IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
ALEXANDRIA DIVISION

LOUISIANA COLLEGE, Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of the United States Department of Health and Human Services; HILDA SOLIS, in her official capacity as Secretary of the United States Department of Labor; TIMOTHY GEITHNER, in his official capacity as Secretary of the United States Department of the Treasury; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES DEPARTMENT OF THE TREASURY, Defendants.	)	Case No. 1:12-cv-463 JUDGE: Dee D. Drell MAGISTRATE: James D. Kirk

DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Pursuant to Federal Rule of Civil Procedure 12(b)(1), Defendants hereby move to dismiss this action. The grounds for this motion are set forth in the accompanying memorandum.

Respectfully submitted this 9th day of July, 2012,

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CERTIFICATE OF SERVICE

I hereby certify that on July 9, 2012, I caused a true and correct copy of this Motion to Dismiss and accompanying memorandum in support to be served on plaintiff's counsel by means of the Court's ECF system.

/s/ Bradley P. Humphreys
BRADLEY P. HUMPHREYS

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DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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INTRODUCTION

The Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010),[1] and implementing regulations, require all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain recommended preventive services without cost-sharing (such as a copayment, coinsurance, or a deductible).[2] As relevant here, except as to group health plans of certain religious employers (and group health insurance coverage sold in connection with those plans), the preventive services that must be covered include all Food and Drug Administration ("FDA")-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider. Plaintiff, Louisiana College, brought suit on February 18, 2012, seeking to have the Court invalidate and enjoin the preventive services coverage regulations. Plaintiff alleges that its sincerely held religious beliefs prohibit it 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 plaintiff in this case. The finalized amendment confirms that group health plans sponsored by certain religious employers (and any group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services. The enforcement safe harbor encompasses a group of non-profit organizations with religious

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

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

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

In light of these actions, this Court lacks authority to adjudicate plaintiff's claims. Plaintiff's suit must be dismissed for lack of jurisdiction because plaintiff has not alleged any imminent injury that would support standing in light of the enforcement safe harbor—which protects plaintiff (and the issuer(s) of plaintiff's employee health plans) until at least January 1, 2014—and defendants' initiation of a rulemaking to amend the preventive services coverage regulations well before that date to accommodate the religious objections of organizations such as 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 initiated a rulemaking to amend the challenged regulations to accommodate religious

organizations' religious objections to providing contraceptive coverage, like plaintiff's. In the meantime, the temporary enforcement safe harbor will be in effect such that plaintiff will not suffer any hardship as a result of its failure to cover certain contraceptive services.

BACKGROUND

I. STATUTORY BACKGROUND

Prior to the enactment of the ACA, many Americans did not receive the preventive health care they needed to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. Due in large part to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."). Section 1001 of the ACA—which includes the preventive services coverage provision that is relevant here—seeks to cure this problem by making recommended preventive care affordable and accessible for many more Americans.

The preventive services coverage provision requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing.[3] 42 U.S.C. § 300gg-13. The preventive services that must be covered are: (1) evidence-based items or services that have in effect a rating of "A" or "B" from the United States Preventive Services Task Force ("USPSTF"); (2) immunizations recommended by the Advisory Committee on Immunization Practices; (3) for infants, children, and adolescents, evidence-informed preventive care and

[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.

screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA")[4]; and (4) for women, such additional preventive care and screenings not rated "A" or "B" by the USPSTF as provided for in comprehensive guidelines supported by HRSA. *Id*.

The requirement to provide coverage for recommended preventive services for women, without cost-sharing, was added as an amendment to the bill during the legislative process. The Women's Health Amendment was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in section 1001 of the ACA. *See* 155 Cong. Rec. S12019, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer) ("The underlying bill introduced by Senator Reid already requires that preventive services recommended by [USPSTF] be covered at little to no cost . . . . But [those recommendations] do not include certain recommendations that many women's health advocates and medical professionals believe are critically important . . . ."); 155 Cong. Rec. S12261, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken) ("The current bill relies solely on [USPSTF] to determine which services will be covered at no cost. The problem is, several crucial women's health services are omitted. [The Women's Health Amendment] closes this gap.").

Research shows that cost-sharing requirements can pose barriers to preventive care and result in reduced use of preventive services, particularly for women. IOM REP. at 109; 155 Cong. Rec. 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

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

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

Defendants issued interim final regulations implementing the preventive services coverage provision on July 19, 2010. 75 Fed. Reg. 41726. The interim final regulations provide, among other things, that a group health plan or health insurance issuer offering non-grandfathered health coverage must provide coverage for newly recommended preventive services, without cost-sharing, for plan years (or, in the individual market, policy years) that begin on or after the date that is one year after the date on which the new recommendation is issued. 26 C.F.R. § 54.9815-2713T(b)(1); 29 C.F.R. § 2590.715-2713(b)(1); 45 C.F.R. § 147.130(b)(1).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services ("HHS") tasked the Institute of Medicine ("IOM")[5] with "review[ing] what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines. IOM REP. at 2. IOM conducted an extensive science-based review and, on July 19,

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

2011, published a report of its analysis and recommendations. *Id*. at 20-26. The report recommended that HRSA guidelines include, among other things, well-woman visits, breastfeeding support, domestic violence screening, and, as relevant here, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id*. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited July 9, 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 Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited July 9, 2012). The amendment to the interim final regulations, issued on the same day, authorized HRSA to exempt group health plans sponsored by certain religious employers (and associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, an employer must meet all of the following criteria:

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

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

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

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

45 C.F.R. § 147.130(a)(1)(iv)(B). The sections of the Internal Revenue Code referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," that are exempt from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033(a)(1), (a)(3)(A)(i), (a)(3)(A)(iii). Thus, as relevant here, the amended interim final regulations required non-grandfathered plans that do not qualify for the religious employer exemption to provide coverage for recommended contraceptive services, without cost-sharing, for plan years beginning on or after August 1, 2012.

Defendants requested comments on the amended interim final regulations and specifically on the definition of religious employer contained in those regulations. 76 Fed. Reg. at 46623. 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).

Under 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 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.[6]

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 with respect to certain religious organizations by providing them with further accommodations.

Those intended changes, which were first announced when defendants finalized the religious employer exemption, will establish alternative means of providing contraceptive coverage without cost-sharing while also accommodating non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began the process of further amending the regulations on March 21, 2012, when they published an ANPRM in the Federal Register. 77 Fed. Reg. 16501 (Mar. 21, 2012). The ANPRM "presents questions and ideas" on potential means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. *Id*. at 16503. The purpose of the ANPRM is to provide "an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made" in the forthcoming amendments to the regulations. *Id*. Among other options, the ANPRM suggests requiring health

[6] HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance"), at 3 (Feb. 10, 2012), *available at* http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf (last visited July 9, 2012); 77 Fed. Reg. 16501, 16504 (Mar. 21, 2012).

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 employers or participants. *Id*. at 16505.

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

II. CURRENT PROCEEDINGS

Plaintiff 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 to cover emergency contraception (such as Plan B and Ella) and related patient education and counseling.[7]

Plaintiff describes itself as a "private Baptist co-educational college of liberal arts," with approximately 180 full-time and 80 part-time employees. Amend. Compl. ¶¶ 20, 27, ECF. No. 29. According to the Amended Complaint, plaintiff currently makes available to its employees health plans that do not cover "drugs, devices, services or procedures inconsistent with its faith," including Plan B and Ella. *Id.* ¶¶ 29, 31. Plaintiff alleges that it "cannot provide health care

[7] After defendants moved to dismiss the complaint for lack of jurisdiction, plaintiff filed an amended complaint and asked the Court to deny defendants' motion. Because the allegations in the amended complaint still fail to establish jurisdiction, defendants again move for dismissal under the assumption that their initial motion to dismiss is now moot. *See* Magistrate Judge's Report and Recommendations, ECF No. 34; *see also, e.g.*, Minute Order, *Belmont Abbey Coll. v. Sebelius*, No. 11-cv-01989-JEB (D.D.C. Mar. 20, 2012) (dismissing defendants' motion to dismiss without prejudice as moot after plaintiff amended its complaint in a similar case).

insurance covering abortion, abortifacient or embryo-endangering methods, or related education and counseling without violating its deeply held religious beliefs and its Christian witness." *Id.* ¶ 32. Plaintiff further asserts that it does not qualify for the religious employer exemption because, among other things, its purpose is other than the inculcation of religious values and it does not primarily serve persons who share the religious tenets of the organization. *Id.* ¶ 53. Plaintiff claims the preventive services coverage regulations violate the First and Fifth Amendments to the United States Constitution, the Religious Freedom Restoration Act, and the Administrative Procedure Act.

STANDARD OF REVIEW

Defendants move to dismiss the Amended Complaint for lack of subject matter jurisdiction under Rule 12(b)(1) of the Federal Rules of Civil Procedure. "The burden of establishing subject matter jurisdiction rests upon the party asserting jurisdiction." *Volvo Trucks N. Am., Inc. v. Crescent Food Truck Sales, Inc.*, 666 F.3d 932, 935 (5th Cir. 2012) (citing *SmallBizPros, Inc. v. MacDonald*, 618 F.3d 458, 461 (5th Cir. 2010)). 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 of the Amended Complaint. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998).

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 "distinct and palpable, as opposed to merely abstract." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (citation omitted). Allegations of possible future injury do not suffice; rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Id.* at 158 (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.*

Under the enforcement safe harbor, defendants will not take any enforcement action against an organization that qualifies for the safe harbor until the first plan year that begins on or after August 1, 2013, at the earliest. Guidance at 3. Although plaintiff asserts that its group health plan is not eligible for the safe harbor, Amend. Compl. ¶ 103, the only fact plaintiff alleges to support this legal conclusion—that plaintiff's plan "*has* included non-abortifacient contraception," *id.* ¶ 99—does not establish that plaintiff does not qualify for the safe harbor. *See Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1949-50 (2009); *see also Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010) (observing that courts "do not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions" (quoting *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005)). Rather, defendants have made clear in the Federal Register that an organization is not disqualified from the protection of the safe harbor with respect to its plan's failure to cover those contraceptive services to which it objects on religious

grounds merely because its plan covers other contraceptive services to which it has no religious objection. 77 Fed. Reg. at 16504. Both the prescribed notice to plan participants and the self-certification required to qualify for the safe harbor must be read in this context. Accordingly, plaintiff's claim that it cannot provide notice or make the necessary certification is a problem of plaintiff's own creation rather than any actual obstacle.

There is, therefore, nothing in the complaint to suggest that plaintiff will be unable to meet the criteria for the enforcement safe harbor. And because plaintiff alleges its plan year begins on January 1, Amend. Compl. ¶ 34, the earliest plaintiff (or the issuer(s) of its employee health plan(s)) 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 the challenged regulations undergoing amendment before then, 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 in Citizens United v. FEC*, 130 S. Ct. 876 (2010); *Whitmore*, 495 U.S. at 159-60.[8]

[8] Plaintiff also maintains that the enforcement safe harbor "can be revoked at any time." Amend. Compl. ¶ 104. But speculation that the defendants will take back the promised safe harbor—which was issued as formal guidance by the Secretary of Health and Human Services, *see* Guidance, and has been repeatedly referenced in the Federal Register, *see, e.g.*, 77 Fed. Reg. at 8728; 77 Fed. Reg. at 16502-03—is not only dubious, it is also insufficient to establish an injury. To begin, plaintiff is dealing with the federal government, which is entitled to a presumption that it acts in good faith. *See Sossamon v. Lone Star State of Texas*, 560 F.3d 316, 325 (5th Cir. 2009) (noting that "government actors in their sovereign capacity and in the exercise of their official duties are accorded a presumption of good faith" and that the court assumes "that formally announced changes to official governmental policy are not mere litigation posturing"). Moreover, courts have found similar promises not to enforce by the government sufficient to defeat jurisdiction. *See Winsness v. Yocom*, 433 F.3d 727, 732 (10th Cir. 2006) (finding plaintiff's prosecution for violation of State flag-abuse statute was too

This defect in plaintiff's suit does not implicate a mere technical issue of counting intermediate days. Nor does it rest on the truism that a final regulation is always subject to change by the agency that promulgated it; the ANPRM goes much further than that by promising imminent regulatory amendments. Thus, the defect in plaintiff's 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, such as plaintiff, that object to providing contraceptive coverage for religious reasons. 77 Fed. Reg. at 16501. The ANPRM provided plaintiff, and any other interested party, with the opportunity to, among other things, comment on ideas suggested by defendants for 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

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speculative to support standing where district attorney filed affidavit promising non-prosecution); *Presbytery of N.J. of Orthodox Presbyterian Church v. Florio*, 40 F.3d 1454, 1470-71 (3d Cir. 1994) (dismissing churches' challenge to discrimination law as unripe where affidavit from State official indicated that State would not prosecute churches for violating law); *Farm-to-Consumer Legal Def. Fund v. Sebelius*, No. C 10–4018–MWB, 2012 WL 1079987, at *2 (N.D. Iowa Mar. 30, 2012) (concluding plaintiffs lacked standing where government stated it did not intend to enforce the challenged regulations against them). Finally, even if defendants were to withdraw the temporary enforcement safe harbor before it expires—and there is absolutely no evidence to suggest that they will—plaintiff could bring suit at that time, seeking preliminary injunctive relief if warranted. Unless (and until) that happens, there is no basis for this Court to issue an advisory opinion to "deal with the possibility that at some point in the future [defendants]" might "reverse [their] position." *Boyle v. Anderson*, 68 F.3d 1093, 1100 (8th Cir. 1995).

amending the regulations. *Id*. at 16503, 16507. And plaintiff (and others) will have additional opportunities to comment as the rulemaking process proceeds. Defendants, moreover, have indicated that they intend to finalize the amendments to the regulations before the rolling expiration of the temporary enforcement safe harbor starting on August 1, 2013. *Id*. at 16503; *see also* 77 Fed. Reg. at 8728. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiff to help shape those amendments, there is no reason to suspect that plaintiff will be required to sponsor a health plan that covers certain contraceptive services in contravention of its religious beliefs once the enforcement safe harbor expires. And any suggestion to the contrary is entirely speculative at this point. At the very least, given the anticipated changes to the preventive services coverage regulations, plaintiff's claims of injury, if any, after the temporary enforcement safe harbor expires would differ substantially from plaintiff's current claims of injury. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of plaintiff's Amended Complaint at this juncture.

Finally, plaintiff cannot transform the speculative possibility of future injury into a current concrete injury for standing purposes by asserting that it has to plan now for its future insurance needs. Amend. Compl. ¶ 86. Such reasoning would gut standing doctrine. A plaintiff could manufacture standing by asserting a current need to prepare for the most remote and ill-defined harms, thus sapping the imminence requirement of any meaning. Even if such manipulation were not so transparent, plaintiff would still bear the burden of pleading standing with specificity. *Ashcroft*, 129 S. Ct. at 1949. Plaintiff does not meet that burden here because it does not explain how it will be injured by its purported inability to plan more than a year in advance as a result of the uncertainty regarding how and whether the regulations will apply to it. Further, any planning plaintiff is engaged in now "stems not from the operation of [the

preventive services coverage regulations], but from [plaintiff's] own . . . personal choice[s]" to prepare for contingencies that may never occur. *McConnell*, 540 U.S. at 228. Thus, even if this preparation were an injury, it would not be fairly traceable to the challenged regulations. *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 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). 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).

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. Plaintiff seeks judicial review of the preventive services coverage regulations as applied to a

non-exempted, non-profit religious organization that objects 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 plaintiff 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 plaintiff. 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 plaintiff raises here by establishing alternative means of providing contraceptive coverage without cost-sharing while accommodating religious organizations' religious objections to covering contraceptive services. And plaintiff will have opportunities to participate in the rulemaking process and to provide comments and/or ideas regarding 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 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 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); *see also Am. Petroleum Inst. v. EPA*, No. 09-1038, 2012 WL 2053572 (D.C. Cir. June 8, 2012) (concluding challenge to regulation was not ripe where agency had initiated a rulemaking

that could significantly amend the regulation); *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); *Wyo. 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)); *Lake Pilots Ass'n, Inc. 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).

Further, although plaintiff's Amended Complaint raises largely legal claims, those claims are leveled at regulations that, as applied to plaintiff and similarly situated organizations, have not "taken on fixed and final shape." *Pub. Serv. Comm'n*, 344 U.S. at 244. Once defendants complete the rulemaking outlined in the ANPRM, plaintiff's 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 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' religious liberty interests. 77 Fed. Reg. at 16503. 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; *see also 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 "plaintiff['s] arguments depend upon the effects of regulatory choices to be made by [state] in the future"); *Tex. Indep. Producers*, 413 F.3d at 482; *Lake Pilots Ass'n*, 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 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. Because of the safe harbor and the forthcoming amendments to the regulations, plaintiff faces no imminent enforcement action by defendants. And although plaintiff alleges that the regulations impact their retention and recruitment efforts, *see* Amend. Compl. ¶¶ 67-68, 112, and that plaintiff must take the regulations into account now because changes to its health plan require advance planning, *id.* ¶ 86, these allegations do not demonstrate a "direct and immediate" effect on plaintiff's "day-to-day business" with "serious 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. Plaintiff's alleged desire to plan for these contingencies does not constitute hardship; if it did, the hardship prong would become meaningless because organizations (and individuals) are always planning for the future. *See Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987) ("Mere economic uncertainty affecting plaintiff's planning is not sufficient to support premature review."); *Tenn. Gas Pipeline Co. v. F.E.R.C.*, 736 F.2d 747, 751 (D.C. Cir. 1984) (concluding plaintiff's "planning insecurity"

was not sufficient to show hardship); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 172 (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 plaintiff's alleged hardship caused by the challenged regulations. *See Abbott Labs.*, 387 U.S. at 152. Rather, it arises from plaintiff's own desire to prepare for a hypothetical situation in which the forthcoming amendments to the preventive services coverage regulations do not sufficiently address their religious concerns.

In sum, plaintiff can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against plaintiff (or the issuer(s) of plaintiff's employee health plan(s)) 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 plaintiff's. *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." *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 [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 this Court should not tread. *See Tenn. Gas Pipeline Co.*, 736 F.2d at 751 (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 plaintiff's Amended Complaint.

Respectfully submitted this 9th day of July, 2012,

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