,
656 F.3d 936 (9th Cir. 2011) ........................................................................22

*United States v. Lee*,
455 U.S. 252 (1982) ........................................................................19

*United States v. Wilgus*,
638 F.3d 1274 (10th Cir. 2011) ........................................................................20, 21

*Wheaton Coll. v. Sebelius*,
Civil Action No. 12-1169 (ESH),
2012 WL 3637162 (D.D.C. Aug. 24, 2012) ........................................................................1

*Winter v. Natural Res. Def. Council*,
555 U.S. 7 (2008) ........................................................................11, 12, 14

*Wisconsin v. Yoder*,
406 U.S. 205 (1972) ........................................................................15, 16

**STATE CASES**

*Catholic Charities of Diocese of Albany v. Serio*,
859 N.E.2d 459 (N.Y. 2006) ........................................................................25

*Catholic Charities of Sacramento*,
85 P.3d at 67 (Cal. 2004) ........................................................................18, 21, 25

**FEDERAL STATUTES**

26 U.S.C. § 501(a) ........................................................................1

26 U.S.C. § 4980H ........................................................................4

26 U.S.C. § 6033(a)(1) ........................................................................9

26 U.S.C. § 6033(a)(3)(A)(i) ....................9

26 U.S.C. § 6033(a)(3)(A)(iii) ....................9

42 U.S.C. § 300gg-13(a) ....................4

42 U.S.C. § 300gg-91(a)(1) ....................4

42 U.S.C. § 2000bb-1(a) ....................15

42 U.S.C. § 2000bb-1(b) ....................15

Pub. L. No. 111-148, 124 Stat. 119 (2010) ....................3

**FEDERAL REGULATIONS**

26 C.F.R. § 54.9815-2713T(b)(1) ....................6

29 C.F.R. § 2590.715-2713(b)(1) ....................6

45 C.F.R. § 147.130(a)(1)(iv) ....................23

45 C.F.R. § 147.130(a)(1)(iv)(A) ....................8

45 C.F.R. § 147.130(a)(1)(iv)(B) ....................8

45 C.F.R. § 147.130(b)(1) ....................6

75 Fed. Reg. 34,538 (June 17, 2010) ....................20

75 Fed. Reg. 41,726 (July 19, 2010) ....................5, 17

76 Fed. Reg. 46,621 (Aug. 3, 2011) ....................8, 9

77 Fed. Reg. 16,501 (Mar. 21, 2012) ....................10, 11, 23

77 Fed. Reg. 8725 (Feb. 15, 2012) ....................9, 10

**LEGISLATIVE MATERIALS**

155 Cong. Rec. S12021-02, S12025 (daily ed. Dec. 1, 2009) ....................4, 5

155 Cong. Rec. S12265-02, S12271 (daily ed. Dec. 3, 2009) ....................4, 18

155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) ....................18

**MISCELLANEOUS**

Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services And Supplies Without Cost-Sharing*, 14 GUTTMACHER POL'Y REV. 7, 10 (2011) ....................6

FDA, Birth Control Guide ....................6

HHS, Guidance on the Temporary Enforcement Safe Harbor ....................10

INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS (2011).................... *passim*

## INTRODUCTION

Plaintiff is not entitled to a preliminary injunction. Plaintiff asks the Court to enjoin regulations that are not being enforced against it and that defendants are amending to accommodate the precise religious liberty concerns that form the basis of plaintiff's Complaint. Under these circumstances, plaintiff cannot meet the basic jurisdictional prerequisites of standing and ripeness; nor can it possibly establish irreparable harm or that an injunction would be in the public interest. Indeed, to date, every court to have considered defendants' jurisdictional arguments has ruled in defendants' favor. *See Belmont Abbey Coll. v. Sebelius*, Civil Action No. 11-1989 (JEB), 2012 WL 2914417 (D.D.C. July 18, 2012), *appeal docketed*, No. 12-5291 (D.C. Cir. Sept. 14, 2012); *Wheaton Coll. v. Sebelius*, Civil Action No. 12-1169 (ESH), 2012 WL 3637162 (D.D.C. Aug. 24, 2012), *appeal docketed*, No. 12-5273 (D.C. Cir. Sept. 12, 2012); *Nebraska v. U.S. Dep't of Health & Human Servs.*, No. 4:12CV3035, 2012 WL 2913402 (D. Neb. July 17, 2012), *appeal docketed*, No. 12-3238 (8th Cir. Sept. 25, 2012). Plaintiff's brief cites none of these cases. *See also Legatus v. Sebelius*, No. 12-cv-12061, 2012 WL 5359630, at *5-6 (E.D. Mich. Oct. 31, 2012).

Instead, plaintiff repeats its argument that it does not qualify for the temporary enforcement safe harbor because its employee health plan covered contraceptive services after February 10, 2012, and therefore—according to plaintiff—it may not sign the required certification. As defendants have explained, however, an organization that provided contraceptive services after February 10, 2012, may nonetheless qualify for the safe harbor so long as it took some action to try to exclude or limit contraceptive coverage prior to February 10, 2012. Despite defendants' invitation to explain what happened prior to February 10, 2012, (*see* ECF No. 22, at 3 n.2) plaintiff's latest filing continues to provide no information on this score.

Because it is plaintiff's burden to establish subject-matter jurisdiction, this omission is conclusive. Accordingly, this Court should decide the fully briefed motion to dismiss for lack of jurisdiction before considering plaintiff's motion for preliminary injunction. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.") (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1869)).

Even if this Court had jurisdiction, plaintiff could not establish a likelihood of success on the merits. In another adverse decision that plaintiff's brief omits altogether, the only court that has decided the merits of a challenge to the preventive services coverage regulations dismissed the plaintiffs' Religious Freedom Restoration Act ("RFRA") and First Amendment claims for failure to state a claim upon which relief may be granted.[1] *See O'Brien v. U.S. Dep't of Health & Human Servs.*, No. 4:12-CV-476 (CEJ), 2012 WL 4481208 (E.D. Mo. Sept. 28, 2012), *appeal docketed*, No. 12-3357 (8th Cir. Oct. 4, 2012). Plaintiff is not likely to succeed on its RFRA claim because it has failed to show that the preventive services coverage regulations impose a substantial burden on its religious exercise. A law does not substantially burden a person's exercise of religion "whenever it requires an outlay of funds that might eventually be used by a third party in a manner inconsistent with [the person's] religious values." *Id.* at *7. But even if plaintiff could show that the preventive services coverage regulations impose a substantial burden on its religious exercise, it could not establish a RFRA violation because the regulations

[1] In *O'Brien*, defendants did not raise – and thus the Court did not address – the jurisdictional arguments defendants assert in this case. Unlike plaintiff here, the plaintiffs in *O'Brien* – a for-profit, secular company and its owner – are not eligible for the enforcement safe harbor, which by its terms applies only to non-profit entities. Nor are the *O'Brien* plaintiffs likely to benefit from the forthcoming amendments to the regulations, which contemplate further accommodations of the religious objections of religious organizations.

are narrowly tailored to serve two compelling governmental interests: improving the health of women and children, and equalizing the provision of preventive care for women and men so that women can contribute to society on an equal playing field with men.

Plaintiff's First Amendment claim is equally meritless. The Free Exercise Clause does not prohibit a law that is neutral and generally applicable even if the law prescribes conduct that an individual's religion proscribes. *Emp't Div., Dep't of Human Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990). The preventive services coverage regulations fall within this rubric because they do not target, or selectively burden, religiously motivated conduct. The regulations apply to all non-exempt, non-grandfathered plans, not just those of employers with a religious affiliation.

## BACKGROUND

### I. STATUTORY BACKGROUND

Prior to the enactment of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), many Americans did not receive the preventive health care they needed to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. Due in large part to cost, Americans used preventive services at about half the recommended rate. See INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), *available at* http://cnsnews.com/sites/default/files/documents/PREVENTIVE%20SERVICES-IOM%20REPORT_0.pdf (last visited Oct. 31, 2012). Section 1001 of the ACA – which includes the preventive services coverage provision that is relevant here – seeks to cure this problem by making recommended preventive care affordable and accessible for many more Americans.

The preventive services coverage provision requires all group health plans and health

insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing.[2] 42 U.S.C. § 300gg-13(a). The services that must be covered are: (1) evidence-based items or services that have in effect a rating of "A" or "B" from the United States Preventive Services Task Force ("USPSTF"); (2) immunizations recommended by the Advisory Committee on Immunization Practices; (3) for infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA");[3] and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA. *Id.*

The requirement to provide coverage for recommended preventive services for women, without cost-sharing, was added as an amendment (the "Women's Health Amendment") to the ACA during the legislative process. The Women's Health Amendment was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in section 1001 of the ACA. *See* 155 Cong. Rec. S12021-02, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer) ("The underlying bill introduced by Senator Reid already requires that preventive services recommended by [USPSTF] be covered at little to no cost . . . . But [those recommendations] do not include certain recommendations that many women's health advocates and medical professionals believe are critically important . . . ."); 155 Cong. Rec. S12265-02, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken) ("The current bill relies

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[2] A group health plan includes a plan established or maintained by an employer that provides medical care to employees. 42 U.S.C. § 300gg-91(a)(1). Group health plans may be insured (i.e., medical care underwritten through an insurance contract) or self-insured (i.e., medical care funded directly by the employer). The ACA does not require employers to provide health coverage for their employees, but, beginning in 2014, certain large employers may face assessable payments if they fail to do so under certain circumstances. 26 U.S.C. § 4980H.

[3] HRSA is an agency within the Department of Health and Human Services ("HHS").

solely on [USPSTF] to determine which services will be covered at no cost. . . . [S]everal crucial women's health services are omitted. [The Women's Health Amendment] closes this gap.").

Research shows that cost-sharing requirements can pose barriers to preventive care and result in reduced use of preventive services, particularly for women. IOM REP. at 109; 155 Cong. Rec. S12021-02, S12026-27 (daily ed. Dec. 1, 2009) (statement of Sen. Mikulski) ("We want to either eliminate or shrink those deductibles and eliminate that high barrier, that overwhelming hurdle that prevents women from having access to [preventive care]."). Indeed, a 2010 survey showed that less than half of women are up to date with recommended preventive care screenings and services. IOM REP. at 19. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. 75 Fed. Reg. 41,726, 41,728 (July 19, 2010). Increased use of preventive services will benefit the health of individual Americans and society at large: individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease; healthier workers will be more productive with fewer sick days; and increased utilization will result in savings due to lower health care costs. *Id.* at 41,728, 41,733; IOM REP. at 20.

Defendants issued interim final regulations implementing the preventive services coverage provision on July 19, 2010. 75 Fed. Reg. 41,726. The interim final regulations provide, among other things, that a group health plan or health insurance issuer offering non-grandfathered health coverage must provide coverage for newly recommended preventive services, without cost-sharing, for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation is issued. 26 C.F.R. § 54.9815-2713T(b)(1); 29 C.F.R. § 2590.715-2713(b)(1); 45 C.F.R. §

147.130(b)(1).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, HHS tasked the Institute of Medicine ("IOM")[4] with "review[ing] what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines to implement the Women's Health Amendment. IOM REP. at 2. IOM conducted an extensive science-based review and, on July 19, 2011, published a report of its analysis and recommendations. *Id.* at 20-26. The report recommended that HRSA guidelines include, among other things, well-woman visits; breastfeeding support; domestic violence screening; and, as relevant here, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited Oct. 31, 2012).

Many women do not utilize contraceptive methods or sterilization procedures because they are not covered by their health plan or they require costly copayments, coinsurance, or deductibles. IOM REP. at 19, 109; Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services And Supplies Without Cost-Sharing*, 14 GUTTMACHER POL'Y REV. 7, 10 (2011), *available at* http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.pdf (last visited Oct. 31, 2012) (citing 2010 study that found women with private insurance that covered prescription drugs paid 53 percent of the cost of their oral contraceptives). IOM determined that

[4] IOM was established in 1970 by the National Academy of Sciences and is funded by Congress. IOM REP. at iv. It secures the services of eminent members of appropriate professions to examine policy matters pertaining to the health of the public and provides expert advice to the federal government. *Id.*

coverage, without cost-sharing, for FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling is necessary to increase utilization of these services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. IOM REP. at 102-03.

According to a national survey, in 2001, an estimated 49 percent of all pregnancies in the United States were unintended. *Id.* at 102. When compared to intended pregnancies, unintended pregnancies are more likely to result in poorer health outcomes for mothers and children. Women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy. *Id.* at 103. Children born as the result of unintended pregnancies are at increased risk of preterm birth and low birth weight as compared to children born as the result of intended pregnancies. *Id.* The use of contraception also allows women to avoid short interpregnancy intervals, which have been associated with low birth weight, prematurity, and small-for-gestational-age births. *Id.* at 102-03. Moreover, women with certain chronic medical conditions may need contraceptive services to postpone pregnancy, or to avoid it entirely, and thereby reduce risks to themselves or their children. *Id.* at 103 (noting women with diabetes or obesity may need to delay pregnancy); *id.* at 103-04 (indicating that pregnancy may be harmful for women with certain conditions, such as pulmonary hypertension).

Contraception, IOM noted, is also highly cost-effective because the costs associated with pregnancy greatly exceed the costs of contraceptive services. *Id.* at 107-08. In 2002, the direct medical cost of unintended pregnancy in the United States was estimated to be nearly $5 billion,

with the cost savings due to contraceptive use estimated to be $19.3 billion. *Id.* at 107. Moreover, it has been estimated to cost employers 15 to 17 percent more to not provide contraceptive coverage in their health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and indirect costs such as employee absence and the reduced productivity associated with such absence. Sonfield, *supra*, at 10.

On August 1, 2011, HRSA adopted IOM's recommendations, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), *available at* http://www.hrsa.gov/womensguidelines/ (last visited Oct. 31, 2012). The amendment to the interim final regulations, issued on the same day, authorized HRSA to exempt group health plans established or maintained by certain religious employers (and associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46,621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, an employer must meet all of the following criteria:

(1) The inculcation of religious values is the purpose of the organization.

(2) The organization primarily employs persons who share the religious tenets of the organization.

(3) The organization serves primarily persons who share the religious tenets of the organization.

(4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

45 C.F.R. § 147.130(a)(1)(iv)(B). The sections of the Internal Revenue Code referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," that are exempt

from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii). Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years beginning on or after August 1, 2012.

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. 76 Fed. Reg. at 46,623. After carefully considering the thousands of comments they received, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations while also creating a temporary enforcement safe harbor for plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage. 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012).

Pursuant to the temporary enforcement safe harbor, defendants will not take any enforcement action against an employer, group health plan, or group health insurance issuer with respect to a non-grandfathered group health plan that fails to cover some or all recommended contraceptive services and that is established or maintained by an organization that meets all of the following criteria:

(1) The organization is organized and operates as a non-profit entity.

(2) From February 10, 2012 onward, the group health plan established or maintained by the organization has consistently not provided all or the same subset of the contraceptive coverage otherwise required at any point, consistent with any applicable state law, because of the religious beliefs of the organization.

(3) The group health plan sponsored by the organization (or another entity on behalf of the plan, such as a health insurance issuer or third-party administrator) provides to plan participants a prescribed notice indicating that some or all contraceptive coverage will not be provided under the plan for the first plan year beginning on or after August 1, 2012.

(4) The organization self-certifies that it satisfies the three criteria above, and documents its self-certification in accordance with prescribed procedures.

The enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. HHS, Guidance on the Temporary Enforcement Safe Harbor 3 ("Guidance") (Aug. 15, 2012), *available at* http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf (last visited Oct. 31, 2012). By that time, defendants expect that significant changes to the preventive services coverage regulations will have altered the landscape with respect to certain religious organizations by providing them with further accommodations.

Those intended changes, which were first announced when defendants finalized the religious employer exemption, will establish alternative means of providing contraceptive coverage without cost-sharing while to accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began the process of further amending the regulations on March 21, 2012, when they published an ANPRM in the Federal Register. 77 Fed. Reg. 16,501 (Mar. 21, 2012). The ANPRM "presents questions and ideas" on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. *Id.* at 16,503. The purpose of the ANPRM is to provide "an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made" in the forthcoming amendments to the regulations. *Id.* Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations sponsor insured group health plans and that object to contraceptive coverage on religious grounds and simultaneously to offer such coverage directly to the organization's plan participants, at no charge to organizations or participants. *Id.* at 16,505. The ANPRM also

suggests ideas and solicits comments on potential ways to accommodate religious organizations that sponsor self-insured group health plans for their employees.[5] *Id.* at 16,506-07.

After receiving comments on the ANPRM, defendants will publish a notice of proposed rulemaking, which will be subject to further public comment, before defendants issue further amendments to the preventive services coverage regulations. *Id.* at 16,501. Defendants intend to finalize the amendments to the regulations such that they are effective before the end of the temporary enforcement safe harbor. *Id.* at 16,503.

## II. CURRENT PROCEEDINGS

Plaintiff brought this action on February 15, 2012, claiming that the preventive services coverage regulations violate RFRA, the First Amendment to the United States Constitution, and the APA. On August 1, 2012, defendants moved to dismiss all of plaintiff's claims for lack of jurisdiction. *See* ECF Nos. 18, 19. That motion is now fully briefed. On October 19, 2012, plaintiff moved for a preliminary injunction, asserting that it would suffer irreparable harm if the preventive services coverage regulations are not enjoined.

## STANDARD OF REVIEW

A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the

[5] The accommodations defendants are considering are not constitutionally or statutorily required; rather, they stem from defendants' commitment to work with, and respond to, stakeholders' concerns. *See* 77 Fed. Reg. at 16,503.

public interest." *Id*. at 20. Plaintiff cannot satisfy any of these requirements.[6]

## ARGUMENT

### I. PLAINTIFF'S CLAIMS MUST BE DISMISSED IN THEIR ENTIRETY FOR LACK OF STANDING AND RIPENESS

As an initial matter, plaintiff is not entitled to a preliminary injunction because this Court lacks jurisdiction to adjudicate its claims. *See Steel Co.*, 523 U.S. at 94. Despite several opportunities to do so, plaintiff has provided no reason to doubt that it qualifies for the temporary enforcement safe harbor, pursuant to which defendants will not take any enforcement action against plaintiff for failure to cover contraceptive services until at least January 1, 2014.[7] And defendants have initiated a rulemaking process to amend the challenged regulations to accommodate the precise religious liberty concerns plaintiff raises here before the safe harbor expires. Therefore, plaintiff cannot show that it faces an actual or imminent injury resulting

[6] Plaintiff incorrectly suggests that the four requirements for obtaining a preliminary injunction are not prerequisites to be satisfied but rather factors to be weighed in the exercise of the Court's discretion. *See* Pl.'s Mot. at 10. *Winter* makes clear that a plaintiff bears the burden of satisfying all four requirements before obtaining preliminary injunctive relief. 555 U.S. at 20. Moreover, as plaintiff recognizes, "[w]here a moving party challenges government action taken in the public interest pursuant to a statutory or regulatory scheme . . . the moving party cannot resort to the 'fair ground for litigation' standard, but is required to demonstrate irreparable harm and a likelihood of success on the merits." *Jolly v. Coughlin*, 76 F.3d 468, 473 (2d Cir. 1996) (internal citation omitted).

[7] As defendants have explained, so long as Priests for Life "took some action to try to exclude or limit such coverage that was not successful as of February 10, 2012," *see* Guidance, an organization may qualify for the safe harbor even if it provided contraceptive coverage after February 10, 2012. The "took some action" threshold is not demanding. For example, plaintiff could qualify by certifying that it asked its health insurance issuer prior to February 10, 2012, for a plan that did not cover contraception but that, on account of some error, its issuer did not provide such a plan. Given Priests for Life's representation that it believes "contraception . . . [and] sterilization . . . involve gravely immoral practices," Am. Compl. ¶ 63, ECF No. 12, the government assumes that Priests for Life asked its health insurance issuer for a plan that did not cover such services and that Priests for Life accordingly qualifies for the safe harbor. If Priests for Life represents in its reply brief that it did not seek a plan without contraceptive coverage, the government respectfully requests the opportunity to take limited jurisdictional discovery to probe such a representation or to make appropriate supplemental filings.

from the preventive services coverage regulations, as necessary to establish standing. Nor can it show that its claims are ripe. Indeed, to date, the only three courts to consider defendants' jurisdictional arguments in the context of a motion to dismiss have dismissed nearly identical challenges to the preventive services coverage regulations for lack of standing and ripeness. *See Belmont Abbey*, 2012 WL 2914417; *Wheaton*, 2012 WL 3637162; *Nebraska*, 2012 WL 2913402. Plaintiff makes no effort to address any of these decisions. And a fourth court denied a preliminary injunction motion filed by a non-profit plaintiff that qualifies for the enforcement safe harbor, concluding that "the court is not persuaded that [the plaintiff] has standing to bring its claim." *Legatus*, 2012 WL 5359630, at *6. The parties have fully briefed these jurisdictional arguments, and, instead of repeating those arguments, defendants respectfully refer the court to the parties' briefing on defendants' motion to dismiss. *See* ECF Nos. 17-22. Because this Court lacks jurisdiction over this case, plaintiff's motion for a preliminary injunction should be denied.

## II. PLAINTIFF HAS NOT ESTABLISHED IMMINENT IRREPARABLE HARM RESULTING FROM THE CHALLENGED REGULATIONS OR THAT AN INJUNCTION WOULD BE IN THE PUBLIC INTEREST

For many of the same reasons that the Court lacks jurisdiction over this case, plaintiff has failed to establish any imminent irreparable harm as it must to obtain a preliminary injunction. A plaintiff must make a "clear showing of immediate irreparable harm." *Kaplan v. Bd. Of Educ. Of City Sch. Dist. Of City of N.Y.*, 759 F.2d 256, 259 (2d Cir. 1985). A harm that may occur in the indefinite future is not sufficient. Plaintiff's assertion of harm to its religious freedom, *see* Pl.'s Mot. at 20-21, (in addition to being meritless for the reasons explained below) is not one of imminent harm. As explained in defendants' motion to dismiss, plaintiff faces no imminent injury resulting from the preventive services coverage regulations because it is likely protected by the enforcement safe harbor until at least January 2014. In the meantime, defendants are amending the challenged regulations to address the precise type of religious liberty concerns that

plaintiff raises in its Complaint. Given the safe harbor and the amendment process, plaintiff cannot even show a substantial risk of future harm to its religious freedom, much less imminent injury. *See Legatus*, 2012 WL 5359630, at *5-6.

Plaintiff's purported operational harms, *see* Pl.'s Mot. at 21, also do not establish imminent irreparable harm. They rest entirely on plaintiff's speculation that the regulations will apply to them in their current form come January 2014. *See id*. This, however, ignores the uncontroverted reality that defendants have begun the process of amending the regulations for the very purpose of addressing the religious objections to covering contraception by religious organizations like plaintiff. Planning for an imagined scenario (the continuation of the challenged regulations in their current form) – even if plaintiff has actually incurred some cost to plan for something that will never happen – does not establish imminent irreparable harm. Any costs plaintiff may incur in planning for a regulation that will become obsolete and will not be enforced against it by defendants is a cost it chooses to incur; it is not one that flows from any action by defendants. Indeed, even if plaintiff were to obtain the relief it seeks, it would still face uncertainties about how the amended rules will affect its January 2014 health plan.

Finally, plaintiff's claim that it is in the public interest to prevent violation of a constitutional right has no application here, as the challenged regulations are not being enforced against plaintiff and are, as discussed below, constitutional.

## III. PLAINTIFF HAS NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS

### A. Plaintiff's Religious Freedom Restoration Act Claim Should Be Rejected

Under RFRA, the federal government generally may not "substantially burden a person's exercise of religion, 'even if the burden results from a rule of general applicability.'" *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 424 (2006) (quoting 42

U.S.C. § 2000bb-1(a)). But the federal government may substantially burden the exercise of religion if it "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b).

Plaintiff cannot show a likelihood of success under these standards. The preventive services coverage regulations do not require plaintiff's employees to use or buy contraceptive services. Rather, the regulations require plaintiff, if it chooses to offer health coverage to its employees, to include coverage for certain preventive services, including contraceptive services. The employee/plan participant may then choose to obtain contraceptive services as well as any other preventive services, but that choice is not one that plaintiff is asked to make or to advocate. Instead, plaintiff is free to provide whatever written materials or make whatever oral statements it deems appropriate to those covered by its health plan to convey plaintiff's objections to the use of contraceptive services and to encourage its employees not to use such services.

As the only court that has decided the merits of a challenge to the preventive services coverage regulations under RFRA concluded, any burden imposed by the regulations is too attenuated to satisfy RFRA's *substantial* burden requirement. *See O'Brien*, 2012 WL 4481208, at *4-7. The *O'Brien* court explained that "the plain meaning of 'substantial,'" as used in RFRA, "suggests that the burden on religious exercise must be more than insignificant or remote." *Id.* at *5. And cases presenting the test that RFRA was intended to restore—*Sherbert v. Verner*, 374 U.S. 398 (1963), and *Wisconsin v. Yoder*, 406 U.S. 205 (1972)—confirm this "common-sense conclusion." *O'Brien*, 2012 WL 4481208, at *5. The plaintiff in *Sherbert*, the court explained, "was forced to 'choose between following the precepts of her religion [by resting, and not working, on her Sabbath] and forfeiting [unemployment] benefits, on the one hand, and abandoning one of the precepts of her religion in order to accept work, on the other.'" *Id.*

(quoting *Sherbert*, 374 U.S. at 404). Similarly, in *Yoder*, the state compulsory-attendance law "'affirmatively compel[led] [plaintiffs], under threat of criminal sanction to perform acts undeniably at odds with the fundamental tenets of their religious beliefs.'" *Id.* (quoting *Yoder*, 406 U.S. at 218).

In contrast to the direct and substantial burdens imposed in those cases, the court in *O'Brien* determined that the preventives services coverage regulations result in only an indirect impact on the plaintiffs. *Id.* at *6-7.

> [T]he challenged regulations do not demand that plaintiffs alter their behavior in a manner that will directly and inevitably prevent plaintiffs from acting in accordance with their religious beliefs. [Plaintiff] is not prevented from keeping the Sabbath, from providing a religious upbringing for his children, or from participating in a religious ritual such as communion. Instead, plaintiffs remain free to exercise their religion, by not using contraceptives and by discouraging employees from using contraceptives. The burden of which plaintiffs complain is that funds, which plaintiffs will contribute to a group health plan, might, after a series of independent decisions by health care providers and patients covered by [the employer's] plan, subsidize *someone else's* participation in an activity that is condemned by plaintiffs' religion. The Court rejects the proposition that requiring indirect financial support of a practice, from which plaintiff himself abstains according to his religious principles, constitutes a substantial burden on plaintiff's religious exercise.

*Id*. at *6. The court noted that the regulations have no more of an impact on the plaintiffs' religious beliefs than the employer's payment of salaries to its employees, which those employees can also use to purchase contraceptives. *Id*. at *7. Just as plaintiff may currently encourage its employees not to use their wages to purchase contraceptive services, so too it may advocate against using their health coverage for that purpose.

Even if plaintiff were able to demonstrate a substantial burden on its religious exercise, however, it would not prevail because the preventive services coverage regulations advance compelling governmental interests in public health and gender equality, and are the least restrictive means to achieve those interests. As explained in the interim final regulations, the primary predicted benefit of the regulations is that "individuals will experience improved health

as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease." 75 Fed. Reg. at 41,733; *see, e.g.*, *Mead v. Holder*, 766 F. Supp. 2d 16, 43 (D.D.C. 2011) ("[T]he Government clearly has a compelling interest in safeguarding the public health by regulating the health care and insurance markets.") (citation omitted). "By expanding coverage and eliminating cost sharing for recommended preventive services, these interim final regulations could be expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733. Of course, it is the insured that will ultimately determine which preventive services they choose to use.

Increased access to contraceptive services is a key part of these predicted health outcomes, as a lack of contraceptive access has proven to have negative health consequences for both women and a developing fetus. As IOM concluded in identifying services recommended to "prevent conditions harmful to women's health and well-being," unintended pregnancy may delay "entry into prenatal care," prolong "behaviors that present risks for the developing fetus," and cause "depression, anxiety, or other conditions." IOM REP. at 20, 103. Contraceptive coverage also helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103. In fact, "pregnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome." *Id.* at 103-04.

Closely tied to this interest is a related, but separate, compelling interest that is furthered by the preventive services coverage regulations. By including in the ACA coverage of gender-specific preventive health services for women, Congress made clear that the goals and benefits of effective preventive health care apply with equal force to women, who might otherwise be excluded from such benefits if their unique health care burdens and responsibilities were not

taken into account in the ACA. As explained by members of Congress, "women have different health needs than men, and these needs often generate additional costs. Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men." *See* 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009); *see also* 155 Cong. Rec. S12265-02, S12269 (daily ed. Dec. 3, 2009); IOM REP. at 19. These costs result in women often forgoing preventive care. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274. Accordingly, this disproportionate burden on women creates "financial barriers . . . that prevent women from achieving health and well-being for themselves and their families." IOM REP. at 20. Congress's attempt to equalize the provision of preventive services, with the benefit of women being able to contribute to the same degree as men as healthy and productive members of society, furthers a compelling governmental interest. *See Roberts v. U.S. Jaycees*, 468 U.S. 609, 626 (1984) (acknowledging the "importance, both to the individual and to society, of removing the barriers to economic advancement and political and social integration that have historically plagued certain disadvantaged groups, including women"); *cf. Cath. Charities of Sacramento*, 85 P.3d at 92-93.

The government's interests in promoting the health of women and newborn children and furthering gender equality are compelling not just in the abstract, but also when applied specifically to plaintiffs and other employers that object to the regulations on religious grounds. *See O Centro*, 546 U.S. at 431-32. Each woman who wishes to use contraceptives and who works for plaintiff or a similarly situated entity (and each woman who is a covered spouse or dependent of an employee of such an entity)—or, for that matter, any woman in such a position in the future—is significantly disadvantaged when her employer chooses to provide a plan that fails to cover such services. *See, e.g.*, *United States v. Friday*, 525 F.3d 938, 956 (10th Cir. 2008) (noting that government's interest is still compelling even when impact is limited in

scope). As revealed by the IOM Report, those female employees (and covered spouses and dependents) would be, as a whole, less likely to use contraceptive services in light of the financial barriers to obtaining them and would then be at risk of unhealthier outcomes, both for the women themselves and their potential newborn children. IOM REP. at 102-03. They would also have unequal access to preventive care and would therefore be at a competitive disadvantage in the workforce due to, among other things, their inability to decide for themselves if and when to bear children. These harms would befall female employees (and covered spouses and dependents) who do not necessarily share their employer's religious beliefs. Plaintiff's desire not to provide a health plan that permits such individuals to exercise their own choice as to contraceptive use must yield to the government's compelling interest in avoiding the adverse and unfair consequences that would be suffered by such individuals as a result of the employer's decision. *See United States v. Lee*, 455 U.S. 252, 261 (1982) (noting that a religious exemption is improper where it "operates to impose the employer's religious faith on the employees").

Furthermore, contrary to plaintiffs' assertion, *see* Pl.'s Mot. at 22, 23, the grandfathering of certain health plans does not undermine the governments' compelling interests. The effect of grandfathering is not really a permanent "exemption," but rather, over the long term, a transition in the marketplace with respect to several provisions of the ACA, including the preventive services coverage provision. The grandfathering provision reflects Congress's attempts to balance competing interests – specifically, the interest in spreading the benefits of the ACA, including those provided by the preventive services coverage provision, and the interest in maintaining existing coverage and easing the transition into the new regulatory regime established by the ACA – in the context of a complex statutory scheme. *See* 75 Fed. Reg. 34,538, 34,540, 34,546 (June 17, 2010); *see also Lee*, 455 U.S. at 259 ("The Court has long

recognized that balance must be struck between the values of the comprehensive social security system, which rests on a complex of actuarial factors, and the consequences of allowing religiously based exemptions."). The incremental transition of the marketplace into the ACA administrative scheme does nothing to call into question the compelling interests furthered by the preventive services coverage regulations. Even under the grandfathering provision, it is projected that more group health plans will transition to the requirements under the regulations as time goes on. Defendants estimate that, as a practical matter, a majority of group health plans will lose their grandfather status by 2013. *See id.* at 34,552. Thus, any purported damage to the compelling interests underlying the regulations will be quickly mitigated, which is in stark contrast to the permanent exemption from the regulations that plaintiff seeks.

The preventive services coverage regulations, moreover, are the least restrictive means of furthering the underlying interests. When determining whether a particular regulatory scheme is "least restrictive," the inquiry is whether the individual or organization with religious objections, and those similarly situated, can be exempted from the scheme—or whether the scheme can otherwise be modified—without undermining the government's compelling interest. *See S. Ridge Baptist Church v. Indus. Comm'n of Ohio*, 911 F.2d 1203, 1206 (6th Cir. 1990). The government is not required "to do the impossible—refute each and every conceivable alternative regulation scheme." *United States v. Wilgus*, 638 F.3d 1274, 1289 (10th Cir. 2011). Instead, the government need only "refute the alternative schemes offered by the challenger." *Id*; *see also New Life Baptist Church Acad. v. Town of E. Longmeadow*, 885 F.2d 940, 946 (1st Cir. 1989) (Breyer, J.).

Instead of explaining how plaintiffs and similarly situated employers could be exempted from the preventive services coverage regulations without significant damage to the

government's compelling interests in the health and equality of women who receive health coverage through employers (as well as the health of their newborn children), plaintiff simply hypothesizes that "the government could set up its own clinics to hand out free diaphragms or birth control pills, or whatever favored contraception method it prefers." *See* Pl.'s Mot. at 18. Plaintiff misunderstands the nature of the "least restrictive means" inquiry. RFRA does not require the government to create an entirely new legislative and administrative scheme at plaintiff's behest. *See Wilgus*, 638 F.3d at 1289 ("Not requiring the government to do the impossible—refute each and every conceivable alternative regulation scheme—ensures that scrutiny of federal laws under RFRA is not 'strict in theory, but fatal in fact.'" (quoting *Fullilove v. Klutznick*, 448 U.S. 448, 507 (1980) (Powell, J., concurring))); *New Life Baptist*, 885 F.2d at 946 ("The term 'least restrictive means,' however, is not self-defining. In applying that term, one must pay heed to Justice Blackmun's caution, offered in another context, that '"least drastic" means is a slippery slope . . . [, for a] judge would be unimaginative indeed if he could not come up with something a little less "drastic" or a little less "restrictive" in almost any situation, and thereby enable himself to vote to strike legislation down.'" (quoting *Ill. State Bd. of Elections v. Socialist Workers Party*, 440 U.S. 173, 188-89 (1979) (Blackmun, J., concurring))). In effect, plaintiff wants the government "to subsidize private religious practices," *Catholic Charities of Sacramento*, 85 P.3d at 94, by expending significant resources to adopt an entirely new legislative and administrative scheme.

Furthermore, even if the Court were to consider plaintiff's proffered scheme, it is not an adequate alternative because it is not "feasible" or "plausible." *See, e.g.*, *New Life Baptist*, 885 F.2d at 947 (considering "in a practical way" whether proffered alternative would "threaten potential administrative difficulties, including those costs and complexities which . . . may

significantly interfere with the state's ability to achieve its . . . objectives"); *Graham v. Comm'r*, 822 F.2d 844, 852 (9th Cir. 1987) ("To allow an exception for Scientologists is, we think, possible; but it is not feasible."). In determining whether a proposed alternative scheme is feasible, courts often consider the burdens and disadvantages that would be imposed on other important interests, including the additional administrative and fiscal costs of the proffered scheme. *See, e.g.*, *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011) (rejecting proffered alternative because it "would place an unreasonable burden" on the government). Plaintiff's alternative would impose considerable new costs and other burdens on the government and is otherwise impractical. *See id.* at 942; *New Life Baptist*, 885 F.2d at 947; *see also, e.g.*, *Gooden v. Crain*, 353 F. App'x 885, 888 (5th Cir. 2009); *Adams v. Comm'r of Internal Revenue*, 170 F.3d 173, 180 n.8 (3d Cir. 1999).

Nor would the proposed alternative be equally effective at advancing the government's compelling interests. Congress determined that the best way to achieve the private health coverage goals of the ACA, including expanding preventive services coverage, was to utilize the existing employer-based system. The anticipated benefits of the preventive services coverage regulations are attributable not only to the fact that contraceptive coverage will be available to women with no cost-sharing but also because this coverage will be available through the existing employer-based system of health coverage, thus ensuring that women will face minimal logistical and administrative obstacles to receiving coverage of their care. Plaintiff's alternative, on the other hand, has none of these advantages.[8]

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[8] Plaintiff relies on the court's compelling interest and least restrictive means analysis in *Newland v. Sebelius*, Civil Action No. 1:12-cv-1123-JLK, 2012 WL 3069154 (D. Colo. July 27, 2012), *appeal docketed*, No. 12-1380 (10th Cir. Sept. 26, 2012). For the reasons explained above, the government respectfully maintains that *Newland* was incorrectly decided.

For these reasons, plaintiff cannot establish that it is likely to succeed on its RFRA claim.[9]

**B. Plaintiff's Free Exercise Claim Is Without Merit**

The preventive services coverage regulations do not violate the Free Exercise Clause because they are neutral laws of general applicability. *See Smith*, 494 U.S. at 879. A law is neutral if it does not target religiously motivated conduct but rather has as its purpose something other than the disapproval of a particular religion, or of religion in general. *Church of the Lukumi Babalu Aye v. City of Hialeah*, 508 U.S. 520, 533, 545 (1993). A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id.* at 535-37, 545 (concluding law was not generally applicable when it prohibited animal killings almost exclusively when they were performed as part of a Santeria religious ritual).

[9] In *Legatus*, the court preliminarily enjoined the government from enforcing the contraceptive coverage requirement against a for-profit company and its owner that are not eligible for the enforcement safe harbor and not likely to benefit from the forthcoming amendments to the regulations. The court appropriately recognized that, with respect to First Amendment and RFRA claims, the likelihood of success on the merits and irreparable harm prongs of the preliminary injunction analysis merge such that, to obtain a preliminary injunction, a plaintiff must establish a likelihood of success on the merits. 2012 WL 5359630, at *3. Nevertheless, the court entered a preliminary injunction without determining that plaintiffs were likely to succeed on the merits. *Id.* at *13. Indeed, the court concluded that "[p]laintiffs . . . have [not] shown a strong likelihood of success on the merits." *Id.* Moreover, in its substantial burden analysis, the court merely "assume[d]" that plaintiffs could demonstrate a substantial burden on their religious exercise, observing that "courts often simply assume that a law substantially burdens a person's exercise of religion when that person so claims." *Id.* at *6. This approach, however, reads the substantial burden requirement right out of the RFRA statute, which the court cannot do. As the court explained in *O'Brien*, Congress's use of the term "substantial" means that "the burden on religious exercise must be more than insignificant or remote." 2012 WL 4481208, at *5. Also, the court inexplicably concluded that "[a] preliminary injunction would serve the public interest to the extent that each party has made some showing of a likelihood of success on the merits." *Id.* at *14. For these reasons, and those set forth above, the government respectfully maintains that *Legatus* was incorrectly decided as to the for-profit company and its owner.

The preventive services coverage regulations are neutral and generally applicable. The regulations do not target religiously motivated conduct. Indeed, to the contrary, defendants have made efforts to accommodate religion by creating the religious employer exemption and announcing their intent to provide additional accommodations for certain religious organizations. *See* 45 C.F.R. § 147.130(a)(1)(iv); 77 Fed. Reg. 16,501. The object of the regulations is to promote public health and gender equality by increasing access to and utilization of recommended preventive services, including those for women. The regulations reflect expert medical recommendations about the medical necessity of the services, without regard to any religious motivations for or against such services. *Lukumi*, 508 U.S. at 533. As shown by the IOM Report, this purpose has nothing to do with religion, as the IOM Report is entirely secular in nature. IOM REP. at 2-4, 7-8.

The regulations, moreover, do not pursue their purpose "only against conduct motivated by religious belief." *Lukumi*, 508 U.S. at 545. The regulations apply to all non-exempt group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage. Thus, "it is just not true . . . that the burdens of the [regulations] fall on religious organizations 'but almost no others.'" *Am. Family Ass'n v. FCC*, 365 F.3d 1156, 1171 (D.C. Cir. 2004) (quoting *Lukumi*, 508 U.S. at 536); *see United States v. Amer*, 110 F.3d 873, 879 (2d Cir. 1997) (concluding law that "punishe[d] conduct within its reach without regard to whether the conduct was religiously motivated" was generally applicable).

Plaintiff maintains that the regulations are not neutral or generally applicable because they contain certain categorical exceptions. Pl.'s Mot. at 16-17. But the existence of "express exceptions for objectively defined categories of [entities]," like the ones plaintiff references, does not negate a law's general applicability. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th

Cir. 2004); see also *Olsen v. Mukasey*, 541 F.3d 827, 832 (8th Cir. 2008); *Ungar v. N.Y.C. Hous. Auth.*, 363 F. App'x 53, 56 (2d Cir. 2010); *Am. Friends Serv. Comm. Corp. v. Thornburgh*, 951 F.2d 957, 961 (9th Cir. 1991); *O'Brien*, 2012 WL 4481208, at *7-9.[10]

The regulations are no different from other neutral and generally applicable laws governing employers that have been upheld against free exercise challenges. *See United States v. Indianapolis Baptist Temple*, 224 F.3d 627, 629 (7th Cir. 2000) (upholding federal employment tax laws despite plaintiff's claim that they violated a religious belief requiring dissociation from secular government authority); *Am. Friends Serv.*, 951 F.2d at 959-60; *Intercommunity Ctr. for Justice & Peace v. INS*, 910 F.2d 42, 44 (2d Cir. 1990) (same). Indeed, the highest courts of two states have rejected free exercise claims like those raised by plaintiff here in cases challenging similar provisions of state law. *See Diocese of Albany*, 859 N.E.2d at 468-69; *Catholic Charities of Sacramento*, 85 P.3d at 81-87. And the *O'Brien* court recently came to the same conclusion. *See* 2012 WL 4481208, at *7-9. Because the regulations are neutral laws of general applicability, plaintiff has not shown a likelihood of success on its free exercise claim.[11]

[10] Plaintiff's reliance on *Fraternal Order of Police v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), is misplaced. *Fraternal Order* improperly reads *Lukumi* as prohibiting categorical exemptions. *See* 170 F.3d at 365. *Lukumi*, however, addresses only "individualized exemptions" and categories of selection that "impose burdens *only* on conduct motivated by religious belief." 508 U.S. at 537, 543 (emphasis added). Here, there is neither. Additionally, *Fraternal Order* addressed a policy that allowed secular exemptions but refused religious exemptions. *Fraternal Order*, 170 F.3d at 365. The preventive services coverage regulations, in contrast, contain both secular and religious exceptions. Thus, contrary to plaintiff's assertion, *see* Pl.'s Mot. at 16, there is simply no basis in this case to infer that the government intended "to target employers who refuse to provide contraceptive services to their employees based on their religious beliefs."

[11] Even if the regulations were not neutral and generally applicable, they would not violate the Free Exercise Clause because they satisfy strict scrutiny. *See supra* pp. 16-23.

**CONCLUSION**

This Court should grant the fully briefed motion to dismiss and dismiss this case in its entirety for lack of jurisdiction. In the alternative, for the reasons given above, this Court should deny the motion for a preliminary injunction.

Respectfully submitted this 2nd day of November, 2012,

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**CERTIFICATE OF SERVICE**

I certify that on November 2, 2012, the foregoing document was served via email on opposing counsel, Charles S. LiMandri, Teresa L. Mendoza, Robert J. Muise, and David E. Yerushalmi at the following e-mail addresses: cslimandri@limandri.com, tmendoza@limandri.com, rmuise@americanfreedomlawcenter.org, and dyerushalmi@americanfreedomlawcenter.org.

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