IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. 13-cv-03363-MSK-KMT

FELLOWSHIP OF CATHOLIC UNIVERSITY STUDENTS, *et al.*

Plaintiffs,

v.

KATHLEEN SEBELIUS, *et al*.

Defendants.

DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Plaintiffs Fellowship of Catholic University Students (FOCUS), Curtis A. Martin, Craig Miller, Brenda Cannella, and Cindy O'Boyle ask this Court to permanently enjoin regulations that are intended to accommodate religious exercise while helping to ensure that women have access to health coverage, without cost-sharing, for preventive services that medical experts deem necessary for women's health and well-being. Subject to an exemption for houses of worship and their integrated auxiliaries, and accommodations for certain other non-profit religious organizations, as discussed below, the regulations require certain group health plans and health insurance issuers to provide coverage, without cost-sharing (such as a copayment, coinsurance, or a deductible), for, among other things, all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

When the contraceptive-coverage requirement was first established, in August 2011, certain non-profit religious organizations objected on religious grounds to having to provide contraceptive coverage in the group health plans they offer to their employees. Although, in the

government's view, these organizations were mistaken to claim that an accommodation was required under the First Amendment or the Religious Freedom Restoration Act (RFRA), the defendant Departments decided to accommodate the concerns expressed by these organizations. First, they established an exemption for the group health plans of houses of worship and their integrated auxiliaries (and any associated group health insurance coverage). In addition, they established accommodations for the group health plans of eligible non-profit religious organizations, like plaintiffs (and any associated group health insurance coverage), that relieve them of responsibility to contract, arrange, pay, or refer for contraceptive coverage or services, but that also ensure that the women who participate in these plans are not denied access to contraceptive coverage without cost-sharing. To be eligible for an accommodation, the organization merely needs to certify that it meets the eligibility criteria, *i.e.*, that it is a non-profit organization that holds itself out as religious and has a religious objection to providing coverage for some or all contraceptives. Once the organization certifies that it meets these criteria, it need not contract, arrange, pay, or refer for contraceptive coverage or services. If the organization has third-party insurance, the third-party insurer takes on the responsibility to provide contraceptive coverage to the organization's employees and covered dependents. If the group health plan of the organization is self-insured—like FOCUS—its third-party administrator (TPA) has responsibility to arrange contraceptive coverage for the organization's employees and covered dependents. In neither case does the objecting employer bear the cost (if any) of providing contraceptive coverage; nor does it administer such coverage; nor does it contract or otherwise arrange for such coverage; nor does it refer for such coverage.

Remarkably, plaintiffs now declare that these accommodations themselves violate their rights under RFRA and the First Amendment. They contend that the mere act of certifying that FOCUS is eligible for an accommodation is a substantial burden on their religious exercise because, once FOCUS makes the certification, its employees will be able to obtain contraceptive coverage through other parties. This extraordinary contention suggests that FOCUS not only seeks to avoid paying for, administering, or otherwise providing contraceptive coverage itself,

but also seeks to prevent the women who work for the organization from obtaining such coverage, even if through other parties. At bottom, plaintiffs' position seems to be that any asserted burden, no matter how *de minimis*, amounts to a substantial burden under RFRA. That is not the law. Congress amended the initial version of RFRA to add the word "substantially," and thus made clear that "any burden" would not suffice.

Plaintiffs' claims all fail as a matter of law. As an initial matter, Mr. Martin, Mr. Miller, Ms. Cannella, and Ms. Boyle (collectively, the "individual plaintiffs") all lack standing because the preventive services coverage provision and accommodations they challenge do not apply to them; they apply to group health plans, health insurance issuers, and eligible organizations. With respect to plaintiffs' RFRA claim, plaintiffs cannot establish a substantial burden on their religious exercise—as they must—because the regulations do not require plaintiffs to change their behavior in any significant way. Plaintiffs are not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, plaintiffs are free to continue to refuse to do so, to voice their disapproval of contraception, and to encourage FOCUS's employees to refrain from using contraceptive services. FOCUS is required only to inform its TPA that it objects to providing contraceptive coverage, which it has done or would have to do voluntarily even absent these regulations in order to ensure that that it is not responsible for contracting, arranging, paying, or referring for such coverage. Plaintiffs can hardly claim that it is a violation of RFRA to require FOCUS to do almost exactly what it would do in the ordinary course. *See Priests for Life v. HHS*, __ F. Supp. 2d __, 2013 WL 6672400, at *5-10 (D.D.C. Dec. 19, 2013) (addressing these regulations), *injunction pending appeal granted*, No. 13-5368 (D.C. Cir. Dec. 31, 2013); *Univ. of Notre Dame v. Sebelius*, __ F. Supp. 2d __, 2013 WL 6804773, at *7-14 (N.D. Ind. Dec. 20, 2013) (same), *injunction pending appeal denied*, No. 13-3853 (7th Cir. Dec. 30, 2013); *Michigan Catholic Conf. v. Sebelius*, No. 1:13-CV-1247, 2013 WL 6838707, at *4-8 (W.D. Mich. Dec. 27, 2013) (same), *injunction pending appeal granted*, No. 13-2723 (6th Cir. Dec. 31, 2013). And the regulations do not require anything of the individual plaintiffs, as the regulations govern only FOCUS.

Plaintiffs' First and Fifth Amendment claims are equally meritless. Indeed, nearly every court to consider such challenges to the regulations has rejected those claims, and their analysis applies here. Plaintiffs also cannot succeed on their APA claims. They lack prudential standing to raise some of their arguments, and in any event, the regulations are in accordance with the APA and with federal law.

Accordingly, defendants respectfully ask that the Court dismiss all of plaintiffs' claims or, in the alternative, enter summary judgment in favor or defendants.

BACKGROUND

Before the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), many Americans did not receive the preventive health care they needed to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. Due largely to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), AR at 317-18, 407.[1] Section 1001 of the ACA—which includes the preventive services coverage provision relevant here—seeks to cure this problem by making preventive care accessible and affordable for many more Americans. Specifically, the provision requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing, including, "[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).[2]

[1] Where appropriate, defendants have provided parallel citations to the Administrative Record (AR).

[2] This provision also applies to immunizations, cholesterol screening, blood pressure screening, mammography, cervical cancer screening, screening and counseling for sexually transmitted infections, domestic violence counseling, depression screening, obesity screening and counseling, diet counseling, hearing loss screening for newborns, autism screening for children, developmental screening for children, alcohol misuse counseling, tobacco use counseling and interventions, well-woman visits, breastfeeding support and supplies, and many other preventive services. *See, e.g.*, U.S. Preventive Services Task Force A and B Recommendations, http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm (last visited Jan. 9, 2014).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services (HHS) requested that the Institute of Medicine (IOM) develop recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. *See* IOM REP. at 2, AR at 300.[3] After conducting an extensive science-based review, IOM 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, AR at 308-10. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices (IUDs). *See id.* at 105, AR at 403. IOM determined that coverage, without cost-sharing, for these services is necessary to increase access to such services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. *See id.* at 102-03, AR at 400-01.[4]

On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, subject to an exemption relating to certain religious employers authorized by regulations issued that same day (the "2011 amended interim final regulations"). *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84.[5]

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[3] IOM, which was established by the National Academy of Sciences in 1970, is funded by Congress to provide expert advice to the federal government on matters of public health. IOM REP. at iv, AR at 289.

[4] At least twenty-eight states have laws requiring health insurance policies that cover prescription drugs to also provide coverage for FDA-approved contraceptives. *See* GUTTMACHER INSTITUTE, STATE POLICIES IN BRIEF: INSURANCE COVERAGE OF CONTRACEPTIVES (June 2013), AR at 1023-26.

[5] To qualify for the religious employer exemption contained in the 2011 amended interim final regulations, an employer had to 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; and
(4) the organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

Group health plans established or maintained by these religious employers (and associated group health insurance coverage) are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See id.*; 45 C.F.R. § 147.131(a).

In February 2012, the government adopted in final regulations the definition of "religious employer" contained in the 2011 amended interim final regulations while also creating a temporary enforcement safe harbor for non-grandfathered group health plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). *See* 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012), AR at 213-14. The government committed to undertake a new rulemaking during the safe harbor period to adopt new regulations to further accommodate non-grandfathered non-profit religious organizations' religious objections to covering contraceptive services. *Id.* at 8728, AR at 215. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,869 (July 2, 2013), AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012) (Advance Notice of Proposed Rulemaking (ANPRM)), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013) (Notice of Proposed Rulemaking (NPRM)), AR at 165-85.

The 2013 final rules represent a significant accommodation by the government of the religious objections of certain non-profit religious organizations while promoting two important policy goals. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the compelling government interests in safeguarding public health and ensuring that women have equal access to health care. The regulations advance these interests in a narrowly tailored fashion that does not require non-profit religious organizations with religious objections to providing contraceptive coverage to contract, pay, arrange, or refer for that coverage.

The 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth criterion. *See supra* note 5. Under the 2013 final

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76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011), AR at 220.

rules, a "religious employer" is "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended," which refers to churches, their integrated auxiliaries, and conventions or associations of churches, and the exclusively religious activities of any religious order. 45 C.F.R. § 147.131(a). The changes made to the definition of religious employer in the 2013 final rules are intended to ensure "that an otherwise exempt plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths." 78 Fed. Reg. at 39,874, AR at 6.

The 2013 final rules also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations" (and group health insurance coverage provided in connection with such plans). *Id.* at 39,875-80, AR at 7-12; 45 C.F.R. § 147.131(b). An "eligible organization" is an organization that satisfies the following criteria:

> (1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.
>
> (2) The organization is organized and operates as a nonprofit entity.
>
> (3) The organization holds itself out as a religious organization.
>
> (4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies.

45 C.F.R. § 147.131(b); *see also* 78 Fed. Reg. at 39,874-75, AR at 6-7.

Under the 2013 final rules, an eligible organization is not required "to contract, arrange, pay, or refer for contraceptive coverage" to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6. To be relieved of any such obligations, the 2013 final rules require only that an eligible organization complete a self-certification form stating that it is an eligible organization and provide a copy of that self-certification to its issuer or TPA. *Id.* at 39,878-79, AR at 10-11. Its participants and beneficiaries, however, will still benefit from separate payments for

contraceptive services without cost sharing or other charge. *Id.* at 39,874, AR at 6. In the case of an organization with an insured group health plan, the organization's health insurance issuer, upon receipt of the self-certification, must provide separate payments to plan participants and beneficiaries for contraceptive services without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See id.* at 39,875-77, AR at 7-9. In the case of an organization with a self-insured group health plan—such as FOCUS—the organization's TPA, upon receipt of the self-certification, must provide or arrange separate payments for contraceptive services for participants and beneficiaries in the plan without cost-sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See id.* at 39,879-80, AR at 11-12. Any costs incurred by the TPA will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See id.* at 39,880, AR at 12.

The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, *see id.* at 39,872, AR at 4, except that the amendments to the religious employer exemption apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013, *see id.* at 39,871, AR at 3.

STANDARD OF REVIEW

Defendants move to dismiss the Complaint in its entirety for failure to state a claim upon which relief may be granted pursuant to Federal Rule of Civil Procedure 12(b)(6). Under this Rule, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Defendants also move to dismiss one count, *see infra* at Section VI.C, under Federal Rule of Civil Procedure 12(b)(1) in part for lack of subject matter jurisdiction. The party invoking federal jurisdiction bears the burden of establishing its existence, and the Court must determine whether it has jurisdiction before addressing the merits of a claim. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998).

To the extent that the Court must consider the administrative record in addition to the face of the complaint, defendants move, in the alternative, for summary judgment pursuant to Federal Rule of Civil Procedure 56. A party is entitled to summary judgment where the administrative record demonstrates "that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).[6]

ARGUMENT

I. THE INDIVIDUAL PLAINTIFFS LACK STANDING

Any claims by Mr. Martin, Mr. Miller, Ms. Cannella, and Ms. O'Boyle (collectively, the "individual plaintiffs") should be denied at the outset because those plaintiffs lack standing. "[T]he irreducible constitutional minimum of standing" requires that a plaintiff (1) have suffered an injury in fact, (2) that is caused by the defendant's conduct, and (3) that is likely to be redressed by a favorable ruling. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). As to the injury prong, a plaintiff must demonstrate that he 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." *Id.* at 560 (quotations omitted). The requirement of a causal connection between the defendant's conduct and the plaintiff's injury means that the injury must be "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Id.* (citation omitted).

Here, the individual plaintiffs cannot show that they are injured at all—let alone that their alleged injury stems from the challenged regulations—because the law they challenge *does not apply to them*. The preventive services coverage provision applies to "group health plans" and "health insurance issuers," 42 U.S.C. § 300gg-13; 45 C.F.R. § 147.130(a)(1) ("[A] group health plan, or a health insurance issuer offering group or individual health insurance coverage, must

[6] Plaintiffs assert that "[n]one of the facts alleged in Plaintiffs' First Amended Verified Compliant (Doc. 10) ('Verified Complaint') . . . are in dispute." Pls.' Mot. for Partial Summ. J. ("Pls.' Mot.") at 6, ECF No. 12. Although defendants' do not dispute the sincerity of plaintiffs' religious beliefs, defendants disagree with this blanket statement and dispute, among other things, plaintiffs' characterizations of the operation of the challenged regulations and the rulemaking process. Defendants do agree, however, that there are no *material* issues of fact that would preclude the Court from deciding this case as a matter of law.

provide coverage for all of the following items and services."), and the accommodations pertain to "eligible organizations," 29 C.F.R. § 2590.715-2713A(a), (b). The individual plaintiffs are none of these. Thus, the only provision that the individual plaintiffs challenge imposes no direct obligation or requirement on them. The challenged regulations do not require the individual plaintiffs to purchase a health insurance policy that covers contraception. Nor do they require them to sign the self-certification form. The obligations imposed by the challenged regulations are instead placed on FOCUS's group health plan. And, under the accommodations, the self-certification form may be signed by any individual authorized to make the necessary certification *on behalf of the organization*. The individual plaintiffs' attempt to piggyback their claims onto those of FOCUS fails as a matter of law. *See, e.g.*, *Potthoff v. Morin*, 245 F.3d 710, 716 (8th Cir. 2001) ("Generally, if a harm has been directed toward the corporation, then only the corporation has standing to assert a claim[.]"); *Smith Setzer & Sons, Inc. v. S.C. Procurement Review Panel*, 20 F.3d 1311, 1317 (4th Cir. 1994) ("It is considered a fundamental rule that [a] shareholder—even the sole shareholder—does not have standing to assert claims alleging wrongs to the corporation."); *see also Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001) ("[I]ncorporation's basic purpose is to create a distinct legal entity, with legal rights, obligations, powers, and privileges different from those of the natural individuals who created it, who own it, or whom it employs."); *Autocam Corp. v. Sebelius*, 730 F.3d 618, 623 (6th Cir. 2013). For similar reasons, the relief plaintiffs seek—a permanent injunction exempting FOCUS from the accommodations and the contraceptive coverage requirement—does not follow from any alleged injury to the individual plaintiffs. The Court, therefore, should dismiss the individual plaintiffs' claims for lack of jurisdiction.

II. PLAINTIFFS' RELIGIOUS FREEDOM RESTORATION ACT CLAIM FAILS

Under RFRA, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified at 42 U.S.C. § 2000bb-1 *et seq.*), the federal government "shall not substantially burden a person's exercise of religion" unless that burden is the least restrictive means to further a compelling governmental interest. 42 U.S.C. 2000bb-1. Importantly, "only *substantial* burdens on the exercise of religion

trigger the compelling interest requirement." *Henderson v. Kennedy*, 253 F.3d 12, 17 (D.C. Cir. 2001) (emphasis added). "A substantial burden exists when government action puts 'substantial pressure on an adherent to modify his behavior and to violate his beliefs.'" *Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008) (citing *Thomas v. Review Bd. of the Ind. Emp't Sec. Div.*, 450 U.S. 707, 718 (1981)). "An inconsequential or *de minimis* burden on religious practice does not rise to this level, nor does a burden on activity unimportant to the adherent's religious scheme." *Kaemmerling*, 553 F.3d at 678; *see Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) ("In order to show a substantial burden, the plaintiff must show that the challenged action 'truly pressures the adherent to significantly modify his religious behavior and significantly violate his religious beliefs.'").

Plaintiffs cannot show—as they must—that the challenged regulations substantially burden their religious exercise. Plaintiffs contend the Tenth Circuit's decision in *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc) controls here, Pls.' Mot. at 9, but it does not. *Hobby Lobby* addressed the RFRA claim of for-profit corporations, which, unlike FOCUS, are not eligible for the accommodations and thus are required by the regulations to contract, arrange, and pay for contraceptive coverage for their employees. The court had no occasion to consider whether the regulation's accommodations, which relieve eligible non-profit religious organizations like FOCUS of any obligation to contract, arrange, pay, or refer for contraceptive coverage, impose a substantial burden on religious exercise. They do not for the reasons discussed below.

The regulations do not impose a substantial burden on plaintiffs because they do not require plaintiffs to modify their behavior in any meaningful way. *See Priests for Life*, 2013 WL 6672400, at *5-10; *Notre Dame*, 2013 WL 6804773, at *7-14; *Michigan Catholic Conf.*, 2013 WL 6838707, at *4-8. To put this case in its simplest terms, plaintiffs challenge regulations that require them to do next to nothing, except what they would have to do even in the absence of the regulations. As explained above, the regulations require nothing of the individual plaintiffs (*i.e.*, Mr. Martin, Mr. Miller, Ms. Cannella, and Ms. O'Boyle), and thus cannot impose a substantial

burden on their religious exercise. Moreover, FOCUS, as an eligible organization, is not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, it is free to continue to refuse to do so, to voice its disapproval of contraception, and to encourage its employees to refrain from using contraceptive services. FOCUS need only fulfill the self-certification requirement and provide the completed self-certification to its TPA. It need not provide payments for contraceptive services to its employees. Instead, a third party—FOCUS's TPA—provides payments for contraceptive services, at no cost to FOCUS. In short, with respect to contraceptive coverage, FOCUS need not do anything more than it did prior to the promulgation of the challenged regulations—that is, to inform its TPA that it objects to providing contraceptive coverage in order to ensure that it is not responsible for contracting, arranging, paying, or referring for such coverage. Thus, the regulations do not require plaintiffs "to modify [their] religious behavior in any way." *Kaemmerling*, 553 F.3d at 679. The Court's inquiry should end here. A law cannot be a substantial burden on religious exercise when "it involves no action or forbearance on [plaintiffs'] part, nor . . . otherwise interfere[s] with any religious act in which [plaintiffs] engage[]." *Kaemmerling*, 553 F.3d at 679.

Because the regulations place no burden *at all* on plaintiffs, they plainly place no cognizable burden on their religious exercise. Plaintiffs' contrary argument rests on an unprecedented and sweeping theory of what it means for religious exercise to be burdened. Not only does FOCUS want to be free from contracting, arranging, paying, or referring for contraceptive services for its employees—which, under these regulations, it is—but plaintiffs would also prevent *anyone else* from providing such coverage to FOCUS's employees and their covered dependents, who might not subscribe to FOCUS's religious beliefs. That this is the *de facto* impact of plaintiffs' stated objections is made clear by their assertion that RFRA is violated whenever FOCUS "trigger[s]" a third party's provision to FOCUS's employees of services to which FOCUS objects. Am. Compl. ¶¶ 61, 129, 139, ECF No. 10. This theory would mean, for example, that even the government itself would not realistically be able to provide contraceptive coverage to FOCUS's employees directly, because such coverage would be "trigger[ed]," *id.*, by

FOCUS's objection to providing such coverage itself. But RFRA is a shield, not a sword, *see O'Brien v. HHS*, 894 F. Supp. 2d 1149, 1158-60 (E.D. Mo. 2012), and accordingly it does not prevent the government from providing alternative means of achieving important statutory objectives once it has provided a religious accommodation. *Michigan Catholic Conf.*, 2013 WL 6838707, at *8 ("The fact that the scheme will continue to operate without them may offend Plaintiffs' religious beliefs, but it does not substantially burden the exercise of those beliefs."); *Notre Dame*, 2013 WL 6804773, at *8 ("Boiled to its essence, what Notre Dame essentially claims is that the government's action after Notre Dame opts out, in requiring the TPA to cover contraception, offends Notre Dame's religious sensibilities. And while I accept that the government's and TPA's actions do offend Notre Dame's religious views, it's not Notre Dame's prerogative to dictate what healthcare services third parties may provide."); *cf. Bowen v. Roy*, 476 U.S. 693, 699 (1986) ("The Free Exercise Clause simply cannot be understood to require the Government to conduct its own internal affairs in ways that comport with the religious beliefs of particular citizens.").

Plaintiffs' RFRA challenge is similar to the claim that the D.C. Circuit rejected in *Kaemmerling*. There, a federal prisoner objected to the FBI's collection of his DNA profile. 553 F.3d at 678. In concluding that this collection did not substantially burden the prisoner's religious exercise, the court reasoned that "[t]he extraction and storage of DNA information are entirely activities of the FBI, in which Kaemmerling plays no role and which occur after the BOP has taken his fluid or tissue sample (to which he does not object)." *Id.* at 679. In the court's view, "[a]lthough the government's activities with his fluid or tissue sample after the BOP takes it may offend Kaemmerling's religious beliefs, they cannot be said to hamper his religious exercise because they do not pressure [him] to modify his behavior and to violate his beliefs." *Id.* (internal citation and quotation marks omitted). The same is true here, where the provision of contraceptive services is "entirely [an] activit[y] of [a third party], in which [plaintiffs] play[] no role." *Id.* As in *Kaemmerling*, "[a]lthough the [third party]'s activities . . . may offend [plaintiffs'] religious beliefs, they cannot be said to hamper [their] religious exercise." *Id.*

Perhaps understanding the tenuous ground on which their RFRA claim rests, given that the regulations do not require FOCUS to contract, arrange, pay, or refer for contraceptive services, plaintiffs attempt to circumvent this problem by framing the allegation in their complaint as part of a novel theory that the regulations require FOCUS to somehow "facilitate[e]" access to contraception coverage, and that it is this facilitation that violates plaintiffs' religious beliefs. *See, e.g.*, Am. Compl. ¶ 141; Pls.' Mot. at 5. But under the challenged regulations FOCUS need *only* self-certify that it objects to providing coverage for contraceptive services and that it otherwise meets the criteria for an eligible organization, and to share that self-certification with its TPA. In other words, FOCUS is required to inform its TPA that it objects to providing contraceptive coverage, which it has done or would have to do voluntarily anyway even absent these regulations in order to ensure that it is not responsible for contracting, arranging, paying, or referring for contraceptive coverage. The sole difference is that FOCUS must inform its TPA that its objection is for religious reasons—a statement which it has already made repeatedly in this litigation and elsewhere.[7] This does not amount to a substantial burden under RFRA. *Michigan Catholic Conf.*, 2013 WL 6838707, at *7 ("[T]he contraceptive mandate requires Catholic Charities to do what it has always done—sponsor a plan for its employees, contract with a TPA, and notify the TPA that it objects to providing contraceptive coverage. Thus, Plaintiffs are not require[d] to 'modify [their] behavior.' . . . Although the TPA's action may be deeply offensive to the religious beliefs of Plaintiffs, RFRA does not allow a plaintiff to restrain the behavior of a third party that conflicts with the plaintiff's religious beliefs.") (citation omitted); *Notre Dame*, 2013 WL 6804773, at *12 ("Notre Dame isn't being

[7] At several points, plaintiffs highlight in their motion for partial summary judgment that, for self-insured eligible organizations, the self-certification form acts "as a designation of the third party administrator(s) as plan administrator and claims administrator for contraceptive benefits." 78 Fed. Reg. at 39,879, AR at 11; *see also* Pls.' Mot. at 4, 10, 25. It is not clear what legal significance plaintiffs attach to this statement, but what is clear is that self-insured entities are subject to the exact same self-certification requirement as third-party-insured entities; they will use the same self-certification form, on which they will state only that they have a religious objection to providing contraceptive coverage—nothing more. As discussed above, this self-certification requirement is, at most, a *de minimis* administrative burden that requires no more of eligible employers—whether self-insured or third-party-insured—than what they would have to do anyway absent the challenged regulations.

required to do anything new or different—its action is the same, although, granted, the result is different due to the actions of the TPA and the government. As I've said, Notre Dame may find the act of opting out less spiritually fulfilling now, but that doesn't make it a new action."); *Priests for Life*, 2013 WL 6672400, at *8 ("This is where Plaintiffs' RFRA challenge must fail—like the challenges in *Kaemmerling* and *Bowen*, the accommodations to the contraceptive mandate simply do not require Plaintiffs to modify their religious behavior."). Any burden imposed by the purely administrative self-certification requirement—which should take FOCUS a matter of minutes—is, at most, *de minimis*, and thus cannot be "substantial" under RFRA.[8]

The mere fact that a plaintiff may claim that the self-certification requirement imposes a substantial burden on its religious exercise does not make it so. *See Priests for Life*, 2013 WL 6672400, at *8 n.5 ("[T]he Court is not persuaded . . . that a plaintiff can meet his burden of establishing that the accommodation creates a 'substantial burden' upon his exercise of religion simply because he claims it to be so."); *Conestoga Wood Specialties Corp. v. Sebelius*, 917 F. Supp. 2d 394, 413 (E.D. Pa. 2013) (same), *aff'd*, 724 F.3d 377 (3d Cir. 2013). Under RFRA, plaintiffs are entitled to their sincere religious beliefs, but they are not entitled to decide what does and does not impose a substantial burden on such beliefs. Although "[c]ourts are not arbiters of scriptural interpretation," *Thomas*, 450 U.S. at 716, "RFRA still requires the court to determine whether the burden a law imposes on a plaintiff's stated religious belief is 'substantial.'" *Conestoga*, 917 F. Supp. 2d at 413. Plaintiffs would limit the Court's inquiry to two prongs: first, whether plaintiffs' religious objection to the challenged regulations are sincere, and second, whether the regulations apply significant pressure to plaintiffs to comply. But plaintiffs ignore a critical third criterion of the "substantial burden" test, which gives meaning to the term "substantial": whether the challenged regulations actually require plaintiffs to modify

[8] RFRA's legislative history makes clear that Congress did not intend such a relaxed standard. The initial version of RFRA prohibited the government from imposing *any* "burden" on free exercise, substantial or otherwise. Congress amended the bill to add the word "substantially," "to make it clear that the compelling interest standards set forth in the act" apply "only to Government actions [that] place a substantial burden on the exercise of" religious liberty. 139 Cong. Rec. S14350-01, S14352 (daily ed. Oct. 26, 1993) (statement of Sen. Kennedy); *see also id.* (text of Amendment No. 1082).

their behavior in a significant—or more than *de minimis*—way. *See Living Water Church of God v. Charter Twp. Of Meridian*, 258 Fed. App'x 729, 734-36 (6th Cir. 2007) (reviewing cases); *see also, e.g.*, *Garner*, 713 F.3d at 241; *Westchester Day Sch. v. Vill. of Mamaroneck*, 504 F.3d 338, 348-49 (2d Cir. 2007).

The Tenth Circuit's decision in *Hobby Lobby* is not to the contrary. There, the court observed that, in determining whether an alleged burden is substantial, the court's "only task is to determine whether the claimant's belief is sincere, and if so, whether the government has applied substantial pressure on the claimant to violate that belief." 723 F.3d at 1137. But, because the for-profit corporation plaintiffs in that case were not eligible for the accommodations (and thus were required to contract, arrange, and pay for contraceptive coverage), the court did not address whether an accommodation that requires a plaintiff to do nothing beyond satisfying a purely administrative self-certification requirement imposes a substantial burden on religious exercise. Indeed, the *Hobby Lobby* court relied heavily on *Abdulhaseeb v. Calbone*, 600 F.3d 1301 (10th Cir. 2010), which makes clear that, for a law to impose a substantial burden, it must require some actual change in religious behavior—either forced participation in conduct or forced abstention from conduct. *See Hobby Lobby*, 723 F.3d at 1138 ("[A] government act imposes a 'substantial burden' on religious exercise if it: (1) '*requires participation* in an activity prohibited by a sincerely held religious belief,' (2) '*prevents participation in conduct* motivated by a sincerely held religious belief,' or (3) 'places substantial pressure on an adherent . . . *to engage in conduct* contrary to a sincerely held religious belief." (emphasis added) (citing *Abdulhaseeb*, 600 F.3d at 1315)). Because the challenged regulations require that FOCUS take the *de minimis* step that it would have to take even in the absence of the regulations (and require nothing of the individual plaintiffs), the regulations do not impose a substantial burden on plaintiffs' religious exercise.

The challenged regulations also do not impose a substantial burden on plaintiffs' religious exercise because any burden is indirect and too attenuated to be substantial. *See Catholic Diocese of Nashville v. Sebelius*, No. 3:13-01303, 2013 WL 6834375, at *4-5 (M.D.

Tenn. Dec. 26, 2013), *injunction pending appeal granted*, No. 13-6640 (6th Cir. Dec. 31, 2013) (addressing these regulations). The ultimate decision of whether to use contraception "rests not with [the employer], but with [the] employees" in consultation with their health care providers. *Conestoga*, 917 F. Supp. 2d at 414-15; *see also, e.g., Autocam Corp. v. Sebelius*, 2012 WL 6845677, at *6 (W.D. Mich. Dec. 24, 2012) ("The incremental difference between providing the benefit directly, rather than indirectly, is unlikely to qualify as a substantial burden on the Autocam Plaintiffs."). Moreover, even if the challenged regulations were deemed to impose a substantial burden on plaintiffs' religious exercise, the regulations satisfy strict scrutiny because they are narrowly tailored to serve compelling governmental interests in public health and gender equality. Defendants recognize that a majority of the en banc Tenth Circuit rejected these arguments in *Hobby Lobby*, and that this Court is bound by that decision. The Supreme Court is currently reviewing the Tenth Circuit's decision. Defendants raise the arguments here merely to preserve them for appeal.

For these reasons, plaintiffs' RFRA claim fails as a matter of law.

II. The Regulations Do Not Violate the Free Exercise Clause

A law that is neutral and generally applicable does not run afoul of the Free Exercise Clause even if it prescribes conduct that an individual's religion proscribes or has the incidental effect of burdening a particular religious practice. *Empt. Div., Dep't of Human Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990); *see also Lukumi*, 508 U.S. 520, 531-32 (1993). "Neutrality and general applicability are interrelated." *Lukumi*, 508 U.S. at 531. A law is neutral if it does not target religiously motivated conduct either on its face or as applied. *Id*. at 533. A neutral law has as its purpose something other than the disapproval of a particular religion, or of religion in general. *Id*. at 545. A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id*.

Unlike such selective laws, the preventive services coverage regulations are neutral and generally applicable. Indeed, every court to have considered a free exercise challenge to these regulations has rejected it, concluding that the regulations are neutral and generally applicable.

See Priests for Life, 2013 WL 6672400, at *10-12, *Notre Dame*, 2013 WL 6804773, at *14-18; *Archbishop of Washington*, 2013 WL 6729515, at *27-31; *Diocese of Nashville*, 2013 WL 6834375, at *5-7; *Michigan Catholic Conf.*, 2013 WL 6838707, at *8-9.[9] "The regulations were passed, not with the object of interfering with religious practices, but instead to improve women's access to health care and lessen the disparity between men's and women's healthcare costs." *O'Brien*, 894 F. Supp. 2d at 1161; *see also Notre Dame*, 2013 WL 6804773, at *16 ("The laws and regulations in question, as well as the legislative history, further show that the ACA and related regulations were enacted for reasons neutral to religion."). The regulations reflect expert medical recommendations about the medical necessity of contraceptive services, without regard to any religious motivations for or against such services. *See, e.g.*, *Conestoga*, 917 F. Supp. 2d at 410 ("It is clear from the history of the regulations and the report published by the Institute of Medicine that the purpose of the [regulations] is not to target religion, but instead to promote public health and gender equality."); *Notre Dame*, 2013 WL 6804773, at *17 (same, and finding it "abundantly clear" that the regulations are neutral).

The regulations, moreover, do not pursue their purpose "only against conduct motivated by religious belief." *Lukumi*, 508 U.S. at 545; *see 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). The regulations apply to all non-grandfathered health plans that do not qualify for the religious employer exemption or the accommodations for eligible organizations. Thus, "it is just not true . . . that the burdens of the

[9] Likewise, nearly every court to have considered a free exercise challenge to the prior version of the regulations rejected it. *See MK Chambers Co. v. U.S. Dep't of Health & Human Servs.*, Civil Action No. 13–11379, 2013 WL 1340719, at *5 (E.D. Mich. Apr. 3, 2013); *Eden Foods*, 2013 WL 1190001, at *4-5; *Conestoga*, 917 F. Supp. 2d at 409-10; *Grote*, 914 F. Supp. 2d at 952-53; *Autocam*, 2012 WL 6845677, at *5; *Korte v. HHS*, 912 F. Supp. 2d 735, 744-47 (S.D. Ill. 2012), *rev'd on other grounds sub nom. Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013); *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp. 2d 1278, 1289-90 (W.D. Okla. 2012), *rev'd on other grounds*, 723 F.3d 1114 (10th Cir. 2013) (en banc), *cert. granted*, 134 S. Ct. 678 (2013); *O'Brien*, 894 F. Supp. 2d at 1160-62; *see also Catholic Charities of Diocese of Albany*, 859 N.E.2d at 468-69 (rejecting similar challenge to state law); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 81-87 (Cal. 2004). *But see Sharpe Holdings, Inc. v. HHS*, No. 2:12-CV-92-DDN, 2012 WL 6738489, at *5 (E.D. Mo. Dec. 31, 2012); *Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 435-37 (W.D. Penn. 2013).

[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 O'Brien*, 894 F. Supp. 2d at 1162; *Autocam*, 2012 WL 6845677, at *5; *Grote*, 914 F. Supp. 2d at 953.

The Tenth Circuit has made clear that the existence of "express categorical exceptions for objectively defined categories of [entities]," like grandfathered plans and religious employers, does not negate a law's general applicability. *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *see also Grace United Methodist Church v. City of Cheyenne*, 451 F.3d 643, 651 (10th Cir. 2006) (refusing to "interpret Smith as standing for the proposition that a secular exemption automatically creates a claim for a religious exemption"); *Swanson v. Guthrie Indep. Sch. Dist.*, 135 F.3d 694, 698, 701 (10th Cir. 1998) (concluding school's attendance policy was not subject to strict scrutiny despite exemptions for "strict categories of students," such as fifth-year seniors and special education students). The exception for grandfathered plans is available on equal terms to all employers, whether religious or secular. And the religious employer exemption and eligible organization accommodations serve to accommodate religion, not to disfavor it. Such categorical exceptions do not trigger strict scrutiny. *See, e.g.*, *Priests for Life*, 2013 WL 6672400, at *11; *Notre Dame*, 2013 WL 6804773 (same); Autocam, 2012 WL 6845677, at *5; *O'Brien*, 894 F. Supp. 2d at 1162.[10]

[10] Grandfathering is not specifically limited to the preventive services coverage regulations. S*ee* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. Moreover, the effect of grandfathering is not a permanent "exemption," but rather, over the long term, a transition in the marketplace with respect to several provisions of the ACA, including the preventive services coverage provision. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19; *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012 Annual Survey at 7-8, 190 (indicating that 58 percent of firms had at least one grandfathered health plan in 2012, down from 72 percent in 2011, and that 48 percent of covered workers were in grandfathered health plans in 2012, down from 56 percent in 2011), AR at 663-64, 846.

The other supposed "exemptions" plaintiffs cite (Am. Compl. ¶ 193) are entirely unrelated to the preventive services coverage provision. First, while 26 U.S.C. § 5000A(d)(2) exempts from the minimum coverage provision of the ACA "member[s] of a recognized religious sect or division thereof" who, on the basis of their religion, are opposed to the concept of health insurance and members of health care sharing ministries, this provision is entirely unrelated to the preventive services coverage regulations. *See also id.* § 1402(g)(1). The minimum coverage provision provides no exemption from the regulations plaintiffs challenge, as it only excludes certain *individuals* from the requirement to obtain health coverage and says nothing about the requirement that non-grandfathered group health plans provide recommended preventive services coverage without cost sharing. It is also clearly an attempt by Congress to *accommodate* religion and, unlike the broad exemption plaintiffs seek, is sufficiently narrow so as not to undermine the larger administrative scheme. *See Lee*, 455 U.S. at 260-61. Exempting these discrete and "readily

"[C]arving out an exemption for defined religious entities [also] does not make a law non-neutral as to others." *Grote*, 914 F. Supp. 2d at 953 (quotation omitted). Indeed, the religious employer exemption "presents a strong argument in favor of neutrality" by "demonstrating that the object of the law was not to infringe upon or restrict practices because of their religious motivation." *O'Brien*, 894 F. Supp. 2d at 1161 (quotations omitted); *see Conestoga*, 917 F. Supp. 2d at 410 ("The fact that exemptions were made for religious employers . . . . shows that the government made efforts to accommodate religious beliefs, which counsels in favor of the regulations' neutrality."). The regulations are not rendered unlawful "merely because the [religious employer exemption] does not extend as far as Plaintiffs wish." *Grote*, 914 F. Supp. 2d at 953.

Plaintiffs' reliance on *Lukumi*, 508 U.S. 520, is of no help, as this case is a far cry from *Lukumi*, where the legislature specifically targeted the religious exercise of members of a single church (Santeria) by enacting ordinances that used terms such as "sacrifice" and "ritual," *id*. at 533-34, and prohibited few, if any, animal killings other than Santeria sacrifices, *id*. at 535-36. Here, there is no indication that the regulations are anything other than an effort to increase women's access to and utilization of recommended preventive services. *See, e.g.*, *O'Brien*, 894 F. Supp. 2d at 1161; *Conestoga*, 917 F. Supp. 2d at 410. And it cannot be disputed that defendants have made extensive efforts—through the religious employer exemption and the eligible organization accommodations—to accommodate religion in ways that will not

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identifiable," *id.*, classes of individuals from the minimum coverage provision is unlikely to appreciably undermine the compelling interests motivating the preventive services coverage regulations. By definition, a woman who is "conscientiously opposed to acceptance of the benefits of any private or public insurance which . . . makes payments toward the cost of, or provides services for, medical care," 26 U.S.C. § 1402(g)(1), or is a member of a health care sharing ministry described in 26 U.S.C. § 5000A(d)(2)(B)(ii) would not utilize health coverage—including contraceptive coverage—even if it were offered.

Second, 26 U.S.C. § 4980H(c)(2) does *not*, as plaintiffs assert, exempt small employers from the challenged regulations. Small businesses that elect to offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive health services without cost sharing. *See* 42 U.S.C. § 300gg-13. And, small employers have business incentives to offer health coverage to their employees; an otherwise eligible small employer would lose eligibility for certain tax benefits if it did not do so. *See* 26 U.S.C. § 45R.

undermine the goal of ensuring that women have access to coverage for recommended preventive services without cost sharing.[11] Accordingly, plaintiffs' free exercise claim fails.[12]

III. The Regulations Do Not Violate the Establishment Clause

Every court to have considered an Establishment Clause challenge to both these regulations and to the prior version of the regulations has rejected it. *See Notre Dame*, 2013 WL 6804773, at *18-20; *Priests for Life*, 2013 WL 6672400, at *14; *Roman Catholic Archbishop of Washington v. Sebelius*, __ F. Supp. 2d __, 2013 WL 6729515, at *39-43 (D.D.C. Dec. 20, 2013); *Diocese of Nashville*, 2013 WL 6834375, at *8-10; *Michigan Catholic Conf.*, 2013 WL 6838707, at *11; see also, e.g., *O'Brien*, 894 F. Supp. 2d at 1162 (upholding prior version of regulations); *Conestoga*, 917 F. Supp. 2d at 416-17; *Grote Indus. v. Sebelius*, 914 F. Supp. 2d 943, 954 (S.D. Ind. 2012), *rev'd on other grounds sub nom. Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013). This Court should do the same.

"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[ring] one religion over another" is subject to strict scrutiny. *Id*. at 246; *see also Olsen v. DEA*, 878 F.2d 1458, 1461 (D.C. Cir. 1989) (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

[11] *Fraternal Order of Police v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), and *Blackhawk v. Pennsylvania*, 381 F.3d 202 (3d Cir. 2004), on which plaintiffs rely, addressed a policy that created a secular exemption but refused all religious exemptions. The challenged regulations, in contrast, contain an exemption and accommodations that specifically seek to accommodate religion. Thus, there is simply no basis in this case to infer a discriminatory object behind the regulations. *See Conestoga*, 917 F. Supp. 2d at 409-10.

[12] Even if the regulations were not neutral or generally applicable, plaintiffs would still be required to demonstrate that the regulations substantially burden their religious exercise to prevail on their free exercise claim, *see Levitan v. Ashcroft*, 281 F.3d 1313, 1320 (D.C. Cir. 2002) ("[T]he First Amendment is implicated when a law or regulation imposes a substantial, as opposed to inconsequential, burden on the litigant's religious practice."), which they cannot do for the reasons explained above.

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 RLUIPA 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 and accommodations for eligible organizations apply to some employers but not others. "[T]he Establishment Clause does not prohibit the government from [differentiating between organizations based on their structure and purpose] when granting religious accommodations as long as the distinction[s] drawn by the regulations . . . [are] not based on religious affiliation." *Grote*, 914 F. Supp. 2d at 954; *accord O'Brien*, 894 F. Supp. 2d at 1163; *see also, e.g., Children's Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084, 1090-93 (8th Cir. 2000); *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"); *Catholic Charities of Diocese of Albany v. Serio*, 859 N.E.2d 459, 468-69 (N.Y. 2006) ("This kind of distinction—not between

denominations, but between religious organizations based on the nature of their activities—is not what *Larson* condemns.").

Moreover, plaintiffs stretch *Colorado Christian University v. Weaver*, 534 F.3d 1245 (10th Cir. 2008), well beyond its facts in asserting that the case stands for the proposition that the Establishment Clause prohibits the government from distinguishing among different types of organizations that adhere to the same religion. *See* Pls.' Mot. at 22-23. The court's decision in *Weaver* was limited to "laws that facially regulate religious issues," *id*. at 1257, and, particularly, those that do so in a way that denies certain religious institutions public benefits that are afforded to all other institutions, whether secular or religious. *Weaver* says nothing about the constitutionality of exemptions from generally applicable laws that are designed to accommodate religion, as opposed to discriminate against religion. A requirement that any religious exemption that the government creates must be extended to all organizations—no matter their structure or purpose—would severely hamper the government's ability to accommodate religion. *See Corp. of Presiding Bishop of 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 Diocese of Albany*, 859 N.E.2d at 464 ("To hold that any religious exemption that is not all-inclusive renders a statute non-neutral would be to discourage the enactment of any such exemptions—and thus to restrict, rather than promote, freedom of religion.").

The distinctions established by the regulations at issue here are not distinctions among denominations. The regulations' definitions of religious employer and eligible organization "do[] not refer to any particular denomination." *Grote*, 914 F. Supp. 2d at 954. The exemption and accommodations are available on an equal basis to organizations affiliated with any and all religions. Therefore, as every court to consider the question has held, the regulations do not discriminate among religions in violation of the Establishment Clause. *See infra*; *see also Liberty Univ., Inc. v. Lew*, 733 F.3d 72, 100-102 (4th Cir. 2013) (upholding another religious exemption

contained in the ACA against an Establishment Clause challenge because the exemption "makes no explicit and deliberate distinctions between sects" (quotation omitted)).

The Supreme Court has "frequently articulated" that "there is space between the religion clauses, in which there is 'room for play in the joints;' government may encourage the free exercise of religion by granting religious accommodations, even if not required by the Free Exercise Clause, without running afoul of the Establishment Clause." *O'Brien*, 894 F. Supp. 2d at 1163 (citations omitted). Accommodations of religion are possible because the type of legislative line-drawing to which the plaintiffs object in this case is constitutionally permissible. *Id*.; *Conestoga*, 917 F. Supp. 2d at 417; *see, e.g.*, *Walz v. Tax Commission of New York*, 397 U.S. 664, 672-73 (1970) (upholding property tax exemption "to religious organizations for religious properties used solely for religious worship"); *Amos*, 483 U.S. at 334 (upholding Title VII's exemption for religious organizations). Plaintiffs' Establishment Clause claim, therefore, lacks merit.[13]

IV. The Regulations Do Not Violate the Right to Free Speech or Expressive Association

Plaintiffs' free speech claim fares no better. The right to freedom of speech "prohibits the government from telling people what they must say." *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* ("*FAIR*"), 547 U.S. 47, 61 (2006). But the preventive services coverage regulations do not "compel speech"—by plaintiffs or any other person, employer, or entity—in violation of the First Amendment. Nor do they limit what plaintiffs may say. Plaintiffs remain free under the

[13] Plaintiffs also assert that the government's rationale for distinguishing between houses of worship and their integrated auxiliaries and other non-profit religious organizations does not necessarily apply to FOCUS's employees, who may be as likely to share the organization's religious beliefs as the employees of a house of worship or integrated auxiliary. *See* Pls.' Mot. at 20. Even assuming this assertion is true, it does not render the distinctions drawn by the government—which are based on the general characteristics of houses of worship and integrated auxiliaries as compared to those of other non-profit religious organizations, and not the characteristics of the specific organization here—unlawful. *See, e.g.*, *Turner Construction Co. v. United States*, 94 Fed. Cl. 561, 571 (Fed. Cl. 2010) (observing that a reviewing court is not to "sift through an agency's rationale with a fine-toothed comb;" instead, the relevant question is whether the agency articulated a rational connection between the facts found and the choice made). Moreover, defendants' decision to incorporate long-standing concepts from the tax code that refer to churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order, in an effort to avoid entangling inquiries regarding the religious beliefs of plaintiffs' employees, is reasonable.

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 about the regulations. Plaintiffs, moreover, may encourage FOCUS's employees not to use contraceptive services.

As plaintiffs point out, to avail itself of an accommodation, an organization must self-certify that it meets the definition of "eligible organization." Plaintiffs appear to object to the self-certification to the extent that it results in FOCUS's TPA making separate payments for contraceptive services for its employees. But completion of the simple self-certification form is "plainly incidental to the . . . regulation of conduct," *FAIR*, 547 U.S. at 62, not speech. Indeed, every court to review a free speech challenge like plaintiffs' as to both the challenged regulations and the prior contraceptive-coverage regulations has rejected it, in part, because the regulations deal with conduct. *See Priests for Life*, 2013 WL 6672400, at *12-14 ("The regulations regarding contraceptive coverage, including the accommodation, place no limits on what Plaintiffs may say; they remain free to oppose contraceptive coverage for all people and in all forms. Rather, the accommodation regulates conduct . . . And like the law schools in *FAIR*, the only speech the accommodations require of Priests for Life is incidental to the regulation of conduct."); *Notre Dame*, 2013 WL 6804773, at *20-21; *Archbishop of Washington*, 2013 WL 6729515, at *31-36; *Diocese of Nashville*, 2013 WL 6834375, at *7-8; *Michigan Catholic Conf.*, 2013 WL 6838707, at *9-10; *see also, e.g.*, *MK Chambers*, 2013 WL 1340719, at *6; *Briscoe v. Sebelius*, 927 F. Supp. 2d 1109 (D. Colo. 2013); *Conestoga*, 917 F. Supp. 2d at 418; *Grote*, 914 F. Supp. at 955; *Autocam*, 2012 WL 6845677, *8; *O'Brien*, 894 F. Supp. 2d at 1165-67; *see also Catholic Charities of Sacramento*, 85 P.3d at 89; *Catholic Charities of Diocese of Albany*, 859 N.E.2d at 465. The accommodations likewise regulate conduct by relieving an eligible organization of the obligation "to contract, arrange, pay, or refer for contraceptive coverage" to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6. Plaintiffs' suggestion that the mere act of self-certifying eligibility for a religious accommodation violates speech rights is baseless. *See FAIR*, 547 U.S. at 61-63.

Similarly flawed is plaintiffs' claim that they are barred from expressing particular views to FOCUS's TPA. Pls.' Mot. at 25. Defendants have been clear that "[n]othing in these final regulations prohibits an eligible organization from expressing its opposition to the use of contraception." 78 Fed. Reg. at 39,880 n.41, AR at 12. What the regulations prohibit is an employer's improper attempt to interfere with its employees' ability to obtain contraceptive coverage from a third party by, for example, threatening the TPA with a termination of its relationship with the employer because of the TPA's "arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries." *See* 26 C.F.R. § 54.9815-2713A(b)(1)(iii); 29 C.F.R. § 2590.715-2713A(b)(1)(iii).

Addressing an analogous argument in the context of the National Labor Relations Act, the Supreme Court concluded that an employer's threatening statements to its employees regarding the effects of unionization fell outside the protection of the First Amendment because they interfered with employee rights. *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 618 (1969). The Court explained that there was no First Amendment violation because the employer was "free to communicate . . . any of his general views . . . so long as the communications do not contain a 'threat of reprisal or force or promise of benefit.'" *Id.*; *see also Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978). The same is true here. Because the regulations do not prevent plaintiffs from expressing their views regarding the use of contraceptive services, but rather, protect employees' right to obtain payments for contraceptive services through issuers/TPAs, there is no infringement of plaintiffs' right to free speech.

Furthermore, plaintiffs are wrong when they contend that the regulations require plaintiffs to "facilitate access" to "counseling related to abortion." Am. Compl. ¶ 258. The regulations simply require coverage of "education and counseling for women with reproductive capacity." HRSA Guidelines, AR at 130-31. The conversations that may take place between a patient and her doctor cannot be known or screened in advance and may cover any number of options. To the extent that plaintiffs intend to argue that the covered education and counseling is objectionable because some of the conversations between a doctor and one of plaintiffs'

employees *might* be supportive of something to which they object, accepting this theory would mean that the First Amendment is violated by the mere possibility of an employer's disagreement with a potential subject of discussion between an employee and her doctor, and would extend to all such interactions, not just those that are the subject of the challenged regulations. The First Amendment does not require such a drastic result. *See, e.g., Conestoga*, 2013 WL 140110, at *17.

Finally, the regulations do not violate the right to expressive association. To be sure, "[t]he right to speak is often exercised most effectively by combining one's voice with the voices of others." *FAIR*, 547 U.S. at 68. "If the government were free to restrict individuals' ability to join together and speak, it could essentially silence views that the First Amendment is intended to protect." *Id*. But the preventive services coverage regulations do not interfere with plaintiff's right of expressive association. The regulations do not interfere in any way with the composition of plaintiffs' workforces, faculties, or student bodies. *See Boy Scouts of Am. v. Dale*, 530 U.S. 640, 656 (2000) (holding Boy Scouts' freedom of expressive association was violated by law requiring organization to accept gay man as a scoutmaster); *Roberts*, 468 U.S. at 623 (concluding statute that forced group to accept women against its desires was subject to strict scrutiny). The regulations do not force plaintiffs to hire employees they do not wish to hire or to admit students they do not desire to be a part of their schools. Moreover, plaintiffs, as well as their employees and students, are free to associate to voice their disapproval of the use of contraception and the regulations. Even the statute at issue in *FAIR*, which required law schools to allow military recruiters on campus if other recruiters were allowed on campus, did not violate the law schools' right to expression association. 547 U.S. at 68-70. The preventive services coverage regulations do not even implicate plaintiffs' right. *See Priests for Life*, 2013 WL 6672400, at *13 (calling plaintiffs' expressive association claim "devoid of merit"); *MK Chambers*, 2013 WL 1340719, at *6 (rejecting expressive association challenge to prior version of regulations); *Diocese of Albany*, 859 N.E. 2d at 465 (upholding similar state law because it "does [not] compel [plaintiffs] to associate, or prohibit them from associating, with anyone").

Accordingly, plaintiffs cannot succeed on any of their free speech claims.

V. The Regulations Do Not Violate the Due Process Clause or the Equal Protection Clause of the Fifth Amendment

Plaintiffs' claim that the preventive services coverage regulations violate the Fifth Amendment's Due Process Clause is misdirected and baseless. A law is not unconstitutionally vague unless it "fails to provide a person of ordinary intelligence fair notice of what is prohibited" or "is so standardless that it authorizes or encourages seriously discriminatory enforcement." *United States v. Williams*, 553 U.S. 285, 304 (2008). Courts relax these standards where, as here, the law in question imposes civil rather than criminal penalties and does not "interfere[] with the right of free speech or of association." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982). In any event, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Holder v. Humanitarian Law Project*, 130 S. Ct. 2705, 2719 (2010)

Plaintiffs do not even attempt to identify a source of vagueness or confusion in the regulations. *See* Am. Compl. ¶ 273. And plaintiffs evidently have no difficulty determining what the regulations require of FOCUS; at the very least, then, the regulations are not vague as applied to FOCUS. *See U.S. Civil Serv. Comm'n v. Nat'l Ass'n of Letter Carriers*, 413 U.S. 548, 579 (1973) ("Surely, there seemed to be little question in the minds of the plaintiffs who brought this lawsuit as to the meaning of the law, or as to whether or not the conduct in which they desire to engage was or was not prohibited by the Act."); *Parker v. Levy*, 417 U.S. 733, 756 (1974) ("One to whose conduct a statute clearly applies may not successfully challenge it for vagueness."). As in *Humanitarian Law Project*, "the dispositive point" is that the regulations' terms "are clear in their application to [FOCUS'] proposed conduct, which means that plaintiffs' vagueness challenge must fail." 130 S. Ct. at 2720.

Plaintiffs also misunderstand the regulations when they assert that the regulations provide defendants with "unbridled discretion in deciding whether to allow exemptions to some, all, or no organizations that possess religious beliefs." Am. Compl. ¶ 275; *see also* Pls.' Mot. at 26.

That is incorrect. Under the regulations at issue here, an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended, qualifies for the exemption. 45 C.F.R. § 147.131(a). And an organization that satisfies the four criteria to be an "eligible organization" is eligible for the accommodations. *Id.* § 137.131(b). There is therefore simply no discretion that is left to defendants to decide who is exempt or who is accommodated; the regulations set out the criteria for both determinations.[14] Similarly, there is no merit to plaintiffs' allegation that the regulations—which contain specific criteria—will lead to discriminatory enforcement.

Finally, like their Free Exercise Clause and Establishment Clause claims, plaintiffs' equal protection claims are based on the theory that the regulations discriminate among religions. Because, as shown above, the regulations do not so discriminate, plaintiffs' equal protection claim warrants only rational basis review. *See, e.g.*, *Johnson v. Robison*, 415 U.S. 361, 375 n. 14 (1974); *St. John's United Church of Christ v. City of Chicago*, 502 F.3d 616, 638 (7th Cir. 2007); *Wirzberger v. Galvin*, 412 F.3d 271, 282-83 & n.6 (1st Cir. 2005); *Cooper v. Tard*, 855 F.2d 125, 130 (3d Cir. 1988). The regulations and, in particular, the religious employer exemption, satisfy rational basis review for the reasons explained above and in the final rules. *See supra*; 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19.

VI. PLAINTIFFS' APA CLAIMS FAIL

A. The Regulations Were Promulgated In Accordance With The APA

Plaintiffs assert that defendants failed to comply with the APA's notice and comment procedures and the ACA's timing provisions. Am. Compl. ¶¶ 284-88. These allegations are 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

[14] The regulations permitted HRSA to create a religious employer exemption, and identified the criteria for such an exemption, and HRSA did so in its August 1, 2011 action. *See* HRSA Guidelines. Any employer that meets the criteria of a "religious employer" is exempt from the contraceptive-coverage requirement. *See id.*; *see, e.g.*, *Grote*, 2012 WL 6725905, at *8.

statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Defendants complied with these requirements.[15]

As to the challenged regulations, defendants issued the ANPRM on March 21, 2012, and solicited comments on it. 77 Fed. Reg. 16,501. Defendants then considered those comments and issued the NPRM on February 6, 2013, requesting comments on the proposals contained in it. 78 Fed. Reg. at 8457, AR at 166. Defendants received over 400,000 comments, and the preamble to the 2013 final rules contains a detailed discussion both of the comments defendants received and of defendants' responses to those comments. *See* 78 Fed. Reg. at 39,871-39,888, AR at 3-20. The mere fact that the regulations as ultimately issued may not satisfy the preferences of each and every commenter is certainly not evidence that those comments were not considered. Given the range of interests and views among commenters, it is unlikely—if not impossible—that any regulation will be fully in line with the comments made by every commenter.

Plaintiffs also contend the regulations violate the ACA because plaintiffs believe they did not exist in final form for one year prior to going into effect. *See* Am. Compl. ¶¶ 289-92. This argument is based on a misunderstanding of both the ACA and the regulations. The provision of the ACA to which plaintiffs refer, 42 U.S.C. § 300gg-13(b), requires only that there be a minimum interval of not less than one year between the date on which a *recommendation or guideline* is issued—here, the HRSA Guidelines—and the plan year for which the coverage of the services included in that recommendation or guideline must take effect. *See* 75 Fed. Reg. at 41,729, AR at 229. That requirement is clearly satisfied here: HRSA published its guidelines on August 1, 2011, *see* HRSA Guidelines, *supra*, and these regulations apply for plan years beginning on or after January 1, 2014, *see* 78 Fed. Reg. at 39,870, AR at 2. Nothing in the ACA prevents defendants from amending the regulations as they have done here, and because the required interval relates only to the issuance of new recommendations or guidelines, nothing in

[15] To the extent plaintiffs attempt to raise any alleged insufficiencies or improprieties as to the prior, interim final rules, they are simply irrelevant. The regulations plaintiffs challenge here are an entirely different set of regulations. The relevant question is whether defendants complied with the APA as to *these* regulations, and as shown below, there is no question that they did.

the ACA requires defendants to provide an interval of one year between the promulgation of these amendments and the date on which the required coverage must take effect.

B. The Regulations Are Neither Arbitrary Nor Capricious

Plaintiffs' claim that the regulations are arbitrary and capricious is belied by the policymaking path discussed above, which illustrates that the regulations are neither arbitrary nor capricious. *See Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action must be upheld so long as "the agency's path may reasonably be discerned"); *DKT Mem'l Fund, Ltd. v. Agency for Int'l Dev.*, 887 F.2d 275, 281 (D.C. Cir. 1989) ("The APA has never been construed to grant to this or any other court the power to review the wisdom of policy decisions of the President."). The preamble to the rules also sets out that path in detail, *see* 78 Fed. Reg. at 39,871-88, AR at 3-20, and there can be no serious question that it can be reasonably discerned. Similarly, plaintiffs' brazen claim that defendants failed to consider the constitutional and statutory implications of the regulations is flatly contradicted by the record, which explicitly discusses that very issue. *See* 78 Fed. Reg. at 39,886-88, AR at 18-20.

Instead of pointing to anywhere in the record where defendants did not "articulate a satisfactory explanation for [their] action," *State Farm*, 463 U.S. at 43, plaintiffs resort to complaining about the content of the regulations themselves. Just as the fact that plaintiffs are disappointed that the regulations are not in keeping with all of their comments does not mean that defendants failed to *consider* plaintiffs' comments, plaintiffs' contrary policy preferences do not render the regulations arbitrary or capricious. The regulations are consistent with the proposals contained in the ANPRM and the NPRM, and, as the record reflects, represent the logical outgrowth of those proposals and the hundreds of thousands of comments received.

C. The Regulations Do Not Violate Restrictions Relating To Abortion

Plaintiffs contend the regulations violate the APA because they conflict with three federal statutes dealing with abortion: section 1303(b)(1) of the ACA, the Weldon Amendment, and the Church Amendment. Plaintiffs appear to reason that, because the preventive services coverage

regulations require group health plans to cover emergency contraception, such as Plan B, they in effect require plaintiffs to provide coverage for abortions in violation of federal law.

Some of these arguments should be rejected at the outset because plaintiffs lack prudential standing to assert them. The doctrine of prudential standing requires that a plaintiffs' claim fall within "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970). But the necessary link between plaintiffs and two of these statutes is missing here. *See Dialysis Ctrs., Ltd. v. Schweiker*, 657 F.2d 135, 138 (7th Cir. 1981); *O'Brien*, 894 F. Supp. 2d at 1167-68 (holding that plaintiff lacked prudential standing to raise similar claims). Section 1303(b)(1) of the ACA provides that "nothing in this title . . . shall be construed to require a qualified health plan to provide coverage of [abortion services]," 42 U.S.C. § 18023(b)(1)(A)(i), but plaintiffs are neither health insurance issuers nor purchasers of a qualified health plan.[16] They therefore do not fall within the zone of interests to be protected by the statute in question. Similarly, the Church Amendment protects individuals from being required to "perform or assist in the performance of any part of a health service program or research activity funded . . . by the Secretary of Health and Human Services if his performance or assistance . . . would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(d). By merely providing a health plan to its employees, FOCUS is not required to, and in fact do not, "perform or assist in the performance" of a "health service program or research activity funded . . . under a program administered by the Secretary of Health and Human Services" within the meaning of the Church Amendment. *See Gray v. Romero*, 697 F. Supp. 580, 590 n.6 (D.R.I. 1988). Nor are plaintiffs "individual[s]" under that provision. And the individual

[16] A "qualified health plan," within the meaning of this provision, is a health plan that has been certified by the health insurance exchange "through which such plan is offered" and that is offered by a health insurance issuer. 42 U.S.C. § 18021(a)(1). Health insurance exchanges are to be set up by states no later than January 1, 2014. *Id.* § 18031. Plaintiffs' health insurance plans were not purchased on a health insurance exchange, and so none is a "qualified health plan."

plaintiffs are not required to do anything whatsoever, as the regulations do not apply to them. None of the plaintiffs therefore is within the Church Amendment's zone of interests either.

Even if the Court were to reach the merits of these claims, and on the merits of plaintiffs' claims, plaintiffs' premise that the contraceptive coverage regulations require abortion coverage is fundamentally incorrect. The regulations do not require that any health plan cover abortion as a preventive service, or that it cover abortion at all, as that term is defined in federal law. Rather, the regulations require only that non-grandfathered, non-exempt and non-accommodated group health plans cover all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider. *See* HRSA Guidelines, *supra*. And the government has made clear that the preventive services covered by the regulations do not include abortifacient drugs.[17] Although plaintiffs believe that Plan B, ella, and certain IUDs are abortifacient drugs or cause abortions, neither the government nor this Court is required to accept that characterization, which is inconsistent with the FDA's scientific assessment and with federal law. While plaintiffs' religious beliefs may define abortion more broadly than federal law to include emergency contraception and certain IUDs, statutory interpretation requires that terms be construed as a matter of law and not in accordance with any particular individual's views or beliefs. *See Michigan Catholic Conf.*, 2013 WL 6838707, at *13 ("Plaintiffs believe that FDA-approved emergency contraceptives are 'abortion-inducing products'—as is their right. However, federal law does not define them as such. Accordingly, the regulations are not contrary to law, and Plaintiffs' APA claim fails.") (citation omitted); *Gov't Empls. Ins. Co. v. Benton*, 859 F.2d 1147, 1149 (3d Cir. 1988).

In recommending what contraceptive services should be covered by health plans without cost-sharing, the IOM Report identified the contraceptives that have been approved by the FDA as safe and effective. *See* IOM REP. at 10, AR at 308. And the list of FDA-approved

[17] HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at* http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html (last visited Jan. 9, 2014); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of permissible recommendations), AR at 320.

contraceptives includes emergency contraceptives such as Plan B. *See id.* at 105, AR at 403. The basis for the inclusion of such drugs among safe and effective means of contraception dates back to 1997, when the FDA first explained why Plan B and similar drugs act as contraceptives rather than abortifacients. *See* Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997) (noting that "emergency contraceptive pills are not effective if the woman is pregnant" and that there is "no evidence that [emergency contraception] will have an adverse effect on an established pregnancy"); 45 C.F.R. § 46.202(f) ("Pregnancy encompasses the period of time from implantation until delivery."). In light of this conclusion by the FDA, HHS informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods—and may not offer abortion except under limited circumstances (e.g., rape, incest, or when the life of the woman would be in danger)—that they "should consider the availability of emergency contraception the same as any other method which has been established as safe and effective." Office of Population Affairs, Memorandum (Apr. 23, 1997), http://www.hhs.gov/opa/pdfs/opa-97-02.pdf (last visited Jan. 9, 2014); *see also* 42 U.S.C. §§ 300, 300a-6.

Because the regulations reflect a settled understanding of FDA-approved contraceptives that is in accordance with existing federal laws prohibiting federal funding for certain abortions, they are consistent with over a decade of regulatory policy and practice and thus cannot be deemed contrary to any law dealing with abortion.[18] *See Bhd. of R.R. Signalmen v. Surface Transp. Bd.*, 638 F.3d 807, 815 (D.C. Cir. 2011) (giving particular deference to an agency's longstanding interpretation) (citing *Barnhart v. Walton*, 535 U.S. 212, 220 (2002)).

[18] Representative Weldon, the sponsor of the Weldon Amendment, himself did not consider the word "abortion" in the statute to include FDA-approved emergency contraceptives. *See* 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002) ("The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. . . . [U]nder the current FDA policy[,] that is considered contraception, and it is not affected at all by this statute."). His statement leaves little doubt that the Weldon Amendment was not intended to apply to emergency contraceptives. *See Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (indicating that a statement of one of the legislation's sponsors deserves to be accorded substantial weight in interpreting a statute).

Plaintiffs' APA claims thus fail.

CONCLUSION

For the foregoing reasons, defendants respectfully ask that the Court dismiss plaintiffs' claims or, in the alternative, enter summary judgment in defendants' favor.

Respectfully submitted this 17th day of February 2014,

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CERTIFICATE OF SERVICE

I hereby certify that on February 17, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sent notice of such filing to all parties.

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