IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROMAN CATHOLIC ARCHBISHOP OF WASHINGTON, *et al.*, Plaintiffs,	)	
v.	)	Case No. 12-cv-00815-ABJ
KATHLEEN SEBELIUS, *et al.*, Defendants.	)	

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

INTRODUCTION 1

BACKGROUND 4

I. STATUTORY BACKGROUND 4

II. CURRENT PROCEEDINGS 11

STANDARD OF REVIEW 11

ARGUMENT 11

I. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE PLAINTIFFS LACK STANDING 11

II. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE IT IS NOT RIPE 15

CONCLUSION 22

TABLE OF AUTHORITIES

CASES

* *AT&T Corp. v. FCC*,
369 F.3d 554 (D.C. Cir. 2004) 18, 20

* *Abbott Labs. v. Gardner*,
387 U.S. 136 (1967) 16, 17, 18, 20, 21, 22

* *Am. Petroleum Inst. v. EPA*,
683 F.3d 382 (D.C. Cir. 2012) 16, 18, 20

Animal Legal Def. Fund, Inc. v. Espy,
23 F.3d 496 (D.C. Cir. 1994) 13

* *Belmont Abbey Coll. v. Sebelius*,
No. 1:11-cv-1989, 2012 WL 2914417 (D.D.C. July 18, 2012) 3, 4, 14, 19, 20

Bethlehem Steel Corp. v. EPA,
536 F.2d 156 (7th Cir. 1976) 21

Bhd. of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.,
457 F.3d 24 (D.C. Cir. 2006) 12

Connecticut v. Duncan,
612 F.3d 107 (2d Cir. 2010) 16

* *Lake Pilots Ass'n v. U.S. Coast Guard*,
257 F. Supp. 2d 148 (D.D.C. 2003) 19, 20

* *Lujan v. Defenders of Wildlife*,
504 U.S. 555 (1992) 12, 13, 15

* *McConnell v. FEC*,
540 U.S. 93 (2003) 13, 15

* *Motor Vehicle Mfrs. Assoc. v. N.Y. State Dep't of Envtl. Conservation*,
79 F.3d 1298 (2d Cir. 1996) 20

Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales,
468 F.3d 826 (D.C. Cir. 2006) 12

Nat'l Park Hospitality Ass'n v. Dep't of the Interior,
538 U.S. 803 (2003) 15

Nebraska v. HHS,
No. 4:12-cv-3035, 2012 WL 2913402 (D. Neb. July 17, 2012) 3

* *Occidental Chem. Corp. v. FERC*,
869 F.2d 127 (2d Cir. 1989) 19

Ohio Forestry Ass'n v. Sierra Club,
523 U.S. 726 (1998) 19

Pennsylvania v. New Jersey,
426 U.S. 660 (1976) 12

Pub. Citizen v. NHTSA,
489 F.3d 1279 (D.C. Cir. 2007) 12

Pub. Serv. Comm'n v. Wycoff Co.,
344 U.S. 237 (1952) 16, 19

Spriggs v. Wilson,
467 F.2d 382 (D.C. Cir. 1972) 19

Steel Co. v. Citizens for a Better Env't,
523 U.S. 83 (1998) 11

* *Tenn. Gas Pipeline Co. v. FERC*,
736 F.2d 747 (D.C. Cir. 1984) 21, 22

* *Tex. Indep. Producers & Royalty Owners Ass'n v. EPA*,
413 F.3d 479 (5th Cir. 2005) 18, 19, 22

Texas v. United States,
523 U.S. 296 (1998) 19

The Toca Producers v. FERC,
411 F.3d 262 (D.C. Cir. 2005) 20

* *Util. Air Regulatory Grp. v. EPA*,
320 F.3d 272 (D.C. Cir. 2003) 18

* *Whitmore v. Arkansas*,
495 U.S. 149 (1990) 12, 13, 15

Wilmac Corp. v. Bowen,
811 F.2d 809 (3d Cir. 1987) 21

Wyo. Outdoor Council v.USFS,

165 F.3d 43 (D.C. Cir. 1999) 19

STATUTES

26 U.S.C. § 4980H 5

26 U.S.C. § 6033(a)(1) 8

26 U.S.C. § 6033(a)(3)(A)(i) 8

26 U.S.C. § 6033(a)(3)(A)(iii) 8

42 U.S.C. § 300gg-13 5

42 U.S.C. § 300gg-13(a) 5

42 U.S.C. § 300gg-91(a)(1) 5

Pub. L. No. 111-152, 124 Stat. 1029 (2010) 1

Pub. L. No. 111-148, 124 Stat. 119 (2010) 1

FEDERAL REGULATIONS

26 C.F.R. § 54.9815-1251T 1

26 C.F.R. § 54.9815-2713T 7

26 C.F.R. § 54.9815-2713T(a) 5

29 C.F.R. § 2590.715-1251 1

29 C.F.R. § 2590.715-2713 7

45 C.F.R. § 147.130 7

45 C.F.R. § 147.130(a) 5

45 C.F.R. § 147.130(a)(1)(iv)(A) 8

45 C.F.R. § 147.130(a)(1)(iv)(B) 8

45 C.F.R. § 147.140 1

45 C.F.R. § 147.145(a) 5

75 Fed. Reg. 41,726 (July 19, 2010).....6

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

77 Fed. Reg. 8725 (Feb. 15, 2012) 8, 10, 14, 18, 22

77 Fed. Reg. 16,501 (Mar. 21, 2012)..... 9, 10, 13, 20

77 Fed. Reg. 16,453 (Mar. 21, 2012)..... 9

LEGISLATIVE HISTORY

155 Cong. Rec. S12019, S12025 (daily ed. Dec. 1, 2009); 5, 6

155 Cong. Rec. S12261, S12271 (daily ed. Dec. 3, 2009) 6

MISCELLANEOUS

Inst. of Med., Clinical Preventive Services for Women:
Closing the Gaps (2011) 4, 6, 7

FDA, Birth Control Guide 7

HHS, Guidance on the Temporary Enforcement Safe Harbor (Feb. 10, 2012).....9, 12, 15, 22

HRSA, Women's Preventive Services: Required Health Plan
Coverage Guidelines 7

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. Plaintiffs, the Roman Catholic Archbishop of Washington (the "Archdiocese"), the Consortium of Catholic Academies of the Archdiocese of Washington, Inc. (the "Consortium"), Archbishop Carroll High School, Inc. ("Carroll"), Catholic Charities of the Archdiocese of Washington, Inc. ("Catholic Charities"), and The Catholic University of America (the "University"), filed suit on May 21, 2012, seeking to have the Court invalidate and enjoin the preventive services coverage regulations as to plaintiffs. Plaintiffs allege that their religious beliefs prohibit them from providing the required coverage for certain services.

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 by plaintiffs. The finalized amendment confirms that group health plans sponsored

[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 existed 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.

by certain religious employers (and any associated group health insurance coverage) 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 enforcement action against such organizations that meet certain criteria (and associated group health plans and insurers) during the safe harbor period, which is 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 safe harbor period ends, 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 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.

In light of these actions, this Court lacks authority to adjudicate plaintiffs' claims. At the outset, plaintiffs' suit must be dismissed for lack of jurisdiction because plaintiffs have not alleged any injury from the operation of the challenged regulations. Plaintiffs allege that they provide health insurance coverage to their employees through self-insured and insured health plans, respectively. Compl. ¶¶ 44 (Archdiocese self-insured plan covering the Archdiocese, the Consortium, Carroll, and Catholic Charities), 86 (insured plan for the University's employees), 90 (insured plan for the University's students), ECF No. 1. But they have not alleged an imminent injury that would support standing in light of the enforcement safe harbor and

forthcoming amendments to the challenged regulations. The safe harbor protects plaintiffs – assuming they did not provide objectionable contraceptive coverage as of February 10, 2012 – until at least January 1, 2014. And defendants' initiation of a rulemaking that commits to amending the preventive services coverage regulations well before January 2014 to accommodate the religious objections of organizations like plaintiffs further demonstrates the absence of any imminent harm to them.

Similarly, the Court lacks jurisdiction because this case is not ripe. Plaintiffs' challenge to the preventive services coverage regulations is not fit for judicial review because defendants have initiated a rulemaking to amend the challenged regulations to accommodate religious organizations' religious objections to providing contraceptive coverage, like plaintiffs'. In the meantime, the enforcement safe harbor will be in effect such that plaintiffs will not suffer hardship as a result of their failure to cover contraceptive services.

Indeed, two recent decisions – in cases nearly identical to this one – confirm this straightforward point. The District Courts for the District of Nebraska and the District of Columbia recently became the first courts to issue rulings on the same jurisdictional arguments advanced by defendants in this motion. *See Nebraska v. HHS*, No. 4:12CV3035, --- F. Supp. 2d ---, 2012 WL 2913402 (D. Neb. July 17, 2012); *Belmont Abbey Coll. v. Sebelius*, Civil Action No. 11-1989, --- F. Supp. 2d ---, 2012 WL 2914417 (D.D.C. July 18, 2012) (Boasberg, J.). 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*, 2012 WL 2913402, at *11-14. 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 the plaintiffs' religious concerns. *Id.* at *20-24. 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 amendments to the regulations. In short, confronted by circumstances virtually identical to those in this case, both courts dismissed the claims of several religious organizations on the same grounds urged in this motion. Defendants respectfully ask this Court to do the same.

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), *available at* http://cnsnews.com/sites/default/files/documents/PREVENTIVE%20SERVICES-IOM%20REPORT.pdf (last visited Aug. 3, 2012) ("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 ("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.* § 300gg-13(a).

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 § 1001 of the ACA. *See* 155 Cong. Rec. S12019, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer) ("The underlying bill . . . already requires that preventive services recommended by [USPSTF] be covered at little to no cost . . . . But [those recommendations] do

[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. 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 receive health insurance through a health insurance issuer, then the obligation to provide coverage for recommended preventive services rests on the issuer, not the institution of higher education. *See, e.g., id.* § 147.130(a).

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

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 the [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 used 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 19-20. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. 75 Fed. Reg. 41,726, 41,728, 41,733 (July 19, 2010). Increased use of preventive services will benefit the health of individual Americans and society at large: individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease; healthier workers will be more productive with fewer sick days; and increased utilization will result in savings due to lower health care costs. *Id.*; IOM REP. at 20.

Defendants issued interim final regulations implementing the preventive services coverage provision on July 9, 2010. 75 Fed. Reg. 41,726. The interim final regulations provide, among other things, that a group health plan or health insurance issuer offering non-grandfathered health coverage must provide coverage for newly recommended preventive

services, without cost-sharing, for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation is issued. 26 C.F.R. § 54.9815-2713T; 29 C.F.R. § 2590.715-2713; 45 C.F.R. § 147.130.

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") 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 and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf (last visited Aug. 3, 2012).

On August 1, 2011, HRSA adopted IOM's recommendations, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited July 13, 2012). That amendment, made effective 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. 46,621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, 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" and "the exclusively religious activities of any religious order," that are exempt from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii). Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years beginning on or after August 1, 2012.

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. 76 Fed. Reg. at 46,623. After carefully considering thousands of comments they received, defendants decided to adopt in final regulations the definition of religious employer contained in the amended interim final regulations while also creating a temporary enforcement safe harbor for 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.[5]

The enforcement safe harbor also applies to any institution of higher education and the issuer of its student health insurance plan if the institution and its student health insurance plan satisfy the criteria above. 77 Fed. Reg. 16,453, 16,456-57 (Mar. 21, 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, defendants expect that significant changes to the preventive services coverage regulations will have altered the landscape as to certain religious organizations by providing them further accommodations.

Those intended changes, which were first announced when defendants finalized the religious employer exemption, will establish alternative means of providing contraceptive

[5] 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 July 13, 2012); 77 Fed. Reg. 16,501, 16,504 (Mar. 21, 2012).

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. 16,501. The ANPRM "presents questions and ideas" on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. *Id.* at 16,503. The purpose of the ANPRM is to provide "an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made" in the forthcoming amendments to the regulations. *Id.* Among other options, the ANPRM suggests requiring health insurance issuers to offer health insurance coverage without contraceptive coverage to religious organizations 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 16,505. The ANPRM also suggests ideas and solicits comments on ways to accommodate religious organizations that sponsor self-insured group health plans for their employees and religious organizations that are non-profit institutions of higher education that arrange health insurance plans for their students. *Id.* at 16,505, 16,506-07.

After receiving comments on the ANPRM, defendants will publish a notice of proposed rulemaking, which will be subject to further public comment, before defendants issue further amendments to the preventive services coverage regulations. *Id.* at 16,501, 16,508. Defendants intend to finalize the amendments to the regulations such that they are effective before the end of the temporary enforcement safe harbor. *Id.* at 16,503.

II. CURRENT PROCEEDINGS

Plaintiffs brought this action on May 21, 2012 to challenge the lawfulness of the preventive services coverage regulations to the extent that the regulations require the health coverage plaintiffs make available to their employees and students to cover contraceptive services. Plaintiffs describe themselves as "Catholic religious entities that provide a wide range of spiritual, educational, and social services to residents in the greater Washington, D.C., community." Compl. ¶ 2. Plaintiffs allege that they cannot provide health insurance covering "abortion, sterilization, and contraceptives" without violating their religious beliefs. *Id.* ¶¶ 4-5. Plaintiffs claim that the challenged regulations 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 under Rule 12(b)(1) of the Federal Rules of Civil Procedure. The party invoking jurisdiction bears the burden of establishing it. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998). Where, as here, defendants challenge 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. *See id.* at 94-95.

ARGUMENT

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

Plaintiffs lack standing because they have 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 "distinct and palpable" and "actual or imminent." *Pub. Citizen v. NHTSA*, 489 F.3d 1279, 1292 (D.C. Cir. 2007) (quotations omitted). Allegations of possible future injury do not suffice; rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (quotation omitted). A plaintiff that "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.*

Here, plaintiffs have not alleged any imminent injury in fact.[6] 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. Guidance at 3. Plaintiffs concede that they will be protected by the safe harbor. *See* Compl. ¶

[6] Defendants note that the only fact offered by plaintiffs that establishes that their group health plans are 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)(i). *See Compl.* ¶¶ 47, 88, 91. But without any allegation that their plans do not qualify for grandfathered status for some other reason, plaintiffs' unexplained refusal to provide the required statement is a self-inflicted injury, insufficient to establish standing. *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' public fiscs were "self-inflicted," and "[n]o State can be heard to complain about damage inflicted by its own hand"); *Bhd. of Locomotive Eng'rs & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006) ("This injury was not in any meaningful way 'caused' by the Board; rather, it was entirely self-inflicted and therefore insufficient to confer standing upon the Union." (citing cases)); *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)). Nevertheless, as explained below, plaintiffs lack standing because they qualify for the enforcement safe harbor and will benefit from the forthcoming amendments to the regulations. Therefore, the Court need not address the issue of grandfathering. And while the University's health plan for students likely is not eligible for grandfathered status, the University likewise has not alleged any injury with respect to its student plan for the reasons explained below. *See infra* pp. 12-15.

130 ("Plaintiffs have until the start of the next plan year following August 1, 2013, to come into compliance with this law.").

The Complaint indicates that plaintiffs' plan years all begin on January 1. *Id.* ¶¶ 48, 87. Thus, the earliest plaintiffs could be subject to any enforcement action by defendants for failing to provide contraceptive coverage is January 1, 2014. With such a long time before the inception of any possible injury and with the regulations undergoing further amendment well before then, plaintiffs cannot satisfy the imminence requirement for standing; the asserted injury is simply "too remote temporally," *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, and too uncertain circumstantially.

This defect in plaintiffs' suit does not implicate a mere technical issue of counting intermediate days until an all-but-certain action takes place. 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 plaintiffs' case 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). The ANPRM published in the Federal Register confirms, and seeks comment on, defendants' intention to propose further amendments to the preventive services coverage regulations that would further accommodate the concerns of religious organizations that object to providing contraceptive coverage for religious reasons, like plaintiffs. 77 Fed. Reg. at 16,501.

The ANPRM provides plaintiffs, and any other interested party, with the opportunity to, among other things: comment on ideas suggested by defendants for further accommodating such 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 16,503, 16,507. 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 16,503; *see also* 77 Fed. Reg. at 8728. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiffs to help shape those amendments, there is no reason to suspect that plaintiffs will be required to sponsor a health plan that covers contraceptive services in contravention of their religious beliefs once the enforcement safe harbor expires. And any suggestion to the contrary is entirely speculative at this point.[7] At the very least, given the anticipated changes to the preventive services coverage regulations, plaintiffs' claims of injury, if any, after the temporary enforcement safe harbor expires would differ substantially from plaintiffs' current claims of injury. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of plaintiffs' Complaint at this juncture.[8] *See Belmont Abbey*, 2012 WL

[7] Plaintiffs allege that the forthcoming accommodations will not "relieve Plaintiffs from the unconscionable position" that the preventive services coverage regulations impose. Compl. ¶ 142. Of course, that allegation is only speculation, as plaintiffs cannot know what form the final accommodations will take. The allegation also prejudges the process and ignores the opportunity for comments by plaintiffs and others to inform the rulemaking. However, even assuming that plaintiffs would continue to object to any future form that the accommodations may take, it would be premature for this Court to evaluate plaintiffs' legal challenges on the basis of that hypothetical objection in the absence of the finalized amendments.

[8] The Archdiocese alleges that it is unclear whether it qualifies for the existing regulations' exemption for certain religious employers. Compl. ¶ 6. Its concern is irrelevant at this stage. Even assuming the Archdiocese does not qualify for the exemption, it is protected by the enforcement safe harbor pending the forthcoming further accommodations. And the Archdiocese need not determine whether it qualifies for the exemption in order to benefit

(continued on next page…)

2914417, at *10 ("Because an amendment to the final rule that may vitiate the threatened injury is not only promised but underway, the injuries alleged by Plaintiff are not 'certainly impending.'" (quoting *Whitmore*, 495 U.S. at 158)).

Finally, plaintiffs cannot transform the speculative possibility of future injury into a current concrete injury for standing purposes by asserting that they must plan now for their future needs. *See* Compl. ¶¶ 170-74. 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, thereby sapping the imminence requirement of any meaning. Further, any planning plaintiffs are engaged in now "stems not from the operation of [the preventive services coverage regulations], but from [plaintiffs'] 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. *See Lujan*, 504 U.S. at 560.

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

---

from the safe harbor. *See* Guidance at 3. Thus, any claim of injury based on the need to determine whether the exemption is applicable, *see, e.g.*, Compl. ¶ 43, is highly speculative and certainly not imminent.

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." *Pub. Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952). "Put simply, the doctrine of prudential ripeness ensures that Article III courts make decisions only when they have to, and then, only once." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012); *see also Connecticut v. Duncan*, 612 F.3d 107, 113-14 (2d Cir. 2010) ("[W]hen a court declares that a case is not prudentially ripe, it means that the case will be *better* decided later . . . [not] that the case is not a real or concrete dispute affecting cognizable current concerns of the parties." (internal quotations and citations omitted)). "Prudential ripeness is, then, a tool that courts may use to enhance the accuracy of their decisions and to avoid becoming embroiled in adjudications that may later turn out to be unnecessary or may require premature examination of, especially, constitutional issues that time may make easier or less controversial." *Duncan*, 612 F.3d at 114 (internal quotations and citation omitted). 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 (1977).

The Supreme Court discussed these two prongs of the ripeness analysis in *Abbott Laboratories*, the seminal 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 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 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 they must "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.

None of the indicia of ripeness discussed in *Abbott Laboratories* is present in this case. Plaintiffs seek judicial review of the preventive services coverage regulations as applied to non-grandfathered religious organizations that object to contraceptive coverage for religious reasons.

Defendants, however, have initiated a rulemaking to amend the preventive services coverage regulations to accommodate the concerns expressed by plaintiffs 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 plaintiffs. 77 Fed. Reg. at 8728-29. Therefore, unlike in *Abbott Laboratories* – where the challenged regulations were definitive and no further administrative proceedings were contemplated – the preventive services coverage regulations are in the process of being amended.

Moreover, the forthcoming amendments are intended to address the very issue that plaintiffs raise here by establishing alternative means of providing contraceptive coverage without cost-sharing while accommodating religious organizations' religious objections to covering contraceptive services. And plaintiffs will have opportunities to participate in the rulemaking process and to provide comments and/or ideas about the proposed 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 Am. Petroleum Inst.*, 683 F.3d 382 (concluding challenge to regulation was not ripe where agency had initiated a rulemaking that could significantly amend the regulation); *AT&T Corp. v. FCC*, 369 F.3d 554, 563 (D.C. Cir. 2004) (per curiam) (dismissing challenge to agency policy as unripe "because the matter is still under consideration in ongoing rulemaking proceedings" that would "address the issues raised by [petitioner]"); *Util. Air Regulatory Grp. v. EPA*, 320 F.3d 272, 279 (D.C. Cir. 2003) (holding case not ripe where agency was "currently undertaking a rulemaking to amend [the regulations]"); *Tex. Indep. Producers & Royalty Owners Ass'n v. EPA*, 413 F.3d 479, 483-84 (5th Cir. 2005) (dismissing challenge to rule as unripe where agency deferred effective date of rule and announced its intent

to consider issues raised by plaintiff in new rulemaking during the deferral period); *Occidental Chem. Corp. v. FERC*, 869 F.2d 127, 129 (2d Cir. 1989) ("[T]he rulemaking process, with its public comments, may lead to new factual information that will inform the [agency]'s final decision."); *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-62 (D.D.C. 2003) (holding challenge to rule was not ripe where agency undertook a new rulemaking to address issue raised by plaintiff in the lawsuit); *see also 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 amendments are finalized, if plaintiffs' concerns are not laid to rest, plaintiffs "will have ample opportunity [] to bring [their] 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); *Wyo. Outdoor Council v. USFS*, 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)); *Occidental Chem. Corp.*, 869 F.2d at 129 ("[T]he pending rulemaking process makes the stayed [] order particularly inappropriate for judicial resolution at this time because the rulemaking could alter the very regulations applied in that order.") (internal citation and quotation marks omitted); *Lake Pilots*, 257 F. Supp. 2d at 160-62.

Further, although plaintiffs' Complaint raises largely legal claims, those claims are leveled at regulations that, as applied to plaintiffs and similarly-situated organizations, have not "'taken on fixed and final shape.'" *Spriggs v. Wilson*, 467 F.2d 382, 387 (D.C. Cir. 1972) (quoting *Wycoff Co.*, 344 U.S. at 243-44); *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, plaintiffs' challenge to the current regulations likely 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 now of any future amendments to the regulations that result from the pending rulemaking would be too speculative to yield meaningful review. 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' liberty interests. 77 Fed. Reg. at 16,503. It does not preordain what amendments to the preventive services coverage regulations defendants will ultimately promulgate; nor does it foreclose the possibility that defendants will adopt alternative proposals 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; *Am. Petroleum Inst.*, 683 F.3d at 386; *AT&T Corp.*, 369 F.3d at 563; *Motor Vehicle Mfrs. Assoc. v. N.Y. State Dep't of Envtl. Conservation*, 79 F.3d 1298, 1306 (2d Cir. 1996) (concluding claims were not ripe where "plaintiffs' arguments depend upon the effects of regulatory choices to be made by [state] in the future"); *Lake Pilots*, 257 F. Supp. 2d at 162. Because judicial review at this time would inappropriately interfere with defendants' pending rulemaking and may result in the Court deciding issues that might never arise, this case is not fit for judicial review. *See Am. Petroleum Inst.*, 683 F.3d at 387-88; *AT&T Corp.*, 369 F.3d at 563 ("[I]t is clear that both the Commission and the court will benefit from postponing review . . . until the policy in question has crystallized into a more definite form."); *Belmont Abbey*, 2012 WL 2914417, at *11-14.

Withholding or delaying judicial review also would not result in any hardship for plaintiffs. Because of the safe harbor and the forthcoming amendments to the regulations, plaintiffs face no imminent enforcement action by defendants. And, although plaintiffs allege (without specificity) that the regulations impact their retention and recruitment efforts, *see* Compl. ¶ 175, and are "already causing serious, ongoing hardship" because changes to their health plans require advance planning, *id.* ¶¶ 170-74, these allegations do not demonstrate a "direct and immediate" effect on plaintiffs' "day-to-day business" with "serious penalties [including criminal penalties] attached to noncompliance," as required to establish hardship. *Abbott Labs.*, 387 U.S. at 152-53. Instead, they are contingencies that may arise in the future. Plaintiffs' alleged desire to plan for these contingencies does not constitute a hardship; if it did, the hardship prong would become meaningless because organizations (and individuals) are always planning for the future. *See Tenn. Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984) (concluding plaintiff's "planning insecurity" was not sufficient to show hardship); *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987) ("Mere economic uncertainty affecting the plaintiff's planning is not sufficient to support premature review."); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 162 (7th Cir. 1976) ("[C]laims of uncertainty in [plaintiff's] business and capital planning are not sufficient to warrant [] review of an ongoing administrative process."). Nor is plaintiffs' alleged hardship caused by the challenged regulations. *See Abbott Labs.*, 387 U.S. at 152. Rather, it arises from plaintiffs' own desire to prepare for a hypothetical (and unlikely) situation in which the forthcoming amendments to the preventive services coverage regulations do not sufficiently address their religious concerns.

In sum, plaintiffs qualify for the temporary enforcement safe harbor, meaning that defendants will not take any enforcement action against them 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 finalized further amendments to the preventive services coverage regulations to further accommodate religious organizations' religious objections to providing contraceptive coverage, like plaintiffs'. *See* 77 Fed. Reg. at 8728-29. Therefore, this simply is not a case where plaintiffs are forced to choose between forgoing lawful activity and risking substantial legal sanctions. *Abbott Labs.*, 387 U.S. at 153; *see also Tex. Indep. Producers*, 413 F.3d at 483 (finding no hardship where effective date of rule was one year away and agency had announced its intention to initiate a new rulemaking to address plaintiff's concerns). Indeed, "[w]ere [this Court] to entertain [the] anticipatory challenge[] pressed by [plaintiffs]" – 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 this Court should not tread. *Tenn. Gas Pipeline Co.*, 736 F.2d at 751 (internal citation omitted).

Because plaintiffs' challenge to the preventive services coverage regulations is not fit for judicial decision and plaintiffs 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 plaintiffs' Complaint.

Respectfully submitted this 6th day of August, 2012,

STUART F. DELERY
Acting Assistant Attorney General

IAN HEATH GERSHENGORN

Deputy Assistant Attorney General

RONALD C. MACHEN JR.
United States Attorney

JENNIFER RICKETTS
Director, Federal Programs Branch

SHEILA M. LIEBER
Deputy Director

/s/ Jacek Pruski
JACEK PRUSKI
California Bar No. 277211
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave., NW
Washington, D.C. 20530
Tel: (202) 616-2035
Fax: (202) 616-8470
jacek.pruski@usdoj.gov

Attorneys for Defendants