IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
ABERDEEN DIVISION

AMERICAN FAMILY ASSOCIATION, INC., Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 1:13-cv-00032-SA-DAS

DEFENDANTS' MEMORANDUM BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Plaintiff is not entitled to a preliminary injunction. Defendants are currently engaged in a rulemaking to further amend the regulations that plaintiff challenges and seeks to enjoin, so as to address religious concerns such as those raised by plaintiff, and defendants intend to issue final regulations shortly. Additionally, given the facts of this case, namely that plaintiff is a religious non-profit organization with religious objections to providing certain contraceptive coverage, and in light of defendants' intent to accommodate entities like plaintiff in the final regulations to be issued shortly, defendants will not take any action to enforce the current regulations against plaintiff, its group health plan, or its insurer, during the timeframe established by the temporary enforcement safe harbor. As a result, plaintiff cannot meet the basic jurisdictional prerequisites of standing and ripeness; indeed, to date, nearly every court (23 out of 25) to have considered these jurisdictional arguments in cases where defendants have, as they do here, committed not to enforce the regulations has ruled in defendants' favor.[1] "Without jurisdiction the court cannot proceed at all in any cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998).

[1] *See Priests for Life v. Sebelius*, No. 12-cv-753 (FB), 2013 WL 1563390 (E.D.N.Y. Apr. 12, 2013); *Criswell College v. Sebelius*, Civil Action No. 3:12-CV-4409-N, slip op. (N.D. Tex. Apr. 9, 2013) (Ex. 1); *Ave Maria Univ. v. Sebelius*, No. 2:12-cv-88-FTM-99SPC, 2013 WL 1326638 (M.D. Fla. Mar. 29, 2013); *Eternal Word Television Network, Inc. v. Sebelius*, No. 2:12-cv-501-SLB, 2013 WL 1278956 (N.D. Ala. Mar. 25, 2013); *Franciscan Univ. v. Sebelius*, No. 2:12-CV-440, 2013 WL 1189854 (S.D. Ohio Mar. 22, 2013); *Geneva Coll. v. Sebelius*, No. 2:12-cv-00207, 2013 WL 838238 (W.D. Pa. Mar. 6, 2013); *Most Reverend Wenski v. Sebelius*, Case No. 12-23820-CIV-GRAHAM/GOODMAN, slip op. (S.D. Fla. Mar. 5, 2013) (Ex. 2); *Roman Catholic Diocese of Dallas v. Sebelius*, Civil Action No. 3:12-cv-01589-B, 2013 WL 687080 (N.D. Tex. Feb. 26, 2013); *Conlon v. Sebelius*, No. 1:12-cv-3932, 2013 WL 500835 (N.D. Ill. Feb. 8, 2013); *Archdiocese of St. Louis v. Sebelius*, No. 4:12-CV-924-JAR, 2013 WL 328926 (E.D. Mo. Jan. 29, 2013); *Roman Catholic Archbishop of Washington v. Sebelius*, No. 12-cv-0815 (ABJ), 2013 WL 285599 (D.D.C. Jan. 25, 2013), *appeal noticed* (D.C. Cir. Mar. 25, 2013); *Persico v. Sebelius*, No. 1:12-cv-123-SJM, 2013 WL 228200 (W.D. Pa. Jan. 22, 2013); *Colo. Christian Univ. v. Sebelius*, No. 11-cv-03350-CMA-BNB, 2013 WL 93188 (D. Colo. Jan. 7, 2013); *Catholic Diocese of Peoria v. Sebelius*, No. 12-cv-1276, 2013 WL 74240 (C.D. Ill. Jan. 4, 2013); *Univ. of Notre Dame v. Sebelius*, No. 3:12-cv-00523, 2012 WL 6756332 (N.D. Ind. Dec. 31, 2012), *appeal docketed*, No. 13-1479 (7th Cir. Mar. 5, 2013); *Catholic Diocese of Biloxi v. Sebelius*, No. 1:12-cv-00158, 2012 WL 6831407 (S.D. Miss. Dec. 20, 2012), *mot. to alter or amend j. denied*, 2013 WL 690990 (S.D. Miss. Feb. 15, 2013); *Zubik v. Sebelius*, No. 2:12-cv-676, 2012 WL 5932977 (W.D. Pa. Nov. 27, 2012); *Catholic Diocese of Nashville v. Sebelius*, No. 3-12-0934, 2012 WL 5879796 (M.D. Tenn. Nov. 21, 2012); *Legatus v. Sebelius*, No. 12-cv-12061, 2012 WL 5359630 (E.D. Mich. Oct. 31, 2012), *appeal docketed*, Nos. 13-1092, 13-1093 (6th Cir. Jan. 24, 2013); *Nebraska v. U.S. Dep't of Health & Human Servs.*, No. 4:12CV3035, 2012 WL 2913402 (D. Neb. July 17, 2012), *appeal docketed*, No. 12-3238 (8th Cir. Sept. 25, 2012); *Wheaton Coll. v. Sebelius*, 703 F.3d 551 (D.C. Cir. 2012) (affirming in part and holding in abeyance appeals in *Wheaton Coll. v. Sebelius*, 887 F. Supp. 2d 102 (D.D.C. 2012), and *Belmont Abbey Coll. v. Sebelius*, 878 F. Supp. 2d 25 (D.D.C. 2012)). *But see Roman Catholic Diocese of Fort Worth v. Sebelius*, No. 4:12-cv-00314-Y-TRM (N.D. Tex. Jan. 31, 2013); *Roman Catholic Archdiocese of N.Y. v. Sebelius*, No. 12 Civ. 2542(BMC), 2012 WL 6042864 (E.D.N.Y. Dec. 4, 2012).

The Court should therefore dismiss plaintiff's case, and in any event should certainly not grant plaintiff the extraordinary relief of a preliminary injunction. Nor can plaintiff possibly establish irreparable harm or that an injunction would be in the public interest.

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

Before the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), 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 largely 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."), *available at* http://www.nap.edu/catalog.php?record_id=13181 (last visited Apr. 12, 2013). Section 1001 of the ACA—which includes the preventive services coverage provision relevant here—seeks to cure this problem by making preventive care affordable and accessible for many more Americans. Specifically, the 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, including, "[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).

The government issued interim final regulations implementing the preventive services coverage provision on July 19, 2010. 75 Fed. Reg. 41,726. Those 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 that begin on or after the date that is one year after the date on which the new recommendation is issued.[2] 26 C.F.R. § 54.9815-2713T(b)(1); 29 C.F.R. § 2590.715-

[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.

2713(b)(1); 45 C.F.R. § 147.130(b)(1). Because there were no existing HRSA guidelines relating to preventive care and screening for women, HHS tasked the Institute of Medicine (IOM) with developing recommendations to implement the requirement to provide preventive services for women. IOM REP. at 2.[3] After an extensive science-based review, IOM recommended that HRSA guidelines include, 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 (IUDs). FDA, Birth Control Guide, *available at* http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118465.htm (last visited Apr. 12, 2013). IOM determined that coverage, without cost-sharing, for these services is necessary to increase access, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. IOM REP. at 102-03.

On August 1, 2011, HRSA adopted IOM's recommendations, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), *available at* http://www.hrsa.gov/womensguidelines/ (last visited Apr. 12, 2013). The amendment, issued the same day, authorized HRSA to exempt group health plans established or maintained by certain religious employers (and associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46,621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A).[4]

[3] 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.*

[4] To qualify for the exemption, the current regulations state that 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, and (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). However, a recently published Notice of Proposed Rulemaking (NPRM) would eliminate the first three criteria and clarify the fourth criterion, thereby ensuring "that an otherwise exempt employer plan is

In February 2012, the government adopted 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 group health plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012). Pursuant to the temporary enforcement safe harbor as clarified on August 15, 2012, defendants will not take any enforcement action against an employer, group health plan, or group health insurance issuer with respect to a 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, the group health plan established or maintained by the organization has consistently not provided all or the same subset of the contraceptive coverage otherwise required at any point, consistent with any applicable State law, because of the religious beliefs of the organization. A group health plan is considered to have satisfied this criterion if the organization "took some action to try to exclude or limit such coverage that was not successful as of February 10, 2012."

(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 some or all 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 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. Defendants

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not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer serves or hires people of different religious faiths." 78 Fed. Reg. 8456, 8459, 8460-61 (Feb. 6, 2013); *see id.* at 8474.

[5] HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance") (Aug. 15, 2012), *available at* http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf (last visited Apr. 12, 2013).

began the process of further amending the regulations on March 21, 2012, when they published an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal Register, 77 Fed. Reg. 16,501 (Mar. 21, 2012), and took the next step in that process on February 6, 2013, with the publication of a Notice of Proposed Rulemaking (NPRM), 78 Fed. Reg. 8456 (Feb. 6, 2013). Defendants have indicated that they will finalize the amendments to the regulations before August 1, 2013. 77 Fed. Reg. at 16,503; 78 Fed. Reg. at 8459; *see also* 77 Fed. Reg. at 8728.

II. CURRENT PROCEEDINGS

Plaintiff, American Family Association ("AFA"), is a religious non-profit organization that "speak[s] out on moral issues in American society" and believes in perpetuating "a culture based on biblical truth." Compl. ¶¶ 15, 17. "Consistent with its beliefs about Scripture," AFA has made "numerous public statements over the years" objecting to procedures and drugs that it believes cause abortions, and has "publically and consistently condemned" and "specifically spoken out against" emergency contraceptives like Plan B and Ella. *Id.* ¶¶ 24-27; *see also* Pls.' Mem. in Supp. of Mot. for Prelim. Inj., Mar. 19, 2013, ECF No. 6, at 7-8 ("Pls.' Mem."). AFA challenges the lawfulness of the preventive services coverage regulations to the extent those regulations require that the health coverage AFA makes available to its employees cover those emergency contraceptives to which it has a religious objection. A year and a half after the contraceptive coverage requirement was established, plaintiff filed suit and moved for a preliminary injunction, claiming it will suffer irreparable harm if the regulations are not enjoined as to it. *See* Compl.; Pls.' Mem.

STANDARD OF REVIEW

A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the

public interest." *Id.* at 20; *Texas Midstream Gas Servs., LLC v. City of Grand Prairie*, 608 F.3d 200, 206 (5th Cir. 2010).

"The party asserting jurisdiction bears the burden of proof for a 12(b)(1) motion to dismiss." *Ballew v. Cont'l Airlines, Inc.*, 668 F.3d 777, 781 (5th Cir. 2012) (citation omitted). This Court must determine whether it has subject matter jurisdiction before addressing the merits of the Complaint. *See Steel Co.*, 523 U.S. at 94-95; *NAACP v. City of Kyle*, 626 F.3d 233 (5th Cir. 2010).

ARGUMENT

I. THE COURT LACKS JURISDICTION TO ADJUDICATE PLAINTIFF'S CLAIMS

A. Plaintiff Lacks Standing To Assert Its Claims

Plaintiff is not entitled to a preliminary injunction, and its case should be dismissed, because this Court lacks jurisdiction to adjudicate its claims. *See Steel Co.*, 523 U.S. at 94. As stated above and in the declaration of Teresa Miller, Apr. 19, 2013 (Ex. 3), defendants will not take any action to enforce the current regulations against plaintiff, its group health plan, or its insurer during the time frame established by the temporary enforcement safe harbor—namely, until the first plan year that begins on or after August 1, 2013. Moreover, defendants have initiated a rulemaking process to amend the challenged regulations to accommodate the precise religious concerns plaintiff raises here, and intend to issue a new set of regulations by August 2013.

For these reasons, plaintiff cannot show that it faces an actual or imminent injury resulting from the preventive services coverage regulations, as necessary to establish standing.[6] To meet its burden to establish standing, plaintiff must demonstrate it has "suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b)

[6] The cases cited above, *see supra* note 1, in which 23 out of 25 courts dismissed challenges to the regulations for lack of jurisdiction, likewise involved instances in which it was clear that the regulations, in their current form, would not be enforced against plaintiffs.

actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quotations omitted). The harm must be "concrete, distinct and palpable, as well as actual or imminent." *United States v. Holy Land Found. for Relief & Dev.*, 445 F.3d 771, 779 (5th Cir. 2006). 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); *see Clapper v. Amnesty Int'l USA*, 568 U.S. ___, 133 S. Ct. 1138, 1147 (2013). 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*.

As explained in the Miller Declaration, Ex. 3, defendants will not take any action to enforce the current regulations against plaintiff, its group health plan, or its insurer during the timeframe established by the temporary enforcement safe harbor. Courts have found similar promises by the government sufficient to defeat jurisdiction. *See Winsness v. Yocom*, 433 F.3d 727, 732-33 (10th Cir. 2006) (finding plaintiff's prosecution for violation of State flag-abuse statute was too speculative to support standing where district attorney filed affidavit promising non-prosecution); *Presbytery of New Jersey 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 plaintiffs).

Moreover, the ANPRM and NPRM published in the Federal Register confirm, and seek comment on, the process of further amending the preventive services coverage regulations so as to further accommodate the concerns of religious organizations like plaintiff that object to providing certain contraceptive coverage for religious reasons. 77 Fed. Reg. at 16,501; 78 Fed.

Reg. at 8459. The rulemaking process provided plaintiff, 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. 77 Fed. Reg. at 16,503, 16,507; *see* 78 Fed. Reg. at 8459. Defendants have indicated that they will finalize the amendments to the regulations before August 1, 2013. 77 Fed. Reg. at 16,503; 78 Fed. Reg. at 8459; *see also* 77 Fed. Reg. at 8728.

In light of the Miller Declaration, 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 emergency contraception in contravention of its religious beliefs, and therefore no basis for this Court to consider plaintiff's objections to the current regulations now. And, of course, the current regulations are all that plaintiff can challenge at this stage.[7] At the very least, given the anticipated changes to the preventive services coverage regulations, plaintiff's alleged injury and substantive legal claims, if any, after the new regulations are finalized would differ substantially

[7] Plaintiff claims the proposals contained in the ANPRM and NRPM are insufficient to protect its rights, Compl. ¶¶ 109-10, but plaintiff cannot now know what form the final accommodations will take once the rulemaking process reaches its conclusion. To suggest otherwise prejudges the process and ignores the opportunity for comments by plaintiff and others to inform the rulemaking. And even assuming that plaintiff would continue to object to any future form the accommodations may take, it would not only be premature for this Court to evaluate plaintiff's challenges to those accommodations in the absence of finalized amendments, but wholly unnecessary and inappropriate to do so, especially in the context of a motion for preliminary injunction as to the *current* regulations. *See, e.g.*, *Persico*, 2013 WL 228200, at *19; *Colo. Christian Univ.*, 2013 WL 93188, at *6 ("[T]he fact remains that Defendants' proposal was just that – a proposed solution subject to comment and alteration. . . . If [the plaintiff] is unsatisfied with the amendment, after it takes shape and is finalized, [the plaintiff] may file suit again. In the meantime, however, the Court declines [the plaintiff's] implicit invitation to issue an advisory opinion on the potential solutions Defendants might propose as it proceeds to further amend the interim final rule." (internal citations omitted)); *Notre Dame*, 2012 WL 6756332, at *4 ("This regulation's replacement might [be objectionable to plaintiff], but no one can say because that future rule hasn't been promulgated."); *Wheaton*, 887 F. Supp. 2d at 113 ("[The plaintiff] only tilts at windmills when it protests that it will not be satisfied with whatever amendments defendants ultimately make. Indeed, [the plaintiff's] argument that various hypothetical accommodations are insufficient only serves to underscore why this Court ought not address the merits of [the plaintiff's] claims until the preventive services regulations 'have taken on fixed and final shape so that [the Court] can see what legal issues it is deciding.'" (quoting *Pub. Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952)); *Belmont Abbey*, 878 F. Supp. 2d at 40.

from plaintiff's current (but unfounded) claims of injury. *See Notre Dame*, 2012 WL 6756332, at *4 ("[T]his regulatory requirement won't require Notre Dame to conduct itself in ways its Catholic mission forbids. . . . It is enough to know that the present regulation is to be replaced by another, and the safe harbor is protecting Notre Dame from harm to its religious precepts until that replacement occurs."); *Conlon*, 2013 WL 500835, at *4-5; *Archdiocese of St. Louis*, 2013 WL 328926, at *6-7; *Zubik*, 2012 WL 5932977, at *12; *Catholic Diocese of Nashville*, 2012 WL 5879796, at *4; *Legatus*, 2012 WL 5359630, at *5-6.

Nor could plaintiff transform the speculative (and highly unlikely) possibility of future injury (i.e., that the regulations in their current form might be enforced against plaintiff in the future) into a current concrete injury for standing purposes by relying on current planning for future needs. *See* Compl. ¶¶ 83, 92-94. Such reasoning would deprive standing doctrine of all force and sap the imminence requirement of all meaning, since a plaintiff could simply manufacture standing by asserting a current need to prepare for the most remote and ill-defined harms. *See Clapper*, 133 S. Ct. at 1151 ("[R]espondents cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm that is not certainly impending."); *Nw. Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986); *ViroPharma, Inc. v. Hamburg*, 777 F. Supp. 2d 140, 147 & n.3 (D.D.C. 2011) (holding that "'uncertainties' regarding the future regulatory . . . environment" and their impact on an entity's "strategic planning" are "highly nebulous in both character and degree, and are a far cry from the type of 'concrete and particularized' injury required for Article III standing," and noting that such uncertainty "only highlights the speculative nature of any future injury"). Such a result cannot be reconciled with the Supreme Court's admonition that the threatened injury must be "certainly impending." *Whitmore*, 495 U.S. at 158. *See Notre Dame*, 2012 WL 6756332, at *4 (expressly rejecting similar alleged planning injuries); *Zubik*, 2012 WL 5932977, at *11-12.[8]

[8] Any planning plaintiff is engaged in now "stems not from the operation of [the current preventive services coverage regulations]," which defendants have committed not to enforce against plaintiff, "but from [plaintiff's] own . . . personal choice[s]" to prepare for contingencies that may never occur. *McConnell v. FEC*, 540 U.S. 93, 228 (2003). 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.

B. Plaintiff's Claims Are 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 (quotation omitted); *see also, e.g., Texas v. United States*, 497 F.3d 491, 498 (5th Cir. 2007).

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*, 344 U.S. at 244. As the Fifth Circuit has explained, "[i]f the purported injury is contingent [on] future events that may not occur as anticipated, or indeed may not occur at all, the claim is not ripe for adjudication." *Lopez v. City of Houston*, 617 F.3d 336, 342 (5th Cir. 2010) (internal quotations 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, 105 (1977); *see Texas*, 497 F.3d at 498.

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. In that case, the Court found the fitness prong to be satisfied where the regulations 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. The Court also found the hardship prong to be satisfied where the regulations "require[d] an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance," such that the plaintiffs faced the "dilemma" of complying and incurring the attendant costs or not complying and "risk[ing] serious criminal and civil penalties." *Id*. at 152-53 (quotation omitted).

None of the indicia of ripeness discussed in *Abbott Laboratories* is present in this case. Plaintiff seeks judicial review now of the preventive services coverage regulations as applied to non-grandfathered religious organizations that object to providing certain contraceptive coverage for religious reasons, but defendants are well into the process of a rulemaking to amend the preventive services coverage regulations to accommodate the concerns expressed by plaintiff and similarly-situated organizations. *See* 77 Fed. Reg. 16,501; 78 Fed. Reg. 8456. Therefore, unlike in *Abbott Laboratories*—where the challenged regulations were definitive and no further administrative proceedings were contemplated—the preventive services coverage regulations are certain to be amended, and are now being amended. Because the forthcoming amendments will eliminate the need for judicial review entirely, or at least narrow and refine the controversy, review now would "waste[] the court's time and interfere[] with the process by which the agency is attempting to reach a final decision." *Cont'l Airlines, Inc. v. Civil Aeronautics Bd.*, 522 F.2d 107, 125 (D.C. Cir. 1975) (en banc). As the D.C. Circuit held in *Wheaton*, a similar challenge to the current regulations, this case is "not fit for review at this time because if we do not decide [the merits of appellants' challenge to the current rule] now, we may never need to." *Wheaton*, 703 F.3d at 552 (internal quotations and citation omitted). Twenty-two other courts have agreed. *See supra* note 1.

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 has had 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. *See 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 Commission's final decision."); *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)); *Lopez*, 617 F.3d at 342 (same).

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 v. Sierra Club*, 523 U.S. 726, 734 (1998); *see Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387-89 (D.C. Cir. 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); *Wilderness Soc'y v. Alcock*, 83 F.3d 386, 390-91 (11th Cir. 1996); *Occidental Chem. Corp.*, 869 F.2d at 129; *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-62 (D.D.C. 2003); *see also Archbishop of Washington*, 2013 WL 285599, at *4 ("If after the new regulations are issued, plaintiffs are still not satisfied, any challenges that they choose to bring will be substantially different from the challenges in the current complaint."); *Criswell College*, Ex. 1, at 11 ("[T]he Court's analysis would in any event be different under a different regulatory scheme.").

Further, although plaintiff 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; *see also Pittman v. Cole*, 267 F.3d 1269, 1278-80 (11th Cir. 2001) ("The ripeness doctrine is designed to prevent federal courts

from engaging in such speculation and prematurely and perhaps unnecessarily reaching constitutional issues."); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 161 (7th Cir. 1976) ("[T]he issues here are fit for judicial review in the sense that they present concrete legal questions, but are not fit for judicial review in the sense that the actions challenged are part of a continuing agency decision-making process which has not yet resulted in an order requiring compliance by the petitioners."). Once defendants complete the rulemaking outlined in the ANPRM and the NPRM, plaintiff's challenge to the current regulations likely will be moot. *See 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.

Like the ANPRM before it, the NPRM proposes 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 concerns, *see* 78 Fed. Reg. at 8459; 77 Fed. Reg. at 16,503, but neither preordains what amendments to the regulations defendants will ultimately promulgate. Thus, review of any of the suggested proposals contained in the NPRM and ANPRM would only entangle the Court "in abstract disagreements over administrative policies." *Abbott Labs.*, 387 U.S. at 148; *see also Tex. Indep. Producers*, 413 F.3d at 482; *Pittman*, 267 F.3d at 1278; *Bethlehem Steel Corp.*, 536 F.2d at 160-61; *Lake Pilots Ass'n*, 257 F. Supp. 2d at 160. Because judicial review now 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 review. *See Wheaton*, 703 F.3d at 552; *supra* note 1.

Withholding or delaying judicial review also would not result in any hardship for plaintiff. Unlike the plaintiffs in *Abbott Laboratories*, plaintiff here is not being compelled to make immediate and significant changes to its day-to-day operations because plaintiff (and the issuer of its health plan) faces no imminent enforcement action of the current regulations by defendants. *See Corey H. v. Bd. of Educ. of Chicago*, 534 F.3d 683, 688-89 (7th Cir. 2008).

Plaintiff thus cannot demonstrate that these regulations have a "direct and immediate" effect on its "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; *see also Rock Energy Coop. v. Vill. of Rockton*, 614 F.3d 745, 749 (7th Cir. 2010) ("[N]or does the record show how the threat of future enforcement is having a present concrete, adverse, and irremediable effect on Rock Energy's day-to-day affairs.").

Furthermore, the events for which plaintiff is allegedly planning are just too speculative to qualify as a hardship for ripeness purposes. *See Cephalon, Inc. v. Sebelius*, 796 F. Supp. 2d 212, 218 (D.D.C. 2011) ("Plaintiff cannot base an argument of undue burden from postponement of a judicial decision on its having to plan for a future event, as opposed to the actual event, if that event is too speculative in the first instance."). Plaintiff's alleged desire to plan for contingencies that may or may not arise in the future does not constitute a hardship; if it did, the hardship prong would become meaningless because organizations are always planning for the future. *See Bethlehem Steel Corp.*, 536 F.2d at 162 ("[C]laims of uncertainty in [plaintiff's] business and capital planning are not sufficient to warrant [] review of an ongoing administrative process."); *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987); *Tenn. Gas Pipeline Co. v. F.E.R.C.*, 736 F.2d 747, 751 (D.C. Cir. 1984); *Cephalon*, 796 F. Supp. 2d at 218. Finally, that alleged hardship arises, not from the challenged regulations, *see Abbott Labs.*, 387 U.S. at 152, but from plaintiff's own desires to prepare for a hypothetical situation in which the forthcoming amendments do not sufficiently address its concerns.

II. PLAINTIFF HAS NOT ESTABLISHED IMMINENT IRREPARABLE HARM RESULTING FROM THE CHALLENGED REGULATIONS OR THAT AN INJUNCTION WOULD BE IN THE PUBLIC INTEREST

For many of the same reasons that the Court lacks jurisdiction over this case, plaintiff has failed to establish any imminent irreparable harm as it must to obtain a preliminary injunction. A plaintiff must show a "substantial threat of irreparable injury," *Byrum v. Landreth*, 566 F.3d 442, 445 (5th Cir. 2009), so a harm that merely may occur in the indefinite future is not sufficient.

Plaintiff's assertion of harm to its religious freedom, *see* Pls.' Mem. at 20-21, is not one of imminent harm. Because defendants will not take any action to enforce the current regulations against plaintiff, its group health plan, or its insurer during the timeframe established by the temporary enforcement safe harbor, plaintiff faces no imminent injury—and therefore no risk of irreparable harm—resulting from the current preventive services coverage regulations. At the same time, defendants are amending the challenged regulations to address the precise type of religious liberty concerns that plaintiff raises in its Complaint. Given these two facts, plaintiff cannot even show a substantial risk of future harm to its religious freedom, much less imminent injury. *See Legatus*, 2012 WL 5359630, at *5-6; *see also supra* note 1 (collecting cases).

Plaintiff's purported planning harm, *see* Pls.' Mem. at 21, also does not establish imminent irreparable harm because it rests entirely on plaintiff's speculation that the regulations will apply to them in their current form. This, however, ignores the uncontroverted reality that defendants will not enforce the current regulations against plaintiff and that defendants have begun the process of amending the regulations for the very purpose of addressing the religious objections to covering contraception by religious organizations like plaintiff. Planning for an imagined scenario (the government's enforcement of the challenged regulations in their current form)—even if plaintiff has actually incurred some cost to plan for something that will never happen—does not establish imminent irreparable harm. Any costs plaintiff may incur in planning for a regulation that will become obsolete and will not be enforced against it by defendants is a cost it chooses to incur; it is not one that flows from any action by defendants. Indeed, even if plaintiff were to obtain the relief it seeks, it would still face uncertainties about how the amended rules will affect its future health plan.

Finally, plaintiff's claim that it is in the public interest to prevent violation of a constitutional right has no application here, as the challenged regulations are not being enforced against it.

CONCLUSION

Because plaintiff lacks standing and has not advanced a ripe claim, the Court lacks jurisdiction and should deny plaintiff's motion for a preliminary injunction and dismiss this case.[9]

Respectfully submitted this 19th day of April, 2013,

STUART F. DELERY
Acting Assistant Attorney General

IAN HEATH GERSHENGORN
Deputy Assistant Attorney General

FELICIA C. ADAMS
United States Attorney

JENNIFER RICKETTS
Director

SHEILA M. LIEBER
Deputy Director

/s/ Michael C. Pollack
MICHAEL C. POLLACK (NY Bar)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue NW, Room 6143
Washington, DC 20530
Tel: (202) 305-8550
Fax: (202) 616-8470
Email: michael.c.pollack@usdoj.gov

Attorneys for Defendants

[9] Defendants disagree with plaintiff's arguments that the regulations violate the Religious Freedom Restoration Act (RFRA), the Free Exercise Clause, and the Administrative Procedure Act. But given that the Court lacks jurisdiction over this case, there is no need to address or reach those arguments at this juncture.

CERTIFICATE OF SERVICE

I hereby certify that on April 19, 2013, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which sent notice of such filing to all parties.

/s/ Michael C. Pollack _____
MICHAEL C. POLLACK