IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MOST REVEREND LAWRENCE T. PERSICO, BISHOP OF THE ROMAN CATHOLIC DIOCESE OF ERIE, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 1:12-cv-00123-SJM

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY AND PERMANENT INJUNCTIONS AND MOTION FOR A RULE 65(a)(2) CONSOLIDATED TRIAL AND PRELIMINARY INJUNCTION HEARING

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INTRODUCTION

Plaintiffs are not entitled to a preliminary injunction. Plaintiffs ask the Court to enjoin regulations that are not being enforced against them and that defendants are amending in order to accommodate the precise religious liberty concerns that form the basis of plaintiffs' Complaint. Under these circumstances, plaintiffs cannot meet the basic jurisdictional prerequisites of standing and ripeness, nor can they possibly establish irreparable harm or that an injunction would be in the public interest. Plaintiffs also cannot establish likelihood of success on the merits.

To date, every court to have considered defendants' jurisdictional arguments has ruled in defendants' favor. Two district courts in the District of Columbia and one in the District of Nebraska dismissed nearly identical challenges to the preventive services coverage regulations for lack of standing and ripeness. *See Belmont Abbey Coll. v. Sebelius*, No. 12-cv-1989, 2012 WL 2914417 (D.D.C. July 18, 2012); *Wheaton Coll. v. Sebelius*, No. 12-cv-1169, 2012 WL 3637162 (D.D.C. Aug. 24, 2012); *Nebraska v. U.S. Dep't of Health & Human Servs.*, No. 12-cv-3035, 2012 WL 2913402 (D. Neb. July 17, 2012).[1] Defendants respectfully ask this Court to do the same. In addition, the only court that has decided the merits of a challenge to the preventive services coverage regulations dismissed the plaintiffs' RFRA claim because the plaintiffs failed to show that the preventive services regulations impose a substantial burden on the employers' religious exercise. *See O'Brien v. U.S. Dep't of Health & Human Servs.*, No. 12-cv-476, 2012 WL 4881208, at *5-7 (E.D. Mo. Sept. 28, 2012) (appeal pending). The court explained that a law does not substantially burden a person's exercise of religion "whenever it requires an outlay of funds that might eventually be used by a third party in a manner inconsistent with [the person's] religious values." *Id*. at *7. But even if plaintiffs could show that the preventive services regulations impose a substantial burden on their religious exercise, they could not establish a RFRA violation because the regulations are narrowly tailored to serve two compelling governmental interests: improving the health of women and children, and equalizing the

[1] The plaintiffs in *Belmont Abbey*, *Wheaton*, and *Nebraska* have appealed the district court's rulings.

provision of preventive care for women and men so that women can contribute to society on an equal playing field with men.

Plaintiffs' face similar obstacles with their First Amendment claims. The Free Exercise Clause does not prohibit a law that is neutral and generally applicable even if the law prescribes conduct that an individual's religion proscribes. *Emp't Div., Dep't of Human Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990). The preventive services coverage regulations fall within this rubric because they do not target, or selectively burden, religiously motivated conduct. The regulations apply to all non-exempt, non-grandfathered plans, not just those of employers with a religious affiliation. Plaintiffs' Establishment Clause claim is similarly flawed. The exemption distinguishes between *organizations* based on their purpose and composition; it does not favor one *religion*, *denomination*, or *sect* over another. The distinctions drawn by the exemption, therefore, simply do not violate the constitutional prohibition against denominational preferences. Furthermore, the regulations do not violate plaintiffs' free speech rights. The regulations compel conduct, not speech. They do not require plaintiffs to say anything; nor, as shown by this very lawsuit, do they prohibit plaintiffs from expressing to their employees or the public their views in opposition to the use of contraceptive services. The highest courts of both New York and California have upheld state laws that are similar to the preventive services coverage regulations against free exercise, Establishment Clause, and free speech challenges like those asserted by plaintiffs here, *see Catholic Charities of the Diocese of Albany v. Serio*, 859 N.E.2d 459, 461 (N.Y. 2006); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 74 n.3 (Cal. 2004), as did the court in *O'Brien*, 2012 WL 4481208, at *7-13. Nor can plaintiffs succeed on their Administrative Procedure Act ("APA") claim, as defendants complied with the procedural requirements of the APA in promulgating the challenged regulations and plaintiffs had ample opportunity to shape the challenged regulations.

For these reasons, the Court should deny plaintiffs' motion for a preliminary injunction. In addition, because the challenged regulations will almost certainly change before they are ever

enforced by the government against plaintiffs, the Court should deny plaintiffs' motion for a permanent injunction and a Rule 65(a)(2) consolidated trial and preliminary injunction hearing.

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."), http://cnsnews.com/sites/default/files/documents/PREVENTIVE%20SERVICES-IOM%20REPORT.pdf (last visited Oct. 15, 2012). 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

[2] 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.

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

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 (the "Women's Health Amendment") to the bill during the legislative process. The Women's Health Amendment was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in 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 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. *Id.* 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")[4] with "review[ing] what preventive services are necessary for women's health and well-being" and developing recommendations for comprehensive guidelines. IOM REP. at 2. IOM conducted an extensive science-based review and, on July 19, 2011, published a report of its analysis and recommendations. *Id*. at 20-26. The report recommended that HRSA guidelines include, among other things, well-woman visits, breastfeeding support, domestic violence screening, and, as relevant here, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id*. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices. FDA, Birth Control Guide, *available at* http://www.fda.gov/ForConsumers/ByAudience/ForWomen/ucm118465.htm (last visited Oct. 15, 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.*

Many women do not utilize contraceptive methods or sterilization procedures because they are not covered by their health plan or they require costly copayments, coinsurance, or deductibles. IOM REP. at 19, 109; Adam Sonfield, *The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost-Sharing*, 14 GUTTMACHER POL'Y REV. 10 (2011), *available at* http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.pdf (last visited Oct. 15, 2012) (citing 2010 study that found women with private insurance that covers prescription drugs paid 53 percent of the cost of their oral contraceptives). IOM determined that coverage, without cost-sharing, for FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling is necessary to increase utilization of these services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. IOM REP. at 102-03.

According to a national survey, in 2001, an estimated 49 percent of all pregnancies in the United States were unintended. *Id*. at 102. When compared to intended pregnancies, unintended pregnancies are more likely to result in poorer health outcomes for mothers and children. Women with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy. *Id*. at 103. Children born as the result of unintended pregnancies are at increased risk of preterm birth and low birth weight as compared to children born as the result of intended pregnancies. *Id*. The use of contraception also allows women to avoid short interpregnancy intervals, which have been associated with low birth weight, prematurity, and small-for-gestational-age births. *Id*. at 102-03. Moreover, women with certain chronic medical conditions may need contraceptive services to postpone pregnancy, or to avoid it entirely, and thereby reduce risks to themselves or their children. *Id*. at 103 (noting women with diabetes or obesity may need to delay pregnancy); *id*. at 103-04 (indicating that pregnancy may be harmful for women with certain conditions, such as pulmonary hypertension).

Contraception, IOM noted, is also highly cost-effective because the costs associated with pregnancy greatly exceed the costs of contraceptive services. *Id*. at 107-08. In 2002, the direct medical cost of unintended pregnancy in the United States was estimated to be nearly $5 billion, with the cost savings due to contraceptive use estimated to be $19.3 billion. *Id*. at 107. Moreover, it has been estimated to cost employers 15 to 17 percent more to not provide contraceptive coverage in their health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and indirect costs such as employee absence and the reduced productivity associated with such absence. Sonfield, *supra*, at 10.

On August 1, 2011, HRSA adopted IOM's recommendations, subject to an exemption relating to certain religious employers authorized by an amendment to the interim final regulations. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited Oct. 15, 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 any associated group health insurance coverage) from any requirement to cover contraceptive services under HRSA's guidelines. 76 Fed. Reg. 46,621 (Aug. 3, 2011); 45 C.F.R. § 147.130(a)(1)(iv)(A). To qualify for the exemption, an employer must meet the following criteria:

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

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

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

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

45 C.F.R. § 147.130(a)(1)(iv)(B). The sections of the Internal Revenue Code referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," 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 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 (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 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.

(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 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

[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 Oct. 15, 2012).

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 to accommodate non-exempt, non-grandfathered religious organizations' religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Defendants began the process of further amending the regulations on March 21, 2012, when they published an ANPRM in the Federal Register. 77 Fed. Reg. 16,501 (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 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 sponsor insured group health plans and that object to contraceptive coverage on religious grounds and simultaneously to offer such coverage directly to the organization's plan participants, at no charge to organizations or participants. *Id*. at 16,505. The ANPRM also suggests ideas and solicits comments on 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 further 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 before the end of the temporary enforcement safe harbor. *Id*. at 16,503.

II. CURRENT PROCEEDINGS

Plaintiffs brought this action on May 21, 2012 to challenge the lawfulness of the preventive services coverage regulations to the extent that the regulations require the health coverage they make available to their employees to cover contraceptive services. Plaintiffs claim that the contraceptive coverage requirement violates RFRA, the First and Fifth Amendments to the United States Constitution, and the APA. On August 6, 2012, defendants moved to dismiss all of plaintiffs' claims for lack of jurisdiction. *See* ECF No. 18. That motion is now fully briefed. On September 4, 2012, plaintiffs moved for preliminary and permanenet injunctions, asserting that they would suffer irreparable harm if the preventive services regulations are not enjoined. *See* ECF No. 29. Plaintiffs have also moved, under Federal Rule of Civil Procedure 65(a)(2), to consolidate a hearing on their motion for a preliminary injunction with a trial on the merits. *See* ECF No. 30.

ARGUMENT

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*, 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. Plaintiffs cannot satisfy these requirements.

I. PLAINTIFFS' CLAIMS MUST BE DISMISSED IN THEIR ENTIRETY FOR LACK OF STANDING AND RIPENESS[6]

As an initial matter, plaintiffs are not entitled to a preliminary injunction because this Court lacks jurisdiction to adjudicate their claims. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.") (quoting *Ex parte McCardle*,

[6] Defendants' jurisdictional arguments are laid out more fully in their memorandum and reply in support of their motion to dismiss.

74 U.S. (7 Wall.) 506, 514 (1869)). 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." *N.J. Physicians, Inc. v. President of the United States*, 653 F.3d 234, 238 (3d Cir. 2011) (citation omitted). Allegations of possible future injury do not suffice; rather, "[a] threatened injury must be certainly impending to constitute injury in fact." *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (quotation omitted). A plaintiff that "alleges only an injury at some indefinite future time" has not shown an injury in fact, particularly where "the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan*, 504 U.S. at 564 n.2. In these situations, "the injury [must] proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all." *Id*.

Plaintiffs face no imminent injury resulting from the preventive services coverage regulations because plaintiffs are protected by the temporary enforcement safe harbor as non-profit entities with religious objections to contraceptive coverage that have not offered contraceptive coverage from February 10, 2012 onwards. The government will accordingly not take any enforcement action against plaintiffs until at least the first plan year that begins on or after August 1, 2013. Guidance at 3. Plaintiffs acknowledge that their plan year begins on January 1, Mem. in Supp. of Pls.' Mot for Prelim. & Perm. Inj. ("Pls. Br."), ECF No. 33, at 9, so the earliest plaintiffs could be subject to any enforcement action by the government 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 further 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), *overruled in part on other grounds, Citizens United v. FEC*, 130 S. Ct. 876 (2010).

Three recent decisions—in cases nearly identical to this one—confirm this straightforward point. The courts in *Belmont Abbey* and *Wheaton College* concluded that the plaintiffs' claims were not ripe because the regulations are not being enforced against the plaintiffs and are currently undergoing a process of amendment to accommodate religious concerns like the plaintiffs'. These courts also held, for similar reasons, that the plaintiffs had not shown any imminent injury necessary to establish standing given the enforcement safe harbor and the forthcoming amendments to the regulations. The *Nebraska* court also concluded that the plaintiffs' claims were not ripe. *See* 2012 WL 2913402, at *20-24. Thus, in circumstances virtually identical to those in this case, these courts dismissed the claims of several religious organizations on the same grounds that the government urges here.

As these decisions implicitly recognize, the defect in plaintiffs' suit does not implicate a mere technical issue of counting intermediate days until an all-but-certain action takes place. 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). Here, the upcoming regulatory amendments will at a minimum change the contours of plaintiffs challenge and may moot their case altogether. The government has indicated that it intends to finalize the amendments to the regulations *before* the rolling expiration of the temporary enforcement safe harbor starting on August 1, 2013. 77 Fed. Reg. at 16,503; *see also* 77 Fed. Reg. at 8728. In light of the forthcoming amendments, and the opportunity the rulemaking process provides for plaintiffs to help shape those amendments, there is no reason to suspect that plaintiffs will be required to sponsor a health plan that covers contraceptive services in contravention of their religious beliefs once the enforcement safe harbor expires. And any suggestion to the contrary is entirely speculative at this point. *See Belmont Abbey*, 2012 WL 2914417, at *10 ("Because an amendment to the final rule that may

vitiate the threatened injury is not only promised but underway, the injuries alleged by Plaintiff are not 'certainly impending.'" (quoting *Whitmore*, 495 U.S. at 158)).[7]

Plaintiffs' challenge also 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 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 807-08. 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).

The Supreme Court, in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), *overruled on other grounds in Califano v. Sanders*, 430 U.S. 99 (1977), laid out the two fundamental considerations for the determination of ripeness: (1) "the fitness of the issues for judicial decision" and (2) "the hardship to the parties of withholding court consideration." *Id.* at 149. In the context of declaratory judgments, the Third Circuit has refined those considerations into the three-pronged framework articulated in *Step-Saver Data Systems, Inc. v. Wyse Technology*, 912 F.2d 643 (3d Cir. 1990). Under the *Step-Saver* framework, courts look to the "adversity of interest" between the parties, the "conclusiveness" that a declaratory judgment would have on

[7] Nor may plaintiffs transform the speculative possibility of future injury into a current concrete injury for standing purposes by asserting that they have to plan now for their future needs. 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. Further, any planning plaintiffs are engaged in now "stems not from the operation of [the preventive services coverage regulations], but from [plaintiffs'] own . . . personal choice" 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.

the legal relationship between the parties, and the "practical help, or utility" of a declaratory judgment. *Id*. at 647.[8]

None of these indicia of ripeness exists with respect to plaintiffs. The government has initiated a rulemaking to amend the preventive services coverage regulations to accommodate the concerns expressed by plaintiffs and similarly situated organizations, and have made clear that the amendments will be finalized well before the earliest date on which the challenged regulations could be enforced by the government against plaintiffs. 77 Fed. Reg. at 8728-29. Therefore, the alleged threatened injury is contingent upon the occurrence of uncertain future events, and cannot support a finding of adversity. *See Presbytery of N.J.*, 40 F.3d at 1470-71 (dismissing churches' challenge to non-discrimination law as unripe where affidavit from State official indicated that State would not prosecute churches for violating law).

Moreover, the forthcoming amendments are intended to address the very issue that plaintiffs raise here by creating alternative means of providing contraceptive coverage without cost-sharing to accommodate religious organizations' objections to covering contraceptive services. There is, therefore, a significant chance that the amendments will eliminate altogether the need for judicial review, or at least narrow the scope of any controversy to more manageable proportions. Once the government finalizes the amendments, if plaintiffs' concerns are not laid to rest, plaintiffs "will have ample opportunity [] to bring [their] legal challenge at a time when harm is more imminent and more certain." *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 734 (1998).[9]

[8] The Third Circuit has indicated that the three-step *Step-Saver* framework can be used somewhat interchangeably with the Supreme Court's two-part framework set out in *Abbott Laboratories. See Phila. Fed'n of Teachers v. Ridge*, 150 F.3d 319, 323 n.4 (3d Cir. 1998). If the Court were to apply the *Abbott Laboratories* framework, this case would still be unripe. Given defendants' ongoing administrative process, their public commitment to regulatory change, and the enforcement safe harbor, the issues presented in this case are unfit for judicial review, and plaintiffs will suffer no hardship from the Court's withholding of consideration.

[9] *See also Tex. Indep. Producers & Royalty Owners Ass'n*, 413 F.3d at 483-84; *Occidental Chem. Corp. v. FERC*, 869 F.2d 127, 129 (2d Cir. 1989); *Am. Petroleum Inst. v. EPA*, 683 F.3d 382 (D.C. Cir. 2012); *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999); *Lake Pilots Ass'n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 160-62 (D.D.C. 2003).

Further, this case lacks conclusivity as it relates to plaintiffs, as it is undoubtedly based on contingent facts. Although plaintiffs' complaint raises largely legal claims, those claims are leveled at regulations that, as applied to plaintiffs and similarly situated organizations, have not "taken on fixed and final shape." *Pub. Serv. Comm'n*, 344 U.S. at 244; *see also Belmont Abbey*, 2012 WL 2914417, at *14 ("Because prudential considerations counsel against reaching the merits of Plaintiff's claims at this stage, the Court need not evaluate whether the suit presents a 'purely legal' question."). Once defendants complete the rulemaking outlined in the ANPRM, plaintiffs' challenge to the current regulations likely will be moot. *See The Toca Producers v. FERC*, 411 F.3d 262, 266 (D.C. Cir. 2005) (rejecting purely legal claim as unripe due to the possibility that it may not need to be judicially resolved). And judicial review now of any future amendments to the regulations that result from the pending rulemaking would be too speculative to yield meaningful review. The ANPRM offers ideas and solicits input on potential alternative means of achieving the goals of providing women access to contraceptive services without cost-sharing and accommodating religious organizations' religious liberty interests. 77 Fed. Reg. at 16,503. It does not preordain what amendments to the preventive services regulations defendants will ultimately promulgate; nor does it foreclose the possibility that defendants will adopt ideas 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 Tex. Indep. Producers*, 413 F.3d at 482; *Motor Vehicle Mfrs. Assoc. v. N.Y. Dep't of Envtl. Conservation*, 79 F.3d 1298, 1305 (2d Cir. 1996); *Lake Pilots Ass'n*, 257 F. Supp. 2d at 160. 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. *See Belmont Abbey*, 2012 WL 2914417, at *11-14.

Here, plaintiffs allege that the regulations impact their retention and recruitment efforts and that they are being affected because changes to their health plans require advance planning. Compl. ¶¶ 146-53. But these reflect contingencies that may (or, more likely, may not) arise in the

future, and plaintiffs are not being compelled to make immediate and significant changes in their day-to-day operations under threat of serious civil and criminal penalties. *Compare Abbott Labs*, 387 U.S. at 152-53. Indeed, the Third Circuit has indicated that "[m]ere economic uncertainty affecting plaintiff's planning is not sufficient to support premature review." *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987); *see also Tenn. Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984) (concluding plaintiff's "planning insecurity" was not sufficient to show hardship); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 162 (7th Cir. 1976) ("[C]laims of uncertainty in [plaintiff's] business and capital planning are not sufficient to warrant [ ] review of an ongoing administrative process."); *Belmont Abbey*, 2012 WL 2914417, at *14 ("Costs stemming from Plaintiff's desire to prepare for contingencies are not sufficient . . . to constitute a hardship for purpose of the ripeness inquiry—particularly when the agency's promises and actions suggest the situation Plaintiff fears may not occur."). Nor is plaintiffs' alleged hardship caused by the challenged regulations. *See Abbott Labs.*, 387 U.S. at 152. Rather, it arises from plaintiffs' own desire to prepare for a hypothetical (and unlikely) situation in which the forthcoming amendments to the preventive services coverage regulations do not sufficiently address their religious concerns.

In sum, plaintiffs can qualify for the temporary enforcement safe harbor, meaning defendants will not take any enforcement action against plaintiffs 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 amendments to accommodate religious objections to providing contraceptive coverage. *See* 77 Fed. Reg. at 8728-29. Therefore, this is not a case where plaintiffs are faced with a "'Hobson's choice' of foregoing lawful behavior or subjecting [themselves] to prosecution under the challenged provision." *Armstrong*, 961 F.2d at 423-24 (relying on the lack of such a choice in concluding declaratory judgment would be of little practical help, or utility); *see also Tex. Indep. Producers & Royalty Owners*, 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). The utility of resolving plaintiffs' claims would be non-existent or, at most, minimal, and insufficient to make their claims justiciable. Indeed, "[w]ere [this Court] to entertain [the] anticipatory challenge[] pressed by [plaintiffs]"—parties "facing no imminent threat of adverse agency action, no hard choice between compliance certain to be disadvantageous and a high probability of strong sanctions"—the Court "would venture away from the domain of judicial review into a realm more accurately described as judicial preview," a realm into which this Court should not tread. *Tenn. Gas Pipeline Co.*, 736 F.2d at 751 (internal citation omitted).

Because plaintiffs lack jurisdiction, plaintiffs' motion for a preliminary injunction should be denied.

II. PLAINTIFFS HAVE 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 plaintiffs' lack jurisdiction, plaintiffs' motion for a preliminary injunction should be denied because they have failed to establish any imminent irreparable harm. The Third Circuit has made clear that "a showing of irreparable harm is insufficient if the harm will occur only in the indefinite future." *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91 (3d Cir. 1992). "Rather, the moving party must make a 'clear showing of *immediate* irreparable harm." *Id.* (emphasis in original). As discussed above, plaintiffs face no imminent injury resulting from the preventive services coverage regulations because plaintiffs are protected by the temporary enforcement safe harbor, under which defendants will not enforce the challenged regulations against plaintiffs—if ever—until January 2014. In the meantime, defendants are amending the challenged regulations to address the precise type of religious liberty concerns that plaintiffs raise in their Complaint. Given the safe harbor and the amendment process, plaintiffs cannot even show a substantial risk of future harm, much less imminent injury. Although plaintiffs allege that they must begin addressing these issues prior to January 1, 2014 and that they will suffer various financial and operational harms before that time, such inconveniences are not the sort of "irreparable" injury that would justify the extraordinary remedy of injunctive relief. *See Sampson v Murray*, 415 U.S. 61, 90 (1974) (holding that "[m]ere

injuries, however substantial, in terms of money, time and energy . . . are not enough" to justify a preliminary injunction). Any injury that plaintiffs now face is not the result of the challenged regulations, but of plaintiffs' desire to plan for future contingencies (i.e. that the regulations may, in the future, take a form to which plaintiffs object). Similarly, plaintiffs 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 plaintiffs and are, as discussed below, constitutional.

III. PLAINTIFFS HAVE NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Plaintiffs Cannot Show a Likelihood of Success on Their Religious Freedom Restoration Act Claim

Under RFRA, the federal government generally may not "substantially burden a person's exercise of religion, 'even if the burden results from a rule of general applicability.'" *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 424 (2006) (quoting 42 U.S.C. § 2000bb-1(a)). But the federal government may substantially burden the exercise of religion if it "(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. § 2000bb-1(b).

Plaintiffs cannot show a likelihood of success under these standards. The preventive services coverage regulations do not require plaintiffs' employees to use or buy contraceptive services. Rather, the regulations require plaintiffs, if they choose to offer health coverage to their employees, to include coverage for certain preventive services, including contraceptive services. The employee/plan participant may then choose to obtain contraceptive services as well as any other preventive services, but that choice is not one that plaintiffs are asked to make or to advocate. Instead, plaintiffs are free to provide whatever written materials or make whatever oral statements they deem appropriate to those covered by their health plans to convey plaintiffs' objections to the use of contraceptive services and to encourage their employees not to use such services.

As the only court that has decided the merits of a challenge to the preventive services coverage regulations under RFRA concluded, any burden imposed by the regulations is too attenuated to satisfy RFRA's *substantial* burden requirement. *See O'Brien*, 2012 WL 4481208, at *4-7.[10] The *O'Brien* court explained that "the plain meaning of 'substantial,'" as used in RFRA, "suggests that the burden on religious exercise must be more than insignificant or remote. *Id.* at 9. And cases presenting the test that RFRA was intended to restore—*Sherbert v. Verner*, 374 U.S. 398 (1963), and *Yoder v. Wisconsin*, 406 U.S. 205 (1972)—confirm this "common sense conclusion." *Id.* at *5. The plaintiff in *Sherbert*, the court explained, "was forced to 'choose between following the precepts of her religion [by resting, and not working, on her Sabbath] and forfeiting [unemployment] benefits, on the one hand, and abandoning one of the precepts of her religion in order to accept work, on the other." *Id.* (quoting *Sherbert*, 374 U.S. at 404). Similarly, in *Yoder*, the state compulsory-attendance law "affirmatively compel[led] [plaintiffs], under threat of criminal sanction to perform acts undeniably at odds with the fundamental tenets of their religious beliefs." *Id.* (quoting *Yoder*, 406 U.S. at 218).

In contrast to the direct and substantial burdens imposed in those cases, the court in *O'Brien* determined that the preventives services coverage regulations result in only an indirect impact on the plaintiffs. *Id.* at *6-7.

> [T]he challenged regulations do not demand that plaintiffs alter their behavior in a manner that will directly and inevitably prevent plaintiffs from acting in accordance with their religious beliefs. [Plaintiff] is not prevented from keeping the Sabbath, from providing a religious upbringing for his children, or from participating in a religious ritual such as communion. Instead, plaintiffs remain free to exercise their religion, by not using contraceptives and by discouraging employees from using contraceptives. The burden of which plaintiffs complain is that funds, which plaintiffs will contribute to a group health plan, might, after a series of independent decisions by health care providers and patients covered by [the employer's] plan, subsidize *someone else's* participation in an activity that is

[10] Plaintiffs rely on the court's decision in *Newland v. Sebelius*, No. 12-cv-1123, 2012 WL 3069154 (D. Colo. July 27, 2012), to suggest that there is "a clear substantial burden" here because this case does not implicate the question of whether a closely held corporation can exercise religion. Pls.' Br. at 12 n.2. The *Newland* court, however, made absolutely no findings with respect to whether the challenged regulations substantially burden religious exercise. Instead, it concluded only that serious questions as to the merits of the plaintiffs' claims deserving of more deliberate investigation. *Id.* at *8. In any event, it is defendants' position that the plaintiffs' motion for a preliminary injunction in that case was wrongly decided, and should have been denied.

> condemned by plaintiffs' religion. The Court rejects the proposition that requiring indirect financial support of a practice, from which plaintiff himself abstains according to his religious principles, constitutes a substantial burden on plaintiff's religious exercise.

Id. at *6. The court noted that the regulations have no more of an impact on the plaintiffs' religious beliefs than the employer's payment of salaries to its employees, which those employees can also use to purchase contraceptives. *Id*. at *7. Just as plaintiffs may currently encourage their employees not to use their wages to purchase contraceptive services, so too they may advocate against using their health coverage for that purpose.

Even if plaintiffs were able to demonstrate a substantial burden on their religious exercise, however, they would not prevail because the preventive services coverage regulations are justified by two compelling governmental interests, and are the least restrictive means to achieve those interests. As explained in the interim final regulations, the primary predicted benefit of the regulations is that "individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease." 75 Fed. Reg. at 41,733; *see also* 77 Fed. Reg. at 8728. Indeed, "[b]y expanding coverage and eliminating cost sharing for recommended preventive services, these interim final regulations could be expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733. Of course it is the insured that will ultimately determine which preventive services they choose to use. Increased access to contraceptive services is a key part of these predicted health outcomes, as a lack of contraceptive access has proven to have negative health consequences for both women and a developing fetus. As IOM concluded in identifying services recommended to "prevent conditions harmful to women's health and well-being," unintended pregnancy may delay "entry into prenatal care," prolong "behaviors that present risks for the developing fetus," and cause "depression, anxiety, or other conditions." IOM REP. at 20, 103. Contraceptive coverage also helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103. In fact, "pregnancy may be contraindicated for women with serious medical conditions such as pulmonary

hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome." *Id.* at 103-04.

Closely tied to this interest is a related, but separate, compelling interest that is furthered by the preventive services coverage regulations. By including in the ACA coverage of gender-specific preventive health services for women, Congress made clear that the goals and benefits of effective preventive health care apply with equal force to women, who might otherwise be excluded from such benefits if their unique health care burdens and responsibilities were not taken into account in the ACA. As explained by members of Congress, "women have different health needs than men, and these needs often generate additional costs. Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men." *See* 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009); *see also* 155 Cong. Rec. S12265-02, S12269 (daily ed. Dec. 3, 2009); IOM REP. at 19. These costs result in women often forgoing preventive care. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274. Accordingly, this disproportionate burden on women creates "financial barriers . . . that prevent women from achieving health and well-being for themselves and their families." IOM REP. at 20. Congress's attempt to equalize the provision of preventive health care services, with the resultant benefit of women being able to contribute to the same degree as men as healthy and productive members of society, furthers a compelling governmental interest. *Cf. Catholic Charities of Sacramento*, 85 P.3d at 92-93 (concluding state law that required group health coverage to provide coverage for prescription contraceptives under certain circumstances served a compelling governmental interest).[11]

The government's interests in promoting the health of women and newborn children and furthering gender equality are compelling not just in the abstract, but also when applied

[11] Plaintiffs miss the point when they attempt to minimize the magnitude of the government's interests by arguing that contraception is widely available and even subsidized for certain individuals at lower income levels. *See* Pls.' Br. at 19. Although a majority of employers do offer coverage of FDA-approved contraceptives, *see* IOM REP. at 109, many women forego recommended preventive services, including recommended contraceptive services, because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109. The challenged regulations advance the compelling interests of promoting the health of women and newborn children and furthering gender equality by eliminating that cost-sharing. 77 Fed. Reg. at 8728. Furthermore, the government's interest in ensuring access to contraceptive services is *particularly* compelling for those women employed by employers that do not currently offer such coverage, like plaintiffs.

specifically to plaintiffs and other employers that object to the regulations on religious grounds. *See O Centro*, 546 U.S. at 431-32. Each woman who wishes to use contraceptives and who works for plaintiffs or a similarly situated entity (and each woman who is a covered spouse or dependent of an employee of such an entity)—or, for that matter, any woman in such a position in the future—is significantly disadvantaged when her employer chooses to provide a plan that fails to cover such services. *See, e.g.*, *United States v. Friday*, 525 F.3d 938, 956 (10th Cir. 2008) (noting that government's interest is still compelling even when impact is limited in scope). As revealed by the IOM Report, those female employees (and covered spouses and dependents) would be, as a whole, less likely to use contraceptive services in light of the financial barriers to obtaining them and would then be at risk of unhealthier outcomes, both for the women themselves and their potential newborn children. IOM REP. at 102-03. They would also have unequal access to preventive care and would therefore be at a competitive disadvantage in the workforce due to, among other things, their inability to decide for themselves if and when to bear children. These harms would befall female employees (and covered spouses and dependents) who do not necessarily share their employer's religious beliefs. Plaintiffs' desire not to provide a health plan that permits such individuals to exercise their own choice as to contraceptive use must yield to the government's compelling interest in avoiding the adverse and unfair consequences that would be suffered by such individuals as a result of the employer's decision. *See United States v. Lee*, 455 U.S. 252, 261 (1982) (noting that a religious exemption is improper where it "operates to impose the employer's religious faith on the employees").

The preventive services coverage regulations, moreover, are the least restrictive means of furthering the underlying interests. When determining whether a particular regulatory scheme is "least restrictive," the inquiry is whether the individual or organization with religious objections, and those similarly situated, can be exempted from the scheme—or whether the scheme can otherwise be modified—without undermining the government's compelling interest. *See S. Ridge Baptist Church v. Indus. Comm'n of Ohio*, 911 F.2d 1203, 1206 (6th Cir. 1990). The government is not required "to do the impossible—refute each and every conceivable alternative regulation

scheme." *United States v. Wilgus*, 638 F.3d 1274, 1289. Instead, the government need only "refute the alternative schemes offered by the challenger." *Id*; *see also New Life Baptist Church Acad. v. Town of E. Longmeadow*, 885 F.2d 940, 946 (1st Cir. 1989) (Breyer, J.).

Instead of explaining how plaintiffs and similarly situated employers could be exempted from the preventive services coverage regulations without significant damage to the government's compelling interests in the health and equality of women who receive health coverage through employers (as well as the health of their newborn children), plaintiffs simply conjure up several new regulatory schemes that they claim would be less restrictive. *See* Pls.' Br. at 20-21. Plaintiffs misunderstand the nature of the "least restrictive means" inquiry. RFRA simply does not require the government to create an entirely new legislative and administrative scheme at plaintiffs' behest. *See Wilgus*, 638 F.3d at 1289 ("Not requiring the government to do the impossible—refute each and every conceivable alternative regulation scheme—ensures that scrutiny of federal laws under RFRA is not 'strict in theory, but fatal in fact.'" (quoting *Fullilove v. Klutznick*, 448 U.S. 448, 507 (1980) (Powell, J., concurring))); *New Life Baptist*, 885 F.2d at 946 ("The term 'least restrictive means,' however, is not self-defining. In applying that term, one must pay heed to Justice Blackmun's caution, offered in another context, that '"least drastic" means is a slippery slope . . . [, for a] judge would be unimaginative indeed if he could not come up with something a little less "drastic" or a little less "restrictive" in almost any situation, and thereby enable himself to vote to strike legislation down.'" (quoting *Ill. State Bd. of Elections v. Socialist Workers Party*, 440 U.S. 173, 188-89 (1979) (Blackmun, J., concurring))). In effect, plaintiffs want the government "to subsidize private religious practices," *Catholic Charities of Sacramento*, 85 P.3d at 94, by expending significant resources to adopt an entirely new legislative and administrative scheme.

Furthermore, even if the Court were to consider plaintiffs' proffered schemes, they are not adequate alternatives because they are not "feasible" or "plausible." *See, e.g.*, *New Life Baptist*, 885 F.2d at 947 (considering "in a practical way" whether proffered alternative would "threaten potential administrative difficulties, including those costs and complexities which . . .

may significantly interfere with the state's ability to achieve its . . . objectives"); *Graham*, 822 F.2d at 852 ("To allow an exception for Scientologists is, we think, possible; but it is not feasible."). In determining whether a proposed alternative scheme is feasible, courts often consider the burdens and disadvantages that would be imposed on other important interests, including the additional administrative and fiscal costs of the proffered scheme. *See, e.g.*, *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011) (rejecting proffered alternative because it "would place an unreasonable burden" on the government), Plaintiffs' alternatives would impose considerable new costs and other burdens on the government and are otherwise impractical. *See Lafley*, 656 F.3d at 942; *New Life Baptist*, 885 F.2d at 947; *see also, e.g.*, *Gooden v. Crain*, 353 F. App'x 885, 888 (5th Cir. 2009);*Adams v. Comm'r of Internal Revenue*, 170 F.3d 173, 180 n.8 (3d Cir. 1999).[12]

Finally, this is not a case where "[u]nderinclusive enforcement of a law suggests that the government's 'supposedly vital interest' is not really compelling" or "that the law is not narrowly tailored." *Friday*, 525 F.3d at 958 (quoting *Lukumi*, 508 U.S. at 546-47). The "exemptions" from the preventive services coverage regulations cited by plaintiffs, *see* Pls.' Br. at 18, do not change the fact that the regulations are the least restrictive means to advance the government's compelling interests. The grandfathering of certain health plans from certain provisions of the ACA, for example, is not specifically limited to the preventive services coverage regulations. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. In fact, in effect, grandfathering is not really, an "exemption," but rather, for many plans, over the long term, a phase-in of several requirements under the ACA, including those in the preventive services coverage regulations. Congress's decision to incrementally transition into the ACA

[12] Nor would the proposed alternatives be equally effective at advancing the government's compelling interests. Congress determined that the best way to achieve the private health coverage goals of the ACA, including expanding preventive services coverage, was to utilize the existing employer-based system. The anticipated benefits of the preventive services coverage regulations are attributable not only to the fact that contraceptive coverage will be available to women with no cost-sharing—an attribute that plaintiffs' alternatives admittedly share—but also because this coverage will be available through the existing employer-based system of health coverage, thus ensuring that women will face minimal logistical and administrative obstacles to receiving coverage of their care. Plaintiffs' alternatives, on the other hand, have none of these advantages.

administrative scheme does nothing to call into question the compelling interests furthered by the preventive services coverage regulations. In light of the complexities inherent in implementing this administrative scheme, this approach is a perfectly reasonable balancing of competing interests.[13]

For these reasons, plaintiffs' cannot establish likelihood of success on their RFRA claim.

B. Plaintiffs Cannot Show Likelihood of Success on Their Free Exercise Claim.

The preventive services coverage regulations do not violate the Free Exercise Clause because they are neutral laws of general applicability. *See Smith*, 494 U.S. at 879. A law is neutral if it does not target religiously motivated conduct but rather has as its purpose something other than the disapproval of a particular religion, or of religion in general. *Lukumi*, 508 U.S. at 533, 545. A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id*. at 535-37, 545 (concluding law was not generally applicable when it prohibited animal killings almost exclusively when they were performed as part of a Santeria religious ritual).

The preventive services coverage regulations are neutral and generally applicable. The regulations do not target religiously motivated conduct. Indeed, the religious employer exemption serves to accommodate religion, not to burden or disapprove of it. The object of the regulations is to promote public health and gender equality by increasing access to and utilization of recommended preventive services, including those for women. The regulations reflect expert

[13] The only true exemption from the preventive services coverage regulations cited by plaintiffs is the exemption for "religious employer[s]," 45 C.F.R. § 147.130(a)(1)(iv). There is a rational distinction between the narrow exception currently in existence and plaintiffs' requested expansion. As revealed by the plain text of the regulations, a "religious employer" is narrowly defined to be an employer that, *inter alia*, has the "inculcation of religious values" as its purpose and "primarily employs persons who share the religious tenets of the organization." *Id*. Thus, the exception does not undermine the government's compelling interests. It anticipates that the impact on employees of exempted organizations will be minimal, given that any religious objections of the exempted organizations are presumably shared by most of the individuals actually making the choice as to whether to use contraceptive services. *See* 77 Fed. Reg. at 8728. The same is not true for plaintiffs, which admittedly employ many people who do not share their religious beliefs. *See* Rauscher Affidavit, ECF No. 27-2, ¶ 14 Stewart Affidavit, ECF No. 27-3, ¶ 27. Should plaintiffs be permitted to extend the protections of RFRA to any employer that objects to the operation of the regulations, it is difficult to see how the regulations could continue to function or be enforced in a rational manner. *See O Centro*, 546 U.S. at 435 ("[T]he government can demonstrate a compelling interest in uniform application of a particular program by offering evidence that granting the requested religious accommodation would seriously compromise its ability to administer the program.").

medical recommendations about the medical necessity of the services, without regard to any religious motivations for or against such services. *Id*. at 533. As shown by the IOM Report, this purpose has nothing to do with religion, as the IOM Report is entirely secular in nature. IOM REP. at 2-4, 7-8. The regulations, moreover, do not pursue their purpose "only against conduct motivated by religious belief." *Lukumi*, 508 U.S. at 545. The regulations apply to all non-exempt group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage. Thus, "it is just not true . . . that the burdens of the [regulations] fall on religious organizations 'but almost no others.'" *Am. Family Ass'n v. FCC*, 365 F.3d 1156, 1171 (D.C. Cir. 2004) (quoting *Lukumi*, 508 U.S. at 536); *see also United States v. Amer*, 110 F.3d 873, 879 (2d Cir. 1997) (concluding law that "punishe[d] conduct within its reach without regard to whether the conduct was religiously motivated" was generally applicable); *O'Brien*, 2012 WL 4881208, at *7 (finding that the preventive services regulations are neutral and generally applicable).[14]

Plaintiffs contend that the regulations are not generally applicable because they are "riddled with [ ] exemptions." Pls' Br. at 22. But the existence of "express exceptions for objectively defined categories of [entities]," like the ones plaintiffs reference, does not negate a law's general applicability. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *see also Olsen v. Mukasey*, 541 F.3d 827, 832 (8th Cir. 2008); *O'Brien*, 2012 WL 4481208, at *9 ("[E]xemptions undermining 'general applicability' are those tending to suggest disfavor of religion."). Nor have defendants created a system of individualized exemptions that enables the government to make a subjective, case-by-case inquiry into the reasons for the relevant conduct to grant exemptions for secular reasons but not for religious reasons. *Smith*, 494 U.S. at 884.[15]

[14] Plaintiffs also contend that the preventive services regulations are subject to strict scrutiny because they implicate "hybrid rights." Pls.' Br. at 22-23. The Third Circuit, however, has expressly declined to endorse such a theory. *See Brown v. City of Pittsburgh*, 586 F.3d 263, 284 n. 24 (3d Cir. 2009); *McTernan v. City of York, Pa.*, 564 F.3d 636, 647 n.5 (3d Cir. 2009); *Combs v. Homer-Center School Dist.*, 540 F.3d 231, 244-47 (3d Cir. 2008).

[15] Plaintiffs rely on the Third Circuit's decision in *Fraternal Order of Police Newark Lodge No. 12 v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), to suggest that the preventive services coverage regulations are not generally applicable. But *Fraternal Order* addressed only a policy that created a secular exemption but refused all religious exemptions. *Id.* at 365. The preventive services coverage regulations, in contrast, contain both secular and religious exemptions, as plaintiffs acknowledge. Pls.' Br. at 22. Thus, unlike the situation in *Fraternal Order*, there is simply no basis to infer "discriminatory intent" on the part of the government. 170 F.3d at 365.

The preventive services coverage regulations are no different from other neutral and generally applicable laws governing employers that have been upheld against free exercise challenges. *See United States v. Indianapolis Baptist Temple*, 224 F.3d 627, 629 (7th Cir. 2000) (upholding federal employment tax laws despite plaintiff's claim that they violated a religious belief requiring dissociation from secular government authority); *Am. Friends Serv.*, 951 F.2d at 960 (upholding law that required employers to verify the immigration status of their employees despite plaintiffs' assertion that their religious beliefs compelled them to employ persons without regard to immigration status); *Intercommunity Ctr. for Justice & Peace v. INS*, 910 F.2d 42, 44 (2d Cir. 1990) (same). Indeed, the highest courts of two states have rejected free exercise claims like those raised by plaintiffs here in cases challenging similar provisions of state law. *See Diocese of Albany*, 859 N.E. 2d at 468-69; *Catholic Charities of Sacramento v. Superior Court*, 85 P.3d 67, 81-87 (Cal. 2004). And the *O'Brien* court recently came to the same conclusion. *See* 2012 WL 4481208, at *7-9. Because the regulations are neutral laws of general applicability, plaintiffs have not shown a likelihood of success on their free exercise claim.[16]

C. Plaintiffs Cannot Show a Likelihood of Success on Their Free Speech Claim

The right to freedom of speech "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights* ("FAIR"), 547 U.S. 47, 61 (2006). But the preventive services coverage regulations do not require plaintiffs—or any other person, employer, or other entity—to say anything. Contrary to plaintiffs' assertion, the regulations do not require plaintiffs themselves to "embrace a particular government-favored message." Pls.' Br. at 23. Rather, the plans plaintiffs offer to their employees must cover recommended education and counseling provided by a health care provider to their participants. It is the health care provider and her patient who will be speaking, not plaintiffs. And the regulations do not purport to regulate the content of the education or counseling provided—that is between the patient and her health care provider. *See O'Brien*, 2012 WL 4481208, at *12 (observing that the

[16] Even if the regulations were not neutral and generally applicable, however, they would not violate the Free Exercise Clause because they satisfy strict scrutiny. *See supra* pp. 20-25.

preventive services coverage regulations "do not require funding of one desired viewpoint"). Plaintiffs cite nothing to suggest that an employer may refuse to provide coverage for medical services because, during the course of a medical visit, a provider or her patient may say something with which the employer disagrees. Plaintiffs' theory would preclude virtually all government efforts to regulate health coverage, as a medical visit almost invariably involves some communication between a patient and a health care provider, and there may be many instances in which the entity providing the health coverage disagrees with the content of this communication.

Thus, the regulations are not like the law at issue in *Wooley v. Maynard*, which compelled speech. 430 U.S. 705, 707 (1977) (requiring residents to display license plate that read "Live Free or Die"). Plaintiffs here are not being required to speak at all. Nor do the regulations limit what plaintiffs may say, and therefore cannot plausibly discriminate based on content or viewpoint. *Compare Rosenberger v. Rector & Visitor of the Univ. of Va.*, 515 U.S. 819, 828-37 (1995) (applying strict scrutiny to university's withholding of authorization for payments to a printer based on the views expressed in the plaintiff's student newspaper); *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 624 (1994) (concluding that requirement for cable television stations to devote a portion of their channels to the transmission of local broadcast television stations warranted intermediate scrutiny). Plaintiffs remain free under the regulations to express whatever views they may have on the use of contraceptive services (or any other health care services) as well as their views on the regulations. Indeed, consistent with the regulations, plaintiffs may encourage their employees not to use contraceptive services. The regulations thus regulate conduct, not speech.

Moreover, the conduct required by the regulations is not "inherently expressive," such that it is entitled to First Amendment protection. *FAIR*, 547 U.S. at 66. An employer that provides a health plan that covers contraceptive services, along with numerous other medical items and services, because it is required by law to do so is not engaged in the sort of conduct the Supreme Court has recognized as inherently expressive. *Compare id*. at 65-66 (making space for

military recruiters on campus is not conduct that indicates colleges' support for, or sponsorship of, recruiters' message), *with Hurley v. Irish-American Gay, Lesbian & Bisexual Grp. of Boston*, 515 U.S. 557, 568-70 (1995) (openly gay, lesbian, and bisexual group marching in parade is expressive conduct), *Texas v. Johnson*, 491 U.S. 397, 406 (1989) (flag burning is expressive conduct), *and Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 505-14 (1969) (wearing black armbands to show disapproval of Vietnam hostilities is expressive conduct). Because the regulations do not compel any speech or expressive conduct, they do not violate the Free Speech Clause. *See Catholic Charities of Sacramento*, 85 P.3d at 89 (upholding similar California law against free speech challenge because "a law regulating health care benefits is not speech").

For these reasons, plaintiffs cannot establish a likelihood of success on the merits with respect to their free speech claim. *See also O'Brien*, 2012 WL 4481208, at *11-13 (dismissing identical free speech challenge to the preventive services coverage regulations).

D. Plaintiffs Cannot Establish a Likelihood of Success on Their Establishment Clause Claim.

Plaintiffs attempt to re-write Establishment Clause jurisprudence by arguing that the Clause prohibits the government from not only expressing denominational preferences but also making any distinctions between organizations based on their purpose, character, or composition. Pls.' Br. at 23; *see also* Comp. ¶¶ 260-73. This is simply not the law.

"The clearest command of the Establishment Clause is that one religious *denomination* cannot be officially preferred over another." *Larson v. Valente*, 456 U.S. 228, 244 (1982) (emphasis added). A law that discriminates among religions by "aid[ing] one religion" or "prefer[ing] one religion over another" is subject to strict scrutiny. *Id*. at 246; *see also Olsen*, 878 F.2d at 1461 (observing that "[a] statutory exemption authorized for one church alone, and for which no other church may qualify" creates a "denominational preference"). Thus, for example, the Supreme Court has struck down on Establishment Clause grounds a state statute that was "drafted with the explicit intention" of requiring "particular religious denominations" to comply

with registration and reporting requirements while excluding other religious denominations. *Larson*, 456 U.S. at 254; *see also Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that created special school district for religious enclave of Satmar Hasidim because it "single[d] out a particular religious sect for special treatment"). The Court, on the other hand, has upheld a statute that provided an exemption from military service for persons who had a conscientious objection to all wars, but not those who objected to only a particular war. *Gillette v. United States*, 401 U.S. 437 (1971). The Court explained that the statute did not discriminate among religions because "no particular sectarian affiliation" was required to qualify for conscientious objector status. *Id*. at 450-51. "[C]onscientious objector status was available on an equal basis to both the Quaker and the Roman Catholic." *Larson*, 456 U.S. at 247 n.23; *see also Cutter v. Wilkinson*, 544 U.S. 709, 724 (2005) (upholding Religious Land Use and Institutionalized Persons Act against Establishment Clause challenge because it did not "confer[] . . . privileged status on any particular religious sect" or "single[] out [any] bona fide faith for disadvantageous treatment").

Like the statutes at issue in *Gillette* and *Cutter*, the preventive services coverage regulations do not grant any denominational preference or otherwise discriminate among religions. It is of no moment that the religious employer exemption applies to some organizations but not others. *See O'Brien*, 2012 WL 4481208, at *9-10; *Droz v. Comm'r of IRS*, 48 F.3d 1120, 1124 (9th Cir. 1995) (concluding that religious exemption from self-employment Social Security taxes did not violate the Establishment Clause even though "some individuals receive exemptions, and other individuals with identical beliefs do not"); *Diocese of Albany*, 859 N.E.2d at 468-69 (rejecting challenge to similar religious employer exemption under New York law; "this kind of distinction—not between denominations, but between religious organizations based on the nature of their activities—is not what *Larson* condemns"). The relevant inquiry is whether the distinction drawn by the regulations between exempt and non-exempt entities is based on religious affiliation. It is not.

The regulations' definition of "religious employer" does not refer to any particular denomination. The criteria for the exemption focus on the purpose and composition of the organization, not on its sectarian affiliation. The exemption is available on an equal basis to organizations affiliated with any and all religions. The regulations, therefore, do not promote some religions over others. Indeed, the Supreme Court upheld a similar statutory exemption for houses of worship in *Walz v. Tax Commission of New York*, 397 U.S. 664, 673 (1970). The statute in *Walz* exempted from property taxes all realty owned by an association organized exclusively for religious purposes and used exclusively for carrying out such purposes. *Id*. The Court determined the statute did not violate the Establishment Clause because it did not "single[] out one particular church or religious group." *Id*. The same result should obtain here. Nothing in the Establishment Clause, or the cases interpreting it, requires the government to create an exemption for all employers whenever it creates an exemption for some. Indeed, such a requirement would severely hamper the government's ability to accommodate religion. *See Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987) ("There is ample room under the Establishment Clause for 'benevolent' neutrality which will permit religious exercise to exist without sponsorship and without interference."); *Catholic Charities of Sacramento*, 85 P.3d at 79.[17]

The religious employer exemption also does not foster excessive government entanglement with religion. Pls.' Br. at 23-25. As an initial matter, plaintiffs' excessive entanglement claim is premised on speculation about how the religious employer exemption could be administered or enforced in the future. *See id.* at 24-25. Plaintiffs do not contend that the government has, in fact, made any inquiries in this regard, much less any excessively entangling ones. Indeed, as discussed above, before plaintiffs are ever subject to enforcement of the preventive services regulations by defendants, defendants will complete an amendment process to address the very types of concerns that plaintiffs raise in this case. Thus, regardless of

[17] Even if the regulations discriminate among religions (and they do not), they are valid under the Establishment Clause, because they satisfy strict scrutiny. *See supra* pp. 20-25; *Larson*, 456 U.S. at 251-52.

whether plaintiffs qualify for the religious employer exemption, it is likely that the preventive services regulations will never be enforced by the government against plaintiffs at all, obviating any need to determine whether plaintiffs qualify for the exemption. For this reason alone, plaintiffs' Establishment Clause claim should be rejected.

In any event, the religious employer exemption does not violate the prohibition against excessive entanglement between government and religion. The Supreme Court has made clear that "[n]ot all entanglements" are unconstitutional. *Agostini v. Felton*, 521 U.S. 203, 233 (1997). "Interaction between church and state is inevitable, and [the Court has] always tolerated some level of involvement between the two." *Id.* (internal citation omitted). To violate the Establishment Clause, "[e]ntanglement must be 'excessive.'" *Id.* "[R]outine regulatory interaction which involves no inquiries into religious doctrine . . . and no detailed monitoring and close administrative contact between secular and religious bodies does not . . . violate the nonentanglement command." *Hernandez v. Comm'r of Internal Revenue*, 490 U.S. 680, 697 (1989).

Any interaction between the government and religious organizations that may be necessary to administer or enforce the religious employer exemption is not so "comprehensive," *Lemon v. Kurtzman*, 403 U.S. 602, 619 (1971), or "pervasive," *Agostini v. Felton*, 521 U.S. 203, 233 (1997), as to result in excessive entanglement. Indeed, the Supreme Court has upheld laws that require government monitoring that was more onerous than any monitoring that may be required to enforce the religious employer exemption. *See Bowen v. Kendrick*, 487 U.S. 589, 615-617 (1988) (concluding there was no excessive entanglement where the government reviewed adolescent counseling programs set up by the religious institution grantees, reviewed the materials used by such grantees, and monitored the programs by periodic visits); *Roemer v. Bd. of Pub. Works of Md.*, 426 U.S. 736, 764-65 (1976) (rejecting excessive entanglement challenge where the State conducted annual audits to ensure that grants to religious colleges were not used to teach religion); *Lemon*, 403 U.S. at 614 (noting that the Supreme Court upheld an exemption for realty owned by an association organized and used exclusively for religious

purposes in *Walz*, 397 U.S. 664 (1970), even though "the State had a continuing burden to ascertain that the exempt property was in fact being used for religious worship"); *see also Agostini*, 521 U.S. at 212 (indicating that unannounced monthly visits by a public employee to religious schools to prevent and detect inculcation of religion by public employees did not constitute excessive entanglement); *United States v. Corum*, 362 F.3d 489, 496 (8th Cir. 2004) (concluding statute did not foster excessive entanglement; "Although the government, in its role as the [statute's] enforcer, may interact with religious organizations, it is not required to engage in persuasive monitoring of or intrusion into the activities of these organizations"); *cf. LeBoon v. Lancaster Jewish Cmty. Ctr.*, 503 F.3d 217, 226 (3d Cir. 2007) (relying on factors similar to the criteria for the religious employer exemption for purposes of Title VII's religious exemption). Plaintiffs therefore cannot show a likelihood of success with respect to their Establishment Clause claim. *See O'Brien*, 2012 WL 4481208, at *11.

E. The Regulations Do Not Violate the Administrative Procedure Act

Plaintiffs' argument that defendants failed to follow the procedures required by the APA in issuing the preventive services coverage regulations, *see* Pls.' Br. at 25-30, is also baseless. The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Plaintiffs' claim that defendants did not comply with these requirements ignores the relevant legal authority. Defendants issued the preventive services coverage regulations pursuant to express statutory authority granting them discretion to promulgate regulations relating to healthcare coverage on an interim final basis (i.e., without prior notice and comment). *See* 29 U.S.C. § 1191c; 26 U.S.C. 9833; 42 U.S.C. § 300gg-92.[18] Moreover, even if there had been a requirement for prior notice-and-comment—which there was not—the absence notice and comment prior to the issuance of the interim final rules would be

[18] Defendants also made a determination, in the alternative, that issuance of the regulations in interim final form was in the public interest, and thus, defendants had "good cause" to dispense with the APA's usual notice-and-comment requirements. 76 Fed. Reg. at 46,624.

harmless error because plaintiffs have since had an opportunity to comment on any perceived deficiencies in those interim final rules.

As stated in both the July 19, 2010 and August 3, 2011 interim final rules, "Section 9833 of the [Internal Revenue] Code, section 734 of ERISA, and section 2792 of the [Public Health Service] Act authorize the Secretaries of the Treasury, Labor, and HHS [ ] to promulgate any interim final rules that they determine are appropriate to carry out the provisions of Chapter 100 [ ] of the Code, part 7 of Subtitle B of Title I of ERISA, and Part A of Title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and [Internal Revenue] Code section 9815." 75 Fed. Reg. at 41729-30 (referring to 29 U.S.C. § 1191c; 26 U.S.C. § 9833; and 42 U.S.C. § 300gg-92); 76 Fed. Reg. at 46,624 (same). In light of this express statutory authority, plaintiffs' claim that defendants violated the APA by issuing the preventive services coverage regulations without prior notice-and-comment fails.

It is well-established that, when Congress sets forth its "clear intent that APA notice and comment procedures need not be followed," an agency may lawfully dispense with those requirements and issue an interim final rule. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994) (upholding issuance of interim final rule where enabling statute provided for an expedited regulatory process and instructed HHS to issue an interim final rule followed by public comment); *see also Nat'l Women, Infants, and Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 105 (D.D.C. 2006) (upholding issuance of interim final regulation where the statute provided that "[t]he Secretary may promulgate interim final regulations to implement the cost containment provision"); *Asiana Airlines v. FAA*, 134 F.3d 393, 397-98 (D.C. Cir. 1998) (upholding adoption of interim final rule where the statute instructed the FAA to "publish in the Federal Register an initial fee schedule and associated collection process as an interim final rule, pursuant to which public comment will be sought and a final rule issued"). The question in determining whether a specific statute authorizes deviation from the notice-and-comment requirement is "whether Congress has established procedures so

clearly different from those required by the APA that it must have intended to displace the norm.'" *Id.* at 397. That is precisely the case here.

The statutory provisions expressly authorizing defendants to issue interim final rules clearly and expressly reflect an intent to confer upon the Secretaries discretion to issue rules without engaging in prior notice-and-comment. Indeed, by authorizing the Secretaries to promulgate "any interim final rules as the Secretar[ies] determine[] are appropriate," 29 U.S.C. § 1191c; 26 U.S.C. § 9833; and 42 U.S.C. § 300gg-92, the rulemaking provisions confer even broader authority upon the Secretaries than the authority upheld in the above-referenced cases. Here, the statutory language unambiguously evidences Congress's "clear intent that APA notice and comment procedures need not be followed." *Methodist Hosp. of Sacramento*, 38 F.3d at 1237. *But see Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 19 (D.C.C. 2010) (declining to rely exclusively on the same congressional authorization in rejecting plaintiff's claim that issuance of an interim final rule violated the APA). In issuing the interim final rule, defendants properly exercised their discretion in balancing the need for both public input and timely guidance. For this reason alone, plaintiffs cannot show likelihood of success on the merits.

Even assuming, *arguendo*, that defendants were not authorized by statute to issue the interim final rules, the absence of prior notice and comment would constitute harmless error. The APA's judicial review provision instructs courts to take "due account . . . of the rule of prejudicial error." 5 U.S.C. § 706. And courts routinely conduct some form of harmless error analysis when they determine whether an agency has failed to comply with the APA's notice-and-comment requirement. *See, e.g.*, *Earthman v. Sherman*, No. 05-188, 2006 WL 238065, at *6 (W.D. Pa. 2006) (applying a harmless error analysis to the Bureau of Prisons's failure to provide thirty-days advance notice under the APA); *AARP v. EEOC*, 390 F. Supp. 2d 437, 461 (E.D. Pa. 2005) ("As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error") (quoting *First Am. Discount Corp. v. Commodity Futures Trading Comm'n*, 222 F.3d 1008, 1015 (D.C. Cir. 2000)); *see also Am. Radio Relay*

League, Inc. v. FCC, 524 F.3d 227, 237 (D.C. Cir. 2008) (noting that the court will not set aside a rule absent a showing by petitioners "that they suffered prejudice from the agency's failure to provide an opportunity for public comment"). The burden falls on the party asserting error to demonstrate prejudice. *AFL-CIO v. Chao*, 496 F. Supp. 2d 75, 89 (D.D.C. 2007).

In this case, plaintiffs cannot demonstrate any prejudice to plaintiffs, or similarly situated entities, stemming from the alleged deficiencies in the administrative process because plaintiffs were, in fact, given an opportunity to comment on the challenged regulations. Defendants solicited comments for two months following the effective date of the original preventive services regulations. *See* 75 Fed Reg. at 41,726 (requesting comments on or before September 17, 2010). Then, following an amendment to the interim final rules on August 3, 2011, defendants solicited comments for an additional two months. *See* 76 Fed Rag. at 46,621 (requesting comment on or before September 30, 2011). That defendants permitted two rounds of public comment "suggest[s] that [defendants have] been open-minded," with the result that "real public reconsideration of the issued rule [has taken] place." *Petry v. Block*, 737 F.2d 1193, 1203 (D.C. Cir. 1984) (finding that, in light of a post-promulgation comment period, remand to the agency for further proceedings was unnecessary); *see also Universal Health Serv. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 721 (D.D.C. 1991) ("Although post-promulgation opportunity to comment is not a substitute for pre-promulgation notice and comment, failure to comply with the pre-promulgation procedures of § 553 of the APA may 'be cured by an adequate later notice' if 'the agency's mind remain[s] open enough at the later stage."). Moreover, the preamble to the amended interim final rule reveals that plaintiffs comments, had they submitted any, would have likely been duplicative of other comments to the same effect that defendants had already received. 76 Fed. Reg. 46,623.[19] And, in response to the concerns of religious organizations, defendants authorized HRSA to exempt certain religious employers from the

[19] The same is true with respect to the guidelines developed by HRSA. As explained in the April 16, 2012 final rule, defendants received "considerable feedback regarding which preventive services for women should be covered without cost sharing," including comments that requiring contraceptive services would be contrary to some religious employers' religious tenets. *See* 77 Fed. Reg. at 8726.

requirement to cover contraceptive services. *Id.* Accordingly, it is clear that defendants enjoyed the benefit of public comment and "the parties have not been deprived of the opportunity to present relevant information by lack of notice that the issue was there." *Am. Radio Relay League, Inc.*, 524 F.3d at 236.

For these reasons, plaintiffs have failed to establish likelihood of success on the merits with respect to their APA claim.

IV. THE COURT SHOULD DENY PLAINTIFFS' REQUEST FOR A PERMANENT INJUNCTION AND A CONSOLIDATED TRIAL AND PRELIMINARY INJUNCTION HEARING

Finally, the Court should reject out of hand plaintiffs' request for a permanent injunction and consolidation of a hearing on their motion for a preliminary injunction with a trial on the merits. As discussed above, with respect to plaintiffs, the challenged regulations are currently undergoing amendment by defendants and will certainly change before they are ever enforced by the government against plaintiffs. The Court, therefore, lacks jurisdiction to hear this case, making a trial on the merits inappropriate. *See Steel Co.*, 523 U.S. at 94. Indeed, even if the Court were to find jurisdiction, any ruling now would become advisory once the accommodation is finalized regardless of whether plaintiffs are satisfied with the accommodation. If the Court were to determine that jurisdiction exists, and that plaintiffs have met their heavy burden to show that an injunction is proper (which they have not), a temporary injunction, rather than a permanent one, would provide ample protection for plaintiffs while defendants complete the amendment process, particularly in light of the fact that the regulations in their current form are not being enforced against them.

CONCLUSION

This Court should deny plaintiffs' motion for preliminary and permanent injunctions and for a Rule 65(a)(2) consolidated trial and preliminary injunction hearing.

Respectfully submitted this 16th day of October, 2012,

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CERTIFICATE OF SERVICE

I hereby certify that on October 16, 2012, I caused a true and correct copy of the foregoing to be served on plaintiffs' counsel by means of the Court's ECF system.

/s/ Bradley P. Humphreys
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