IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

AVE MARIA UNIVERSITY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 2:12-cv-00088-UA-SPC
	)	
KATHLEEN SEBELIUS, *et al.*,	)	
	)	
Defendants.	)	
_____	)	

DEFENDANTS' MOTION TO DISMISS AND MEMORANDUM IN SUPPORT

COME NOW defendants, the Secretary of the United States Department of Health and Human Services, Kathleen Sebelius, *et al.*, through the undersigned counsel at the Department of Justice, and move to dismiss plaintiff's Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1). As explained below, plaintiff's Complaint should be dismissed because this Court lacks jurisdiction over plaintiff's request to invalidate and enjoin regulations that have not yet been enforced against plaintiff or amended in final form.

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). 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, Ave Maria University, filed suit on February 21, 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 have issued guidance on a temporary enforcement safe harbor and initiated a rulemaking to further amend the regulations to address religious concerns such as those raised by plaintiff in this case. The enforcement safe harbor provides that defendants will not bring any enforcement action against non-profit organizations with religious objections to providing contraceptive coverage (and

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

associated plans and issuers) if they meet certain criteria. The safe harbor protects such organizations until the first plan year that begins on or after August 1, 2013. Moreover, 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.

This Court lacks authority to adjudicate plaintiff's claims. At the outset, plaintiff's suit must be dismissed for lack of jurisdiction because plaintiff has not alleged any imminent injury from the operation of the regulations. Plaintiff sponsors a group health plan for its employees, and plaintiff has not made sufficient factual allegations that establish that the plan – which according to the Complaint does not cover contraceptive services – is ineligible for grandfather status. It has merely offered a legal conclusion to that effect. Thus, even apart from defendants' most recent actions, plaintiff has not borne its burden to allege facts from which this Court could conclude that plaintiff is under any current obligation to offer coverage for contraceptive services. Moreover, even assuming

that plaintiff's group health plan is ineligible for grandfather status, plaintiff has not alleged an imminent injury that would support standing in light of the enforcement safe harbor – which plaintiff admits protects it (and the issuer(s) of plaintiff's employee health plan) 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 like plaintiff.

The Court likewise lacks jurisdiction because this case is not ripe. Plaintiff's challenge to the preventive services coverage regulations is not fit for judicial review because defendants have initiated a rulemaking to amend the challenged regulations to accommodate religious objections to providing contraceptive coverage, like plaintiff's. In the meantime, the temporary enforcement safe harbor will be in effect such that plaintiff, even if its group health plan is not eligible for grandfather status, will not suffer any imminent hardship as a result of its failure to cover contraceptive services.

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.[2] 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")[3]; and (4) for women, such additional preventive care and screenings not described by the USPSTF as provided in comprehensive guidelines supported by HRSA. *Id.*

The requirement to provide coverage for recommended preventive services for women, without cost-sharing, was added as an amendment to the ACA 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

[2] A group health plan includes a plan established or maintained by an employer that provides medical care to employees. 42 U.S.C. § 300gg-91(a)(1). Group health plans may be insured (i.e., medical care underwritten through an insurance contract) or self-insured (i.e., medical care funded directly by the employer). The ACA does not require employers to provide health coverage for their employees, but, beginning in 2014, certain large employers may face assessable payments if they fail to do so under certain circumstances. 26 U.S.C. § 4980H.

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

identified in section 1001 of the ACA. *See* 155 Cong. Rec. S12019, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer); 155 Cong. Rec. S12261, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken).

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). Indeed, a 2010 survey showed that less than half of women are up to date with recommended preventive care screenings and services. IOM Rep. at 19. By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. 75 Fed. Reg. 41,726, 41,728 (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 41,728, 41,733; IOM Rep. at 20.

Defendants published interim final regulations implementing the preventive services coverage provision on July 19, 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(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")[4] with "reviewing 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 all women with reproductive capacity." *Id*. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited May 4, 2012).

[4] 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*.

On August 1, 2011, HRSA adopted IOM's recommendations in full, 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 May 4, 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. 46,621 (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 46,623. After carefully considering the more than 200,000 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 plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage that do not qualify for the religious employer exemption. 77 Fed. Reg. 8,725-27 (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 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.[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 significant changes to the preventive services coverage regulations will have altered the landscape with respect to religious accommodations under the regulations by providing further relief to organizations such as plaintiff.

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 religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8,728. Defendants began the process of 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). The ANPRM "presents questions and ideas" on potential alternative means of achieving the goals of providing

[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 May 4, 2012); 77 Fed. Reg. 16,501, 16,504 (Mar. 21, 2012).

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. *Id*. at 16,505. The ANPRM also suggests ideas and solicits comments on potential ways to accommodate religious organizations that sponsor self-insured group health plans for their employees. *Id*. at 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 additional amendments to the preventive services coverage regulations. *Id*. at 16,501. Defendants intend to finalize the amendments to the regulations such that they are effective by the end of the temporary enforcement safe harbor. *Id*. at 16,503.

II. CURRENT PROCEEDINGS

Plaintiff brings 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 contraceptive services. Plaintiff describes itself as "an institution of Catholic higher education" located in Naples, Florida, with approximately

1,200 students and 200 employees. Compl. ¶¶ 22, 30, 31, Dkt. No. 1. According to the Complaint, plaintiff currently "ensures" that its health plans do not cover "sterilization, contraception, or abortion." *Id*. ¶ 33. Plaintiff alleges that it "cannot provide health care insurance covering artificial contraception, sterilization, or abortion, or related education and counseling, without violating its deeply held religious beliefs." *Id*. ¶ 34. Plaintiff further asserts that it does not qualify for the religious employer exemption because, among other things, the inculcation of religious values is only one of its purposes and it employs and serves many persons who do not share its religious tenets. *Id*. ¶¶ 105-09. Plaintiff claims the preventive services coverage 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 pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. "[T]he party invoking federal jurisdiction bears the burden of establishing its existence." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998); *Bischoff v. Osceola Cnty.*, 222 F.3d 874, 878 (11th Cir. 2000). Where 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 Steel Co.*, 523 U.S. at 94-95.

ARGUMENT

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

Plaintiff lacks standing because it has not alleged a concrete and imminent injury resulting from the operation of the preventive services coverage regulations. To meet its burden to establish standing, a plaintiff must demonstrate that it has "suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (quotations and citations 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); *see also Koziara v. City of Casselberry*, 392 F.3d 1302, 1306 (11th Cir. 2004). 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*.

The preventive services coverage regulations do not apply to grandfathered plans. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T; 29 C.F.R. § 2590.715-1251; 45 C.F.R. § 147.140. A grandfathered plan is a health plan in which at least one individual

was enrolled on March 23, 2010 and that has continuously covered at least one individual since that date. 42 U.S.C. § 18011(a)(2); 26 C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1). A grandfathered plan may lose its grandfather status if, compared to its existence on March 23, 2010, it undergoes one or more of the changes set forth in 45 C.F.R. § 147.140(g)(1). *See also* 26 C.F.R. § 54.9815-1251T(g)(1); 29 C.F.R. § 2590.715-1251(g)(1).

Here, plaintiff alleges that its current insurance plans do not cover contraceptive services. Compl. ¶ 33. Plaintiff asserts that "[g]iven plan changes since March 23, 2010, the University's health insurance plan does not qualify as a grandfathered health plan." *Id*. ¶ 100. However, plaintiff's conclusory assertion about the status of its health plan, based on unspecified "plan changes," does not satisfy plaintiff's burden to allege facts sufficient to establish that its plan is ineligible for grandfather status. *See Ashcroft v. Iqbal*, 556 U.S. 662 (2009); *Davila v. Delta Air Lines, Inc.*, 326 F.3d 1183, 1185 (11th Cir. 2003) ("[C]onclusory allegations, unwarranted factual deductions or legal conclusions masquerading as facts will not prevent dismissal.").

Merely making changes to an existing policy will not cause a plan to lose its grandfather status. Instead, changes to an existing plan must, when compared to the plan in existence on March 23, 2010, eliminate all or substantially all benefits to diagnose or treat a particular condition, increase a percentage cost-sharing requirement, significantly increase a fixed-amount cost-sharing requirement, significantly reduce the employer's contribution, or impose or tighten an annual limit on the dollar value of any benefit. 26

C.F.R. § 54.9815-1251T(a), (g)(1); 29 C.F.R. § 2590.715-1251(a), (g)(1); 45 C.F.R. § 147.140(a), (g)(1). Plaintiff does not allege that its plan has undergone any of these specified changes; instead, plaintiff simply concludes that certain unspecified changes render the plan ineligible for grandfather status.[6] Accordingly, the allegations in the Complaint simply do not show that plaintiff will be required by the preventive services coverage regulations to provide coverage for contraceptive services – as opposed to continuing to offer the same grandfathered plan that does not, and presumably would not, cover contraceptive services. Plaintiff therefore has not alleged any imminent injury as a result of the challenged regulations.

Furthermore, even if plaintiff had given any sufficient basis for its allegation that its group health plan does not qualify for grandfather status, plaintiff still would not have alleged an injury in fact. 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. Plaintiff alleges that it is eligible for the safe harbor and, that, based on the beginning date of its plan year, it could not be subject to any enforcement action by defendants for failing to provide contraceptive coverage until at least January 1, 2014. Compl. ¶ 116. With such a long time before the inception of any possible injury and the challenged regulations

[6] A plan also may lose its status as a grandfathered health plan if it fails to satisfy the disclosure and record-keeping requirements described in 45 C.F.R. § 147.140(a)(2), (3). *See also* 26 C.F.R. § 54.9815-1251T(a)(2), (3); 29 C.F.R. § 2590.715-1251(a)(2), (3). Plaintiff, however, does not allege that its group health plan has failed to satisfy these requirements either.

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*, *Citizens United v. FEC*, 130 S. Ct. 876 (2010); *Whitmore*, 495 U.S. at 159-60; *Koziara*, 392 F.3d at 1306, and too uncertain circumstantially.

Although the mere passage of time alone may not defeat standing, *see, e.g.*, *Fla. State Conf. of NAACP v. Browning*, 522 F.3d 1153, 1161 (11th Cir. 2008), the 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. "Imminence, while an 'elastic concept,' requires that 'the injury 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.'" *Alabama-Tombigbee Rivers Coalition v. Norton*, 338 F.3d 1244, 1253 (11th Cir. 2003) (quoting *Lujan*, 504 U.S. at 564 n.2). The ANPRM published in the Federal Register confirms defendants' stated intention to propose amendments to the preventive services coverage regulations that accommodate the concerns of religious organizations that object to providing contraceptive coverage for religious reasons, like plaintiff. 77 Fed. Reg. at 16,501. And it seeks public comment on and requests suggestions for how to

accomplish that goal through final regulatory amendments that will take effect 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 8,728. The ANPRM provides plaintiff, and any other interested party, with the opportunity to, among other things, comment on ideas suggested by defendants for accommodating religious organizations, offer new ideas to "enable religious organizations to avoid . . . objectionable cooperation when it comes to the funding of contraceptive coverage," and identify considerations defendants should take into account when amending the regulations. *Id*. at 16,503, 16,507.

In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiff to help shape those amendments, there is no basis to conclude that plaintiff will be, or is likely to be, required to sponsor a health plan that covers 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 claim of injury, if any, after the temporary enforcement safe harbor expires and after the promised new regulations are promulgated, would differ substantially from plaintiff's current claim of injury. And, given the existing enforcement safe harbor, there is no basis for this Court to consider the merits of plaintiff's Complaint at this juncture.

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 (quotation omitted). 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).

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 of Utah 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); *Wilderness Soc'y v. Alcock*, 83 F.3d 386, 390 (11th Cir. 1996).

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 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 (quotations 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 non-exempted, non-profit 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 plaintiff and similarly-situated organizations and have made clear that the amendments are intended to be finalized well before the earliest date on which the challenged regulations could be enforced by defendants against plaintiff. 77 Fed. Reg. at 8,728-29. Therefore, unlike in *Abbott Laboratories* – where the challenged regulations were definitive and no further administrative proceedings were contemplated – the preventive services coverage regulations will be amended in the near future.

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 several 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.") (quotation 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 v. Sierra Club*, 523 U.S. 726, 734 (1998); *see also Texas Indep. Producers and Royalty Owners Assoc. 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); *Alcock*, 83 F.3d at 390-91 ("Until such actions have been proposed, however, there is no controversy for us to resolve. We have no doubt that some decisions [in the challenged action] make an injury to the appellants more likely. 'More likely,' however, does not make the injury imminent enough for purposes of judicial decisionmaking."); *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-162 (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 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." *Public 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 Pittman v. Cole*, 267 F.3d 1269, 1280 (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."). And judicial review of any future amendments to the regulations that result from the pending rulemaking would be impossible at this time.

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 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; *see also Texas Indep. Producers*, 413 F.3d at 484; *Motor Vehicle Mfrs. Assoc. v. New York 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"); *Alabama v. United States*, 630 F. Supp. 2d 1320, 1329 (S.D. Ala. 2008) ("These are hypotheticals the accuracy and significance of which can best be evaluated in light of the Secretary's actual conduct . . . ."). 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. Unlike the plaintiffs in *Abbott Laboratories*, plaintiff here is not being compelled to make immediate and significant changes in its day-to-day operations under threat of serious civil and criminal penalties. As explained above, if the group health plan made available by plaintiff to its employees is a grandfathered health plan – and there are no non-conclusory factual allegations in the Complaint to indicate that it is not – then the plan is not required to cover contraceptive services. Moreover, even if plaintiff sponsors a non-grandfathered group health plan, it qualifies 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) for failure to cover contraceptive services until January 1, 2014, at the earliest. *See* Compl. ¶ 116. And, by that time, defendants will have finalized amendments to the preventive services coverage regulations to accommodate religious objections to providing contraceptive coverage, like plaintiff's. *See* 77 Fed. Reg. at 8,728-29. Therefore, this is simply not a case where plaintiff is "forced to choose between foregoing lawful activity and risking substantial legal sanctions."[7] *Cheffer v. Reno*, 55 F.3d 1517, 1524 (11th Cir. 1995); *see also Texas*

[7] Plaintiff's allegation that it will have to continue to devote time and resources to "determin[e] how to respond" to the forthcoming amendments, Compl. ¶ 99, despite the fact that plaintiff is admittedly not required by law to do anything at the present, 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 Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987); *Tennessee 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, 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

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); *Alabama*, 630 F. Supp. 2d at 1330 (noting that plaintiff "may participate in the making of public comments for the agency's consideration as it refines its proposal, or it may choose not to do so and risk a less satisfactory final rule, but it would be a strange world indeed if [plaintiff] could select neither option and instead take the agency to court to avoid no greater hardship than the expense and aggravation of utilizing the public comment period").

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 Complaint.

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process."); *Alabama*, 630 F. Supp. 2d at 1330 ("[M]ere uncertainty as to the validity of a legal rule [does not] constitut[e] a hardship for purposes of the ripeness analysis, because under such a regime courts would soon be overwhelmed with requests.") (quotation omitted). 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 plaintiff's religious concerns.

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CERTIFICATE OF SERVICE

I hereby certify that on May 4, 2012, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system.

/s/ Eric Womack
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