IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 1:12-cv-01123-JLK

WILLIAM NEWLAND;
PAUL NEWLAND;
JAMES NEWLAND;
CHRISTINE KETTERHAGEN;
ANDREW NEWLAND; and
HERCULES INDUSTRIES, Inc., a Colorado corporation;

Plaintiffs,

v.

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

Defendants.

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS THE FIRST AMENDED COMPLAINT AND AMENDED MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs ask this Court to preliminarily enjoin regulations that are intended to ensure that women have access to health coverage, without cost-sharing, for certain preventive services that medical experts have deemed necessary for women's health and well-being. Plaintiffs' challenge rests largely on the theory that a for-profit, secular corporation established to manufacture heating, ventilation, and air conditioning ("HVAC") products can claim to exercise a religion and thereby avoid the reach of laws designed to regulate commercial activity. This cannot be. Indeed, the Supreme Court has recognized that, "[w]hen followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity." *United States v. Lee*, 455 U.S. 252, 261 (1982). Nor can the owners of a for-profit, secular company eliminate the legal separation provided by the corporate form to impose their personal religious beliefs on the corporate entity's employees. To hold otherwise would permit for-profit, secular companies and their owners to become laws unto themselves, claiming countless exemptions from an untold number of general commercial laws designed to improve the health and well-being of individual employees based on an infinite variety of alleged religious beliefs. Such a system would not only be unworkable, it would also cripple the government's ability to solve national problems through laws of general application. This Court, therefore, should reject plaintiffs' effort to bring about an unprecedented expansion of constitutional and statutory free exercise rights.

The preventive services coverage regulations that plaintiffs challenge require all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain recommended preventive

services without cost-sharing (such as a copayment, coinsurance, or a deductible).[1] As relevant here, except as to group health plans of certain non-profit religious employers (and group health insurance coverage sold in connection with those plans), the preventive services that must be covered include all Food and Drug Administration ("FDA")-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider. The plaintiffs in this case are Hercules Industries, Inc., a Colorado corporation that manufactures HVAC products, and five owners and/or officers of the company.[2] Plaintiffs claim their sincerely held religious beliefs prohibit them from providing health coverage for contraceptive services. Plaintiffs seek to preliminarily enjoin the regulations as to them before August 2012 – the date on which plaintiffs allege they must begin arranging for Hercules Industries's group health plan for the 2012 plan year.

Plaintiffs' motion for preliminary injunction should be denied because plaintiffs have not shown that they are likely to succeed on the merits of their claims. Indeed, plaintiffs' claims are all subject to dismissal for failure to state a claim upon which relief may be granted. With respect to plaintiffs' Religious Freedom Restoration Act ("RFRA") claim, none of the plaintiffs can show, as each must, that the preventive services coverage regulations impose a substantial rather than an incidental burden on religious exercise. Hercules Industries is a for-profit, secular employer, and a secular entity by definition does not practice religion. The Newlands' allegations of a burden on their own individual religious exercise fare no better, as the regulations that purportedly impose such a burden apply only to group health plans and health insurance issuers. The Newlands themselves are neither. It is well established that a corporation and its owners are wholly separate entities, and the Court should not permit the Newlands to eliminate

[1] A grandfathered plan is one that was in existence on March 23, 2010 and that has not undergone any of a defined set of changes. 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140.

[2] The individual plaintiffs will be referred to collectively as "the Newlands."

that legal separation to impose their personal religious beliefs on the corporate entity or its employees. The Newlands cannot use the corporate form alternatively as a shield and a sword, depending on which suits them in any given circumstance. Furthermore, even if the preventive services coverage regulations were deemed to impose a substantial burden on any plaintiff's religious exercise, the regulations would not violate RFRA because they 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 who choose to do so can be a part of the workforce on an equal playing field with men.

Plaintiffs' First Amendment claims are 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. Plaintiffs' Establishment Clause claim, which rests primarily on the theory that the religious employer exemption discriminates among religions, is similarly flawed. The exemption distinguishes between *organizations* based on their purpose and composition; it does not favor one *religion, denomination,* or *sect* over another. The distinctions drawn by the exemption, therefore, simply do not violate the constitutional prohibition against denominational preferences. Furthermore, the regulations do not violate plaintiffs' free speech rights. The regulations compel conduct, not speech. They do not require plaintiffs to say anything; nor, as shown by this very lawsuit, do they prohibit plaintiffs from expressing to Hercules Industries's employees or the public their views in opposition to the use of contraceptive services. Indeed, the highest courts of both New York and California have upheld state laws that are similar to the preventive services

coverage regulations against free exercise, Establishment Clause, and free speech challenges like those asserted by plaintiffs here. *See Catholic Charities of the Diocese of Albany v. Serio*, 859 N.E.2d 459, 461 (N.Y. 2006); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 74 n.3 (Cal. 2004).

Nor can plaintiffs succeed on their Fifth Amendment due process or Administrative Procedure Act ("APA") claims. Plaintiffs fail to identify any vagueness in the challenged regulations and, indeed, acknowledge that they understand how the regulations apply to Hercules Industries. Moreover, in promulgating the challenged regulations, defendants complied with the procedural requirements of the APA and carefully considered – and continue to consider – the impact of the regulations on all employers, including for-profit, secular employers like Hercules Industries.

Finally, even if plaintiffs could show a likelihood of success on the merits, the Court should not grant plaintiffs' request for a preliminary injunction because the balance of equities tips toward defendants. Enjoining application of the regulations as to Hercules Industries would prevent defendants from effectuating Congress's goals of improving the health of women and children and equalizing the coverage of preventive services for women and men. It would also harm the public, given the large number of employees at Hercules Industries – as well as any covered spouses and other dependents – who could suffer the negative health consequences that the regulations are intended to prevent.

For these reasons, the Court should deny plaintiffs' motion for a preliminary injunction and grant defendants' motion to dismiss this case in its entirety.

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),[3] 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."). 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.[4] 42 U.S.C. § 300gg-13. The preventive 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")[5];

[3] Amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

[4] 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.

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

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. S12019, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer); 155 Cong. Rec. S12261, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken) ("The current bill relies solely on [USPSTF] to determine which services will be covered at no cost. The problem is, several 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. S12019, 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")[6] 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 June 8, 2012).

[6] 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*.

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. 10 (2011), *available at* http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.pdf (last visited June 8, 2012) (citing 2010 study that found women with private insurance that covers prescription drugs paid 53 percent of the cost of their oral contraceptives). IOM determined that 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 June 8, 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).

The religious employer exemption was modeled after the method of religious accommodation used in several states that already required health insurance issuers to provide coverage for contraception.[7] 76 Fed. Reg. at 46,623. The scope of the exemption is "intended to reasonably balance the extension of any coverage of contraceptive services under the HRSA Guidelines to as many women as possible, while respecting the unique relationship between certain religious employers and their employees in certain religious positions." *Id.*

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. *Id*. After carefully considering the more than 200,000 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 that do not qualify for the religious employer exemption. 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-exempt, non-grandfathered group health plan that fails to

[7] At least 28 states have laws requiring health insurance policies that cover prescription drugs to also provide coverage for FDA-approved contraceptives. *See* Guttmacher Institute, State Policies in Brief: Insurance Coverage of Contraceptives (May 1, 2012), *available at* http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf (last visited June 8, 2012).

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, contraceptive coverage has not been provided at any point by the group health plan sponsored by the organization, 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 the plan will not provide contraceptive coverage 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.[8]

The enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. Guidance at 3.

During the safe harbor period, defendants intend to amend the preventive services coverage regulations to further accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began this process on March 21, 2012, when they published an Advance Notice of Proposed Rulemaking ("ANPRM") in the Federal Register. 77 Fed. Reg. 16,501 (Mar. 21, 2012). The ANPRM presents ideas and solicits public comment on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests.[9] *Id*. at 16,503. Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage on religious grounds and

[8] HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance"), at 3 (Feb. 10, 2012), *available at* http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf (last visited June 8, 2012); 77 Fed. Reg. 16,501, 16,504 (Mar. 21, 2012).

[9] 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.

simultaneously to offer contraceptive coverage directly to the organization's plan participants, at no charge. *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. And the ANPRM seeks comment on which religious organizations should be eligible for the accommodations, including whether for-profit religious companies should be eligible. *Id*. at 16,504. 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 (i.e., August 1, 2013). *Id*. at 16,503.

II. CURRENT PROCEEDINGS

Plaintiffs brought this action to challenge the lawfulness of the preventive services coverage regulations to the extent that they require the health coverage Hercules Industries, Inc., makes available to its employees to cover contraceptive services. Plaintiffs claim this requirement violates RFRA, the First and Fifth Amendments to the United States Constitution, and the APA.

Plaintiff Hercules Industries describes itself as an "s-corporation," organized under Colorado law, that is engaged in the manufacturing of "HVAC products." First Am. Compl. ¶ 11, ECF No. 19. Plaintiffs William Newland, Paul Newland, James Newland, and Christine Ketterhagen allege that "[t]ogether they possess full ownership of and management responsibility for [Hercules Industries]." *Id*. ¶ 11; *see also id*. ¶¶ 12-15. Plaintiff Andrew Newland asserts that he is currently the Vice President of Hercules Industries and will take over for William Newland as the President of the company on January 1, 2013. *Id*. ¶¶ 12, 16. The Newlands assert that they are "practicing and believing Catholic Christians," *id*. ¶ 27, and that they cannot "intentionally participate in, pay for, facilitate, or otherwise support abortifacient drugs, contraception, or sterilization,

through health insurance coverage they offer at Hercules" without violating their sincerely held religious beliefs, *id*. ¶ 3.

According to the First Amended Complaint, Hercules Industries currently has 265 full-time employees who are covered under a self-insured group health plan that does not cover contraceptive services. *Id*. ¶¶ 3, 38-39. The company's plan year begins on November 1 of each year, *id*. ¶ 40, but plaintiffs allege that they "must make insurance coverage decisions and logistical arrangements on or by about August 1, 2012, in order for the plan to be arranged, reviewed, finalized, and offered to employees for open enrollment in time for the plan year's November 1 start date," *id*. ¶ 43. Based on the allegations in the First Amended Complaint, the company does not qualify for the religious employer exemption or the temporary enforcement safe harbor for certain non-profit organizations. *See id*. ¶¶ 64, 85.

On April 30, 2012, plaintiffs filed a motion for preliminary injunctive relief, asserting that they will suffer irreparable harm if the preventive services coverage regulations are not enjoined as to them before August 1, 2012. Pls.' Br. in Supp. of Mot. for Prelim. Inj. at 6, ECF No. 5-1 ("Pls.' Mot."). In support of their motion, plaintiffs rely solely on their RFRA and First Amendment claims. *See* Pls.' Mot. at 6-27.

After defendants filed an opposition to plaintiffs' motion for preliminary injunction and moved to dismiss the Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), plaintiffs filed an amended complaint. *See* First Am. Compl. The Court gave defendants until July 13, 2012 to answer or otherwise respond to plaintiffs' First Amended Complaint and to file an amended brief in opposition to plaintiffs' motion for preliminary injunction. *See* Minute Order, ECF No. 23, June 28, 2012. Because the allegations in the First Amended Complaint still fail to satisfy the requirements of Rule 12 as well as the criteria for obtaining preliminary injunctive relief, defendants again move for dismissal and oppose plaintiffs' motion for preliminary injunction.

STANDARD OF REVIEW

Defendants move to dismiss the First Amended Complaint for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. Under this Rule, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

Defendants also move to dismiss one claim, *see infra* p. 52, under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. The party invoking federal jurisdiction bears the burden of establishing its existence, and the Court must determine whether it has subject matter jurisdiction before addressing the merits of a claim. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998).

This memorandum also responds to plaintiffs' motion for a preliminary injunction. 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 public interest." *Id*. at 20.

ARGUMENT

I. PLAINTIFFS' FIRST AMENDED COMPLAINT FAILS TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED, AND PLAINTIFFS HAVE NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Plaintiffs' Religious Freedom Restoration Act Claim Is Without Merit And Should Be Dismissed

1. Plaintiffs have not sufficiently alleged that the preventive services coverage regulations substantially burden their religious exercise

Congress enacted the Religious Freedom Restoration Act, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified at 42 U.S.C. §§ 2000bb-1, *et seq.*) in response to *Employment Division v. Smith*, 494 U.S. 872 (1990). RFRA was intended to reinstate the pre-*Smith* compelling interest test for evaluating legislation that substantially burdens the free exercise of religion. 42 U.S.C. § 2000bb-1(b). 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 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).

Here, plaintiffs have not sufficiently alleged that the preventive services coverage regulations substantially burden their religious exercise. Hercules Industries, Inc., is not a religious employer; it is "an HVAC manufacturer." First Am. Compl. ¶ 2. The company's pursuits and products are not religious. Under the heading "Purposes for Which Organized," the company's Articles of Incorporation describe a litany of purely commercial activities: "[t]o manufacture, produce, purchase, or otherwise acquire, sell, or otherwise dispose of, import, export, distribute, deal in and with . . . goods, wares, merchandise, and materials of every kind and description." *See* Hercules Supply Co., Inc., Articles of Incorporation at 1, *available at*

http://www.sos.state.co.us/biz/ViewImage.do?fileId=19871159893&masterFileId=19871159893 (last visited June 8, 2012). Specifically, Hercules Industries "engage[s] in the business of purchasing, selling, and distributing, as a wholesaler, air conditioning equipment, appliances, fixtures, and supplies, including equipment for the cooling, heating, and circulating of air." *Id.* And the Articles of Incorporation leave no doubt that Hercules Industries's overriding purpose is to make money: the company is organized "to carry on any business undertaking, transaction or operation commonly carried on or undertaken by capitalists, promoters, financiers . . . or calculated directly or indirectly to enhance the value of or render profitable any of the company's property or rights." *Id.* at 2. The First Amended Complaint does not allege that the company is affiliated with a formally religious entity such as a church. Nor does it allege that the company employs persons of a particular faith. In short, Hercules Industries is plainly a for-profit, secular employer.[10]

Hercules Industries's status is conclusive here. The government is aware of no case in which a for-profit, secular employer with Hercules Industries's characteristics prevailed on a RFRA claim. By definition, a secular employer does not engage in any "exercise of religion," 42 U.S.C. § 2000bb-1(a), as required by RFRA. *See Levitan v. Ashcroft*, 281 F.3d 1313, 1320 (D.C. Cir. 2002) ("[T]he practice[] at issue must be of a religious nature."); *see also Holy Land Found. for Relief & Dev. v. Ashcroft*, 219 F. Supp. 2d 57, 83 (D.D.C. 2002), *aff'd on other grounds*, 333 F.3d 156 (rejecting an organization's RFRA claim because "nowhere in Plaintiff's Complaint does it contend

[10] The Board of Directors and shareholder plaintiffs' June 25, 2012 amendments to the company's Articles of Incorporation, *see* First Am. Compl. ¶112, do not show otherwise. Vague references to "following" and "establishing" "appropriate religious, ethical or moral standards," *id.*, are not enough to convert a for-profit, secular organization into a religious one, particularly when these references are contrasted with the more specific list of secular purposes contained in the company's Articles of Incorporation. Indeed, nothing in the amended Articles of Incorporation identifies any "exercise of religion," 42 U.S.C. § 2000bb-1(a), that the preventive services coverage regulations burden.

that it is a religious organization. Instead, [Plaintiff] defines itself as a 'non-profit charitable corporation,' without any reference to its religious character or purpose.").

It is significant that Hercules Industries elected to organize itself as a secular, for-profit entity and to enter commercial activity. "When followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity." *Lee*, 455 U.S. at 261. Having chosen the secular, for-profit path, the company may not impose its owners' religious beliefs on its employees (many of whom may not share, or even know of, the owners' beliefs). *See id*. ("Granting an exemption from social security taxes to an employer operates to impose the employer's religious faith on the employees."). Hercules Industries could not, for example, fire an employee for religious reasons, even if its owners claimed that their own religious beliefs required the termination. *See Spencer v. World Vision, Inc.*, 633 F.3d 723, 724 (9th Cir. 2011) (per curiam). In this respect, "[v]oluntary commercial activity does not receive the same status accorded to directly religious activity." *Swanner v. Anchorage Equal Rights Comm'n*, 874 P.2d 274, 283 (Alaska 1994) (interpreting the Free Exercise Clause of the Alaska Constitution). Hercules Industries has "made no showing of a religious belief which requires that [it] engage in the [HVAC] business." *Id.* Any burden is therefore caused by the company's "choice to enter into a commercial activity." *Id.*[11] *Cf. Roberts v. U.S. Jaycees*, 468 U.S.

[11] Because the company is a for-profit, secular employer, the First Amended Complaint's allegation that "[p]laintiffs' sincerely held religious beliefs prohibit them from providing coverage for" contraceptive services, First Am. Compl. ¶ 114, cannot be attributed to the company itself. An employer like Hercules Industries stands in a fundamentally different position from a church or a religiously-affiliated non-profit organization. *Cf. Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 344 (1987) (Brennan, J., concurring in the judgment) ("The fact that an operation is not organized as a profit-making commercial enterprise makes colorable a claim that it is not purely secular in orientation. In contrast to a for-profit corporation, a non-profit organization must utilize its earnings to finance the continued provision of the goods or services it furnishes, and may not distribute any surplus to the owners. This makes plausible a church's contention that an entity is not operated simply in order to generate revenues for the church, but that the activities themselves are infused with a religious purpose.").

609, 636 (1984) (O'Connor, J., concurring) (observing in the First Amendment expressive association context that "[o]nce [an organization] enters the marketplace of commerce in any substantial degree it loses the complete control over its membership that it would otherwise enjoy if it confined its affairs to the marketplace of ideas").

The preventive services coverage regulations also do not substantially burden the Newlands' religious exercise. By their terms, the regulations apply to group health plans and health insurance issuers; they do not impose any obligations on individuals. 42 U.S.C. § 300gg-91(a)(1); 26 C.F.R. § 54.9815-2713T; 29 C.F.R. § 2590.715-2713; 45 C.F.R. § 147.130. The Newlands nonetheless claim that the regulations substantially burden *their* religious exercise because the regulations may require the group health plan sponsored by their secular *company* to provide health insurance that includes contraceptive coverage. But a plaintiff cannot establish a substantial burden by invoking this type of trickle-down theory; to constitute a substantial burden within the meaning of RFRA, the burden must be imposed on the plaintiff himself. "To strike down, without the most critical scrutiny, legislation which imposes only an indirect burden on the exercise of religion, i.e., legislation which does not make unlawful the religious practice itself, would radically restrict the operating latitude of the legislature." *Braunfeld v. Brown*, 366 U.S. 599, 606 (1961). Indeed, "[i]n our modern regulatory state, virtually all legislation (including neutral laws of general applicability) imposes an incidental burden at some level by placing indirect costs on an individual's activity. Recognizing this . . . [t]he federal government . . . ha[s] identified a substantiality threshold as the tipping point for requiring heightened justifications for governmental action." *Combs v. Homer-Center Sch. Dist.*, 540 F.3d 231, 262 (3d Cir. 2008) (Scirica, C.J., concurring). Here, any burden on the Newlands' religious exercise results from obligations that the preventive services

coverage regulations impose on a legally separate, secular corporation. This type of attenuated burden is not cognizable under RFRA.[12]

Precedent confirms this commonsense point. Cases that find a substantial burden uniformly involve a direct prohibition on the plaintiff rather than a burden imposed on another entity. In *Potter v. District of Columbia*, 558 F.3d 542, 546 (D.C. Cir. 2009), for example, Muslim firefighters who wore "beards because of sincere religious beliefs" challenged a policy prohibiting the wearing of beards. *O Centro* was about a prohibition on a sect's use of hoasca, a tea with hallucinogenic qualities, in its religious ceremonies. 546 U.S. at 423. And *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 524 (1993), involved a prohibition on the sacrifice of animals – a prohibition that directly conflicted with "one of the principal forms of devotion" of the Santeria religion. In all these cases, the challenged law or policy applied directly to the plaintiff. Not so here, where the preventive services coverage regulations apply to the group health plan sponsored by Hercules Industries, not to the Newlands themselves.

The Newlands' theory boils down to the claim that what's done to the corporation (or the group health plan sponsored by the corporation) is also done to its officers and shareholders. But, as a legal matter, that is simply not so. The Newlands have voluntarily chosen to enter into commerce and elected to do so by establishing a for-profit corporation, which "is treated as a separate legal entity, unique from its officers, directors, and shareholders." *In re Phillips*, 139 P.3d 639, 643 (Colo. 2006); *see* Colo. Rev. Stat. §§ 7-106-203, 7-108-401. Those individuals thereby enjoy limited liability – "an inherent purpose of incorporation" – provided they respect the corporation's separate existence and adhere to a standard of care. *Leonard v. McMorris*, 63 P.3d 323, 330 (Colo. 2003); *In re Phillips*, 139 P.3d at 644; Colo. Rev. Stat. § 7-108-401. As a Colorado corporation with a "perpetual" existence, Hercules Industries, Inc., has broad

[12] The attenuation is in fact twice removed. A group health plan is a legally separate entity from the company that sponsors it. 29 U.S.C. § 1132(d). And, as explained below, Hercules Industries is a legally separate entity from its owners.

powers to conduct business, hold and transact property, and enter into contracts, among others. *See* Colo. Rev. Stat. § 7-103-102; Hercules Supply Co., Articles of Incorporation, *supra*. In the company's employment relationships, for example, Hercules Industries – not its officers or shareholders – "is the employing party." *Sipma v. Mass. Cas. Ins. Co.*, 256 F.3d 1006, 1010 (10th Cir. 2001). In short, Hercules Industries's "separate status isolates the actions, profits, and debts of the corporation from the individuals who invest in and run the entity" – the Newlands. *In re Phillips*, 139 P.3d at 643. The Newlands should not be permitted to eliminate that legal separation only when it suits them, in order to impose their religious beliefs on the corporation's group health plan or its 265 employees.

Although the preventive services coverage regulations do not require the Newlands or Hercules Industries to provide contraceptive services directly, the Newlands' complaint appears to be that, through their company's group health plan and the benefits it provides to employees, plaintiffs will facilitate conduct (the use of contraceptives) that they find objectionable.[13] But this complaint has no limits. A company provides numerous benefits, including a salary, to its employees and by doing so in some sense facilitates whatever use its employees make of those benefits. The owners of Hercules Industries have no right to control the choices of their company's employees, many of whom may not share the Newlands' religious beliefs. These employees have a legitimate interest in access to the preventive services coverage made available under the challenged regulations. In light of the Newlands' choice to structure their company in such a way as to separate themselves from the corporate entity, the

[13] Plaintiffs do not claim that providing coverage for contraceptive services imposes a financial burden. Indeed, experience with the Federal Employees Health Benefits Program shows that contraceptive coverage does not affect employer premiums. *See* Cynthia Dailard, *Special Analysis: The Cost of Contraceptive Insurance Coverage*, Guttmacher Rep. on Pub. Pol'y (Mar. 2003), *available at* http://www.guttmacher.org/pubs/tgr/06/1/gr060112.pdf (last visited June 8, 2012). And Hercules Industries can deduct contributions toward its employees' health plan from its income as a business expense. *See* 26 U.S.C. § 162.

burden of which they complain is not a burden that establishes a violation of RFRA. *See Lee*, 455 U.S. at 261.[14]

The D.C. Circuit's recent decision in *Seven-Sky v. Holder*, 661 F.3d 1, 5 n.4 (D.C. Cir. 2011), further confirms that there is no substantial burden here. There, the plaintiffs brought a RFRA challenge to the minimum coverage provision of the ACA, which, starting in 2014, will require most Americans to obtain qualifying health coverage or pay a tax penalty. The plaintiffs alleged that they "believe[] in trusting in God to protect [them] from illness or injury" and that they do not "want to be forced to buy . . . health insurance coverage." *Mead v. Holder*, 766 F. Supp. 2d 16, 42 (D.D.C. 2011). In concluding that the minimum coverage provision does not substantially burden the plaintiffs' religious practice, the court reasoned, among other things, that "Plaintiffs routinely contribute to other forms of insurance, such as Medicare, Social Security, and unemployment taxes, which present the same conflict with their belief that God will provide for their medical and financial needs." *Id.*[15] The same is true in this case. Plaintiffs presumably "routinely contribute to other" schemes that present the same conflict with their religious beliefs alleged here. A portion of plaintiffs' taxes, for example, are used for Medicaid, a federal-state program that routinely pays for contraceptive services for the needy. *See* Consolidated Appropriations Act of 2012, Pub.

[14] In this respect, the Newlands' RFRA challenge is similar to the claim that the D.C. Circuit rejected in *Kaemmerling v. Lappin*, 553 F.3d 669 (D.C. Cir. 2008). There, a federal prisoner objected to the FBI's collection of his DNA profile. *Id*. at 678. In concluding that this collection did not substantially burden the prisoner's religious exercise, the court concluded that "[t]he extraction and storage of DNA information are entirely activities of the FBI, in which Kaemmerling plays no role and which occur after the BOP has taken his fluid or tissue sample (to which he does not object)." *Id.* at 679. In the court's view, "[a]lthough the government's activities with his fluid or tissue sample after the BOP takes it may offend Kaemmerling's religious beliefs, they cannot be said to hamper his religious exercise because they do not pressure [him] to modify his behavior and to violate his beliefs." *Id.* (citation and quotation omitted). The same is true here, where the choice to obtain or use contraceptive services is "entirely [an] activit[y] of the [employee], in which [the Newlands] play[] no role." *Id.* As in *Kaemmerling*, "[a]lthough the [employee]'s activities . . . may offend [the Newlands'] religious beliefs, they cannot be said to hamper [their] religious exercise because they do not pressure [the Newlands] to modify [their] behavior and to violate [their] beliefs." *Id.* (quotation omitted).

[15] The court of appeals adopted the district court's substantial burden analysis. *See Seven-Sky*, 661 F.3d at 5 n.4.

L. No. 112-74, div. F, tit. II, 125 Stat. 786, 1075 (2012); 42 U.S.C. § 1396a(a)(10); *id*. § 1396d(a)(4)(C); *see also* Kaiser Family Found., State Medicaid Coverage of Family Planning Services, at 7, 9 (Nov. 2009), *available at* http://www.kff.org/womenshealth/upload/8015.pdf (last visited June 8, 2012) (identifying contraceptive services covered under Colorado's Medicaid State Plan). If there was no substantial burden in *Seven-Sky*, there is no substantial burden here.

2. Even if there is a substantial burden, the preventive services coverage regulations serve compelling governmental interests and are the least restrictive means to achieve those interests

a. The regulations significantly advance compelling governmental interests in women's health and equality

Even if plaintiffs were able to demonstrate a substantial burden on their religious exercise, they would not prevail because the preventive services coverage regulations are justified by two compelling governmental interests, and are the least restrictive means to achieve those interests. As an initial matter, "the Government clearly has a compelling interest in safeguarding the public health by regulating the health care and insurance markets." *Mead*, 766 F. Supp. 2d at 43 (citing *Olsen v. Drug Enforcement Admin.*, 878 F.2d 1458, 1462 (D.C. Cir. 1989)); *see also, e.g.*, *Buchwald v. Univ. of N.M. Sch. of Med.*, 159 F.3d 487, 498 (10th Cir. 1998) (concluding that "public health is a compelling government interest"); *Dickerson v. Stuart*, 877 F. Supp. 1556, 1559 (M.D. Fla. 1995) ("The State . . . has a compelling interest in the health of expectant mothers and the safe delivery of newborn babies.") (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992)). There can be no question that this compelling interest in the promotion of public health is furthered by the regulations at issue here.

As explained in the interim final regulations, the primary predicted benefit of the preventive services coverage 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 also* 77 Fed. Reg. at 8728. Indeed,

"[b]y 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.

Increased access to FDA-approved contraceptive services is a key part of these predicted health outcomes, as a lack of contraceptive use has proven in many cases 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. In addition, contraceptive coverage 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. Accordingly, through the requirement that health coverage include coverage for contraceptive services without cost-sharing, defendants seek to further an indisputably compelling interest in the promotion of women's health and the health of potential newborn children.

Closely tied to this interest is a related, but separate, compelling interest that is furthered by the preventive services coverage regulations. As the Supreme Court explained in *Roberts v. United States Jaycees*, 468 U.S. at 626, there is a fundamental "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." Thus, "[a]ssuring women equal access to . . . goods, privileges, and advantages clearly furthers compelling state interests." *Id.* In passing the Women's Health Amendment to include 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." 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 ("When the economy is hurting, women on the whole tend to think of caring for their families first and not caring for themselves . . . . In May of 2009 . . . a report by the Commonwealth Foundation found that more than half of women today are delaying or avoiding preventive care because of its cost. That is not good for women, it is not good for their families, and it is not good for their ability to be able to take care of their families and to take care of themselves."). 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.

Thus, Congress's goal was to equalize the provision of health care for women and men in the area of preventive care, including the provision of family planning services for women. *See, e.g.*, 155 Cong. Rec. S12265-02, S12271 ("[HRSA] will be able to include other important services at no cost, such as the well woman visit, prenatal care, and family planning."); *see also* 77 Fed. Reg. at 8728. Through the equalization of such health care, women, like men, were expected to be able to contribute to "the creation of a more productive and prosperous America." IOM REP. at 20; *see also* 77 Fed. Reg. at 8728 ("Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force.").

Congress's attempt to equalize the provision of preventive health care services, with the resultant 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. *Cf. Catholic Charities of Sacramento*, 85 P.3d at 92-93 (concluding state law that required employers to provide coverage for prescription contraceptives under certain circumstances served a compelling governmental interest).

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 Hercules Industries and other companies that object to the regulations on religious grounds. *See O Centro*, 546 U.S. at 431-32. Taking into account the "particular claimant whose sincere exercise of religion is [purportedly] being substantially burdened," *id.* at 430-31 – that is, plaintiffs and similarly situated entities[16] – an exemption of Hercules Industries and other similar employers from the obligation to

[16] In at least one point in their brief, plaintiffs appear to argue that the Government must show a compelling interest as to Hercules Industries specifically, and even suggest that the regulations would have to cite "scientific and compelling data about [p]laintiffs' employees" in order to establish such an interest. Pls.' Mot. at 13. If plaintiffs do indeed advance such an argument, they go too far. This level of specificity is not supported by the case law and would lead to a completely unworkable standard. The Government cannot possibly be expected to analyze the impact or need for the regulations on each and every employer in America. In practice, an exemption would rarely be limited to a single individual or organization, and courts have recognized that it is appropriate to analyze the impact of an exemption on all similarly situated individuals. *See, e.g.*, *Lee*, 455 U.S. at 260 (considering the impact on the tax system if all religious adherents – not just the plaintiff – could opt out); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1398 (4th Cir. 1990) ("There is no principled way of exempting the school without exempting all other sectarian schools and thereby the thousands of lay teachers and staff members on their payrolls."); *see also, e.g.*, *Graham v. Comm'r of Internal Revenue Serv.*, 822 F.2d 844, 853 (9th Cir. 1987), *overruled in part on other grounds by Navajo Nation v. U.S. Forest Serv.*, 479 F.3d 1024, 1033 (9th Cir. 2007) (en banc); *United States v. Winddancer*, 435 F. Supp. 2d 687, 697 (M.D. Tenn. 2006). *O Centro* is not to the contrary. To be sure, the Court rejected "slippery-slope" arguments for refusing to accommodate a particular claimant. *See* 546 U.S. at 435-36. But as plaintiffs recognize elsewhere in their filings, the exemption that they seek would purportedly apply with equal force to all "religiously-objecting employers," Pls.' Mot. at 13; *see also* First Am. Compl., Prayer for Relief (seeking relief for Hercules Industries "and others similarly situated").

make available to their employees a health plan that covers contraceptive services would remove these employees from the very protections that were intended to further the compelling interests recognized by Congress. *See, e.g.*, *Graham*, 822 F.2d at 853 ("Where, as here, the purpose of granting the benefit is squarely at odds with the creation of an exception, we think the government is entitled to point out that the creation of an exception does violence to the rationale on which the benefit is dispensed in the first instance.").

Each woman who wishes to use contraceptives and who works for Hercules Industries or a similarly situated company (and each woman who is a covered spouse or dependent of an employee) – or, for that matter, any woman in such a position in the future – is significantly disadvantaged when her company chooses to provide a plan that fails to cover such services. *See United States v. Friday*, 525 F.3d 938, 956 (10th Cir. 2008) (noting that the 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 be at a competitive disadvantage in the workforce due to their lost productivity.[17] These harms would befall female employees (and covered spouses and dependents) who do not share their employer's religious beliefs and might

[17] The allegations in plaintiffs' First Amended Complaint regarding the pre- and post-natal care available to Hercules Industries's employees, *see* First Am. Compl. ¶¶ 93-95, do not advance plaintiffs' RFRA claim. As explained in the IOM Report, unwanted or unplanned pregnancies are associated with adverse health outcomes for a variety of reasons unrelated to a lack of access to pre- and post-natal care. IOM REP. at 103. Thus, access to such care, while certainly desirable, does not fully address the compelling interest in women's and infants' health underlying the preventive services coverage regulations. Furthermore, access to pre- and post-natal care does little to advance the Government's compelling interest in gender equality. Nor does the care available to Hercules Industries's employees reveal anything about the care provided to the employees of similarly situated entities.

not have been aware of those beliefs when they joined the ostensibly secular company. Hercules Industries's desire not to make available 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 company's decision. *See Lee*, 455 U.S. at 261 (noting that a religious exemption is improper where it "operates to impose the employer's religious faith on the employees").[18]

b. The regulations are the least restrictive means of advancing the Government's compelling interests

The preventive services coverage regulations, moreover, are the least restrictive means of furthering the underlying dual, albeit intertwined, interests. When determining whether a particular regulatory scheme is "least restrictive," the appropriate 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, e.g.*, *United States v. Wilgus*, 638 F.3d 1274, 1289-95 (10th Cir. 2011) (describing the "least restrictive means" inquiry and examining proffered alternatives, all of which simply modify the existing scheme or exempt the plaintiff and those like him from the scheme);

[18] Plaintiffs miss the point when they attempt to minimize the magnitude of the Government's interest by arguing that contraception is widely available and even subsidized for certain individuals at lower income levels. *See* Pls.' Mot. at 12-13. Although a majority of employers do offer coverage of FDA-approved contraceptives, *see* IOM REP. at 109, many women forego preventive services, including certain reproductive health care, because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109. The challenged regulations would eliminate that cost-sharing. 77 Fed. Reg. at 8728. And, of course, the Government has a compelling interest in ensuring access to contraceptive services for those women whose employers do not currently offer such coverage.

Plaintiffs' allegation regarding the salary paid to Hercules Industries's employees, *see* First Am. Compl. ¶ 96 – which defendants can only assume is meant to suggest that Hercules Industries's employees could purchase contraception should they choose to do so – is similarly misguided. It simply relies on a more severe form of cost-sharing (i.e., requiring employees to pay all of the costs of contraception) and would thus completely fail to achieve the purposes of the regulations.

New Life Baptist Church Acad. v. Town of E. Longmeadow, 885 F.2d 940, 946 (1st Cir. 1989) (Breyer, J.); *Graham*, 822 F.2d at 853; *Callahan v. Woods*, 736 F.2d 1269, 1272-73 (9th Cir. 1984) ("If the compelling state goal can be accomplished despite the exemption of a particular individual, then a regulation which denies an exemption is not the least restrictive means of furthering the state interest.").

Instead of explaining how Hercules Industries and similarly situated companies 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 such companies, plaintiffs conjure up several new regulatory schemes that they claim would be less restrictive. *See* Pls.' Mot. at 10. Plaintiffs misunderstand the nature of the "least restrictive means" inquiry. Rather than suggesting modifications to the current employer-based system that Congress enacted, *see generally* H.R. Rep. No. 111-443, pt. 2, at 984-86 (2010) (explaining why Congress chose to build on the employer –based system), plaintiffs would have the whole system turned upside-down to accommodate their religious beliefs at enormous administrative and financial cost to the Government. RFRA simply does not require the Government to create an entirely new legislative and administrative scheme at plaintiffs' 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 *Illinois State Bd. of Elections v. Socialist Workers Party*, 440

U.S. 173, 188–89 (1979) (Blackmun, J., concurring))). In effect, plaintiffs want 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 or administrative scheme. For this reason alone, the Court need not consider the drastic and burdensome proposed alternatives offered by plaintiffs. *See, e.g.*, *Friday*, 525 F.3d at 957 ("Demands for affirmative governmental assistance are generally disfavored in free exercise cases.").

Furthermore, even if the Court were to consider plaintiffs' proffered schemes, they are not adequate alternatives because they are 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*, 822 F.2d at 852 ("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); *New Life Baptist*, 885 F.2d at 947 ("[T]he Court has made clear that administrative considerations play an important role in determining whether or not the state can follow its preferred means."). Plaintiffs' alternatives would impose considerable new costs and other burdens on the Government and are otherwise impractical. *See Lafley*, 656 F.3d 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) ("The trial court found that Appellees satisfied the 'least restrictive means' prong by demonstrating that Gooden's suggested alternative was not administratively or financially feasible."); *Adams v. Comm'r of Internal Revenue*, 170 F.3d 173, 180 n.8 (3d Cir. 1999) ("The fact that

[plaintiff] has suggested a number of alternative modes of tax collection for herself . . . is beside the point."); *Warner v. Patterson*, No. 2:08-CV-519TC, 2011 WL 5117917, at *12 (D. Utah Oct. 27, 2011) ("[T]here is no evidence that a less restrictive alternative is available that satisfies relevant safety and security concerns without imposing significant costs or burdens on the prison.").

Nor would the proposed alternatives be equally effective at advancing the Government's compelling interests. As discussed below, Congress determined that the best way to achieve the 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 services will be available to women with no cost sharing – an attribute that plaintiffs' alternatives admittedly share – but also because these services 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. Plaintiffs' alternatives, on the other hand, have none of these advantages. They would require establishing entirely new government programs and infrastructures, and would almost certainly require women to take steps to find out about the availability of and sign up for this new benefit, thereby ensuring that fewer women would take advantage of it. Nor do plaintiffs offer any suggestions as to how these programs could be integrated with the employer-based system or how women would obtain Government-provided preventive services in practice. Thus, plaintiffs' proposals – in addition to raising myriad administrative and logistical difficulties – are far less likely to achieve the compelling interests furthered by the regulations, and therefore do not represent reasonable less restrictive means.

c. The regulations are not underinclusive, but are carefully tailored to achieve the government's compelling interests

Finally, the "exemptions" from the preventive services coverage regulations cited by plaintiffs, *see* Pls.' Mot. at 15-18, do not change the fact that the regulations are the least restrictive means to advance the Government's compelling interests. This is not a case where "[u]nderinclusive enforcement of a law suggests that the government's 'supposedly vital interest' is not really compelling" or "that the law is not narrowly tailored." *Friday*, 525 F.3d at 958 (quoting *Lukumi*, 508 U.S. at 546-47). Three of the four exemptions raised by plaintiffs are not exemptions from the preventive services coverage regulations at all, but are instead provisions of the ACA that exclude individuals and entities from other requirements imposed by the ACA. These exemptions reflect the Government's attempts to balance the compelling interests underlying the challenged regulations against other significant interests supporting the complex administrative scheme created by the ACA. *See 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."); *Wilgus*, 638 F.3d at 1290 (endorsing the balancing of compelling interests); *United States v. Hardman*, 297 F.3d 1116, 1134-35 (10th Cir. 2002) (same). And unlike the exemption plaintiffs seek for all employers that object to the regulations on religious grounds, the existing exemptions do not undermine the Government's interests in any significant way. *See Lukumi*, 508 U.S. at 547.

First, 26 U.S.C. § 4980H(c)(2) does *not* exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 76 Fed. Reg. at 46,622 n.1. The exemption that plaintiffs refer to excludes employers with fewer than 50 full-time equivalent employees from the employer responsibility provision, meaning that such employers are not subject to assessable payments if they do not provide health coverage to their full-time employees and certain other criteria are met. *See* 26 U.S.C.

§ 4980H(c)(2). But this exemption has nothing to do with preventive services coverage. Small businesses that choose to offer non-grandfathered health coverage to their employers are required to provide coverage for recommended preventive services – including contraceptive services, starting in plan years on or after August 1, 2012 – without cost-sharing. And there is reason to believe that many small employers will continue to offer health coverage, because the ACA, among other things, provides for a system of tax incentives for small businesses to encourage the purchase of health insurance for their employees. *See id*. § 45R.[19]

Second, 26 U.S.C. § 5000A(d)(2)(A) exempts from the minimum coverage provision of the ACA those "member[s] of a recognized religious sect or division thereof" who, on the basis of their religion, are opposed to the concept of health insurance. *See also id.* § 1402(g). The minimum coverage provision will require certain individuals who fail to maintain a minimum level of health insurance to pay a tax penalty beginning in 2014. Again, this provision is entirely unrelated to the preventive services coverage regulations. Nor could it provide any exemption from the preventive services coverage regulations, as it only excludes certain *individuals* from the requirement to obtain health coverage and says nothing about the requirement that non-grandfathered group health plans provide preventive services coverage to their participants. It is also clearly an attempt by Congress to *accommodate* religion and, unlike the exemption sought by plaintiffs, is sufficiently narrow so as not to undermine the larger administrative scheme. *See Lee*, 455 U.S. at 260-61 (discussing 26 U.S.C. § 1402(g),

[19] Employees of small employers that do not provide health coverage will be able to obtain a "qualified health plan" from a "health insurance issuer" through a health insurance exchange. *See* 42 U.S.C. § 18021; *id.* § 18031(d)(2)(B)(i). Because the preventive services coverage requirement applies to a "health insurance issuer offering group or individual health insurance coverage," *id*. § 300gg-13(a), the coverage individuals buy on the Exchanges will necessarily cover recommended contraceptive services. For this additional reason, the small employer exemption will not undermine the compelling interests underlying the preventive services coverage regulations.

which is incorporated by reference into 26 U.S.C. § 5000A(d)(2)(A) and is thus identical in scope to the exemption at issue here).

Furthermore, exempting this particular "readily identifiable," *see id.* at 261, class of individuals from the minimum coverage provision is unlikely to appreciably undermine the compelling interests motivating the preventive services coverage regulations. By definition, a woman who is "conscientiously opposed to acceptance of the benefits of any private or public insurance which . . . makes payments toward the cost of, or provides services for, medical care," 26 U.S.C. § 1402(g)(1), would not utilize health coverage – including contraceptive coverage – even if it were offered.

The third "exemption" cited by plaintiffs – the grandfathering of certain health plans from certain provisions of the ACA – also is not specifically limited to the preventive services coverage regulations. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. In fact, grandfathering is not really an "exemption," but rather, over the long term, a phase-in of several requirements under the ACA, including those in the preventive services coverage regulations. The grandfathering provision reflects Congress's attempts to balance competing interests – specifically, the interest in spreading the benefits of the ACA, including those under 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).

Congress's decision to incrementally transition into the ACA administrative scheme does nothing to call into question the compelling interests furthered by the preventive services coverage regulations. Even under grandfathering, more and more group health plans will be subject to 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. Plaintiffs would have this Court believe that an interest cannot truly be "compelling" unless Congress is willing to impose it on everyone all at

once despite competing interests, but offers no support for such an untenable proposition. In short, Congress determined that the compelling interests underlying the regulations, as well as other provisions of the ACA, could be satisfactorily furthered with gradual implementation, whereby more women would enjoy coverage of recommended preventive services as fewer plans are eligible for grandfather status. In light of the complexities inherent in implementing this administrative scheme, this approach is a perfectly reasonable balancing of competing interests.

The only true exemption from the preventive services coverage regulations cited by plaintiffs is the exemption for "religious employer[s]," 45 C.F.R. § 147.130(a)(1)(iv). There is a rational distinction between the narrow exception currently in existence and plaintiffs' requested expansion. As revealed by the plain text of the regulations, a "religious employer" is narrowly defined to be an employer that, *inter alia*, has the "inculcation of religious values" as its purpose and "primarily employs persons who share the religious tenets of the organization." *Id*. Thus, the exception does not undermine the government's compelling interests. It anticipates that the impact on employees of exempted organizations will be minimal, given that any religious objections of the exempted organizations are presumably shared by most of the individuals actually making the choice as to whether to use contraceptive services. *See* 77 Fed. Reg. at 8728.

The same is not true for Hercules Industries, which cannot discriminate based upon anyone's religious beliefs when hiring, and therefore almost certainly employs many individuals who do not share the Newlands' religious beliefs. Should plaintiffs be permitted to extend the protections of RFRA to any employer whose owners or shareholders object to the operation of the regulations, it is difficult to see how the regulations could continue to function or be enforced in a rational manner. *See O Centro*, 546 U.S. at 435 ("[T]he Government can demonstrate a compelling interest in uniform application of a particular program by offering evidence that granting the requested religious accommodation would seriously compromise its ability to administer the

program."). The preventive services coverage regulations are nationwide, and providing for voluntary participation among for-profit enterprises would be "almost a contradiction in terms and difficult, if not impossible, to administer." *Lee*, 455 U.S. at 258. We are a "cosmopolitan nation made up of people of almost every conceivable religious preference," *Braunfeld*, 366 U.S. at 606, and many people object to countless medical services. If any organization, no matter the high degree of attenuation between the mission of that organization and the exercise of religious belief, were able to seek an exemption from the operation of the preventive services coverage regulations, then it is difficult to see how defendants could administer the regulations in a manner that would achieve Congress's goals of improving the health of women and children and equalizing the coverage of preventive services for women. Indeed, women who receive their health coverage through organizations like Hercules Industries would be subject to negative health and employment outcomes because they had obtained employment with an organization that imposes its owners' religious beliefs on their health care needs. *See* 77 Fed. Reg. at 8728.

For these reasons, plaintiffs' RFRA challenge should be rejected.

B. Plaintiffs' First Amendment Claims Are Without Merit And Should Be Dismissed

1. The regulations do not violate the Free Exercise Clause

Plaintiffs' free exercise claim fails at the outset because, as explained above, *see supra* pp. 15-18, for-profit, secular employers generally, and Hercules Industries in particular, do not engage in any exercise of religion protected by the First Amendment. Nevertheless, even if they did, the preventive services coverage regulations are neutral laws of general applicability and thus do not violate the Free Exercise Clause. And, to the extent the preventive services coverage regulations contain an exemption for certain religious employers, that exemption serves to accommodate religion, not to burden or disapprove of it.

The Supreme Court has made clear that a law that is neutral and generally applicable does not run afoul of the Free Exercise Clause even if it prescribes conduct that an individual's religion proscribes or has the incidental effect of burdening a particular religious practice. *Smith*, 494 U.S. at 879; *see also Lukumi*, 508 U.S. at 531-32. The Court reasoned that "mak[ing] an individual's obligation to obey [a neutral law of general applicability] contingent upon the law's coincidence with his religious beliefs, except where the [government's] interest is compelling," would "permit[] him, by virtue of his beliefs, to become a law unto himself" in contravention of both "constitutional tradition and common sense." *Smith*, 494 U.S. at 885 (quotations omitted).

"Neutrality and general applicability are interrelated." *Lukumi*, 508 U.S. at 531. A law is neutral if it does not target religiously motivated conduct either on its face or as applied. *Id*. at 533. A neutral law has as its purpose something other than the disapproval of a particular religion, or of religion in general. *Id*. at 545. A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id*. In *Lukumi*, for example, the Court determined a law that prohibited animal killings almost exclusively when they were performed as part of a Santeria religious ritual was not generally applicable. *Id*. at 535-37.

Unlike such selective laws, the preventive services coverage regulations are neutral and generally applicable. As an initial matter, the regulations do not target religiously motivated conduct. They do not, on their face, refer to any religion or religious practice,[20] and they do not evidence any "official purpose to disapprove of a particular religion, or of religion in general." *Id*. at 532. The object of the regulations is to increase access to and utilization of recommended preventive services, including those

[20] The regulations refer to religion in the context of exempting certain religious employers from the requirement to cover contraceptive services. But this reference does not destroy the regulations' neutrality. Any burden on plaintiffs' religious beliefs – and there is none – would "arise[] not from the religious terminology used in the exemption, but from the generally applicable requirement to provide coverage for contraceptives." *Catholic Charities of Sacramento*, 85 P.3d at 83.

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. *Id*. at 533. The requirement to provide coverage for recommended contraceptive services, in particular, is meant to improve the health of mothers and children and to reduce health care costs by reducing unintended pregnancies and promoting healthy birth spacing. 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; *see also Lighthouse Inst. for Evangelism, Inc. v. City of Long Branch*, 510 F.3d 253, 275 (3d Cir. 2007) (concluding law was neutral where there was no evidence "it was developed with the aim of infringing on religious practices").[21]

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 group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage and do not qualify for the religious employer exemption. 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

[21] Plaintiffs' characterization of the preventive services coverage regulations as an intentional attempt to target non-insularly-focused religious objectors, *see* Pls.' Mot. at 21-24, is mere rhetorical bluster. Plaintiffs provide no evidence to show that the regulations were designed as an assault on some religious objectors, as opposed to an effort to increase women's access to and utilization of recommended preventive services. And plaintiffs cannot dispute that defendants have made efforts to accommodate religion in ways that will not undermine the goal of ensuring that women have access to coverage for recommended preventive services without cost-sharing. *See supra* pp. 34-35; 77 Fed. Reg. 16,503. This case, therefore, is a far cry from *Lukumi*, 508 U.S. 520, on which plaintiffs rely. In *Lukumi*, the legislature specifically targeted the religious exercise of members of a single church (Santeria) by enacting ordinances that used terms such as "sacrifice" and "ritual," *id*. at 533-34, and prohibited few, if any, animal killings other than Santeria sacrifices, *id*. at 535-36. There is no evidence of a similar targeting of religious practice here.

without regard to whether the conduct was religiously motivated" was generally applicable).

Plaintiffs maintain that the regulations are not generally applicable because they do not apply to grandfathered plans or plans of employers that qualify for the religious employer exemption. Pls.' Mot. at 20-21.[22] But the Tenth Circuit has made clear that the existence of "express exceptions for objectively defined categories of [entities]" does not negate a law's general applicability. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *see also Grace United Methodist Church v. City of Cheyenne*, 451 F.3d 643, 651 (10th Cir. 2006) (refusing to "interpret *Smith* as standing for the proposition that a secular exemption automatically creates a claim for a religious exemption"). The exception for grandfathered plans is available on equal terms to all employers, whether religious or secular. And the religious employer exemption serves to accommodate religion, not to disfavor it. These categorical exceptions do not trigger strict scrutiny. *See Swanson v. Guthrie Indep. Sch. Dist.*, 135 F.3d 694, 698, 701 (10th Cir. 1998) (concluding school district's attendance policy was not subject to strict scrutiny despite exemptions for "strict categories of students," such as fifth-year seniors and special education students); *see also Ungar v. New York City Hous. Auth.*, 363 F. App'x 53, 56 (2d Cir. 2010) (holding exemptions to housing policy for, *inter alia*, victims of domestic violence, did not negate general applicability because exemptions were "only for specified categories" and were available to plaintiffs on same terms as everyone else); *Am. Friends Serv. Comm. Corp. v. Thornburgh*, 951 F.2d 957, 961 (9th Cir. 1991) (concluding employer verification statute was not subject to strict scrutiny even though it exempted independent contractors, household employees, and employees hired prior to November 1986 because exemptions "exclude[d] entire, objectively-defined categories of

[22] Plaintiffs also point to purported exemptions for small employers and members of religious sects opposed to health insurance. Pls.' Mot. at 20. As explained above, however, these exceptions do not apply to the preventive services coverage regulations. *See supra* pp. 31-33.

employees"); *Intercommunity Ctr. for Justice & Peace v. INS*, 910 F.2d 42, 45 (2d Cir. 1990) (same). What plaintiffs are asserting here is not that the regulations favor non-religion over religion, but rather that they do not favor religion enough. Such a claim is not cognizable under the First Amendment.

Indeed, the preventive services coverage regulations are no different from other neutral and generally applicable laws governing employers that have been upheld against free exercise challenges. Courts, for example, have rejected challenges brought by religious employers to provisions of the Immigration Reform and Control Act that require employers to verify the immigration status of their employees and impose sanctions for non-compliance. *See Am. Friends Serv. Comm.*, 951 F.2d at 960; *Intercommunity Ctr. for Justice*, 910 F.2d at 44. Despite the plaintiffs' allegation in those cases that their religious beliefs compelled them to employ persons in need without regard to immigration status, the courts upheld the statute because it did not regulate religious belief or burden acts *because of* their religious motivation. *See Am. Friends Serv. Comm*, 951 F.2d at 960; *Intercommunity Ctr. for Justice*, 910 F.2d at 44.

Similarly, in *United States v. Indianapolis Baptist Temple*, 224 F.3d 627, 629 (7th Cir. 2000), the court upheld laws requiring employers to file federal employment tax returns and pay federal employment taxes despite the plaintiff church's allegation that the laws contravened its religious belief requiring dissociation from all secular government authority. The court determined that the laws were neutral and generally applicable because they were "not restricted to [the church] or even religion-related employers generally, and there [was] no indication that they were enacted for the purpose of burdening religious practices." *Id*. The same is true here. The preventive services coverage regulations are not restricted to plans of religion-related employers. They apply to all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage and do not qualify for the religious employer exemption. There is, moreover, no evidence that the object of the regulations is to burden religious

practices. To the contrary, defendants have made efforts to accommodate religion through the religious employer exemption and the forthcoming amendments. Because the preventive services coverage regulations are neutral laws of general applicability, they do not run afoul of the Free Exercise Clause.[23]

2. The regulations do not violate the Establishment Clause

Plaintiffs claim that the preventive services coverage regulations violate the Establishment Clause because the religious employer exemption amounts to a denominational preference forbidden by *Larson v. Valente*, 456 U.S. 228, 244 (1982), and requires the government to unlawfully scrutinize an organization's religious practices. Pls.' Mot. at 24-26; *see also id*. at 22-23. Plaintiffs are wrong on both counts.

"The clearest command of the Establishment Clause is that one religious *denomination* cannot be officially preferred over another." *Larson*, 456 U.S. at 244 (emphasis added). A law that discriminates among religions by "aid[ing] one religion" or "prefer[ing] one religion over another" is subject to strict scrutiny. *Id*. at 246; *see also Olsen*, 878 F.2d at 1461 (observing that "[a] statutory exemption authorized for one church alone, and for which no other church may qualify" creates a "denominational preference"). Thus, for example, the Supreme Court has struck down on Establishment Clause grounds a state statute that was "drafted with the explicit intention" of requiring "particular religious denominations" to comply with registration and reporting requirements while excluding other religious denominations. *Larson*, 456 U.S. at 254; *see also Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that created special school district for religious enclave of Satmar Hasidim because it "single[d] out a particular religious sect for special treatment").[24] The Court, on the other hand, has upheld a statute that provided an

[23] Even if the regulations were subject to strict scrutiny, plaintiffs' free exercise challenge still would fail. As explained above, *see supra* pp. 15-35, the regulations satisfy strict scrutiny.

[24] The law at issue in *Wilson v. NLRB*, 920 F.2d 1282, 1285, 1287 (6th Cir. 1990), on which plaintiffs rely, also discriminated among religious denominations, because it favored

exemption from military service for persons who had a conscientious objection to all wars, but not those who objected to only a particular war. *Gillette v. United States*, 401 U.S. 437 (1971). The Court explained that the statute did not discriminate among religions because "no particular sectarian affiliation" was required to qualify for conscientious objector status. *Id.* at 450-51. "[C]onscientious objector status was available on an equal basis to both the Quaker and the Roman Catholic." *Larson*, 456 U.S. at 247 n.23; *see also Cutter v. Wilkinson*, 544 U.S. 709, 724 (2005) (upholding Religious Land Use and Institutionalized Persons Act against Establishment Clause challenge because it did not "confer[] . . . privileged status on any particular religious sect" or "single[] out [any] bona fide faith for disadvantageous treatment").

Like the statutes at issue in *Gillette* and *Cutter*, the preventive services coverage regulations do not grant any denominational preference or otherwise discriminate among religions. It is of no moment that the religious employer exemption applies to some religious employers but not others. *See Droz v. Comm'r of IRS*, 48 F.3d 1120, 1124 (9th Cir. 1995) (concluding that religious exemption from self-employment Social Security taxes did not violate the Establishment Clause even though "some individuals receive exemptions, and other individuals with identical beliefs do not"); *Diocese of Albany*, 859 N.E.2d at 468-69 (rejecting challenge to similar religious employer exemption under New York law; "this kind of distinction – not between denominations, but between religious organizations based on the nature of their activities – is not what *Larson* condemns"). The relevant inquiry is whether the distinction drawn by the regulations between exempt and non-exempt entities is based on religious affiliation. Here, it is not.

The regulations' definition of "religious employer" does not refer to any particular denomination. The criteria for the exemption focus on the purpose and composition of the organization, not on its sectarian affiliation. The exemption is available on an equal

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established denominations – i.e., "a bona fide religion, body, or sect" with historical objections to supporting labor unions – over less established religions.

basis to organizations affiliated with any and all religions. The regulations, therefore, do not promote some religions over others. Indeed, the Supreme Court upheld a similar statutory exemption for houses of worship in *Walz v. Tax Commission of New York*, 397 U.S. 664, 673 (1970). The statute in *Walz* exempted from property taxes all realty owned by an association organized exclusively for religious purposes and used exclusively for carrying out such purposes. *Id*. The Court determined the statute did not violate the Establishment Clause because it did not "single[] out one particular church or religious group." *Id*. The same result should obtain here.[25]

The religious employer exemption also does not foster excessive government entanglement with religion. As an initial matter, Hercules Industries acknowledges that it does not qualify for the religious employer exemption. First Am. Compl. ¶ 64. In particular, Hercules Industries admits that it fails to satisfy even the fourth criterion for the religious employer exemption – the requirement that it be a nonprofit organization as described in section 6033 of the Internal Revenue Code. *Id*. ¶ 64; 45 C.F.R. § 147.130(a)(1)(iv)(B)(4). Plaintiffs cannot credibly claim that this criterion requires any inquiries that would pose a potential entanglement issue. Accordingly, any entanglement

[25] Plaintiffs stretch *Colorado Christian University v. Weaver*, 534 F.3d 1245 (10th Cir. 2008), well beyond its facts in asserting that the case stands for the proposition that the Establishment Clause prohibits the government from distinguishing between different types of organizations that adhere to the same religion. In *Weaver*, the court struck down a state law that provided scholarship funds for students to attend college, including religious colleges, but denied such funding to students attending colleges that were determined by the state on an ad hoc basis to be pervasively sectarian. *Id*. at 1250. The court's decision was limited to "laws that facially regulate religious issues," *id*. at 1257, and, particularly, those that do so in a way that denies certain religious institutions public benefits that are afforded to all other institutions, whether secular or religious. The court in *Weaver* said nothing about the constitutionality of exemptions from generally applicable laws that are designed to accommodate religion, as opposed to discriminate against religion. Requiring that such exemptions apply to all organizations – no matter their purpose, composition, or religious character – would severely hamper the government's ability to accommodate religion. *See Amos*, 483 U.S. at 334 ("There is ample room under the Establishment Clause for 'benevolent' neutrality which will permit religious exercise to exist without sponsorship and without interference."); *Catholic Charities of Sacramento*, 85 P.3d at 79. Because the preventive services coverage regulations do not "facially regulate religious issues," *Weaver*, 534 F.3d at 1257, and because the religious employer exemption serves to accommodate – rather than disadvantage – religion, *Weaver* is inapposite.

that might result from the religious employer exemption would not exist with respect to these plaintiffs.

In any event, the religious employer exemption does not violate the prohibition against excessive entanglement between government and religion. The Supreme Court has made clear that "[n]ot all entanglements" are unconstitutional. *Agostini v. Felton*, 521 U.S. 203, 233 (1997). "Interaction between church and state is inevitable, and [the Court has] always tolerated some level of involvement between the two." *Id*. (internal citation omitted). To violate the Establishment Clause, "[e]ntanglement must be 'excessive.'" *Id*. "[R]outine regulatory interaction which involves no inquiries into religious doctrine . . . and no detailed monitoring and close administrative contact between secular and religious bodies does not . . . violate the nonentanglement command." *Hernandez v. Comm'r of Internal Revenue*, 490 U.S. 680, 697 (1989).

Any interaction between the government and religious organizations that may be necessary to administer or enforce the religious employer exemption is not so "comprehensive," *Lemon v. Kurtzman*, 403 U.S. 602, 619 (1971), or "pervasive," *Agostini*, 521 U.S. at 233, as to result in excessive entanglement. Indeed, the Supreme Court has upheld laws that require government monitoring that is more onerous than any monitoring that may be required to enforce the religious employer exemption. *See Bowen v. Kendrick*, 487 U.S. 589, 615-617 (1988) (concluding there was no excessive entanglement where the government reviewed adolescent counseling programs set up by the religious institution grantees, reviewed the materials used by such grantees, and monitored the programs by periodic visits); *Roemer v. Board of Public Works of Md.*, 426 U.S. 736, 764–765 (1976) (rejecting excessive entanglement challenge where the State conducted annual audits to ensure that grants to religious colleges were not used to teach religion); *Lemon*, 403 U.S. at 614 (noting that the Supreme Court upheld an exemption for realty owned by an association organized and used exclusively for religious purposes in *Walz*, 397 U.S. 664, even though "the State had a continuing burden to ascertain that

the exempt property was in fact being used for religious worship"); *see also Agostini*, 521 U.S. at 212 (indicating that unannounced monthly visits by a public employee to religious schools to prevent and detect inculcation of religion by public employees does not constitute excessive entanglement); *cf. LeBoon v. Lancaster Jewish Comty. Ctr. Ass'n*, 503 F.3d 217, 226 (3d Cir. 2007) (relying on factors similar to the criteria for the religious employer exemption for purposes of Title VII's exemption).[26]

Accordingly, plaintiffs' Establishment Clause claim fails.[27]

3. The regulations do not violate the Free Speech Clause

Plaintiffs' free speech claim fares no better. The right to freedom of speech "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* ("*FAIR*"), 547 U.S. 47, 61 (2006). But the preventive services coverage regulations do not require plaintiffs – or any other person, employer, or entity – to say anything. Contrary to plaintiffs' assertion, *see* Pls.' Mot. at 27; First Am. Compl. ¶ 149, the regulations do not require plaintiffs themselves to provide any education or counseling.[28] Thus, the regulations are unlike the laws at issue in the cases on which plaintiffs rely. Those laws compelled speech. *See Wooley v. Maynard*, 430

[26] Moreover, unlike in *Weaver*, on which plaintiffs rely, the religious employer exemption does not require the government to "troll[] through" or "second-guess[]" any entity's religious beliefs. 534 F.3d at 1261, 1266. Instead, the religious employer exemption utilizes "neutral, objective criteria" regarding the organization's tax classification, purpose, and composition. *Id*. at 1266;

[27] Even if the regulations discriminate among religions (and they do not), they are valid under the Establishment Clause, because they satisfy strict scrutiny. *See supra* pp. 15-35; *Larson*, 456 U.S. at 251-52.

[28] Rather, if Hercules Industries decides to offer a non-grandfathered health plan to its employees, that plan must cover the costs of any education and counseling provided by medical professionals to its participants. It is the medical professionals who will be speaking, not plaintiffs. And the regulations do not purport to regulate the content of any education or counseling provided. Taken to its logical conclusion, plaintiffs' assertion that the government cannot constitutionally require group health plans to provide coverage for education and counseling would stymie the government's efforts to regulate health coverage entirely: a doctor's visit invariably involves some communication between the patient and the doctor or other medical professional, and there may be many instances in which the entity providing the health coverage disagrees with the content of this communication.

U.S. 705, 707 (1977) (requiring residents to display on their automobile a license plate that read "Live Free or Die"); *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 630 (1994) (requiring cable operators to carry local broadcast television stations). Here, plaintiffs are not being required to "speak" at all. Pls.' Mot. at 27.

Nor do the preventive services coverage regulations limit what plaintiffs may say. Plaintiffs remain free under the regulations to express to Hercules Industries's employees (or anyone else) whatever views they may have on the use of contraceptive services (or any other health care services) as well as their views on the regulations' requirement that certain group health plans and health insurance issuers cover certain contraceptive services. Indeed, plaintiffs may encourage Hercules Industries's employees not to use contraceptive services. The preventive services regulations regulate conduct, not speech. *See FAIR*, 547 U.S. at 60-62 (concluding that statute that required law schools to provide military recruiters with equal access to campus and students regulated conduct, not speech).

Moreover, the conduct required by the preventive services coverage regulations is not "inherently expressive," such that it is entitled to First Amendment protection. *Id*. at 66. An employer that provides a health plan that covers contraceptive services, along with numerous other medical items and services, because it is required by law to do so is not engaged in the sort of conduct the Supreme Court has recognized as inherently expressive. *Compare id*. at 65-66 (making space for military recruiters on campus is not conduct that indicates colleges' support for, or sponsorship of, recruiters' message), *with Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 568-70 (1995) (openly gay, lesbian, and bisexual group marching in parade is expressive conduct), *Texas v. Johnson*, 491 U.S. 397, 406 (1989) (flag burning is expressive conduct), *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 505-14 (1969) (wearing black armbands in school to show disapproval of Vietnam hostilities is expressive conduct), *and W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624 (1943) (not

saluting American flag is expressive conduct). Because the preventive services coverage regulations do not compel any speech or expressive conduct, they do not violate the Free Speech Clause.

Indeed, the highest courts of two states have rejected First Amendment claims like those raised by plaintiffs here in cases challenging similar provisions of state law. Under both California and New York law, group health insurance coverage that includes coverage for prescription drugs must also provide coverage for prescription contraceptives. *Diocese of Albany*, 859 N.E.2d at 461; *Catholic Charities of Sacramento*, 85 P.3d at 74 n.3. Both states' laws contain an exemption for religious employers that is similar to the exemption contained in the preventive services coverage regulations. *Diocese of Albany*, 859 N.E.2d at 462; *Catholic Charities of Sacramento*, 85 P.3d at 74 n.3. Religiously-affiliated employers with group health insurance coverage that did not qualify for the state law exemptions brought suit, claiming, as plaintiffs do here, that the laws violate the rights to free exercise and free speech protected by the First Amendment and amount to an establishment of religion as prohibited by the First Amendment.

The highest courts in both states rejected these claims. They held that the laws do not violate the Free Exercise Clause because they are neutral laws of general applicability. *Diocese of Albany*, 859 N.E.2d at 468-69; *Catholic Charities of Sacramento*, 85 P.3d at 81-87. The courts rejected the Establishment Clause challenge because the exemptions for religious employers do not discriminate among religious denominations or sects. *Diocese of Albany*, 859 N.E.2d at 468-69; *Catholic Charities of Sacramento*, 85 P.3d at 83-87. And they upheld the laws under the Free Speech Clause because "a law regulating health care benefits is not speech." *Catholic Charities of Sacramento*, 85 P.3d at 89; *see also Diocese of Albany*, 859 N.E.2d at 465.

For these reasons, plaintiffs' First Amendment claims fail.

C. The Court Should Dismiss Plaintiffs' Fifth Amendment Due Process Clause Claim

Plaintiffs' terse assertion that the preventive services coverage regulations violate the Fifth Amendment's Due Process Clause is as puzzling as it is baseless. In the First Amended Complaint, plaintiffs not only fail to identify any purported vagueness in the challenged regulations; they show that the regulations are not vague at all as applied to Hercules Industries.

A law is not unconstitutionally vague unless it "fails to provide a person of ordinary intelligence fair notice of what is prohibited" or "is so standardless that it authorizes or encourages seriously discriminatory enforcement." *United States v. Williams*, 553 U.S. 285, 304 (2008). Courts relax these standards where, as here, the law in question imposes civil rather than criminal penalties and does not "interfere[] with the right of free speech or of association." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982). "But 'perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity.'" *Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2719 (2010).

Tellingly, the First Amended Complaint sets out plaintiffs' due process claim in only general, conclusory terms. Rather than specify what they find vague in the preventive services coverage regulations, plaintiffs merely recite the above vagueness test and baldly assert that the regulations fail it. *See* First Am. Compl. ¶¶ 152-157. Such "'labels and conclusions'" and "'naked assertion[s]'" fall far short of stating a plausible claim for relief. *Iqbal*, 556 U.S. at 678.

Further, the First Amended Complaint demonstrates that plaintiffs understand how the challenged regulations apply to Hercules Industries. Contrary to the premise of their vagueness claim, plaintiffs have no difficulty concluding that the regulations "impos[e] . . . requirements on Plaintiffs' plan year beginning November 1, 2012." First Am. Compl. ¶ 86. Indeed, the First Amended Complaint methodically explains why Hercules Industries is "subject to" the preventive services coverage regulations and what those

regulations require of the company. *Id*. ¶¶ 44-46, 52-54, 62, 64, 74-86. In other words, the regulations are not vague as applied to plaintiffs. *See U.S. Civil Serv. Comm'n v. Nat'l Ass'n of Letter Carriers*, 413 U.S. 548, 579 (1973) ("Surely, there seemed to be little question in the minds of the plaintiffs who brought this lawsuit as to the meaning of the law, or as to whether or not the conduct in which they desire to engage was or was not prohibited by the Act."); *West v. Derby Unified Sch. Dist.*, 206 F.3d 1358, 1368 (10th Cir. 2000) (same). Plaintiffs' due process claim accordingly fails, for "[o]ne to whose conduct a statute clearly applies may not successfully challenge it for vagueness." *Parker v. Levy*, 417 U.S. 733, 756 (1974). As in *Humanitarian Law Project*, "the dispositive point here is that the statutory terms are clear in their application to plaintiffs' proposed conduct, which means that plaintiffs' vagueness challenge must fail." 130 S. Ct. at 2720.[29]

D. The Court Should Dismiss Plaintiffs' Administrative Procedure Act Claims

1. Issuance of the preventive services coverage regulations was procedurally proper

Plaintiffs' claim that defendants failed to follow the procedures required by the APA in issuing the preventive services coverage regulations, *see* First Am. Compl. ¶¶ 159-61, is baseless. The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Defendants complied with these requirements.

[29] As a corollary, plaintiffs cannot raise the due process rights of "other parties not before the Court." First Am. Compl. ¶ 153; *see Humanitarian Law Project*, 130 S. Ct. at 2719 (invoking "the rule that '[a] plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others'"). And plaintiffs' suggestion that the preventive services coverage regulations are overbroad is not only incorrect, *see supra* pp. 44-46, but irrelevant to their due process claim, *see Humanitarian Law Project*, 130 S. Ct. at 2719 ("[A] Fifth Amendment vagueness challenge does not turn on whether a law applies to a substantial amount of protected expression.").

On August 1, 2011, defendants issued an amendment to the interim final regulations authorizing HRSA to exempt group health plans sponsored 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. The amendment was issued pursuant to express statutory authority granting defendants discretion to promulgate regulations relating to health coverage on an interim final basis.[30] *Id*. at 46,624. Defendants requested comments for a period of sixty days on the amendment to the regulations and specifically on the definition of religious employer contained in the exemption authorized by the amendment. *Id*. at 46,621. After receiving and carefully considering over 200,000 comments, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations and to create a temporary enforcement safe harbor period during which time defendants would consider additional amendments to the regulations to further accommodate religious organizations' religious objections to providing contraception coverage. 77 Fed. Reg. at 8726-27.

Because defendants provided notice and an opportunity to comment on the amendment to the interim final regulations, they satisfied the APA's procedural requirements. To the extent plaintiffs challenge the amended interim final regulations on the ground that they were issued on an interim final basis, that argument is moot, as defendants have now finalized the amended interim final regulations after notice and opportunity for comment. *See, e.g.*, *Nat'l Cmty. Reinvestment Coal. v. Nat'l Credit Union Admin.*, 290 F. Supp. 2d 124, 137-38 (D.D.C. 2003).

2. The regulations are neither arbitrary nor capricious

Plaintiffs also contend that defendants acted arbitrarily and capriciously by failing to exempt plaintiffs and other similar organizations from the scope of the preventive

[30] Defendants also made a determination, in the alternative, that issuance of the regulations in interim final form was in the public interest, and thus, defendants had "good cause" to dispense with the APA's notice-and-comment requirements. 76 Fed. Reg. at 46,624.

services coverage regulations. First Am. Compl. ¶¶ 162-64. But plaintiffs' contention is belied by defendants' careful consideration of the scope of the religious employer exemption, which is intended to "reasonably balance the extension of any coverage of contraceptive services . . . to as many women as possible, while respecting the unique relationship between certain religious employers and their employees in certain religious positions." 76 Fed. Reg. at 46,623.

In response to comments on the amended interim final regulations, defendants "carefully considered whether to eliminate the religious employer exemption or to adopt an alternative definition of religious employer, including whether the exemption should be extended to a broader set of religiously-affiliated sponsors of group health plans and group insurance coverage." 77 Fed. Reg. at 8727. Ultimately, defendants chose not to expand the exemption, as a broader exemption "would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives, which would undermine the benefits described above." *Id*. at 8728. Defendants also explained that including a broader class of employers within the scope of the exemption "would subject their employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care." *Id*. Although plaintiffs may take issue with defendants' purported omission of a discussion about for-profit corporate employers *per se*, plaintiffs cannot dispute that defendants' conclusions in the final rules as applied to religiously-affiliated organizations could only apply with greater force to for-profit, secular corporations like Hercules Industries. *See Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (indicating that, under the arbitrary and capricious standard, agency action must be upheld, so long as "the agency's path may reasonably be discerned"); *Biodiversity Legal Found. v. Babbitt*, 146 F.3d 1249, 1257 (10th Cir. 1998) (under APA, reviewing court's role "is not to assess the wisdom of policy choices").

Moreover, while plaintiffs seek to characterize defendants' response to comments as simply reaffirming the existing religious employer exemption, that characterization is incomplete. Defendants stated that, in response to comments, they "are adopting the definition in the amended interim final regulations for purposes of these final regulations while also creating a temporary enforcement safe harbor," concurrent with which defendants intend to amend the preventive services coverage regulations to further accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8727. And defendants have begun the amendment process by issuing an ANPRM, which expressly notes that defendants will consider whether "for-profit religious employers with [religious] objections" should be provided an accommodation. 77 Fed. Reg. at 16,504. Thus, it can hardly be argued that defendants have failed to consider the implications of the preventive services coverage regulations on for-profit employers. Defendants' consideration of the relevant concerns shows that they acted neither arbitrarily nor capriciously.

3. The preventive services coverage regulations do not violate federal restrictions relating to abortions

Plaintiffs also contend that the preventive services regulations violate the APA because they conflict with two federal prohibitions relating to abortions: (1) section 1303(b)(1) of the ACA, and (2) the Weldon Amendment to the Consolidated Appropriations Act of 2012. First Am. Compl. ¶¶ 166-67, 169. Section 1303(b)(1)(A) of the ACA provides that "nothing in this title . . . shall be construed to require a qualified health plan to provide" abortion services. 42 U.S.C. § 18023(b)(1)(A). The Weldon Amendment denies funds made available in the Consolidated Appropriations Act of 2012 to any federal, state, or local agency, program, or government that "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L.

No. 112-74, § 506(d)(1), 125 Stat. 786, 1111 (2012). Plaintiffs reason that, because the preventive services regulations require group health plans to cover emergency contraception, such as Plan B, they in effect require plaintiffs to provide coverage for abortions in violation of federal law.

Plaintiffs' claim that the challenged regulations conflict with section 1303(b)(1) of the ACA should be dismissed at the outset because plaintiffs lack prudential standing to assert it. The doctrine of prudential standing requires that a plaintiff's claim fall within "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970). The necessary link between plaintiffs and section 1303(b)(1) is missing here. Section 1303(b)(1) protects health insurance issuers that offer qualified health plans. 42 U.S.C. § 18023(b)(1). But plaintiffs do not allege that they are either health insurance issuers or purchasers of a qualified health plan. Nor could they reasonably do so. A "health insurance issuer" is an "insurance company, insurance service or insurance organization" that is "licensed to engage in the business of insurance in a State." *Id*. § 300gg-91(b)(2); *see id*. § 18021(b)(2). And plaintiffs do not purport to hold any such license. Moreover, a "qualified health plan" is one that, among other things, has in effect a certification from an Exchange. *Id*. § 18021(a)(1)(A); *see also id*. § 18031. The Exchanges contemplated by the ACA, however, will not be operational until 2014, *id*. § 18031(b), and Hercules Industries, a large employer, will not be able to purchase a qualified health plan until 2017, at the earliest, *id*. § 18032(f). Because section 1303(b)(1) is inapplicable to the health plan that Hercules Industries offers to its employees, the Court should dismiss this claim for lack of prudential standing. *See Hernandez-Avalos v. INS*, 50 F.3d 842, 847-48 (10th Cir. 1995).

Even if the Court were to reach the merits of plaintiffs' claims that the regulations violate section 1303(b)(1) and the Weldon Amendment, the Court should nevertheless dismiss those claims because they are based on a misunderstanding of the scope of these

laws as they relate to emergency contraceptives. The preventive services coverage regulations do not, in contravention of federal law, mandate that any health plan cover abortion as a preventive service or that it cover abortion at all. Rather, they require that non-grandfathered group health plans cover all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider. *See* HRSA Guidelines, *supra*. In fact, the federal government has made it clear that these regulations "do not include abortifacient drugs." HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at* http://www.healthcare.gov/news/factsheets/2011/08/womensprevention08012011a.html (last visited June 8, 2012); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of permissible recommendations).

In recommending what contraceptive services should be covered by health plans without cost-sharing, the IOM Report identified those contraceptives that have been approved by the FDA as safe and effective. *See* IOM REP. at 10. And the list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See* FDA, Birth Control Guide, *supra*. The basis for the inclusion of such drugs as safe and effective means of contraception dates back to 1997, when the FDA first explained why Plan B, and similar drugs, act as contraceptives rather than abortifacients:

> Emergency contraceptive pills are not effective if the woman is pregnant; they act by delaying or inhibiting ovulation, and/or altering tubal transport of sperm and/or ova (thereby inhibiting fertilization), and/or altering the endometrium (thereby inhibiting implantation). Studies of combined oral contraceptives inadvertently taken early in pregnancy have not shown that the drugs have an adverse effect on the fetus, and warnings concerning such effects were removed from labeling several years ago. There is, therefore, no evidence that these drugs, taken in smaller total doses for a short period of time for emergency contraception, will have an adverse effect on an established pregnancy.

Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997). In light of this

conclusion by the FDA, HHS over 15 years ago informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods and may not offer abortion as a family planning method, that they "should consider the availability of emergency contraception the same as any other method which has been established as safe and effective." Office of Population Affairs, Memorandum (Apr. 23, 1997), http://www.hhs.gov/opa/title-x-family-planning/initiatives-and-resources/documents-and-tools/opa-97-02.html (last visited June 8, 2012); *see also* 42 U.S.C. §§ 300, 300a-6.

Thus, although plaintiffs might seek to relitigate this issue in the present context, the preventive services coverage regulations simply adopted a settled understanding of FDA-approved emergency contraceptives that is in accordance with existing federal laws prohibiting federal funding for certain abortions.[31] Such an approach cannot be deemed arbitrary or capricious or contrary to law when it is consistent with over a decade of regulatory policy and practice. *See Bhd. of R.R. Signalmen v. Surface Transp. Bd.*, 638 F.3d 807, 815 (D.C. Cir. 2011) (giving particular deference to an agency's longstanding interpretation) (citing *Barnhart v. Walton*, 535 U.S. 212, 220 (2002)).

The conclusion that the term "abortion" in these federal laws was not intended to cover contraceptives, including emergency contraceptives, is reinforced by the legislative history of the Weldon Amendment. The Weldon Amendment was initially passed by the House of Representatives as part of the Abortion Non-Discrimination Act of 2002, and was later incorporated as a "rider" to the Consolidated Appropriations Act of 2005, Pub. L. No. 108-447, 118 Stat. 2809 (2005), and subsequent years. *See California ex rel. Lockyer v. United States*, 450 F.3d 436, 439 (9th Cir. 2006). During the floor debate on

[31] Title X specifically prohibits the Secretary from providing funds "used in programs where abortion is a method of family planning." 42 U.S.C. § 300a-6. Yet, as members of Congress are, and have been, aware, this prohibition does not prevent the use or distribution of emergency contraceptives as a method of family planning. *See, e.g.*, Statement of Senator Helms, 146 Cong. Rec. S6062-01, S6095 (daily ed. June 29, 2000) ("In fact, the Congressional Research Service confirmed to me that Federal law does, indeed, permit the distribution of the 'morning-after pill' at school-based health clinics receiving Federal funds designated for family planning services.").

the House vote, Representative David Weldon, after whom the Amendment is named, went out of his way to make clear that the definition of "abortion" is a narrow one. Weldon remarked:

> There have been people who have come to this floor today and tried to assert that the language in this bill would bar the provision of contraception services in many institutions that are already providing it. Please show me in the statute where you find that interpretation. I think it could be described as a tremendous misinterpretation or a tremendous stretch of the imagination.
>
> The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. Now some religious groups may interpret that as abortion, but we make no reference in this statute to religious groups or their definitions; and under the current FDA policy that is considered contraception, and it is not affected at all by this statute.

148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002). That Representative Weldon himself did not consider "abortion" to include FDA-approved emergency contraceptives leaves little doubt that the Weldon Amendment was not intended to apply to those items. *See Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (indicating that a statement of one of the legislation's sponsors deserves to be accorded substantial weight in interpreting a statute).

Plaintiffs additionally contend that the preventive services coverage regulations conflict with a provision of the Church Amendments, 42 U.S.C. § 300a-7(d),[32] and thereby violate the APA. First Am. Compl. ¶¶ 168-69. The provision plaintiffs cite states:

> No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

[32] "The conscience provisions contained in 42 U.S.C. § 300a-7 (collectively known as the 'Church Amendments') were enacted at various times during the 1970s to make clear that receipt of Federal funds did not require the recipients of such funds to perform abortions or sterilizations." 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011).

42 U.S.C. § 300a-7(d). This provision has no application to the current dispute. Indeed, plaintiffs' First Amended Complaint does not explain how the cited provision is in any tension with the challenged regulations. Hercules Industries, by merely providing a health plan to its employees, does not "perform or assist in the performance" of a "health service program or research activity funded . . . under a program administered by the Secretary of Health and Human Services." *Id.*; *see also Gray v. Romero*, 697 F. Supp. 580, 590 n.6 (D.R.I. 1988) (rejecting a doctor's claim that the statute protected his refusal to remove the feeding tube of a patient on the request of his family, indicating that the statute did not apply because the patient was not being treated "through a 'health service program'"). Nor is Hercules Industries an "individual." 42 U.S.C. § 300a-7(d). The Church Amendments, therefore, are not violated here.

For these reasons, plaintiffs' APA claim should be dismissed.

II. EVEN IF PLAINTIFFS COULD ESTABLISH A LIKELIHOOD OF SUCCESS ON THE MERITS, THEY ARE NOT ENTITLED TO PRELIMINARY INJUNCTIVE RELIEF

A. Plaintiffs Have Not Established Imminent Irreparable Harm

Plaintiffs argue incorrectly that the mere allegation of a potential RFRA or First Amendment violation – at some point in the future – is sufficient to establish irreparable harm. Pls.' Mot. at 27-28. To obtain preliminary injunctive relief, plaintiffs must show that "the injury complained of is of such *imminence* that there is a clear and present need for equitable relief to prevent irreparable harm." *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (emphasis in original)); *see also Holiday Inns of Am., Inc. v. B & B Corp.*, 409 F.2d 614, 618 (3d Cir. 1969) ("The dramatic and drastic power of injunctive force may be unleashed only against conditions generating a presently existing actual threat[.]"). Although the Tenth Circuit has stated that, "[w]hen an alleged constitutional right is involved, most courts hold no further showing of irreparable injury is necessary," *Kikumura v. Hurley*, 242 F.3d 950, 963 (10th Cir. 2001), it has also indicated that "this statement relates only to the irreparability aspect of the alleged injury,

and not to its imminence," *Pinson v. Pacheco*, 397 F. App'x 488, 492 (10th Cir. 2010). That a potential future harm may be irreparable is simply not enough; it must also be an imminent one.[33]

Here, plaintiffs have failed to establish any actual or imminent statutory or constitutional injury resulting from the preventive services coverage regulations. Plaintiffs do not dispute that the challenged regulations will not apply to Hercules Industries until November 2012. First Am. Compl. ¶ 86. And, although plaintiffs allege that they "must make insurance coverage decisions and logistical arrangements" before that time, *id*. ¶ 43; *see also id.* ¶¶ 103-09, such inconveniences are not the sort of "irreparable" injury that would justify the extraordinary remedy of injunctive relief. *See Sampson v Murray*, 415 U.S. 61, 90 (1974) (holding that "[m]ere injuries, however substantial, in terms of money, time and energy . . . are not enough" to justify entry of a preliminary injunction). Plaintiffs therefore have not met their burden to establish imminent irreparable harm.

B. Entry Of A Preliminary Injunction Would Adversely Affect The Interests Of Defendants And The Public

Plaintiffs contend that defendants would suffer no harm if the Court were to issue an injunction, and that an injunction is in the public interest. Pls.' Mot. at 28-29. But that is not the case. With regard to defendants, "there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to

[33] The cases plaintiffs cite, *see* Pls.' Mot. at 28, are not to the contrary. *See Kikumura*, 242 F.3d at 963 (finding irreparable injury resulting from repeated denials of prisoner's request for pastoral visits); *Jolly v. Coughlin*, 76 F.3d 468, 471-72, 482 (2d Cir. 1996) (holding that an inmate's ongoing indefinite confinement for refusal to submit to a tuberculosis screening test on religious grounds was an irreparable injury); *see also Elrod v. Burns*, 427 U.S. 347, 374 (1976) (remarking that, because plaintiff's injury was "both threatened and occurring at the time of [plaintiff's] motion," "the Court of Appeals might properly have held that the District Court abused its discretion in denying preliminary injunctive relief"); *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009) (vacating the district court's grant of preliminary injunctive relief even though plaintiff's First Amendment claim had "raise[d] the specter of irreparable injury").

direct that agency to develop and enforce." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *see also Connection Distrib. Co. v. Reno*, 154 F.3d 281, 296 (6th Cir. 1998) (indicating that granting an injunction against the enforcement of a likely constitutional statute would harm the government). Plaintiffs seek to preliminarily enjoin application of the preventive services coverage regulations as to Hercules Industries. Pls.' Mot. at 29; Proposed Order, ECF No. 5-2. But enjoining the regulations as to a for-profit, secular corporation would undermine defendants' ability to effectuate Congress's goals of improving the health of women and children and equalizing the coverage of preventive services for women and men so that women who choose to do so can be a part of the workforce on an equal playing field with men.

It is also contrary to the public interest to deny the employees of Hercules Industries the benefits of the preventive services coverage regulations. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982) ("[C]ourts . . . should pay particular regard for the public consequences in employing the extraordinary remedy of injunction."). Because Hercules Industries is a for-profit, secular employer, many of its employees undoubtedly do not share the Newlands' particular religious beliefs. Those women should not be denied the benefits of receiving a health plan that includes coverage of contraceptive services without cost-sharing. As discussed above, *see supra* pp. 6-9, 22-27, despite the general availability of contraceptive services, many women do not utilize such services because they are not covered by their health plan or require costly copayments, coinsurance, or deductibles.[34] IOM REP. at 19-20, 109; Sonfield, *supra*, at

[34] Plaintiffs appear to suggest that it is defendants' burden to establish that the public interest does not favor an injunction rather than plaintiffs' burden to show that it does. *See* Pls.' Mot. at 28 ("Defendants can offer no evidence to show that harm will come to [p]laintiffs' employees" given "the ubiquity of contraception access and government subsidization thereof."). Even putting aside the considerable evidence that such services are under-utilized because of their cost, the Court should also reject plaintiffs' argument because it is plaintiffs' burden, not defendants', to demonstrate that "the injunction, if issued, would not be adverse to the public interest." *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1258 (10th Cir. 2005).

9-10; 77 Fed. Reg. at 8728. As a result, in many cases, both women and developing fetuses suffer negative health consequences. *See* IOM REP. at 20, 102-04; 77 Fed. Reg. at 8728. And women are put at a competitive disadvantage in the workforce due to their lost productivity and the disproportionate financial burden they bear in regard to preventive health services. 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009); *see also* IOM REP. at 20; 77 Fed. Reg. at 8728.

Enjoining defendants from enforcing, as to Hercules Industries, the preventive services coverage regulations – the purpose of which is to eliminate these burdens, 75 Fed. Reg. at 41,733; *see also* 77 Fed. Reg. at 8728 – would thus inflict a very real harm on the public.[35] *See Stormans*, 586 F.3d at 1139 (vacating preliminary injunction entered by district court and noting that "[t]here is a general public interest in ensuring that all citizens have timely access to lawfully prescribed medications"). Hercules Industries employs over 250 people, First Am. Compl. ¶ 38, and the scope of its health plan could additionally affect those employees' spouses and other dependents. Accordingly, even assuming plaintiffs were likely to succeed on the merits (which they are not for the reasons explained above), any potential harm to plaintiffs resulting from their desire not to provide contraceptive coverage is outweighed by the significant harm an injunction would cause to the public.

CONCLUSION

For the forgoing reasons, this Court should deny plaintiffs' motion for a preliminary injunction and grant defendants' motion to dismiss this case in its entirety.

[35] The allegations in plaintiffs' First Amended Complaint regarding the salaries paid to Hercules Industries's employees and the pre- and post-natal care available to them, *see* First Am. Compl. ¶¶ 93-96, do not negate the public harms that will result from enjoining the preventive services coverage regulations for the reasons explained above. *See supra* n. 17, 18.

Respectfully submitted this 13th day of July, 2012,

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CERTIFICATE OF SERVICE (CM/ECF)

I hereby certify that on July 13, 2012, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses:

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and I hereby certify that I have mailed or served the document or paper to the following non- CM/ECF participants in the manner (mail, hand-delivery, etc.) indicated by nonparticipant's name:

None.

s/ Michelle R. Bennett
MICHELLE R. BENNETT
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