IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BELMONT ABBEY COLLEGE, Plaintiff, v. KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; HILDA SOLIS, Secretary of the United States Department of Labor; UNITED STATES DEPARTMENT OF LABOR; TIMOTHY GEITHNER, Secretary of the United States Department of the Treasury, and UNITED STATES DEPARTMENT OF THE TREASURY, Defendants.	Civil Action No. 1:11-cv-01989-JEB

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND REGULATIONS

MISCELLANEOUS

INTRODUCTION

The Patient Protection and Affordable Care Act, and implementing regulations, require all group health plans – except those sponsored by certain religious employers – and health insurance issuers that offer non-grandfathered group or individual health coverage[1] to provide coverage for certain recommended preventive services without cost-sharing (such as a copayment, coinsurance, or a deductible). As relevant here, 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. Plaintiff, Belmont Abbey College, filed suit on November 10, 2011, seeking to have the Court invalidate and enjoin the preventive services coverage regulations, in their interim final form. Plaintiff alleges that its sincerely-held religious beliefs prohibit it from providing coverage for the required services.

On February 10, 2012, after plaintiff filed this action, defendants finalized the preventive services coverage amended interim final regulations, issued guidance on a one-year enforcement safe harbor, and gave notice of a future rulemaking, all designed (in whole or in part) to address religious concerns such as those raised by plaintiff. The final regulations confirm that group health plans sponsored by certain religious employers (and any associated group health insurance coverage) are exempt from the requirement to cover contraceptive services. The temporary enforcement safe harbor provision includes a larger group of employers with religious objections to providing contraceptive coverage. It provides that defendants will not bring any enforcement action against employers that meet certain criteria 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

[1] A grandfathered plan or policy is one that was in existence on March 23, 2010 and that has not undergone any of a defined set of changes.

explained that, before the expiration of the one-year enforcement safe harbor, they will propose and finalize changes to the preventive services coverage regulations to further accommodate non-profit religious organizations' religious objections to covering contraceptive services. The forthcoming modifications, among other things, will require health insurance issuers to offer group health insurance coverage without contraceptive coverage to non-profit religious organizations that object to contraceptive coverage and simultaneously to offer contraceptive coverage directly to such organization's plan participants who desire it, at no charge.

In light of these actions, this Court lacks authority to adjudicate plaintiff's claims. At the outset, plaintiff's suit must be dismissed for lack of jurisdiction because plaintiff has not alleged any imminent injury from the operation of the regulations. Plaintiff currently offers a group health plan to its employees, and plaintiff has not alleged that the plan – which according to the Complaint does not cover contraceptive services – is ineligible for grandfather status. Thus, even prior to defendants' most recent modifications, plaintiff has not borne its burden to prove that it is under any current obligation to offer coverage for contraceptive services. Moreover, even assuming *arguendo* that plaintiff's group health plan is ineligible for grandfather status, plaintiff cannot demonstrate an imminent injury that would support standing in light of the enforcement safe harbor – which protects plaintiff until at least January 1, 2014 – and defendants' announced intention to promulgate new regulations before that date that are intended to accommodate the religious objections of employers like plaintiff.

The Court likewise lacks jurisdiction because this case is not ripe. Plaintiff's challenge to the preventive services coverage regulations is not fit for judicial review because defendants have indicated that they will propose and finalize changes to the regulations that are intended to accommodate plaintiff's religious objections to providing contraceptive coverage. In the

meantime, the enforcement safe harbor will be in effect such that plaintiff, even if its group health plan is not eligible for grandfather status, will not suffer any hardship as a result of its failure to cover contraceptive services.

BACKGROUND

I. STATUTORY BACKGROUND

Prior to the enactment of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010),[2] 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 REPORT"). Section 1001 of the ACA – which includes the preventive services coverage provision at issue 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 recommended preventive services without cost-sharing.[3] 42 U.S.C. § 300gg-13.

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

[3] A group health plan includes a plan established or maintained by an employer that provides medical care to employees. 42 U.S.C. § 300gg-91(a)(1). Group health plans may be insured (i.e., medical care underwritten through an insurance contract) or self-insured (i.e., medical care funded directly by the employer). The ACA does not require employers to provide health coverage for their employees, but, beginning in 2014, certain large employers may face assessable penalties if they fail to do so. 26 U.S.C. § 4980H (requiring an employer that has an average of at least 50 full-time equivalent employees during the preceding calendar year to make an assessable payment if it (1) "fails to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan," and at least one of its full-time employees has enrolled in a qualified health plan

The preventive services that must be covered are: (1) evidence-based items or services that have in effect a rating of "A" or "B" from the United States Preventive Services Task Force ("USPSTF"); (2) immunizations recommended by the Advisory Committee on Immunization Practices; (3) for infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA")[4]; and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA. *Id.*

The requirement to provide coverage for recommended preventive services for women, without cost-sharing, was added as an amendment to the ACA as initially proposed. The Women's Health Amendment was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines incorporated into 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

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purchased on a health insurance exchange "with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee;" or (2) offers health coverage to its full-time employees (and their dependents), but one or more of its full-time employees receives a premium tax credit or cost-sharing reduction to assist in the purchase of a qualified health plan on a health insurance exchange because the employer-provided coverage is not affordable or does not provide minimum value).

A health insurance issuer that offers health insurance coverage is an insurance company, insurance service, or insurance organization that is licensed to engage in the business of insurance in a state and that issues a policy or contract to provide group or individual health insurance coverage. 42 U.S.C. § 300gg-91(b)(2).

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

of Sen. Franken) ("The current bill relies solely on [USPSTF] to determine which services will be covered at no cost. The problem is, several crucial women's health services are omitted. [The Women's Health Amendment] closes this gap.").

Research shows that cost-sharing requirements can pose barriers to preventive care and result in reduced use of preventive services, particularly for women. IOM REPORT 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 REPORT at 19. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and the utilization of recommended preventive services. 75 Fed. Reg. 41726, 41728 (July 19, 2010). Increased use of preventive services, in turn, will benefit the health of individual Americans and society at large. 75 Fed. Reg. at 41728, 41733; IOM REPORT at 20. Individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease. 75 Fed. Reg. at 41728, 41733; IOM REPORT at 20. Healthier workers will be more productive with fewer sick days. 75 Fed. Reg. at 41728, 41733; IOM REPORT at 20. And increased utilization will result in savings due to lower health care costs. 75 Fed. Reg. at 41728, 41730, 41733; IOM REPORT at 20.

Defendants promulgated 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 recommended preventive services,

without cost-sharing, for plan years (or, in the individual market, policy years) that begin on or after September 23, 2010. 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). With respect to new recommendations or guidelines, coverage must be provided 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 or guideline 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 "reviewing what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines. IOM REPORT 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 Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *Id*. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited Feb. 16, 2012). IOM determined that coverage, without cost-sharing, for FDA-approved

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

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 REPORT at 102-103.

On August 1, 2011, HRSA adopted IOM's recommendations relating to preventive services for women in full, subject to an exemption relating to certain religious employers authorized by amended interim final regulations. *See* HRSA Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited Feb. 16, 2012). The amended interim final regulations, issued on the same day, authorize 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 guidelines. 76 Fed. Reg. 46621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, an employer must meet all of the following criteria:

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

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

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

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

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

and policies that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years (or, in the individual market, policy 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. In response, defendants received over 200,000 comments. 77 Fed. Reg. 8725, 8726 (Feb. 15, 2012). After carefully considering these comments, defendants decided to adopt the definition of religious employer contained in the amended interim final regulations for purposes of the final regulations while also creating a one-year enforcement safe harbor for plans sponsored by certain organizations with religious objections to contraceptive coverage that do not qualify for the religious employer exemption. *Id*. at 8727.

Pursuant to the enforcement safe harbor, defendants will not take any enforcement action against an employer, group health plan, or group health insurance issuer that fails to cover recommended contraceptive services without cost-sharing in a non-exempted, non-grandfathered group health plan sponsored by an organization that meets all of the following criteria:

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

(2) From February 10, 2012 onward, contraceptive coverage has not been provided at any point by the group health plan sponsored by the organization, consistent with any applicable state law, because of the religious beliefs of the organization.

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

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

HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance"), at 3 (Feb. 10, 2012), *available at* http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf (last visited Feb. 16, 2012). The enforcement safe harbor will be in effect until the first plan year that begins on or after August 1, 2013. Guidance at 3. By that time, significant changes announced by defendants will have altered the landscape with respect to religious accommodations under the regulations by further removing organizations such as plaintiff from the provision of coverage for contraceptive services.

Defendants explained in the preamble to the final regulations, which were announced on February 10, 2012 and published in the Federal Register on February 15, 2012, that they will work with stakeholders to propose and finalize changes to the preventive services coverage regulations before the end of the temporary enforcement safe harbor. 77 Fed. Reg. at 8728-29. The changes would provide alternative means of arranging for contraceptive coverage without cost-sharing with respect to non-exempted, non-profit religious organizations that object to contraceptive coverage for religious reasons. *Id*. Specifically, defendants stated that they will initiate a rulemaking to require health insurance issuers to offer group health insurance coverage without contraceptive coverage to such organizations and simultaneously to offer contraceptive coverage directly to the organization's plan participants who desire it, at no charge. *Id*. Defendants further explained that they intend to develop policies to achieve the same goals – i.e., providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit religious organizations' religious objections to covering contraceptive services – with respect to self-insured group health plans sponsored by such organizations. *Id*.

II. CURRENT PROCEEDINGS

Plaintiff, Belmont Abbey College, brought this action to challenge the lawfulness of the preventive services coverage regulations to the extent that they require the health coverage it makes available to its employees and students to cover contraceptive services. Plaintiff filed suit after defendants promulgated the amended interim final regulations but before defendants finalized those regulations and before defendants created the temporary enforcement safe harbor.

Plaintiff describes itself as a "Benedictine Catholic College in Belmont, North Carolina," with approximately 1,700 students and 200 full-time and 105 part-time employees. Compl. ¶¶ 12, 26, 27. According to the Complaint, plaintiff currently makes available health plans – which do not cover contraception, sterilization, or abortion – to its full-time faculty and staff and to its undergraduate students. *Id*. ¶¶ 28-30. Plaintiff alleges that its "sincerely held religious beliefs prohibit it from providing coverage for contraception, sterilization, abortion, or related education and counseling." *Id*. ¶ 106. Plaintiff further asserts that it does not qualify for the religious employer exemption because the inculcation of religious values is only one of its purposes and it employs and serves many persons who do not share its religious tenets. *Id*. ¶¶ 100-102. Plaintiff claims the preventive services coverage regulations – in their interim final form – violate the First Amendment to the United States Constitution, the Religious Freedom Restoration Act, and the Administrative Procedure Act.

STANDARD OF REVIEW

Defendants move to dismiss the Complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. "'[T]he party invoking federal jurisdiction bears the burden of establishing its existence.'" *NRDC v. Pena*, 147 F.3d 1012, 1020 (D.C. Cir. 1998) (quoting *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104

(1998)). Where, as here, the defendant challenges jurisdiction on the face of the complaint, the complaint must plead sufficient facts to establish that jurisdiction exists. This Court must determine whether it has subject matter jurisdiction before addressing the merits of the complaint. *See Steel Co.*, 523 U.S. at 94-95.

ARGUMENT

I. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE PLAINTIFF LACKS STANDING

Plaintiff lacks standing because it has not alleged a concrete and imminent injury resulting from the operation of the preventive services coverage regulations. To meet its burden 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) (quotations omitted). The harm must be "direct, real, and palpable." *Public Citizen v. NHTSA*, 489 F.3d 1279, 1292 (D.C. Cir. 2007). Allegations of possible future injury do not suffice. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). Rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Id*. (quotation omitted). A plaintiff who "alleges only an injury at some indefinite future time" has not shown an injury in fact, particularly where "the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2. In these situations, "the injury [must] proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." *Id*.

The preventive services coverage 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. A grandfathered plan is a health plan in which an individual was enrolled on March 23,

2010 and that has continuously covered an 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 only if, compared to its existence on March 23, 2010, it eliminates all or substantially all benefits to 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).

Here, plaintiff alleges that it currently offers to its employees a group health plan that does not cover contraceptive services. Compl. ¶¶ 28-30. There is no allegation in the Complaint that this plan was not in place on March 23, 2010. Plaintiff, moreover, does not allege that it has altered its plan since March 23, 2010 in a way that would cause it to lose grandfather status. Nor does plaintiff allege that it will alter the plan in such a way in the imminent future. And it is not to be expected that plaintiff would act to forego its grandfather status lightly, which would require the plan to comply with all other ACA requirements. Accordingly, the allegations in the Complaint simply do not show that plaintiff will be required by the preventive services coverage regulations to provide coverage for contraceptive services – as opposed to continuing to offer the same grandfathered plan that does not, and would not, cover contraceptive services. Plaintiff therefore has not alleged any imminent injury as a result of the challenged regulations.[6]

[6] Any speculation about whether plaintiff might change its plan in the future in a way that causes it to lose its grandfather status – and plaintiff does not in fact engage in any such speculation in the Complaint – would not be sufficient to establish an injury or a ripe claim. *See Lujan*, 504 U.S. at 560 (indicating an injury in fact must be "actual or imminent, not conjectural or hypothetical" (quotations omitted)); *Texas v. United States*, 523 U.S. 296, 300 (1998) (observing that a claim is not ripe if it rests on "contingent future events that may not occur as anticipated, or indeed may not occur at all").

Furthermore, even if plaintiff had alleged that its group health plan does not qualify for grandfather status, plaintiff still could not demonstrate an injury in fact. Plaintiff does not allege that it will not satisfy the criteria for the temporary enforcement safe harbor, and there is nothing in the Complaint to suggest that plaintiff will be unable to meet those criteria. Under the temporary enforcement safe harbor, defendants will not take any enforcement action against an organization that qualifies for the enforcement safe harbor until the first plan year that begins on or after August 1, 2013. Guidance at 3. The Complaint indicates that plaintiff's plan year begins on January 1. Compl. ¶ 33. Thus, if plaintiff qualifies for the safe harbor – and, as noted above, the allegations in the Complaint suggest that it will – then the earliest that plaintiff could be subject to any enforcement action by defendants for failing to provide contraceptive coverage is January 1, 2014. With such a long time gap before the inception of any possible injury and the challenged regulations still in flux, plaintiff cannot satisfy the imminence requirement for standing; the asserted injury is simply "too remote temporally." *See McConnell v. FEC*, 540 U.S. 93, 226 (2003) (concluding Senator lacked standing based on claimed desire to air advertisements five years in the future), *overruled in part on other grounds*, *Citizens United v. FEC*, 130 S. Ct. 876 (2010); *Whitmore*, 495 U.S. at 159-60.

This defect in plaintiff's suit does not implicate a mere technical issue of counting intermediate days; rather, it goes to the fundamental 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). This concern is particularly appropriate here. Defendants have indicated in the preamble to the final regulations that, before the expiration of the one-year enforcement safe

harbor, they will propose and finalize changes to the preventive services coverage regulations to accommodate the concerns of non-profit religious organizations, like plaintiff, that object to providing contraceptive coverage for religious reasons. 77 Fed. Reg. at 8728-29. In light of these forthcoming modifications, there is no reason to suspect that plaintiff will be required to offer a group health plan that covers contraceptive services in contravention of its alleged 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, plaintiff's claim of injury, if any, after the one-year enforcement safe harbor expires would differ substantially from plaintiff's current claim of injury.

Plaintiff's Complaint also makes passing reference to its student health plan, but plaintiff likewise has not alleged any injury from the operation of the preventive services coverage regulations with respect to that plan. Neither the preventive services coverage regulations nor any other federal law requires plaintiff to provide health insurance to its students – much less health insurance that covers contraceptive services. The preventive services coverage regulations only apply to "group health plan[s]" and "health insurance issuer[s]." 26 C.F.R. § 54.9815-2713T(a); 29 C.F.R. § 2590.715-2713(a); 45 C.F.R. § 147.130(a); *see also* 42 U.S.C. § 300gg-13(a). Only health coverage offered to employees or their dependents qualifies as a group health plan, 42 U.S.C. § 300gg-91(a)(1), and plaintiff is not a health insurance issuer for purposes of the ACA, *see id*. § 300gg-91(b)(2). If plaintiff chooses to provide a self-insured health plan[7] to its students – and again, there is no requirement in federal law that it do so – then the health plan is not required to cover contraceptive services. *See* Student Health Insurance

[7] In a self-insured health plan, medical care is funded directly by the sponsoring organization, as opposed to being underwritten through an insurance contract.

Coverage, 76 Fed. Reg. 7767, 7769 (Feb. 11, 2011). If plaintiff's students instead receive health insurance through a health insurance issuer, then the obligation to provide coverage for recommended contraceptive services rests on the issuer, not plaintiff. *See* 26 C.F.R. § 54.9815-2713T(a); 29 C.F.R. § 2590.715-2713(a); 45 C.F.R. § 147.130(a). Plaintiff is not required by law to arrange for such coverage, contract with an issuer for such coverage, or subsidize any coverage provided by an issuer to its students. In short, students may receive health coverage either by contracting directly with an insurance issuer (in which case plaintiff does not itself provide the insurance), or from plaintiff through a self-insured plan (in which case the plan is not subject to the preventive services coverage requirement). In either event, plaintiff is under no federal obligation to provide its own plan that covers contraception or other recommended preventive services, and thus lacks standing.

Accordingly, this case should be dismissed in its entirety for lack of standing.

II. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE IT IS NOT RIPE

"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) (quotation omitted). It "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies." *Id*. at 807. 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*. at 807-08.

A case ripe for judicial review cannot be "nebulous or contingent but must have taken on fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them."

Public Serv. Comm'n v. Wycoff Co., 344 U.S. 237, 244 (1952). In assessing ripeness, courts evaluate both "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *overruled on other grounds in Califano v. Sanders*, 430 U.S. 99, 105 (1977).

These two prongs of the ripeness analysis are discussed in *Abbott Laboratories*, the seminal Supreme Court case on pre-enforcement review of agency action. 387 U.S. 136. *Abbott Laboratories* involved a pre-enforcement challenge to Federal Food, Drug and Cosmetic Act regulations that required drug manufacturers to include a drug's established name every time the drug's proprietary name appeared on a label. *Id*. at 138. The regulations in effect required the plaintiff drug manufacturers to change all their labels, advertisements, and promotional materials at considerable burden and expense. *Id*. at 152. Noncompliance would have triggered significant civil and criminal penalties. *Id*. at 153 & n.19.

The Court determined the challenged regulations were fit for judicial review because they were "quite clearly definitive," *id*. at 151; the regulations "were made effective immediately upon publication," *id*. at 152, and "[t]here [was] no hint that th[e] regulation[s] [were] informal . . . or tentative." *Id*. at 151. Moreover, the Court noted that "the issue tendered [was] a purely legal one" and there was no indication that "further administrative proceedings [were] contemplated." *Id*. at 149. The Court therefore was not concerned that judicial intervention would inappropriately interfere with further administrative action.

With respect to the hardship prong, the Court determined that delayed review would cause sufficient hardship to the plaintiffs. The impact of the regulations, the Court noted, was "sufficiently direct and immediate" because their promulgation put the drug manufacturers in a "dilemma" – "[e]ither they must comply with the every time requirement and incur the costs of

changing over their promotional material and labeling" or "risk serious criminal and civil penalties for the unlawful distribution of misbranded drugs." *Id*. at 152–53 (quotation omitted). In other words, the challenged regulations "require[d] an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance." *Id*. at 153.

The indicia of ripeness discussed in *Abbott Laboratories* are not present in this case. Plaintiff seeks judicial review of the preventive services coverage regulations as applied to non-exempted, non-profit religious organizations, like plaintiff, that object to contraceptive coverage for religious reasons. Defendants, however, have made clear that they will propose and finalize changes to the preventive services coverage regulations intended to accommodate the concerns expressed by plaintiff and other similarly-situated organizations. 77 Fed. Reg. at 8728-29. The forthcoming modifications would require health insurance issuers to offer group health insurance coverage without contraceptive coverage to such organizations and simultaneously to offer contraceptive coverage at no charge directly to the organization's plan participants who desire it, thus allowing organizations such as plaintiff to avoid providing coverage for contraceptive services. *Id*. And defendants have stated that they intend to develop similar policies with respect to self-insured group health plans of such organizations. *Id*. Therefore, unlike in *Abbott Laboratories*, where the challenged regulations were "definitive" and no "further administrative proceedings [were] contemplated," the preventive services coverage regulations will be modified.

Moreover, because these modifications are intended to address the very issue that plaintiff raises here, there is a significant chance that the modifications 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" (quotations omitted).). Once the forthcoming modifications are finalized, if plaintiff's concerns are not laid to rest, plaintiff "will have ample opportunity [] to bring its legal challenge at a time when harm is more imminent and more certain." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 734 (1998); *Wyoming Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999) ("Prudence . . . restrains courts from hastily intervening into matters that may best be reviewed at another time or another setting, especially when the uncertain nature of an issue might affect a court's ability to decide intelligently" (quotation omitted).).

Further, although plaintiff's Complaint raises largely legal claims, those claims are leveled at the amended interim final regulations, not the final regulations or, more importantly, the proposed modifications to the final regulations that defendants have announced. Plaintiff therefore challenges regulations that, as applied to it and similarly-situated organizations, have not "taken on fixed and final shape." *Public Serv. Comm'n*, 344 U.S. at 244. Once defendants complete the rulemaking process outlined in the preamble to the final regulations, plaintiff's challenge to the current regulations will 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 may not need to be resolved by the courts). And judicial review of these future changes to the preventive services coverage regulations as a result of the forthcoming rulemaking would be too speculative to yield meaningful review; it would only entangle the Court "in abstract disagreements over administrative policies." *Abbott Labs.*, 387 U.S. at 148. Because judicial review at this time would inappropriately interfere with defendants' forthcoming rulemaking and

may result in the Court deciding issues that may never arise, this case is not fit for judicial review.

Withholding or delaying judicial review also would not result in any hardship for plaintiff. Unlike the plaintiffs in *Abbott Laboratories*, 387 U.S. at 153, plaintiff here is not being compelled to make immediate and significant changes in its day-to-day operations under threat of serious civil and criminal penalties. As explained above, if the health plan made available by plaintiff to its employees is eligible for grandfather status – and there are no allegations in the Complaint to indicate that it is not – then the plan is not required to cover contraceptive services. Moreover, even if plaintiff offers a non-grandfathered group health plan, it can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against plaintiff for failure to cover contraceptive services until January 1, 2014, at the earliest. *See* Guidance at 3. And, by the time the enforcement safe harbor expires, defendants will have issued modified regulations to accommodate plaintiff's religious objections to providing contraceptive coverage. *See* 77 Fed. Reg. at 8728-29. Therefore, this is simply not a case where plaintiff is "forced to choose between foregoing lawful activity and risking substantial legal sanctions." *See Abbott Labs.*, 387 U.S. at 153. Indeed, "[w]ere [this Court] to entertain [the] anticipatory challenge[] pressed by [plaintiff]" – a party "facing no imminent threat of adverse agency action, no hard choice between compliance certain to be disadvantageous and a high probability of strong sanctions" – the Court "would venture away from the domain of judicial review into a realm more accurately described as judicial preview," a realm into which the D.C. Circuit has cautioned courts not to tread. *Tennessee Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984) (internal citation omitted).

Because plaintiff's challenge to the preventive services coverage regulations is not fit for judicial decision and plaintiff would not suffer substantial hardship if judicial review were withheld or delayed, this case should be dismissed in its entirety as unripe.

CONCLUSION

For all the foregoing reasons, this Court should grant defendants' motion to dismiss.

Respectfully submitted this 16th day of February, 2012,

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