IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

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| GENEVA COLLEGE, *et al.*<br><br>Plaintiffs,<br><br>v.<br><br>KATHLEEN SEBELIUS, *et al.*<br><br>Defendants. | Civil Action No.<br>2:12-cv-00207-JFC |

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT**

**TABLE OF CONTENTS**

## TABLE OF AUTHORITIES

### CASES

**STATE CASES**



**STATE STATUTES**



**STATUTES**

**FEDERAL REGULATIONS**

**LEGISLATIVE MATERIALS**



**MISCELLANEOUS**

## INTRODUCTION

The Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010),[1] and implementing regulations, 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).[2] As relevant here, except as to group health plans of certain 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. Plaintiff Geneva College ("Geneva") brought suit on February 21, 2012, seeking to have the Court invalidate and enjoin the preventive services coverage regulations, alleging that its sincerely held religious beliefs prohibit it from providing the required coverage for certain services. On May 31, 2012, the Complaint was amended to add several new plaintiffs: The Seneca Hardwood Lumber Company, Inc. ("Seneca"); two of its shareholders, Wayne Hepler and Carrie Kolesar ("the Heplers"); and WLH Enterprises (collectively, "the Hepler Plaintiffs").

Over the past few months, defendants finalized an amendment to the preventive services coverage regulations, issued guidance on a temporary enforcement safe harbor, and initiated a rulemaking to further amend the regulations, all designed to address religious concerns such as those raised in this case. The finalized amendment confirms that group health plans sponsored by certain religious employers (and any group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services. The enforcement safe harbor encompasses a group of non-profit organizations with religious objections to providing contraceptive coverage; it provides that defendants will not bring any

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

[2] 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 since that date. 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140.

enforcement action against such organizations that meet certain criteria (and associated plans and issuers) during the safe harbor period, which will be in effect until the first plan year that begins on or after August 1, 2013. Finally, defendants published an advance notice of proposed rulemaking ("ANPRM") in the Federal Register that confirms defendants' intent, before the expiration of the safe harbor period, to propose and finalize additional amendments to the preventive services coverage regulations to further accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. The ANPRM suggests ideas and solicits public comment on potential accommodations, including, but not limited to, requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage and simultaneously to offer contraceptive coverage directly to such organizations' plan participants, at no charge to the organization or participant.

Plaintiffs' suit must be dismissed for lack of jurisdiction because no plaintiff has alleged an imminent injury that supports standing. The Hepler Plaintiffs, for their part, have failed to allege with specificity that their health plan, sponsored by Seneca, is ineligible for grandfather status for any reason other than Seneca's own unexplained failure to submit the required statement. Thus, these plaintiffs have not satisfied their burden to allege facts from which this Court could conclude that they will suffer a legally cognizable injury in fact. With respect to Geneva, its claims must be dismissed because it has failed to allege an imminent injury that would support standing in light of the enforcement safe harbor—which protects it until at least August 1, 2013—and defendants' initiation of a rulemaking to amend the preventive services coverage regulations well before that date to accommodate the religious objections of organizations like Geneva. The Court likewise lacks jurisdiction over Geneva's claims because they are not ripe under the Third Circuit's three-factor framework articulated in *Step-Saver Data Systems, Inc. v. Wyse Technology*, 912 F.2d 643 (3d Cir. 1990). "Adversity of interest," "conclusivity," and "practical help, or utility" are all lacking because defendants have initiated a rulemaking to amend the challenged regulations to accommodate religious organizations'

religious objections to providing contraceptive coverage. In the meantime, the temporary enforcement safe harbor will be in effect such that Geneva will not suffer hardship.

The District Courts for the District of Nebraska and the District of Columbia recently became the first courts in any of the cases across the country challenging the preventive services coverage regulations to issue rulings on the same jurisdictional arguments. *See Nebraska v. HHS*, No. 4:12-cv-3035 (D. Neb. July 17, 2012); *Belmont Abbey College v. Sebelius*, No. 1:11-cv-1989 (D.D.C. July 18, 2012). The court in *Nebraska* held that the religious organization plaintiffs lacked standing because they did not allege with sufficient specificity that their health plans were not grandfathered. *See Nebraska*, slip op. at 22-25. The court also concluded, although it did not need to reach the issue, that the plaintiffs' claims were not ripe because the preventive services coverage regulations are not being enforced against the plaintiffs and are currently undergoing a process of amendment to accommodate their religious concerns. *Id.*, slip op. at 37-44. The court in *Belmont Abbey* reached the same conclusion regarding ripeness, and also held, for similar reasons, that the plaintiff had not shown any imminent injury necessary to establish standing given the enforcement safe harbor and the forthcoming amendment to the regulations. In short, confronted by circumstances similar to those here, both courts dismissed the claims of organizations on the same jurisdictional grounds urged in this motion. Defendants respectfully ask this Court to do the same.

In the alternative to dismissal for these jurisdictional deficiencies, the Hepler Plaintiffs' claims must be dismissed under Federal Rule of Civil Procedure 12(b)(6). Their challenge rests largely on the theory that a for-profit, secular employer established to buy, sell, and manufacture lumber 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 (notably, one that works to their advantage, for example, by shielding them from liability for corporate actions) 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 the Hepler Plaintiffs' effort to bring about an unprecedented expansion of constitutional and statutory free exercise rights.

All of the Hepler Plaintiffs' claims are subject to dismissal for failure to state a claim upon which relief may be granted. With respect to the Hepler Plaintiffs' Religious Freedom Restoration Act ("RFRA") claim, none of the Hepler Plaintiffs can show, as each must, that the preventive services coverage regulations impose a substantial rather than an incidental burden on their religious exercise. Seneca is a for-profit, secular employer, and a secular entity by definition does not exercise religion. The Heplers' allegations of a burden on their own individual religious exercise fare no better, as the regulations they challenge apply only to group health plans and health insurance issuers. The Heplers themselves are neither. Nor is WLH Enterprises, which participates in the health plan offered by Seneca. It is well established that a corporation and its owners are wholly separate entities, and the Court should not permit the Heplers to eliminate that legal separation to impose their personal religious beliefs on the corporate entity's employees. The Heplers cannot use the corporate form alternatively as a shield and a sword, depending on which suits them in a 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 access to recommended preventive care for women and men so that women who so choose can be a part of the workforce on an equal playing field.

The Hepler 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 do not apply only to plains of employers with a religious affiliation. The Hepler 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 religious employer exemption, therefore, simply do not violate the constitutional prohibition against denominational preferences. Furthermore, the regulations do not violate the Hepler Plaintiffs' free speech rights. The regulations compel conduct, not speech. They do not require the Hepler Plaintiffs to say anything; nor, as shown by this very lawsuit, do they prohibit them from expressing to Seneca's or WLH Enterprises's employees or the public any 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 v. Sup. Court*, 85 P.3d 67, 74 n.3 (Cal. 2004).

Nor can the Hepler Plaintiffs succeed on their Administrative Procedure Act ("APA") claim. As an initial matter, the Hepler Plaintiffs' lack prudential standing to raise a claim under section 1303(b)(1) of the ACA because they are not "health insurance issuers" and have not purchased a "qualified health plan." In any event, the preventive services coverage regulations do not require qualified health plans to cover abortion services as prohibited by section

1303(b)(1). And defendants carefully considered—and continue to consider—the impact of the regulations on all employers, including for-profit, secular employers like Seneca.

## BACKGROUND

### I. STATUTORY BACKGROUND

Prior to the enactment of the ACA, 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.[3] 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

[3] A group health plan includes a plan established or maintained by an employer that provides health coverage 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. Because Seneca and WLH Enterprises are not large employers, *see* Amend. Compl. ¶¶ 90-91; *see also* 26 U.S.C. § 4980H(c)(2)(A), neither would not be subject to payments under the ACA for failing to provide health coverage for their employees.

Individual health coverage offered by a health insurance issuer includes student health insurance coverage, which is defined as individual health insurance "that is provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students enrolled in that institution of higher education and their dependents, that meets [certain conditions]." 45 C.F.R. § 147.145(a).Institutions of higher education are not required by federal law to provide, or to contract with health insurance issuers to provide, health insurance to their students. If the students at an institution of higher education receive health insurance coverage through a health insurance issuer, the obligation to provide coverage for recommended preventive services rests on the issuer, not the institution of higher education. *See* 26 C.F.R. § 54.9815-2713T(a); 29 C.F.R. § 2590.715-2713(a); 45 C.F.R. § 147.130(a).

("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");[4] and (4) for women, such additional preventive care and screenings not rated "A" or "B" by the USPSTF as provided for 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 bill 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) ("The underlying bill introduced by Senator Reid already requires that preventive services recommended by [USPSTF] be covered at little to no cost . . . . But [those recommendations] do not include certain recommendations that many women's health advocates and medical professionals believe are critically important . . . ."); 155 Cong. Rec. 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 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. at 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

[4] HRSA is an agency within the Department of Health and Human Services.

recommended preventive services. 75 Fed. Reg. 41726, 41728 (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. 75 Fed. Reg. at 41728, 41733; IOM REP. at 20.

Defendants issued interim final regulations implementing the preventive services coverage provision on July 19, 2010. 75 Fed. Reg. 41726. 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, the Department of Health and Human Services ("HHS") tasked the Institute of Medicine ("IOM")[5] with "review[ing] what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines. 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

[5] IOM was established in 1970 by the National Academy of Sciences and is funded by Congress. IOM REP. at iv.

and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm.

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 Aug. 2, 2012) (citing 2010 study that found women with private insurance that covered prescription drugs paid 53 percent of the cost of their oral contraceptives). IOM determined that coverage, without cost-sharing, for 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 health conditions).

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 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 Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited Aug. 2, 2012). The amendment to the interim final regulations, issued on the same day, authorized HRSA to exempt group health plans sponsored by certain religious employers (and any associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To be exempt, an employer must meet the following criteria:

> (1) The inculcation of religious values is the purpose of the organization.
>
> (2) The organization primarily employs persons who share the religious tenets of the organization.
>
> (3) The organization serves primarily persons who share the religious tenets of the organization.
>
> (4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

45 C.F.R. § 147.130(a)(1)(iv)(B). The sections of the Internal Revenue Code referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," that are exempt from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii). Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do

not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years beginning on or after August 1, 2012.

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. 76 Fed. Reg. at 46623. After carefully considering the thousands of comments that 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 non-grandfathered plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage that do not qualify for the religious employer exemption (and any associated group health insurance coverage). 77 Fed. Reg. 8725, 8727 (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 cover some or all recommended contraceptive services and that is sponsored by an organization that meets 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.[6]

The enforcement safe harbor also applies to student health insurance coverage arranged by non-profit institutions of higher education that satisfy comparable criteria. 77 Fed. Reg. at 16504. The enforcement safe harbor will be in effect until the first plan year that begins on or after August 1,

[6] 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;77 Fed. Reg. 16501, 16504 (Mar. 21, 2012).

2013. Guidance at 3. By that time, defendants expect that significant changes to the preventive services coverage regulations will have altered the landscape with respect to certain religious organizations by providing them with further accommodations.

Those intended changes, which were first announced when defendants finalized the religious employer exemption, will establish alternative means of providing contraceptive coverage without cost-sharing while also accommodating non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began the process of further amending the regulations on March 21, 2012, when they published an ANPRM in the Federal Register. 77 Fed. Reg. 16501 (Mar. 21, 2012). The ANPRM "presents questions and ideas" on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. *Id*. at 16503. The purpose of the ANPRM is to provide "an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made" in the forthcoming amendments to the regulations. *Id*. Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations that object to such coverage on religious grounds and simultaneously to offer contraceptive coverage directly to the organization's plan participants, at no charge to organizations or participants. *Id*. at 16505.

After receiving and reviewing 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 16501. Defendants intend to finalize the amendments to the regulations such that they are effective before the end of the temporary enforcement safe harbor. *Id*. at 16503.

## 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 that Geneva and Seneca

make available to their employees to cover some or all contraceptive services. Plaintiffs claim this requirement violates RFRA, the First and Fifth Amendments to the United States Constitution, and the APA.

Geneva describes itself as a "Christ-centered institution of higher learning" organized as a Pennsylvania not-for-profit corporation. Amend. Compl. ¶ 2. Geneva alleges that it believes emergency contraceptives prevent a fertilized egg from implanting in the wall of the uterus thereby causing what plaintiff believes to be an abortion. *Id.* ¶¶ 43-44. Geneva further alleges that its "sincerely held religious beliefs prohibit it from providing coverage for abortion, abortifacients, embryo-harming pharmaceuticals, and related education and counseling, or providing a plan that causes access to the same through its insurance company." *Id.* ¶ 185. Based on the allegations in the Amended Complaint, Geneva does not qualify for the religious employer exemption. *Id*. ¶ 129.

Seneca describes itself as a "Pennsylvania Corporation" that is engaged in the lumber business. *Id.* ¶¶ 13, 89. Wayne L. Hepler alleges that he owns a 58 percent share of Seneca. Carrie E. Kolesar, Mr. Hepler's daughter, owns another 6 percent. *Id.* at ¶ 89. "Together [along with Ms. Kolesar's siblings, who are not plaintiffs in this case] they constitute the owners and the Board of Directors of Seneca." *Id.* Mr. Hepler and Ms. Kolesar ("the Heplers") assert that they are "practicing and believing Catholic Christians," *id*. ¶ 75, and that they believe "it would be immoral and sinful for them to intentionally participate in, pay for, facilitate, or otherwise support abortifacient drugs, contraception, sterilization, and related education and counseling, through the inclusion of such items in health insurance coverage that they offer at their businesses or participate in for their own individual families," *id*. ¶ 80. WLH Enterprises "is a sawmill and sole proprietorship owned by Wayne L. Hepler." *Id.* ¶ 13. Seneca currently has twenty-two full-time employees who are covered under a health plan that does not cover contraceptive services. *Id*. ¶¶ 90, 99. WLH Enterprises has six full-time employees, five of which "are covered under Seneca's health insurance plan, in which WLH Enterprises participates." *Id.*

¶ 91. Seneca alleges that it does not qualify for the religious employer exemption or the temporary enforcement safe harbor. *See id*. ¶¶ 13-14, 90-91.

## STANDARD OF REVIEW

Defendants move to dismiss the complaint for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure, and for failure to state a claim upon which relief may be granted under Rule 12(b)(6). The party invoking federal jurisdiction bears the burden of establishing its existence. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998). Where, as here, defendants challenge jurisdiction on the face of the complaint, the complaint must plead sufficient facts to establish jurisdiction. Under Rule 12(b)(6), "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).

## ARGUMENT

### I. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION

#### A. Plaintiffs Lack Standing to Assert Their Claims

Plaintiffs lack standing because they have not alleged a concrete and imminent injury resulting from the operation of the challenged regulations. To establish standing, a plaintiff must demonstrate that it has "suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Allegations of possible future injury do not suffice. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990).

The Hepler Plaintiffs' claims should be dismissed at the outset. The challenged regulations do not apply to grandfathered plans. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140.[7] And the only fact offered by the

[7] A grandfathered plan is a health plan in which at least one individual was enrolled on March 23, 2010 and that has continuously covered at least one individual since that date. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1). A grandfathered plan may lose its grandfather status if, compared to its existence on March 23, 2010, it eliminates all or substantially all benefits to

Hepler Plaintiffs that establishes that their group health plan is not grandfathered is the allegation that their plan materials did not include a statement that the plan is believed to be grandfathered, as required by 26 C.F.R. § 54.9815-1251T(a)(2)(ii). *See* Amend. Compl. ¶ 97. But without any allegation that their plans do not qualify for grandfathered status for some other reason, the Hepler Plaintiffs' unexplained refusal to provide the required statement is a self-inflicted injury, which is not a legally cognizable injury in fact. *See Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 831 (D.C. Cir. 2006) ("[S]elf-inflicted harm doesn't satisfy the basic requirements for standing."); *see also Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (concluding that injuries to plaintiff states were "self-inflicted," and "[n]o State can be heard to complain about damage inflicted by its own hand"); *Lujan*, 504 U.S. at 564 n.2 (observing that the imminence requirement "has been stretched beyond the breaking point when, as here, the plaintiff alleges only an injury at some indefinite future time, *and the acts necessary to make the injury happen are at least partly within the plaintiff's own control*" (emphasis added)). The only other allegation pertaining to grandfathering offered by the Hepler Plaintiffs is that "changes made in the past several years" to their health plan have caused them to lose grandfathered status. Amend. Compl. ¶ 97. Such bare legal conclusions, absent supporting factual allegations, do not provide the specificity required at the pleading stage to establish standing. *See Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949-50 (2009); *see also Nebraska*, 2010 WL 2913402, at *12 ("[P]laintiffs have failed to plead specific facts showing that [their plans] are not grandfathered.").

Geneva, for its part, lacks standing for a different reason. Under the enforcement safe harbor, defendants will not take any enforcement action against an organization that qualifies for the safe harbor until the first plan year that begins on or after August 1, 2013, at the earliest. Guidance at 3. Although Geneva asserts that its group health plan is not eligible for the safe

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diagnose or treat a particular condition, increases a percentage cost-sharing requirement, significantly increases a fixed-amount cost-sharing requirement, significantly reduces the employer's contribution, or imposes or tightens an annual limit on the dollar value of any benefits. 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1).

harbor, Amend. Compl. ¶ 174, the only fact plaintiff alleges to support this legal conclusion—that its employee plan "did offer non-abortifacient contraception and sterilization after February 10, 2012," *id.*—does not establish that it is ineligible. *See Iqbal*, 556 U.S. at 677-79; *Santiago*, 629 F.3d at 131. Geneva explains that it had in place contractual language with its insurer, prior to February 10, 2012, intended to exclude coverage for emergency contraceptives on religious grounds. Amend. Compl. ¶ 58. Under such circumstances, where the actual coverage of emergency contraception was the result of an error, despite a good faith attempt prior to February 10, 2012 to exclude such coverage under the plan, it is defendants' position that an organization is not disqualified from eligibility for the safe harbor.

Because Geneva appears to qualify for the safe harbor, and because it alleges its plan years begin on August 1 and January 1, Amend. Compl. ¶¶ 52, 74, the earliest it (or the issuer of its employee or student health plan) could be subject to any enforcement action by defendants for failing to provide coverage of emergency contraception is August 1, 2013. With such a long time before the inception of any possible injury and the challenged regulations undergoing further amendment before then, Geneva cannot satisfy the imminence requirement; the asserted injury is simply "too remote temporally." *See McConnell v. FEC*, 540 U.S. 93, 226 (2003).[8]

This defect in Geneva's case does not implicate a mere technical issue of counting intermediate days. Nor does it rest on the truism that a final regulation is always subject to change by the agency that promulgated it; the ANPRM goes much further than that by promising imminent regulatory amendments. Thus, the defect in Geneva's claims goes to the fundamental

[8] Geneva also maintains that the enforcement safe harbor "can be revoked at any time." Amend. Compl. ¶ 175. But speculation that the defendants will take back the promised safe harbor—which was established in formal guidance by defendants, *see* Guidance, and has been repeatedly referenced in the Federal Register, *see, e.g.*, 77 Fed. Reg. at 8728; 77 Fed. Reg. at 16502-03—is not only dubious, it is also insufficient to establish an injury. To begin, Geneva is dealing with the federal government, which is entitled to a presumption that it acts in good faith. *See Bridge v. U.S. Parole Com'n*, 981 F.2d 97, 106 (3d Cir. 1992)). Moreover, courts have found similar promises not to enforce by the government sufficient to defeat jurisdiction. *See Presbytery of N.J. of Orthodox Presbyterian Church v. Florio*, 40 F.3d 1454, 1470-71 (3d Cir. 1994). Finally, even if defendants were to withdraw the enforcement safe harbor before it expires—and there is no evidence to suggest that they will—Geneva could bring suit at that time, seeking preliminary injunctive relief if warranted.

limitations on the role of federal courts. The "underlying purpose of the imminence requirement is to ensure that the court in which suit is brought does not render an advisory opinion in 'a case in which no injury would have occurred at all.'" *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 500 (D.C. Cir. 1994) (quoting *Lujan*, 504 U.S. at 564 n.2). The ANPRM published in the Federal Register confirmed, and sought comment on, defendants' intention to propose amendments to the preventive services coverage regulations that would accommodate the concerns of religious organizations, such as Geneva, that object to providing contraceptive coverage for religious reasons. 77 Fed. Reg. at 16501. The ANPRM provided Geneva, and any other interested party, with the opportunity to, among other things, comment on ideas suggested by defendants for further accommodating religious organizations, offer new ideas to "enable religious organizations to avoid . . . objectionable cooperation when it comes to the funding of contraceptive coverage," and identify considerations defendants should take into account when amending the regulations. *Id*. at 16503, 16507. And Geneva (and others) will have additional opportunities to comment as the rulemaking process proceeds. Defendants, moreover, have indicated that they intend to finalize the amendments to the regulations before the rolling expiration of the temporary enforcement safe harbor starting on August 1, 2013. *Id*. at 16503; *see also* 77 Fed. Reg. at 8728. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for Geneva to help shape those amendments, there is no reason to suspect that Geneva will be required to sponsor a health plan that covers certain contraceptive services in contravention of its religious beliefs once the enforcement safe harbor expires. And any suggestion to the contrary is entirely speculative at this point. At the very least, given the anticipated changes to the preventive services coverage regulations, Geneva's claims of injury, if any, after the enforcement safe harbor expires would differ substantially from its current claims of injury. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of Geneva's claims now. *See Belmont Abbey*, 2012 WL 2914417, at *10.

Finally, Geneva cannot transform the speculative possibility of future injury into a current concrete injury for standing purposes by asserting that it has to plan now for its future

insurance needs. Amend. Compl. ¶¶ 177-78. Such reasoning would gut standing doctrine. A plaintiff could manufacture standing by asserting a current need to prepare for the most remote and ill-defined harms, thus sapping the imminence requirement of any meaning. Even if such manipulation were not so transparent, plaintiff would still bear the burden of pleading standing with specificity. *Iqbal*, 556 U.S. at 678. Geneva does not meet that burden here because it does not explain how it will be injured by its purported inability to plan more than a year in advance as a result of uncertainty regarding how and whether the regulations will apply to it. Further, any planning plaintiff is engaged in now "stems not from the operation of [the preventive services coverage regulations], but from [plaintiff's] own . . . personal choice[s]" to prepare for contingencies that may never occur. *McConnell*, 540 U.S. at 228. Thus, even if this preparation were an injury, it would not be fairly traceable to the challenged regulations.

Because all plaintiffs lack standing, their claims should be dismissed.

**B. Geneva Has Not Established That Its Claims Are Ripe For Review**

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hospitality Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies." *Id*. at 807-08. It also "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Id*. A case ripe for review cannot be "nebulous or contingent but must have taken on fixed and final shape." *Pub. Serv. Comm'n v. Wycoff*, 344 U.S. 237, 244 (1952).

The Supreme Court, in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), laid out the two fundamental considerations determining ripeness: (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration." *Id.* at 149. In the context of declaratory judgments, the Third Circuit has refined those considerations into the three-pronged framework articulated in *Step-Saver Data Systems, Inc. v. Wyse Technology*, 912 F.2d 643 (3d Cir. 1990). Under the *Step-Saver* framework, courts look to the "adversity of

interest" between the parties, the "conclusivity" that a declaratory judgment would have on the legal relationship between the parties, and the "practical help, or utility" of a declaratory judgment. *Id*. at 647.[9] None of these indicia of ripeness exists with respect to Geneva.

**1. Adversity of interest**

To satisfy the first prong of the *Step-Saver* framework, "the defendant must be so situated that the parties have adverse legal interests." 912 F.2d at 648. "Although the party seeking review need not have suffered a completed harm to establish adversity of interest, it is necessary that there be a substantial threat of real harm and that the threat must remain real and immediate throughout the course of the litigation." *Presbytery of N.J. v. Florio*, 40 F.3d 1454, 1463 (3d Cir. 1994). "[A] potential harm that is 'contingent' on a future event occurring will likely not satisfy this prong of the ripeness test." *Pittsburgh Mack Sales & Serv. v. Int'l Union of Operating Eng'rs*, 580 F.3d 185, 190 (3d Cir. 2009).

Geneva seeks judicial review of the preventive services coverage regulations as applied to non-exempted religious organizations that object to contraceptive coverage for religious reasons. Defendants, however, have initiated a rulemaking to amend the preventive coverage regulations to accommodate further the concerns expressed by Geneva and similarly situated organizations and have made clear that the amendments will be finalized well before the earliest date on which the challenged regulations could be enforced by defendants against Geneva. 77 Fed. Reg. at 8728-29. Therefore, the alleged threatened injury is contingent upon the occurrence of uncertain future events, and cannot support a finding of adversity.

Moreover, the forthcoming amendments are intended to address the very issue that Geneva raises here by establishing alternative means of providing contraceptive coverage without cost-sharing to women, as prescribed by a health care provider, while further accommodating religious objections to covering contraceptive services by religious

[9] The Third Circuit has indicated that the three-step *Step-Saver* framework can be used somewhat interchangeably with the Supreme Court's two-part framework set out in *Abbott Laboratories. See Phila. Fed'n of Teachers v. Ridge*, 150 F.3d 319, 323 n.4 (3d Cir. 1998). If the Court were to apply the *Abbott Laboratories* framework, this case would still be unripe for the same reasons set out below.

organizations like Geneva. And Geneva will have several opportunities to participate in the rulemaking process and to provide comments and/or ideas regarding the intended accommodations. There is, therefore, a significant chance that the amendments will alleviate altogether the need for judicial review, or at least narrow and refine the scope of any actual controversy to more manageable proportions. *See Texas v. United States*, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all."). Once the forthcoming amendments are finalized, if Geneva's concerns are not laid to rest, it "will have ample opportunity [ ] to bring its legal challenge at a time when harm is more imminent and more certain." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 734 (1998); *see also Tex. Indep. Prod. v. EPA*, 413 F.3d 479, 483 (5th Cir. 2005); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999); *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160 (D.D.C. 2003).

**2. Conclusivity**

The second *Step-Saver* factor requires courts to determine whether there is a "real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical set of facts." 912 F.2d at 649. This requirement is based on the recognition that a declaratory judgment granted in the absence of a concrete set of facts "would itself be a 'contingency,' and applying it to actual controversies which subsequently arise would be an 'exercise in futility.'" *Armstrong World Indus., Inc. v. Adams*, 961 F.2d 405, 412 (3d Cir. 1992).

This case lacks conclusivity as it relates to Geneva, as it is undoubtedly based on contingent facts. Although Geneva raises largely legal claims, those claims are leveled at regulations that have not "taken on fixed and final shape." *Pub. Serv. Comm'n*, 344 U.S. at 244; *see also Belmont Abbey*, 2012 WL 2914417, at *14 ("Because prudential considerations counsel against reaching the merits of Plaintiff's claims at this stage, the Court need not evaluate whether the suit presents a 'purely legal' question."). Once defendants complete the rulemaking outlined in the ANPRM, Geneva's challenge to the current regulations will likely be moot. *See The Toca*

*Producers v. FERC*, 411 F.3d 262, 266 (D.C. Cir. 2005) (rejecting purely legal claim as unripe due to the possibility that it not need to be judicially resolved). And judicial review now of any future amendments to the regulations that result from the ongoing rulemaking would be too speculative to yield meaningful review, let alone constitute a challenge to a final rule as required by the APA. The ANPRM offers ideas and solicits input on potential, alternative means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. 77 Fed. Reg. at 16503. It does not preordain what amendments to the preventive services regulations defendants will ultimately promulgate; nor does it foreclose the possibility that defendants will adopt ideas not set out in the ANPRM. Thus, review of any of the suggested proposals contained in the ANPRM would only entangle the Court "in abstract disagreements over administrative policies." *Abbott Labs.*, 387 U.S. at 148. Judicial review of Geneva's claims at this time would inappropriately interfere with defendants' ongoing rulemaking and may result in the Court deciding issues that may never arise. *See Belmont Abbey*, 2012 WL 2914417, at *11-14.

**3. Practical Help, or Utility**

Finally, because "one of the primary purposes behind the Declaratory Judgment Act was to enable plaintiffs to preserve the status quo, a case should not be considered justiciable unless the court is convinced that [by its action] a useful purpose will be served." *Armstrong*, 961 F.2d at 412 (quoting *Step-Saver*, 912 F.2d at 649). This prong of the *Step-Saver* framework requires the Court to consider whether a declaratory judgment will affect the parties' plans of actions by alleviating legal uncertainty. 912 F.2d at 649 n.9.

Here, Geneva alleges (without specificity) that, despite the temporary enforcement safe harbor and the upcoming amendments, it will have to take the preventive services coverage regulations into account "as it plans expenditures, including employee compensation and benefits packages." Amend. Compl. ¶¶ 171, 177. But "[m]ere economic uncertainty affecting plaintiff's planning is not sufficient to support premature review." *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987); *see also Tenn. Gas Pipeline Co. v. F.E.R.C.*, 736 F.2d 747, 751 (D.C. Cir.

1984) (concluding plaintiff's "planning insecurity" was not hardship); *Belmont Abbey*, 2012 WL 2914417, at *14 ("Costs stemming from Plaintiff's desire to prepare for contingencies are not sufficient . . . to constitute hardship for purpose of the ripeness inquiry—particularly when the agency's promises and actions suggest the situation Plaintiff fears may not occur."). Geneva is not being compelled to make immediate and significant changes in its day-to-day operations under threat of serious civil and criminal penalties. *Compare Abbott Labs*, 387 U.S. at 153. As explained above, if the group health plan made available by Geneva to its employees is eligible for grandfather status—and there are no factual allegations to indicate that it is not—then Geneva can continue to sponsor this plan, which allegedly does not cover the contraceptive services to which plaintiff objects on religious grounds. Even if Geneva sponsors a non-grandfathered group health plan, it can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against Geneva (or the issuer of plaintiff's employee or student health plan) for failure to cover contraceptive services until August 1, 2013, at the earliest. *See* Guidance at 3. And, by the time the enforcement safe harbor expires, defendants will have finalized amendments to the regulations to further accommodate religious objections to providing contraceptive coverage. *See* 77 Fed. Reg. at 8728-29. Therefore, this is not a case where plaintiff is faced with a "'Hobson's choice' of foregoing lawful behavior or subjecting [itself] to prosecution under the challenged provision." *Armstrong*, 961 F.2d at 423-24. The utility of resolving Geneva's claims is insufficient to make its claims justiciable.[10]

## II. THE HEPLER PLAINTIFFS FAIL TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

### A. The Hepler Plaintiffs' RFRA Claim Should Be Dismissed

#### 1. The Hepler Plaintiffs have not sufficiently alleged that the regulations substantially burden any exercise of religion

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.*

[10] Because Geneva lacks standing and because it is unclear how the preventive services coverage regulations in their final form will be applied to Geneva, defendants do not address whether Geneva has failed to state a claim upon which relief can be granted.

*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, the Hepler Plaintiffs have not sufficiently alleged that the preventive services coverage regulations substantially burden any exercise of religion.[11] The Seneca Hardwood Lumber Company, Inc., is not a religious employer; it is "lumber business that Mr. Hepler runs in conjunction with a sawmill." Amend. Compl. ¶ 3. The company's pursuits and products are not religious. Under the heading "purpose or purposes of the corporation," the company's Articles of Incorporation describe a litany of purely commercial activities: "[t]o buy, sell and manufacture at wholesale and retail lumber and lumber products, novelties, hardware, building supplies, construction materials and any and all other products incidental thereto and to do any and all other things necessary or incidental to the carrying out of said purposes." *See* The Seneca Hardwood Lumber Company, Inc., Articles of Incorporation at 1, *available at* https://www.corporations.state.pa.us/corp/soskb/Filings.asp?307207 (last visited Aug. 2, 2012) (login required). The company's Articles of Incorporation make no reference at all to any religious purpose. *See id*. The Amended Complaint does not allege that the company is affiliated

[11] Defendants acknowledge that one court has preliminarily enjoined implementation of the preventive services coverage regulations as applied to the plan of a closely held, self-insured Colorado corporation. *See Newland v. Sebelius*, No. 1:12-cv-1123-JLK (D. Colo. July 27, 2012). The court did not find that the challenged regulations impose a substantial burden on the corporation's exercise, if any, of religion, but merely stated that the plaintiffs' motion presented "difficult questions" that "merit more deliberate investigation." *See Newland*, slip op. at 12. Even so, it is defendants' position that plaintiffs' motion for a preliminary injunction in that case was wrongly decided, and should have been denied. Defendants' also note that, unlike the corporation in *Newland*, Seneca is not self-insured, but instead purchases its health plan "from a company in the health insurance market." Amend. Compl. ¶ 96.

with a formally religious entity such as a church. Nor does it allege that the company employs persons of a particular faith. In short, there is nothing to indicate that Seneca itself is anything other than a for-profit, secular employer.

Seneca's status is conclusive here. The government is aware of no case in which a for-profit, secular employer with Seneca'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 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 Seneca 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 corporation 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."). Seneca could not, for example, fire an employee for religious reasons, even if its owners claimed that their 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). Seneca has "made no showing of a religious belief which requires that [it] engage in the [lumber] business." *Id.* Any burden is therefore caused by the company's "choice to enter

into a commercial activity." *Id.*[12] *Cf. Roberts v. U.S. Jaycees*, 468 U.S. 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 Heplers' 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.[13] The Heplers nonetheless claim that the regulations substantially burden *their* religious exercise because the regulations may require the group health plan sponsored by the secular *corporation* that they own to provide health coverage that includes contraceptive coverage, and because they and their families will be forced into a plan—either provided by Seneca or available in the open market—that does so. Amend. Compl. ¶¶ 81, 94-95. 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.

[12] Because the corporation is a for-profit, secular employer, the Amended Complaint's allegation that the Heplers' sincerely held religious beliefs prohibit them from providing coverage for contraceptive services, Amend. Compl. ¶¶ 94-95, cannot be attributed to the company itself. An employer like Seneca 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.").

[13] For similar reasons, the preventive services coverage regulations do not apply to WLH Enterprises, which does not maintain its own group health plan. *See* Amend. Compl. ¶ 91.

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 Heplers' 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.[14]

Precedent confirms this commonsense point. Cases that find a substantial burden uniformly involve a direct obligation 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 Seneca, not to the Heplers themselves.

The Heplers' 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 Heplers have voluntarily chosen to enter into commerce and elected to do so by establishing a for-profit, secular corporation, which "is a distinct and separate entity, irrespective of the persons who own all its stock." *Barium Steel Corp. v. Wiley*, 108 A.2d 336, 341 (Pa. 1954); *see* Pa. Cons. Stat. §§ 1501-02. Those individuals

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

thereby enjoy limited liability provided they respect the corporation's separate existence and adhere to a standard of care. *Lumax Indus., Inc. v. Aultman*, 669 A.2d 893, 895, (Pa. 1995) (noting Pennsylvania's "strong presumption" against piercing the corporate veil). As a Pennsylvania corporation with a "perpetual" existence, *see* Pa. Cons. Stat. § 1502, Seneca has "broad powers to conduct business, hold and transact property, and enter into contracts, among others." *See id.*; The Seneca Hardwood Lumber Company, Inc., Articles of Incorporation, *supra*. In short, "[e]ven when a corporation is owned by one person or a family, the corporate form shields the individual members of the corporation from personal liability." *Kelleytown Co. v.* Williams, 426 A.2d 663, 668 (Pa. Super. Ct. 1981). Those individuals 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 employees.

Although the preventive services coverage regulations do not require the Heplers or Seneca to provide contraceptive services directly, the Heplers' complaint appears to be that, through their company's group health plan and the benefits it provides to employees, the Heplers will facilitate conduct (the use of contraceptives) that they find objectionable.[15] 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 Seneca have no right to control the choices of their company's employees, some of whom may not share the owners' 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 owners' choice to structure their company in such a way as

[15] 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 Aug. 2, 2012). And Seneca can deduct contributions toward its employee health plan from its income as a business expense. *See* 26 U.S.C. § 162.

to separate themselves from the corporate entity, the burden of which they complain is not a burden that establishes a violation of RFRA. *See Lee*, 455 U.S. at 261.[16]

**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**

Even if the Hepler 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.*, *United States v. Stevens*, 533 F.3d 218, 241 (3d Cir. 2008) (recognizing public health as a compelling 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."). 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

[16] In this respect, the Heplers' RFRA challenge is similar to the claim 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 stated 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. As in *Kaemmerling*, "[a]lthough the [employee]'s activities . . . may offend [the owners'] religious beliefs, they cannot be said to hamper [their] religious exercise because they do not pressure [the owners] to modify [their] behavior and to violate [their] beliefs." *Id.* (quotation omitted).

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 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*, 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." 468 U.S. at 626. 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 ("[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 certain family planning services for women. *See, e.g.*, 155 Cong. Rec. S12265-02, S12271 ("Mikulski's amendment closes this gap. Under her amendment, [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 ("Furthermore, in directing non-grandfathered group health plans and health insurance issuers to cover preventive services and screenings for women described in HRSA-supported guidelines without cost sharing, Congress determined that both existing healthcare coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women."). 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 . . . 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 (finding state law that required employers to provide coverage for contraceptives under certain circumstances served a compelling interest).

The preventive services coverage regulations issued by defendants, moreover, are the least restrictive means of furthering these dual, albeit intertwined, interests. Taking into account the "particular claimant whose sincere exercise of religion is [purportedly] being substantially burdened," *O Centro*, 546 U.S. at 430-31, exempting Seneca, and similarly situated companies, from the obligation to cover contraceptive services under their plans would remove women covered under those plans from the very protections that were intended to further the compelling interests recognized by Congress. *See, e.g.*, *Graham v. Comm'r of Internal Revenue*, 822 F.2d 844, 853 (9th Cir. 1987) ("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 Seneca or a similarly situated employer (as well as each woman who is a covered spouse or dependent of an employee of such an employer)—or, for that matter, any woman in such a position in the future—would be significantly disadvantaged if her company were to choose to provide a plan that fails to cover such services. 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 therefore be at risk of unhealthier outcomes, both for the women themselves and their newborn children. IOM REP. at 102-03. They would also be at a competitive disadvantage in the workforce due to their lost productivity. These harms would befall female employees (and covered spouses and dependents) who do not share their employer's beliefs and might not have been aware of those beliefs when they joined the company. Seneca'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 exemption is improper if it "operates to impose the employer's religious faith on the employees").

For these reasons, the Hepler Plaintiffs' RFRA challenge should be rejected.

### B. The Hepler Plaintiffs' First Amendment Claims Are Meritless

#### 1. The regulations do not violate the Free Exercise Clause

The Hepler Plaintiffs' free exercise claim fails at the outset because, as explained above, *see supra* pp. 23-28, for-profit, secular employers generally, and Seneca 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. 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." *Id.* 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 prohibiting 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,[17] 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 recommended preventive services, including those for women. The regulations reflect expert medical recommendations about the medical necessity of the services without regard to any religious motivations for or against such services. *Id*. at 533. The requirement to provide coverage for certain contraceptive services, in particular, is meant to improve the health of women 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.

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) (finding law that "punishe[d] conduct within its reach without regard to whether the conduct was religiously motivated" was generally applicable).

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.*

[17] 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.

*Friends Serv. Comm. v. Thornburgh*, 951 F.2d 957, 960 (9th Cir. 1991); *Intercommunity Ctr. for Justice v. I.N.S.*, 910 F.2d 42, 44 (2d Cir. 1990). 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.

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. And there is 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 challenged regulations are neutral laws of general applicability, they do not offend the Free Exercise Clause.

**2. The regulations do not violate the Establishment Clause**

The Hepler Plaintiffs claim that the preventive services coverage regulations, and particularly the religious employer exemption, violate the Establishment Clause because they discriminate among religions and require the government to examine and evaluate plaintiffs' religious beliefs. Amend. Compl. ¶¶ 273-76. They 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. The Court, on the other hand, has upheld a statute that provided an 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.

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 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.

The religious employer exemption also does not foster excessive government entanglement with religion. As an initial matter, Seneca admits that it fails to satisfy even the fourth criterion for the religious employer exemption, *see id.* ¶ 130, and the Hepler Plaintiffs cannot credibly claim that this criterion requires any inquiries that would pose a potential entanglement issue, *see* 45 C.F.R. § 147.130(a)(1)(iv)(B)(4) (requiring employer to be a nonprofit organization as described in 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii)). Accordingly, any entanglement 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 Intn. 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 inquiry that may be required to enforce the religious employer exemption. *See, e.g.*, *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. Bd. of Pub. Works of Md.*, 426 U.S. 736, 764-65 (1976) (rejecting excessive entanglement challenge where the State conducted annual audits to ensure that grants to religious colleges were not used to teach religion). Accordingly, the Hepler Plaintiffs' Establishment Clause claim fails.[18]

**3. The regulations do not violate the Free Speech Clause**

The Hepler 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 the Hepler Plaintiffs—or any other person, employer, or entity—to say anything. Nor do the preventive services coverage regulations limit what plaintiffs may say. The Hepler Plaintiffs remain free under the regulations to express to Seneca's or WLH Enterprises'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, the Hepler Plaintiffs may encourage Seneca's and WLH's employees not to use contraceptive services. The preventive services coverage regulations regulate conduct, not speech. *See id.* (concluding that statute that required law schools to provide military recruiters with equal access to campus and students regulated conduct, not speech).

[18] 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. 23-31.

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 covers contraceptive services, along with numerous other medical items and services, under its group health plan 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), *and Texas v. Johnson*, 491 U.S. 397, 406 (1989) (flag burning 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.

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, the Hepler Plaintiffs' First Amendment claims fail.

**C. The Court Should Dismiss the Hepler Plaintiffs' Due Process Clause Claim**

The Hepler Plaintiffs' allegation that the preventive services coverage regulations violate the Fifth Amendment's Due Process Clause is as puzzling as it is baseless. In the 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 Seneca's plan.

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 Amended Complaint demonstrates that the Hepler Plaintiffs understand how the challenged regulations apply to Seneca's plan. Contrary to the premise of their vagueness claim, the Hepler Plaintiffs have no difficulty concluding that the regulations "will force [their] July 2013 health insurance plan to provide" coverage for FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Amend. Compl. ¶ 100. Indeed, the Amended Complaint methodically explains why the preventive services coverage regulations apply to Seneca's plan and what those regulations require of the corporation. *Id*. ¶¶ 97, 100, 116, 130, 143, 176. In other words, the regulations are not vague as applied to Seneca. *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."). Plaintiffs' due process claim must fail, 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.[19]

### D. The Court Should Dismiss the Hepler Plaintiffs' APA Claims

#### 1. Issuance of the challenged regulations was procedurally proper

The Hepler Plaintiffs' claim that defendants failed to follow the procedures required by the APA in issuing the challenged regulations, *see* Amend. Compl. ¶¶ 289-91, 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.

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.[20] *Id*. at 46624. Defendants requested comments for a period of sixty days on the amendment to the regulations and specifically on the definition of

[19] As a corollary, the Hepler Plaintiffs cannot raise the due process rights of "other parties not before the Court." Amend Compl. ¶ 283; *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" (internal quotations omitted)). And the Hepler Plaintiffs' suggestion that the preventive services coverage regulations are overbroad is not only incorrect, but also irrelevant to their due process claim, *see Humanitarian Law Project*, 130 S. Ct. at 2719 ("[A] vagueness challenge does not turn on whether a law applies to a substantial amount of protected expression.").

[20] 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.

religious employer contained in the exemption authorized by the amendment. *Id*. at 46621. After receiving and carefully considering thousands of comments, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations and to create an 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 the Hepler 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 amendment to the interim final regulations after notice and opportunity for comment.

**2. The regulations are neither arbitrary nor capricious**

The Hepler Plaintiffs also contend that defendants acted arbitrarily and capriciously by failing to exempt them "and other religionists" from the scope of the preventive services coverage regulations. Amend. Compl. ¶¶ 293-94. But their 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 46623.

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 of for-profit, secular 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 Seneca. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins*, 463 U.S. 29, 43 (1983) (stating that agency action must be upheld if "the agency's path may reasonably be discerned").

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

The Hepler 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. Amend. Compl. ¶¶ 296-99. 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). The Hepler Plaintiffs reason that, because the challenged regulations require group health plans to cover emergency contraception, they, in effect, require coverage for abortion services in violation of federal law.

The Hepler Plaintiffs' claim that the challenged regulations conflict with section 1303(b)(1) of the ACA should be dismissed, first, 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. 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 health insurance issuers or that Seneca's plan is 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 will not be operational until 2014, *id*. § 18031(b), and, in any event, Seneca's plan has no such certification. Because section 1303(b)(1) is inapplicable to Seneca's plan, the Court should dismiss this claim for lack of prudential standing.

Even if the Court were to reach the merits of plaintiffs' argument 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 those laws. 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 (August 1, 2011), *available at* http://www.healthcare.gov/news/factsheets/2011/08/womensprevention08012011a.html (last visited Aug. 2, 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 such drugs act as contraceptives and not abortifacients:

> Emergency contraceptive pills are not effective if the woman is pregnant . . . . 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.

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, http://www.hhs.gov/opa/title-x-family-planning/initiatives-and-resources/documents-and-tools/opa-97-02.html (last visited Aug. 2, 2012); *see also* 42 U.S.C. §§ 300, 300a-6.

Thus, although the Hepler Plaintiffs might seek to relitigate this issue here, 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.[21] 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).

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

[21] Title X 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).

incorporated as a "rider" to the Consolidated Appropriations Act of 2005, Pub. L. No. 108-447, 118 Stat. 2809 (2005), and subsequent years. During the floor debate on 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:

> 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).

The Hepler Plaintiffs additionally contend that the preventive services coverage regulations conflict with a provision of the Church Amendments, 42 U.S.C. § 300a-7(d), and thereby violate the APA. Amend. Compl. ¶298. The Church Amendments, however, have no application to the current dispute. Indeed, plaintiffs' Amended Complaint does not explain how the cited provision is in any tension with the challenged regulations. Seneca, by merely offering a health plan, 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." 42 U.S.C. § 300a-7(d); *see also Gray v. Romero*, 697 F. Supp. 580, 590 n.6 (D.R.I. 1988). Nor is Seneca an "individual." 42 U.S.C. § 300a-7(d). The Church Amendments, therefore, are not violated here.

For these reasons, the Hepler Plaintiffs' APA claim should be dismissed.

## CONCLUSION

For the foregoing reasons, this Court should dismiss plaintiffs' Amended Complaint.

Respectfully submitted this 2nd day of August, 2012,

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