IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA

GRACE SCHOOLS and BIOLA UNIVERSITY, INC., Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 3:12-cv-00459-JD-CAN

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, AND IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs Grace Schools and Biola University ask this Court to preliminarily 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 that plaintiffs challenge 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—like Biola, and like Grace Schools does for its student plan—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 Grace Schools' employee plan—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 they are eligible for an accommodation is a substantial burden on their religious exercise because, once they make the certification, their employees will be able to obtain contraceptive coverage through other parties. This extraordinary contention suggests that plaintiffs not only seek to avoid paying for, administering, or otherwise providing contraceptive coverage themselves, but also seek to prevent the women who work for their organizations 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. Although these regulations require virtually nothing of them, plaintiffs claim that the regulations run afoul of their sincerely held religious beliefs prohibiting them from providing or facilitating health coverage for certain contraceptive services, and that the challenged regulations violate RFRA, the First and Fifth Amendments, and the Administrative Procedure Act (APA). Plaintiffs move for a preliminary injunction on their RFRA claim, which should be denied because plaintiffs have not shown that they are likely to

succeed on the merits of that claim. Moreover, all of plaintiffs' claims fail, and thus should be dismissed in their entirety; alternatively, the Court should enter summary judgment in favor of the government.

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 their employees to refrain from using contraceptive services. Plaintiffs are required only to inform their issuers/TPAs that they object to providing contraceptive coverage, which they have done or would have to do voluntarily even absent these regulations in order to ensure that that they are not responsible for contracting, arranging, paying, or referring for such coverage. Plaintiffs can hardly claim that it is a violation of RFRA to require them to do almost exactly what they would do in the ordinary course.

Furthermore, plaintiffs' challenge rests largely on the theory that even the extremely attenuated connection between them and the independent provision by issuers/TPAs of payments for contraceptive services to which plaintiffs object on religious grounds—but for which plaintiffs pay nothing—amounts to a substantial burden on their religious exercise. This cannot be. Regardless of how plaintiffs frame their religious beliefs, courts must independently consider whether a given law imposes a substantial burden on those beliefs. *See Autocam Corp. v. Sebelius*, No. 1:12-CV-1096, 2012 WL 6845677, at *6 (W.D. Mich. Dec. 24, 2012), *aff'd*, __ F.3d __, 2013 WL 5182544 (6th Cir. Sept. 17, 2013). The regulations impose, at most, only the most *de minimis* burden on plaintiffs' religious exercise— one too slight and attenuated to be "substantial" under RFRA, and little different from plaintiffs' payment of salaries to their employees, which those employees can use to purchase contraceptive services if they so choose.

Moreover, even if the challenged regulations were deemed to impose a substantial burden on plaintiffs' religious exercise, the regulations would not violate RFRA because they are

narrowly tailored to serve two compelling governmental interests: improving the health of women and newborn children, and equalizing the provision of preventive care for women and men so that women can participate in the work force, and society more generally, on an equal playing field with men.

Plaintiffs' First Amendment claims are equally meritless. Indeed, nearly every court to consider similar First Amendment challenges to the prior version of the regulations rejected the claims, and their analysis applies here. Nor do the regulations violate the Due Process Clause. 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. Finally, plaintiffs cannot satisfy the remaining requirements for obtaining a preliminary injunction.

For these reasons, and those explained below, plaintiffs' motion for a preliminary injunction should be denied, and defendants' motion to dismiss or, in the alternative, for summary judgment should be granted.

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-

[1] Where appropriate, defendants have provided parallel citations to the Administrative Record (AR), which is being filed contemporaneously with this motion and brief.

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]

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. 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]

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[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 Sept. 11, 2013).

[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.

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] 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

[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 non profit 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.

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

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 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—such as Grace, with respect to its student health plan, and Biola—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 Grace—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 Amended 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 I.F.3, under Federal Rule of Civil Procedure 12(b)(1) 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 Amended 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).

This memorandum also responds to plaintiffs' motion for a preliminary injunction on their RFRA claim. A preliminary injunction is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A plaintiff "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; *see United States v. NCR Corp.*, 688 F.3d 833, 837 (7th Cir. 2012).[6]

[6] While the Seventh Circuit has applied the "sliding scale" analysis after *Winter*, *see, e.g.*, *Judge v. Quinn*, 612 F.3d 537, 546 (7th Cir. 2010), and defendants acknowledge that this Court is bound by the Seventh Circuit on this issue, the government reserves the right to argue that the "sliding scale" analysis is inconsistent with *Winter* and subsequent Supreme Court precedent. In any event, the "sliding scale" analysis does not relieve plaintiffs of their burden to show that they are likely to succeed on the merits. *See Judge*, 612 F.3d at 546; *NCR Corp.*, 688 F.3d at 837.

ARGUMENT

I. PLAINTIFFS' CLAIMS LACK MERIT

A. Plaintiffs' Religious Freedom Restoration Act Claim Is Without Merit

1. The regulations do not substantially burden plaintiffs' exercise of religion

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)); *see Vision Church v. Vill. of Long Grove*, 468 F.3d 975, 997 (7th Cir. 2006) (noting same in the context of the Religious Land Use and Institutionalized Persons Act (RLUIPA)). "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 also Braunfeld v. Brown*, 366 U.S. 599, 606 (1961) ("To strike down, without the most careful scrutiny, legislation which imposes only an indirect burden on the exercise of religion, *i.e.*, legislation which does not make unlawful the religious practice itself, would radically restrict the operating latitude of the legislature."); *Combs v. Homer-Center Sch. Dist.*, 540 F.3d 231, 262 (3d Cir. 2008) (Sciricа, C.J., concurring) ("In our modern regulatory state, virtually all legislation (including neutral laws of general applicability) imposes an incidental burden at some level by placing indirect costs on an individual's activity. Recognizing this . . . [t]he federal government . . . ha[s] identified a substantiality threshold as the tipping point for requiring heightened justifications for governmental action.").

For two reasons, plaintiffs cannot show that the challenged regulations substantially burden their religious exercise. [7] First, because the regulations require virtually nothing of plaintiffs, and certainly do not require plaintiffs to modify their behavior in any meaningful way, the regulations do not impose any more than a *de minimis* burden on plaintiffs—let alone a substantial one. Second, even if this Court were to find that the regulations impose some burden on plaintiffs' religious exercise, any such burden would be far too attenuated to be substantial.

a. The regulations impose no more than a de minimis *burden on plaintiffs' exercise of religion because the regulations require virtually nothing of plaintiffs*

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. Plaintiffs, as eligible organizations, are not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, they are free to continue to refuse to do so, to voice their disapproval of contraception, and to encourage their employees to refrain from using contraceptive services. Plaintiffs need only fulfill the self-certification requirement and provide the completed self-certification to their issuers/TPAs. They need not provide payments for contraceptive services to their employees. Instead, third parties—plaintiffs' issuers/TPAs—provide payments for contraceptive services, at no cost to plaintiffs. In short, with respect to contraceptive coverage, plaintiffs need not do anything more than they did prior to the

[7] Plaintiffs repeatedly refer to cases involving for-profit companies that object to the contraceptive coverage regulations. *See, e.g.*, Pls.' Br. at 4-10. But those cases are inapposite because for-profit corporations—unlike plaintiffs—do not qualify for the accommodations for eligible organizations. Furthermore, plaintiffs disregard the substantial body of opinions in the government's favor. *See Hobby Lobby Stores, Inc. v. Sebelius*, 133 S. Ct. 641 (2012) (Sotomayor, J., in chambers) (denying application for injunction pending appellate review); *Conestoga Wood Specialties Corp. v. Sebelius*, 724 F.3d 377 (3d Cir. 2013); *Autocam Corp. v. Sebelius*, __ F.3d __, 2013 WL 5182544 (6th Cir. Sept. 17, 2013); *Mersino Mgmt. Co. v. Sebelius*, __ F. Supp. 2d __, 2013 WL 3546702 (E.D. Mich. July 11, 2013); *M.K. Chambers Co. v. HHS*, No. 13-cv-11379, 2013 WL 1340719 (E.D. Mich. Apr. 3, 2013); *Eden Foods, Inc. v. Sebelius*, No. 13-cv-11229, 2013 WL 1190001 (E.D. Mich. Mar. 22, 2013); *Gilardi v. Sebelius*, 926 F. Supp. 2d 273, 282 (D.D.C. 2013), *appeal pending sub nom. Gilardi v. HHS*, No. 13-5069 (D.C. Cir.); *Conestoga Wood Specialties Corp. v. Sebelius*, 917 F. Supp. 2d 394 (E.D. Pa. Jan. 11, 2013); *Annex Medical, Inc. v. Sebelius*, No. 12-cv-2804, 2013 WL 101927 (D. Minn. Jan. 8, 2013), *appeal pending*, No. 13-1118 (8th Cir.); *Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943 (S.D. Ind. 2012), *appeal pending* No. 13-1077 (7th Cir.); *Autocam*, 2012 WL 6845677; *Korte v. U.S. Dep't of Health & Human Servs.*, 912 F Supp. 2d 735 (S.D. Ill. 2012), *appeal pending*, No. 12-3841 (7th Cir.); *O'Brien v. HHS*, 894 F. Supp. 2d 1149 (E.D. Mo. 2012), *appeal pending*, No. 12-3357 (8th Cir.).

promulgation of the challenged regulations—that is, to inform their issuers/TPAs that they object to providing contraceptive coverage in order to ensure that they are 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; *see also Civil Liberties for Urban Believers v. City of Chi.*, 342 F.3d 752, 761 (7th Cir. 2003) (holding, in the context of RLUIPA, that "a substantial burden on religious exercise is one that necessarily bears direct, primary, and fundamental responsibility for rendering religious exercise . . . effectively impracticable").

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 do plaintiffs want to be free from contracting, arranging, paying, or referring for contraceptive services for their employees—which, under these regulations, they are—but plaintiffs would also prevent *anyone else* from providing such coverage to their employees, who might not subscribe to plaintiffs' religious beliefs. That this is the *de facto* impact of plaintiffs' stated objections is made clear by their assertion that RFRA is violated whenever they "trigger" a third party's provision to plaintiffs' employees of services to which plaintiffs object. Am. Compl. ¶¶ 153, 155; *see* Pls.' Br. at 2. This theory would mean, for example, that even the government would not realistically be able to provide contraceptive coverage to plaintiffs' employees, because such coverage would be "trigger[ed]," *id.*, by plaintiffs' objection to providing such coverage themselves. But RFRA is a shield, not a sword, *see O'Brien*, 894 F. Supp. 2d at 1158-60, and accordingly it does not prevent the government from providing alternative means of achieving important statutory objectives once it has provided a religious accommodation. *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 them to contract, arrange, pay, or refer for contraceptive services, plaintiffs attempt to circumvent this problem by advancing the novel theory that the regulations require them to somehow "facilitate access" to contraception coverage, and that it is this "facilitation" that violates plaintiffs' religious beliefs. *See, e.g.*, Pls.' Br. at 4. But under the challenged regulations plaintiffs need *only* to self-certify that they object to providing coverage for contraceptive services and that they otherwise meet the criteria for an eligible organization, and to share that self-certification with their issuers/TPAs. In other words, plaintiffs are required to inform their issuers/TPAs that they object to providing contraceptive coverage, which they have done or would have to do voluntarily anyway even absent these regulations in order to ensure that they are not responsible for contracting, arranging, paying, or referring for contraceptive coverage. The sole difference is that they must inform their issuers/TPAs that their

objection is for religious reasons—a statement which they have already made repeatedly in this litigation and elsewhere.

Furthermore, any burden imposed by the purely administrative self-certification requirement—which should take plaintiffs a matter of minutes—is, at most, *de minimis*, and thus cannot be "substantial" under RFRA. The substantial burden hurdle is a high one. *Living Water Church of God v. Charter Twp. of Meridian*, 258 Fed. App'x 729, 734 (6th Cir. 2007); *see also Kaemmerling*, 553 F.3d at 678 ("An inconsequential or *de minimis* burden on religious practice does not rise to this level [of a substantial burden]."); *Washington v. Klem*, 497 F.3d 272, 279-81 (3d Cir. 2007); *McEachin v. McGuinnis*, 357 F.3d 197, 203 n.6 (2d Cir. 2004); *Civil Liberties for Urban Believers*, 342 F.3d at 761. Indeed, if this is not a *de minimis* burden, it is hard to see what would be. In fact, plaintiffs' alternative proposals only confirm that the alleged "burden" of self-certification is *de minimis*. They contend that, as an alternative to the accommodations developed by the Departments, the federal government should somehow expand or create other public programs so as to provide contraceptive coverage to the women who participate in plaintiffs' group health plans. RFRA plainly does not require defendants to expand or create government programs, particularly where, as here, there is no statutory authority to do so. *See infra* at 27-30. But, in any event, plaintiffs' own proposals would entail the same putative "burden" as the existing accommodations, or an even greater burden: one way or another, plaintiffs would have to certify that they are eligible for an accommodation and that they object to providing contraceptive coverage, and the result would be that the women who participate in their plan would get contraceptive coverage through another source such as Medicaid. The government would of course, as it does with Medicaid, have to verify employment and/or dependent beneficiary status with the eligible organization. The current accommodations are thus likely to require less of plaintiffs' involvement than would be required under a government program that would separately provide contraceptive coverage for their employees and dependents.[8]

[8] Plaintiffs state that, for self-insured eligible organizations, the self-certification form "designat[es]. . . the third party administrator(s) as plan administrator and claims administrator for contraceptive benefits." Pls.' Br. at 2 (quoting 78 Fed. Reg. at 39,879, AR at 11). It is not clear what legal significance plaintiffs attach to this statement,

Contrary to plaintiffs' suggestion, the mere fact that plaintiffs claim that the self-certification requirement imposes a substantial burden on their religious exercise does not make it so. *See Conestoga Wood Specialties Corp. v. Sebelius*, 917 F. Supp. 2d 394, 413 (E.D. Pa. 2013) ("[W]e reject the notion . . . that a plaintiff shows a burden to be substantial simply by claiming that it is."), *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 their behavior in a significant—or more than *de minimis*—way. *See Living Water Church of God*, 258 Fed. App'x at 734-36 (reviewing cases); *see also, e.g.*, *Vision Church*, 468 F.3d at 997; *Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013); *Westchester Day Sch. v. Vill. of Mamaroneck*, 504 F.3d 338, 348-49 (2d Cir. 2007); *Church of Scientology of Ga., Inc. v. City of Sandy Springs, Ga.*, 843 F. Supp. 2d 1328, 1353-54 (N.D. Ga. 2012). As plaintiffs themselves appear to recognize, a "law 'substantially burdens' an exercise of religion if it compels one 'to *perform acts* undeniably at odds with fundamental tenets of [one's] religious beliefs,'" Pls.' Br. at 6 (quoting *Wisconsin v. Yoder*, 406 U.S. 205, 218 (1972)) (emphasis added), "or 'put[s] substantial pressure on an

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but what is clear is that self-insured entities are subject to the 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 are nonprofit religious organizations with 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 entities—whether self-insured or third-party-insured—than what they would have to do anyway absent the challenged regulations.

adherent to *modify his behavior* and violate his beliefs,'" *id.* (quoting *Thomas*, 450 U.S. at 717-18) (emphasis added).[9]

Under plaintiffs' alternative interpretation of RFRA, courts would play virtually no role in determining whether an alleged burden is "substantial"—as long as a plaintiff's religious belief is sincere, that would be the end of the inquiry. *See* Pls.' Br. at 5. Plaintiffs would thus be allowed to evade RFRA's threshold by simply asserting that the burden on their religious exercise is "substantial," thereby paradoxically reading the term "substantial" out of RFRA. *See Gilardi*, 926 F. Supp. at 282 ("[T]he Court declines to follow several recent cases suggesting that a plaintiff can meet his burden of establishing that a law creates a 's ubstantial burden' upon his exercise of religion simply because he claims it to be so."); *Autocam*, 2012 WL 6845677, at *6 ("The Court does not doubt the sincerity of Plaintiff Kennedy's decision to draw the line he does, but the Court still has a duty to assess whether the claimed burden—no matter how sincerely felt—really amounts to a substantial burden on a person's exercise of religion."); *see also Grote*, 914 F. Supp. 2d at 949. "If every plaintiff were permitted to unilaterally determine that a law burdened their religious beliefs, and courts were required to assume that such burden was substantial, simply because the plaintiff claimed that it was the case, then the standard expressed by Congress under the RFRA would convert to an 'any burden' standard." *Conestoga*, 917 F. Supp. 2d at 413-14; *see also Autocam*, 2012 WL 6845677, at *7; *Grote*, 914 F. Supp. 2d at 952; *Mersino*, 2013 WL 3546702, at *16.[10] The result would be to subject every act of Congress to

[9] In *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc), a bare majority of the en banc Tenth Circuit concluded that, in determining whether a burden is substantial, a 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." *Id.* at 1137. The government believes that the majority's ruling in *Hobby Lobby* was wrong on this and many other points. However, even if this Court were inclined to agree with the Tenth Circuit, the majority proceeded to rely on *Abdulhaseeb v. Calbone*, 600 F.3d 1301 (10th Cir. 2010), which makes clear that in order 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 (citing *Abdulhaseeb*, 600 F.3d at 1315). The *Hobby Lobby* substantial burden analysis is also inapposite because for-profit corporations are not eligible for the accommodations.

[10] 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

strict scrutiny every time any plaintiff could articulate a sincerely held religious objection to compliance with that law. The "most demanding test known to constitutional law," *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997), would thus be transformed into a norm against which Congress must always legislate.[11]

For the reasons stated above, the regulations do not impose a substantial burden on plaintiffs' religious exercise, and thus plaintiffs' motion for a preliminary injunction should be denied, and plaintiffs' RFRA claims (Count I of the Amended Complaint) should be dismissed or summary judgment granted to defendants.

b. Even if the regulations were found to impose some more than de minimis *burden on plaintiffs' exercise of religion, any such burden would be far too attenuated to be "substantial" under RFRA*

Although the regulations do not require plaintiffs to contract, arrange, pay, or refer for contraceptive coverage, plaintiffs' complaint appears to be that the regulations require plaintiffs to indirectly facilitate conduct on the part of their employees that they find objectionable (*i.e.*, the use of certain contraceptives). But this complaint has no limits. An employer provides numerous benefits, including a salary and other fringe benefits, to its employees and by doing so in some sense facilitates whatever use its employees make of those benefits. Plaintiffs not only seek to be free from the requirement to contract, arrange, pay, or refer for contraceptive coverage themselves—which they are under these regulations—but also seek to prevent anyone else from providing such coverage to their employees. But an employer has no right to control the choices

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Cong. Rec. S14350-01, S14352 (daily ed. Oct. 26, 1993) (statement of Sen. Kennedy); *see also id.* (text of Amendment No. 1082).

[11] Plaintiffs seem to recognize that this general imposition of strict scrutiny would be both doctrinally inappropriate and practically problematic. But it is no answer to blithely assert, as they do, that courts can prevent these problems by "screening claims for sincerity." Pls.' Br. at 5. *See Braunfeld*, 366 U.S. at 606 (noting that we are a "cosmopolitan nation made up of people of almost every conceivable religious preference"); *Autocam*, 2012 WL 6845677, at *7 ("[Such a theory] would subject virtually every government action to a potential private veto based on a person's ability to articulate a sincerely held objection tied in some rational way to a particular religious belief. Such a rule would paralyze the normal process of governing, and threaten to replace a generally uniform pattern of economic and social regulation with a patchwork array of theocratic fiefdoms. After all, almost every governmental decision involves policy choices. And religiously inclined persons can often sincerely trace their preferred policy outcome to some religious and moral principle. . . . Applying RFRA in a way that permits the disappointed side simply to opt out because it tied its opposition to a religious or moral principle would be a recipe for chaos, not a meaningful protection of religious liberty.").

of its employees, who may not share its religious beliefs, when making use of their benefits. Those employees have a legitimate interest in access to the preventive services coverage made available under the challenged regulations.

Indeed, courts have held that claims raised by for-profit companies challenging the contraceptive coverage regulations, which require them to provide the relevant coverage themselves, are too attenuated to amount to a substantial burden under RFRA. Any burden on plaintiffs, which are eligible for the accommodations, is *a fortiori* too attenuated to be substantial. For example, the district court in *Conestoga* reasoned that the ultimate decision of whether to use contraception "rests not with [the employer], but with [the] employees" and that "any burden imposed by the regulations is too attenuated to be considered substantial." 917 F. Supp. 2d at 414-15. The *Conestoga* district court further explained that the indirect nature of any burden imposed by the regulations distinguished them from the statutes challenged in *Yoder*, *Sherbert*, *Thomas*, and *Gonzales*. *See id.* at 415. Other courts, too, have relied on similar reasoning to reject similar plaintiffs' RFRA claims. *See, e.g.*, *Autocam*, 2012 WL 6845677, at *6 ("The incremental difference between providing the benefit directly, rather than indirectly, is unlikely to qualify as a substantial burden on the Autocam Plaintiffs."); *O'Brien*, 894 F. Supp. 2d at 1158-60 ("[RFRA] is not a means to force one's religious practices upon others. RFRA does not protect against the slight burden on religious exercise that arises when one's money circuitously flows to support the conduct of other free-exercise-wielding individuals who hold religious beliefs that differ from one's own.").[12]

As these courts concluded, the preventive services coverage regulations result in only an indirect impact on for-profit companies, which must provide contraceptive coverage themselves. Any burden on plaintiffs and similar eligible organizations that qualify for the accommodations is even more attenuated. Not only are plaintiffs separated from the use of contraception by "a series of events" that must occur before the use of contraceptive services to which plaintiffs

[12] *See also Grote v. Sebelius*, 708 F.3d 850 (7th Cir. 2013) (Rovner, J., dissenting); *Eden Foods*, 2013 WL 1190001 at *4; *Annex Medical*, 2013 WL 101927 at *4-*5; *Grote*, 914 F. Supp. 2d at 949-52.

object would "come into play," *Conestoga*, 917 F. Supp. 2d at 414-15, but they are also further insulated by the fact that a third party—plaintiffs' issuers/TPAs—and *not* plaintiffs, will actually contract, arrange, pay, and refer for such services, and thus plaintiffs are in no way subsidizing—even indirectly—the use of preventive services that they find objectionable. Under plaintiffs' theory, their religious exercise is substantially burdened when one of their employees and her health care provider make an independent determination that the use of certain contraceptive services is appropriate, and when such services are paid for exclusively by plaintiffs' issuers/TPAs—with none of the cost being passed on to plaintiffs—and no administration of the payments by plaintiffs, solely because plaintiffs self-certified that they have religious objections to providing contraceptive coverage and so informed their issuers/TPAs.

But a burden simply cannot be "substantial" under RFRA when it is attenuated. Cases that find a substantial burden uniformly involve a direct burden on the plaintiff rather than a burden imposed on another entity. *See, e.g.*, *Potter v. Dist. of Columbia*, 558 F.3d 542, 546 (D.C. Cir. 2009); *see also Grote*, 914 F. Supp. 2d at 951-52; *Conestoga*, 917 F. Supp. 2d at 413-14. A plaintiff cannot establish a substantial burden on his religious exercise by invoking this type of trickle-down theory; to constitute a substantial burden within the meaning of RFRA, the burden must be imposed on the plaintiff himself. *See Conestoga*, 917 F. Supp. 2d at 411, 413; *Korte v. U.S. Dep't of Health & Human Servs.*, 912 F. Supp. 2d 735, 748 (S.D. Ill. 2012), *appeal pending*, No. 12-3841 (7th Cir.); *Autocam*, 2012 WL 6845677, at *7; *Grote*, 914 F. Supp. 2d at 950-51.[13] Here, of course, there is no such direct burden. In fact, given that any payment for

[13] *Thomas* is not to the contrary. In *Thomas*, the Supreme Court recognized that "a *compulsion* may certainly be indirect and still constitute a substantial burden, such as the denial of a benefit found in *Thomas*." *Conestoga*, 917 F. Supp. 2d at 415 n.15. But that is not so where the *burden* itself is indirect, as it is here. *See id.*; *Gilardi*, 926 F. Supp. 2d at 283. As previously explained, in *Hobby Lobby*, 723 F.3d 1114, a bare majority of the en banc Tenth Circuit concluded that the word "substantial" in RFRA refers to the "intensity of coercion" rather than to the directness or indirectness of the burden, if any, on a plaintiff's religious exercise. *Id.* at 1137-40. The Tenth Circuit's conclusion that the substantial burden requirement relates to the intensity of the coercion, however, is inconsistent with *Kaemmerling*, discussed above, as well as other decisions that have analyzed "substantial burden" in terms of the degree to which the challenged law directly imposes a requirement or prohibition on religious practice. *See* 553 F.3d at 678-79; *Living Water Church of God*, 258 F. App'x at 734; *McEachin*, 357 F.3d at 203 n.6; *Civil Liberties for Urban Believers*, 342 F.3d at 761. And, again, the *Hobby Lobby* substantial burden analysis is inapplicable to this case. *See supra* note 9.

contraceptive services is made by plaintiffs' issuers/TPAs, the regulations have even less impact on plaintiffs' religious exercise than plaintiffs' payment of salaries to their employees, which those employees can use to purchase contraceptives. *See O'Brien*, 894 F. Supp. 2d at 1160; *see also Conestoga*, 917 F. Supp. 2d at 414 ("The fact that Conestoga's employees are free to look outside of their insurance coverage and pay for and use any contraception . . . through the salary they receive from Conestoga, amply illustrates this point."); *Grote*, 708 F.3d at 861 (Rovner, J., dissenting) ("To the extent this burdens the Grotes' religious interests, it is worth considering whether the burden is different in kind from the burden of knowing that an employee might be using his or her Grote Industries paycheck (or money in a health care reimbursement account) to pay for contraception him or herself."); *Autocam*, 2012 WL 6845677, at *6.

Plaintiffs remain free to refuse to contract, arrange, pay, or refer for contraceptive coverage; to voice their disapproval of contraception; and to encourage their employees to refrain from using contraceptive services. The preventive services coverage regulations therefore affect plaintiffs' religious practice, if at all, in a highly attenuated way. In short, because the preventive services coverage regulations "are several degrees removed from imposing a substantial burden on [plaintiffs]," *O'Brien*, 894 F. Supp. 2d at 1160, the Court should dismiss plaintiffs' RFRA claim, or grant summary judgment to defendants, even if it finds—contrary to the government's argument—that the challenged regulations impose some burden on plaintiffs' religious exercise.

2. Even if there were a substantial burden on religious exercise, the regulations serve compelling governmental interests and are the least restrictive means to achieve those interests

a. The regulations significantly advance compelling governmental interests in public health and gender equality

Even if plaintiffs were able to demonstrate a substantial burden on their religious exercise, they would not prevail because the challenged regulations are justified by two compelling governmental interests, and are the least restrictive means to achieve those interests. First, the promotion of public health is unquestionably a compelling governmental interest. *Mead*

v. Holder, 766 F. Supp. 2d 16, 43 (D.D.C. 2011); *see also, e.g.*, *Buchwald v. Univ. of N.M. Sch. of Med.*, 159 F.3d 487, 498 (10th Cir. 1998); *Dickerson v. Stuart*, 877 F. Supp. 1556, 1559 (M.D. Fla. 1995). And the challenged regulations further this compelling interest by "expanding access to and utilization of recommended preventive services for women." 78 Fed. Reg. at 39,887, AR at 19.

The primary predicted benefit of the preventive services coverage 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. 41,726, 41,733 (July 19, 2010), AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19. "By expanding coverage and eliminating cost sharing for recommended preventive services, [the regulations are] expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733, AR at 233; 78 Fed. Reg. at 39,873 ("Research [ ] shows that cost sharing can be a significant barrier to access to contraception." (citation omitted)), AR at 5.[14]

Increased access to the full range of FDA-approved contraceptive services is a key part of these predicted health outcomes, as unintended pregnancies have proven in many cases to have negative health consequences for women and developing fetuses. *See* 78 Fed. Reg. at 39,872, AR at 4. 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, 103-04, AR at 318, 401-02. Contraceptive coverage further helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103, AR at 401; *see also* 78 Fed. Reg. at 39,872 ("Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-

[14] Plaintiffs miss the point, therefore, when they attempt to minimize the magnitude of these interests by arguing that the contraceptive methods to which they object are "widely available." *See* Pls.' Br. at 9. Although a majority of employers cover FDA-approved contraceptives, *see* IOM REP. at 109, AR at 407, many women forgo preventive services because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109, AR at 317-18, 407. The challenged regulations eliminate that cost-sharing. 78 Fed. Reg. at 39,873, AR at 5.

gestational age births.") (citing studies), AR at 4. And "[c]ontraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrative preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne." 78 Fed. Reg. at 39,872, AR at 4; *see also* IOM Rep. at 103-04 ("[P]regnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome."), AR at 401-02.

Closely tied to this interest is a related, but separate, compelling interest that is furthered by the regulations: assuring that women have equal access to health care services. 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19. As the Supreme Court explained in *Roberts v. U.S. Jaycees*, 468 U.S. 609 (1984), there is a fundamental "importance, both to the individual and to society, of removing the barriers to economic advancement and political and social integration that have historically plagued certain disadvantaged groups, including women." *Id.* at 626. Thus, "[a]ssuring women equal access to . . . goods, privileges, and advantages clearly furthers compelling state interests." *Id.* By including in the ACA gender-specific preventive health services for women, Congress made clear that the goals and benefits of effective preventive health care apply equally to women, who might otherwise be excluded from such benefits if their unique health care needs 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." 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 19, AR at 317. These costs result in women often forgoing preventive care and place women in the workforce at a disadvantage compared to their male coworkers. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274 (daily ed. Dec. 3, 2009) (statement of Sen. Murray); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 20, AR at 318. Congress's attempt to equalize the provision of preventive health care services, with the resulting 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, Inc. v. Superior Court*, 85 P.3d 67, 92-93 (Cal. 2004).[15]

Although the challenged regulations further these two compelling governmental interests, while simultaneously accommodating the religious objections of eligible organizations, plaintiffs maintain that the interests underlying the regulations cannot be considered compelling when millions of people are not protected by the regulations at the moment. Pls.' Br. at 8. But this is not a case where underinclusive enforcement of a law suggests that the government's "supposedly vital interest" is not really compelling. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546-47 (1993). Many of the "exemptions" referred to by plaintiffs are not exemptions from the preventive services coverage regulations at all, but are instead provisions of the ACA that exclude individuals and entities from other requirements imposed by the ACA. Or they reflect the government's attempts to balance the compelling interests underlying the challenged regulations against other significant interests supporting the complex administrative scheme created by the ACA. *See Lee*, 455 U.S. at 259 ("The Court has long

[15] In arguing that the government's interests are not compelling, plaintiffs suggest the government must separately analyze the impact of and need for the regulations as to each and every employer and employee in America. *See* Pls.' Br. at 8. But this level of specificity would be impossible to establish and would render this regulatory scheme—and potentially every regulatory scheme that is challenged due to religious objections—completely unworkable. *See United States v. Lee*, 455 U.S. 252, 259-60 (1982). In practice, courts have not required the government to analyze the impact of a regulation on the single entity seeking an exemption, but have conducted the inquiry with respect to all similarly situated individuals or organizations. *See, e.g.*, *id*. at 260 (considering the impact on the tax system if all religious adherents—not just the plaintiff—could opt out); *United States v. Oliver*, 255 F.3d 588, 589 (8th Cir. 2001) (per curiam) ("Oliver has argued a one-man exemption should be made, however, there is nothing so peculiar or special with Oliver's situation which warrants an exception. There are no safeguards to prevent similarly situated individuals from asserting the same privilege and leading to uncontrolled eagle harvesting."); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1398 (4th Cir. 1990) ("There is no principled way of exempting the school without exempting all other sectarian schools and thereby the thousands of lay teachers and staff members on their payrolls."); *see also, e.g.*, *Graham v. Comm'r*, 822 F.2d 844, 853 (9th Cir. 1987), *overruled in part on other grounds by Navajo Nation v. U.S. Forest Serv.*, 479 F.3d 1024, 1033 (9th Cir. 2007) (en banc); *United States v. Winddancer*, 435 F. Supp. 2d 687, 697 (M.D. Tenn. 2006). *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 435 (2006), is not to the contrary. To be sure, the Court rejected "slippery-slope" arguments for refusing to accommodate a particular claimant. *See* 546 U.S. at 435-36. But it construed the scope of the requested exemption as encompassing all members of the plaintiff religious sect. *See id.* at 433. Similarly, the exemption in *Yoder*, 406 U.S. 205, encompassed *all* Amish children; and the exemption in *Sherbert v. Verner*, 374 U.S. 398 (1963), encompassed *all* individuals who had a religious objection to working on Saturdays. *See O Centro*, 546 U.S. at 431. The Court's warning in *O Centro* against "slippery-slope" arguments was a rejection of arguments by analogy—that is, speculation that providing an exemption to one group will lead to exemptions for other *non*-similarly situated groups. It was not an invitation to ignore the reality that an exemption for a particular claimant might necessarily lead to an exemption for an entire category of similarly situated entities.

recognized that balance must be struck between the values of the comprehensive social security system, which rests on a complex of actuarial factors, and the consequences of allowing religiously based exemptions."); *Winddancer*, 435 F. Supp. 2d at 695-98 (recognizing that the regulations governing access to eagle parts "strike a delicate balance" between competing interests). And the existing exceptions do not undermine the government's interests in a significant way. *See Lukumi*, 508 U.S. at 547; *S. Ridge Baptist Church v. Indus. Comm'n of Ohio*, 911 F.2d 1203, 1208-09 (6th Cir. 1990) (rejecting the plaintiff's argument that the existence of exemptions indicates that a law is not the least restrictive means of achieving a compelling interest where the exemptions do not undermine that interest); *see also* 78 Fed. Reg. at 39,887, AR at 19.

For example, the grandfathering of certain health plans with respect to certain provisions of the ACA is not specifically limited to the preventive services coverage regulations. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. In fact, the effect of grandfathering is not really 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. The grandfathering provision reflects Congress's attempts to balance competing interests—specifically, the interest in spreading the benefits of the ACA, including those provided by the preventive services coverage provision, and the interest in maintaining existing coverage and easing the transition into the new regulatory regime established by the ACA—in the context of a complex statutory scheme. *See* 75 Fed. Reg. 34,538, 34,546 (June 17, 2010).

This incremental transition does nothing to call into question the compelling interests furthered by the preventive services coverage regulations. Even under the grandfathering provision, it is projected that more group health plans will transition to the requirements under the regulations as time goes on. Defendants have estimated that a majority of group health plans will have lost their grandfather status by the end of 2013. *See id.* at 34,552; *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012

Annual Survey at 7-8, 190 (indicating that 58 per cent 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. Thus, any purported adverse effect on the compelling interests underlying the regulations will be quickly mitigated, which is in stark contrast to the *permanent* exemption plaintiffs seek. Plaintiffs would have this Court believe that an interest cannot truly be "compelling" unless Congress is willing to impose it on everyone all at once despite competing interests, but plaintiffs offer no support for such an untenable proposition. *See Legatus v. Sebelius*, 901 F. Supp. 2d 980, 994 (E.D. Mich. 2012) ("[T]he grandfathering rule seems to be a reasonable plan for instituting an incredibly complex health care law while balancing competing interests.").

Moreover, 26 U.S.C. § 4980H(c)(2) does *not*, as plaintiffs claim, exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. at 39,887 n.49, AR at 19. Instead, it excludes employers with fewer than fifty full-time equivalent employees from the employer responsibility provision, meaning that, starting in 2015, such employers are not subject to the possibility of assessable payments if they do not provide health coverage to their full-time employees and their dependents. *See* 26 U.S.C. § 4980H(c)(2). Small businesses that *do* offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive services, including contraceptive services, without cost-sharing. 78 Fed. Reg. at 39,887 n.49, AR at 19. And there is reason to believe that small employers will continue to offer health coverage to their employees, because the ACA, among other things, provides tax incentives for small businesses to encourage the purchase of health insurance. *See* 26 U.S.C. § 45R. But even if a small business were to choose not to offer health coverage, employees of such business could get health insurance coverage that is facilitated by other ACA provisions—primarily those establishing both small group market and individual market health insurance exchanges and those establishing tax credits to make the purchase of coverage through such exchanges more affordable—and the coverage they receive

through such exchanges will include coverage of all recommended preventive services, including contraception. 78 Fed. Reg. at 39,887 n.49, AR at 19.

The only true exemption from the preventive services coverage regulations is the exemption for the group health plans of religious employers. 45 C.F.R. § 147.131(a). But there is a rational distinction between this narrow exception and the expansion plaintiffs seek. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are, as a group, more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. *See* 78 Fed. Reg. at 39,874, 39,877, AR at 6, 19. In any event, it would be perverse to hold that the government's provision of a limited religious exemption eliminates its compelling interest in the regulation, thus effectively extending the same exemption to anyone else who wants it under RFRA. Such a reading of RFRA would *discourage* the government from accommodating religion, the exact opposite of what Congress intended to accomplish in enacting RFRA.

Granting plaintiffs the much broader exemption they request would undermine defendants' ability to enforce the regulations in a rational manner. *See Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 435 (2006). We are a "cosmopolitan nation made up of people of almost every conceivable religious preference," *Braunfeld*, 366 U.S. at 606; *see also S. Ridge Baptist Church*, 911 F.2d at 1211, and many people object to various medical services. If any organization with a religious objection were able to claim an exemption from the operation of the preventive services coverage regulations—even where the regulations require virtually nothing of the organization—it is difficult to see how defendants could administer the regulations in a manner that would achieve Congress's goals of improving the health of women and newborn children and equalizing the coverage of preventive services for women. *See United States v. Israel*, 317 F.3d 768, 772 (7th Cir. 2003) (recognizing that plaintiff's RFRA logic "would lead to significant administrative problems for the [government] and open the door to a . . . proliferation of claims"). Indeed, women who receive their health

coverage through employers like plaintiffs would face negative health and other outcomes because they had obtained employment with an organization that objects to its employees' use of contraceptive services, even when those services are paid for, administered, and otherwise provided by a third party. *See id.* (noting consequences "for the public and the government"); 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,887, AR at 19.

b. The regulations are the least restrictive means of advancing the government's compelling interests

When determining whether a particular regulatory scheme is the "least restrictive," the appropriate 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 interests. *See, e.g.*, *United States v. Schmucker*, 815 F.2d 413, 417 (6th Cir. 1987) (describing the least restrictive means test as "the extent to which accommodation of defendant would impede the state's objectives"); *United States v. Wilgus*, 638 F.3d 1274, 1289-95 (10th Cir. 2011). The government is not required "to do the impossible—refute each and every conceivable alternative regulation scheme." *Wilgus*, 638 F.3d at 1289. Instead, the government need only "refute the alternative schemes offered by the challenger." *Id.*

Instead of explaining how plaintiffs and similarly situated eligible organizations could be exempted from the regulations without significant damage to the government's compelling interests, plaintiffs conjure up, without any statutory support, several brand new statutory and regulatory schemes—most of which would require the government to pay for contraceptive coverage—that they claim would be less restrictive. *See* Pls.' Br. at 10. Yet plaintiffs fail to recognize that such alternatives would be incompatible with the fundamental statutory scheme set forth in the ACA, which plaintiffs do not challenge in this lawsuit. Congress did not adopt a single (government) payer system financed through taxes and instead opted to build on the existing system of employment-based coverage. *See* H.R. Rep. No. 111-443, pt. II, at 984-86 (2010). Plaintiffs point to no statutory authority for any of their proffered less restrictive

alternatives. Nor is there any indication that Congress would have contemplated that agency action could be invalidated under RFRA because the agency, in discharging its statutorily delegated authority, failed to adopt an alternative scheme for which it lacked statutory authority. Thus, even if defendants wanted to adopt one of plaintiffs' non-employer-based alternatives, they would be constrained by the statute from doing so. *See* 78 Fed. Reg. at 39,888, AR at 20.

Furthermore, plaintiffs themselves indicate that they "in no way recommend [their proposed] alternatives, and, indeed, might oppose many of them as a matter of policy." Pls.' Br. at 10. Indeed, as noted above, it is not clear why the government's provision of contraceptive coverage to women based upon their employer's objection to providing it would not be subject to exactly the same RFRA claim that plaintiffs advance here. By their own admission then, plaintiffs' proposals would do little—if anything—to satisfy their religious objections, and therefore should not be considered viable less restrictive alternatives. *See New Life Baptist Church Acad. v. Town of E. Longmeadow*, 885 F.2d 940, 950-51 (1st Cir. 1989) (Breyer, J.) (considering the limited extent to which an alternative would alleviate a religious burden in rejecting it as a "less restrictive alternative," even though the plaintiff had expressed a preference for the alternative over the challenged requirements). An eligible organization's objection to providing or paying for contraceptive coverage would still "facilitate" its availability—in this case, by the government—and the eligible organization would likely be called upon to verify or certify matters such as the non-provision of contraceptive coverage, and employment or plan beneficiary status.

Finally, even if plaintiffs would be satisfied by their proposed alternatives, just because plaintiffs can devise an entirely new legislative and administrative scheme does not make that scheme a feasible less restrictive means, *see Wilgus*, 638 F.3d at 1289; *Adams v. Comm'r of Internal Revenue*, 170 F.3d 173, 180 n.8 (3d Cir. 1999) (" 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.'" (quotations omitted)), particularly where such alternatives would come at enormous administrative and

financial cost to the government. A proposed alternative scheme is not an adequate alternative—and thus not a viable less restrictive means to achieve a compelling interest—if it is not feasible. *See, e.g.*, *New Life Baptist*, 885 F.2d at 947; *Graham*, 822 F.2d at 852. In determining whether a proposed alternative scheme is feasible, courts often consider the additional administrative and fiscal costs of the scheme. *See, e.g.*, *S. Ridge Baptist Church*, 911 F.2d at 1206; *Fegans v. Norris*, 537 F.3d 897, 905-06 (8th Cir. 2008); *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011); *New Life Baptist*, 885 F.2d at 947. Defendants considered plaintiffs' alternatives and determined that they were not feasible because the agencies lacked statutory authority to implement them, they would impose considerable new costs and other burdens on the government, and they would otherwise be impractical. *See* 78 Fed. Reg. at 39,888, AR at 20; *see also, e.g.*, *Lafley*, 656 F.3d at 942; *Gooden v. Crain*, 353 F. App'x 885, 888 (5th Cir. 2009); *Adams*, 170 F.3d at 180 n.8.

Nor would the proposed alternatives be equally effective in advancing the government's compelling interests. *See* 78 Fed. Reg. at 39,888, AR at 20; *see also, e.g.*, *Kaemmerling*, 553 F.3d at 684 (finding that means was least restrictive where no alternative means would achieve compelling interests); *Murphy v. State of Ark.*, 852 F.2d 1039, 1042-43 (8th Cir. 1988) (same). As discussed above, Congress determined that the best way to achieve the goals of the ACA, including expanding preventive services coverage, was to build on the existing employer-based system, and the anticipated benefits of the regulations are attributable not only to the fact that recommended contraceptive services will be available to women with no cost-sharing, but also to the fact that these services will be available through the existing employer-based system of health coverage through which women will face minimal logistical and administrative obstacles to receiving coverage of their care. Plaintiffs' alternatives, by contrast, have none of these advantages. They would require establishing entirely new government programs and infrastructures or fundamentally altering an existing one, and would almost certainly require women to take burdensome steps to find out about the availability of and sign up for a new benefit, thereby ensuring that fewer women would take advantage of it. *See* 78 Fed. Reg. at

39,888, AR at 20. Nor do plaintiffs offer any suggestion as to how these programs could be integrated with the employer-based system or how women would obtain government-provided preventive services in practice. Thus, plaintiffs' proposals—in addition to raising myriad administrative and logistical difficulties and being unauthorized by any statute and not funded by any appropriation—are less likely to achieve the compelling interests furthered by the regulations, and therefore do not represent reasonable less restrictive means. *Id.*

Because plaintiffs have failed to put forth viable less restrictive alternatives that would achieve the government's compelling interests, the Court should reject plaintiffs' argument that the regulations fail strict scrutiny.

B. The Regulations Do Not Violate the Free Exercise Clause

The Supreme Court has made clear that 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. at 531-32. "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, nearly every court to have considered a free exercise challenge to the prior version of the regulations has rejected it, concluding that the regulations are neutral and generally applicable.[16] "The regulations were passed, not with the object of interfering with

[16] *See MK Chambers*, 2013 WL 1340719, at *5; *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*, 912 F. Supp. 2d at 744-47; *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp. 2d 1278, 1289-90 (W.D. Okla. 2012), *rev'd on other grounds*, 2013 WL 3216103; *O'Brien*, 894 F. Supp. 2d at 1160-62; *see also Catholic Charities of Diocese of Albany v. Serio*, 859 N.E.2d 459, 468-69 (N.Y. 2006) (rejecting similar challenge to state law); *Catholic Charities of Sacramento*, 85 P.3d at 81-87. *But see Sharpe Holdings, Inc. v. HHS*, No. 2:12-CV-92-DDN, 2012 WL 6738489, at

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. 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."); *Grote*, 914 F. Supp. 2d at 952-53 ("[T]he purpose of the regulations is a secular one, to wit, to promote public health and gender equality.").

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 [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 existence of express exceptions or accommodations for objectively defined categories of entities, like grandfathered plans, religious employers, and eligible organizations, "does not mean that [the regulations do] not apply generally." *Autocam*, 2012 WL 6845677, at *5. "General applicability does not mean absolute universality." *Olsen v. Mukasey*, 541 F.3d 827, 832 (8th Cir. 2008); *accord Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *Am. Friends Serv. Comm. Corp. v. Thornburgh*, 951 F.2d 957, 960-61 (9th Cir. 1991) (concluding employer verification statute was generally applicable even though it exempted

*5 (E.D. Mo. Dec. 31, 2012); *Geneva Coll. v. Sebelius*, No. 2:12–cv–00207, 2013 WL 838238, at *24-26 (W.D. Penn. Mar. 6, 2013).

independent contractors, household employees, and employees hired prior to November 1986 because exemptions "exclude[d] entire, objectively-defined categories of employees"); *Intercommunity Ctr. for Justice & Peace v. INS*, 910 F.2d 42, 44 (2d Cir. 1990) (same). "Instead, exemptions undermining 'general applicability' are those tending to suggest disfavor of religion." *O'Brien*, 894 F. Supp. 2d at 1162. 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. *Id.*; *see also 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."); *Grote*, 914 F. Supp. 2d at 953 ("[C]arving out an exemption for defined religious entities . . . tends to support an argument in favor of neutrality."). 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). 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. Thus, these categorical exceptions and accommodations do not trigger strict scrutiny.

Finally, Plaintiffs' unsupported assertions that the regulations were "designed" to "target the Schools and others like them," and that defendants promulgated the regulations "in order to suppress the religious exercise of the Schools and others," Am. Compl. ¶ 233-34, are mere rhetorical bluster. 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 O'Brien*, 894 F. Supp. 2d at 1161; *Conestoga*, 917 F. Supp. 2d at 410; *Grote*, 914 F. Supp. 2d at 952-53. 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 undermine the goal of ensuring that women have access to coverage for recommended preventive services without cost sharing.[17]

For these reasons Count II fails.

C. The Regulations Do Not Violate the Establishment Clause

"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 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

[17] Even if the regulations were not neutral or generally applicable, plaintiffs' free exercise challenge still would fail because the regulations satisfy strict scrutiny. *See supra*.

"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 the Diocese of Albany*, 859 N.E.2d at 468-69 ("This kind of distinction—not between denominations, but between religious organizations based on the nature of their activities—is not what *Larson* condemns."). Here, the distinctions established by the regulations are not so drawn.

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. The regulations, therefore, do not discriminate among religions in violation of the Establishment Clause. Indeed, every court to have considered an Establishment Clause challenge to the prior version of the regulations—which also included a requirement that the organization be an organization as described in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended—has rejected it. *See, e.g.*, *O'Brien*, 894 F. Supp. 2d at 1162 (upholding prior version of religious employer exemption because it did "not differentiate between religions, but applie[d] equally to all denominations"); *Conestoga*, 917 F. Supp. 2d at 416-17 (same);

Grote, 914 F. Supp. 2d at 954 (same); *see also Liberty Univ., Inc. v. Lew*, __ F.3d__, 2013 WL 3470532, at *17-18 (4th Cir. July 11, 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)).

"As the Supreme Court has frequently articulated, 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"); *Corp. of the Presiding Bishop v. Amos*, 483 U.S. 327, 334 (1987) (upholding Title VII's exemption for religious organizations).[18] For all of these reasons, Count III fails.[19]

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

Plaintiffs' free speech claims fare 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 regulations to express whatever views they may have on the use of contraceptive services (or any

[18] 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*; *Larson*, 456 U.S. at 251-52.

[19] Plaintiffs also that the regulations interfere with plaintiffs' "internal decisions." Am. Compl. ¶¶ 243-48. But that is merely a restatement of plaintiffs' substantial burden theory, which fails for reasons explained already.

other health care services) as well as their views about the regulations. Plaintiffs, moreover, may encourage their employees not to use contraceptive services.

Indeed, every court to review a Free Speech challenge to the prior contraceptive-coverage regulations has rejected it, in part, because the regulations deal with conduct. *See MK Chambers Co. v. U.S. Dep't of Health & Human Servs.,* Civil Action No. 13–11379, 2013 WL 1340719, *6 (E.D. Mich. Apr. 3, 2013) ("Like the [law at issue in *FAIR*], the contraceptive requirement regulates conduct, not speech." (quotations omitted)); *Briscoe v. Sebelius*, 927 F. Supp. 2d 1109 (D. Colo. 2013) ("The plaintiffs cite no authority and I am not aware of any authority holding that such conduct qualifies as speech so as to trigger First Amendment protection."); *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.

The regulations also do not require plaintiffs to subsidize any conduct that is "inherently expressive." *FAIR*, 547 U.S. at 66; *see also United States v. O'Brien*, 391 U.S. 367, 376 (1968) (recognizing that some forms of "symbolic speech" are protected by the First Amendment). As an initial matter, the regulations explicitly prohibit plaintiffs' issuers/TPAs from imposing any cost sharing, premium, fee, or other charge on plaintiffs or their plans with respect to the separate payments for contraceptive services made by the issuers/TPAs. *See* 78 Fed. Reg. at 39,880, AR at 12. Plaintiffs, therefore, are not funding or subsidizing anything pertaining to contraceptive coverage. Moreover, even if plaintiffs played some role in an issuer's or TPA's provision of payments for contraceptive services (and they do not), making payments for health care services is not the sort of conduct the Supreme Court has recognized as inherently expressive. *See Conestoga*, 917 F. Supp. 2d at 418; *Grote*, 2012 WL 6725905, at *10; *Autocam*, 2012 WL 6845677, at *8 ("Including contraceptive coverage in a health care plan is not inherently expressive conduct."); *O'Brien*, 894 F. Supp. 2d at 1166-67 ("Giving or receiving health care is

not a statement in the same sense as wearing a black armband or burning an American flag." (internal citations omitted)); *Catholic Charities of Sacramento*, 85 P.3d at 89 ("a law regulating health care benefits is not speech"); *Diocese of Albany*, 859 N.E.2d at 465; *see also FAIR*, 547 U.S. at 65-66 (making space for military recruiters on campus is not conduct that indicates colleges' support for, or sponsorship of, recruiters' message).

Furthermore, plaintiffs are wrong when they contend that the regulations require plaintiffs to "facilitate access" to "counseling related to abortion." Compl. ¶ 254. 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 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' free speech and expressive association claims—Counts IV and VI—fail.

E. The Regulations Do Not Violate the Due Process Clause

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. ¶¶ 261-62. And plaintiffs evidently have no difficulty determining what the regulations require of them; at the very least, then, the regulations are not vague as

applied to Plaintiffs. *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 plaintiffs' proposed conduct, which means that plaintiffs' vagueness challenge must fail." 130 S. Ct. at 2720.

Finally, plaintiffs 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. ¶ 264. 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.[20] Similarly, there is no merit to plaintiffs' allegation that the regulations—which contain specific criteria—will lead to discriminatory enforcement. For these reasons, Count V fails.

F. Plaintiffs' APA Claims Fail

1. 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. These allegations are baseless. The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite

[20] 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.

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). Defendants complied with these requirements.[21]

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. This argument is based on a misunderstanding of both the ACA and the regulations. The provision of the ACA to which plaintiff refers, 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 the ACA requires

[21] 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.

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.

2. 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.

3. 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.

This set of arguments should be rejected at the outset because plaintiffs lack prudential standing to assert it. 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 each 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.[22] They therefore do not fall within the zone of interests to be protected by the statute in question. Similarly, the Weldon Amendment denies funds made available in the Consolidated Appropriations Act of 2012 to any federal, state, or local agency, program, or government that "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. No. 112-74, §§ 506, 507, 125 Stat. 786, 1111-12 (Dec. 23, 2011). Plaintiffs are not institutional or individual health care entities, *see id.* at § 507(d)(2), so they are not within this statute's zone of interests either. Finally, 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. §

[22] 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."

300a-7(d). By merely providing a health plan to its employees, plaintiffs are 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. They are therefore not within the Church Amendment's zone of interests either.

Even if the Court were to reach the merits of these 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.[23] 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. *E.g.*, *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

[23] 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 Sept. 27, 2013); *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 Sept. 27, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

Because they reflect a settled understanding of FDA-approved contraceptives that is in accordance with existing federal laws prohibiting federal funding for certain abortions, the regulations are consistent with over a decade of regulatory policy and practice and thus cannot be deemed contrary to any law dealing with abortion.[24] *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)).

[24] 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—collected at Count VII— thus fail.

II. PLAINTIFFS CANNOT ESTABLISH IRREPARABLE HARM, AND AN INJUNCTION WOULD INJURE THE GOVERNMENT AND THE PUBLIC

"The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Even assuming arguendo that same rule applies to a statutory claim under RFRA, plaintiffs have not shown that the challenged regulations violate their First Amendment or RFRA rights, so there has been no "loss of First Amendment freedoms" for any period of time, *id.* In this respect, the merits and irreparable injury prongs of the preliminary injunction analysis merge together, and plaintiffs cannot show irreparable injury without also showing a likelihood of success on the merits, which they cannot do. *See McNeilly v. Land*, 684 F.3d 611, 621 (6th Cir. 2012).

Plaintiffs' motion for preliminary injunctive relief suffers from an additional, critical flaw: The harm that Biola alleges is in no way imminent. *See Bedrossian v. Northwestern Memorial Hosp.*, 409 F.3d 840, 844 (7th Cir. 2005) (noting that the irreparable harm must be imminent); *Chacon v. Granata*, 515 F.2d 922, 925 (5th Cir. 1975) ("An injunction is appropriate only if the anticipated injury is *imminent* and irreparable.") (emphasis added); *Holiday Inns of Am., Inc. v. B & B Corp.*, 409 F.2d 615, 618 (3d Cir. 1969) ("The dramatic and drastic power of injunctive force may be unleashed only against conditions generating a *presently existing* actual threat[.]") (emphasis added). Because defendants have extended the enforcement safe harbor to encompass plan years that begin between August 1 and December 31, 2013, the challenged regulations will not be enforced by defendants against Biola until April 1, 2014, when its next plan year begins.[25] Am. Compl. ¶ 179. There is ample time between now and then for the parties to litigate the merits of Biola's claims in the normal course of motions practice, without the extraordinary relief of a preliminary injunction. It is also no answer to say, as plaintiffs do, that they require a preliminary injunction because of "uncertainty" surrounding the regulations. Pls.' Br. at 11. There is no uncertainty—the regulations have been issued in final form, and

[25] Similarly, Grace's student health plan year does not begin until July 25, 2014, *see* Am. Compl. ¶ 181, so the challenged regulations will not be enforced by defendants against Grace as to that health plan until July 25, 2014.

defendants' health plans must comply as of the first plan year beginning on or after January 1, 2014. To the extent any uncertainty remains as to these obligations, it has been introduced only by the filing of this lawsuit.

As to the final two preliminary injunction factors—the balance of equities and the public interest—"there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop and enforce." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *see also Connection Distrib. Co. v. Reno*, 154 F.3d 281, 296 (6th Cir. 1998) (indicating that granting an injunction against the enforcement of a likely constitutional statute would harm the government). Enjoining the preventive services coverage regulations as to plaintiffs would undermine the government's ability to achieve Congress's goals of improving the health of women and newborn children and equalizing the coverage of preventive services for women and men.[26]

It would also be contrary to the public interest to deny plaintiffs' employees (and their families) the benefits of the preventive services coverage regulations. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982) ("[C]ourts . . . should pay particular regard for the public consequences in employing the extraordinary remedy of injunction."). Those employees should not be deprived of the benefits of payments provided by a third party that is not their employer for the full range of FDA-approved contraceptive services, as prescribed by a health care provider, on the basis of their employers' religious objection. Many women do not use contraceptive services because they are not covered by their health plan or require costly copayments, coinsurance, or deductibles. IOM REP. at 19-20, 109, AR at 317-18, 407; 77 Fed. Reg. at 8727, AR at 214; 78 Fed. Reg. at 39,887, AR at 19. As a result, in many cases, both

[26] Plaintiffs note that defendants consented to preliminary injunctions in some cases involving for-profit corporations, *see* Pls.' Br. at 12-13, but defendants' consent in those cases was nothing more than an effort to conserve judicial and governmental resources. Those cases were filed after motions panels in those circuits had preliminary enjoined the regulations pending appeal in similar cases. *See Mersino*, 2013 WL 3546702 at *16 ("[W]here the government has conceded to injunctive relief, it appears that it has generally done so in jurisdictions where the legal landscape has been set against them, and continuing to litigate the claims in those jurisdictions would be a waste of both judicial and client resources."). The government continues to oppose preliminary injunctions sought by for-profit corporations in other circuits, and opposes in all circuits preliminary injunctions sought by non-profit entities as to the regulations challenged in this case.

women and developing fetuses suffer negative health consequences. *See* IOM REP. at 20, 102-04, AR at 318, 400-02; 77 Fed. Reg. at 8728, AR at 215. And women are put at a competitive disadvantage due to their lost productivity and the disproportionate financial burden they bear in regard to preventive health services. 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009); *see also* IOM REP. at 20, AR at 318.

Enjoining defendants from enforcing, as to plaintiffs, the preventive services coverage regulations—the purpose of which is to eliminate these burdens, 75 Fed. Reg. at 41,733, AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215—would thus inflict a very real harm on the public and, in particular, a readily identifiable group of individuals. *See Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) (vacating preliminary injunction entered by district court and noting that "[t]here is a general public interest in ensuring that all citizens have timely access to lawfully prescribed medications"). Plaintiffs' health plans cover nearly 2,000 people. Compl. ¶¶45, 50, 71. Accordingly, even assuming plaintiffs were likely to succeed on the merits (which they are not for the reasons explained above), any potential harm to plaintiffs resulting from their offense at a third party providing payment for contraceptive services at no cost to, and with no administration by, plaintiffs' would be outweighed by the significant harm an injunction would cause these employees and their families.

CONCLUSION

For the foregoing reasons, defendants respectfully ask that the Court deny plaintiffs' motion for a preliminary injunction, and grant defendants' motion to dismiss or, in the alternative, for summary judgment on all of plaintiffs' claims.

Respectfully submitted this 27th day of September, 2013,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notice of such filing to all parties.

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

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA

GRACE SCHOOLS and BIOLA UNIVERSITY, INC., Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 3:12-cv-00459-JD-CAN

DEFENDANTS' STATEMENT OF MATERIAL FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 56.1(a), defendants hereby submit the following statement of material facts as to which defendants contend there is no genuine issue in connection with their motion for summary judgment under Rule 56(b) of the Federal Rules of Civil Procedure:

1. Before the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), 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.

2. Section 1001 of the ACA 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).

3. 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) with developing recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300.

4. After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, among other things, "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.

5. 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.

6. 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.

7. On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, encompassing all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider, 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.

8. 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.

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

9. Group health plans established or maintained by religious employers (and associated group health insurance coverage) are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84; 45 C.F.R. § 147.131(a).

10. 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.

11. 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.

12. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,870, AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21,

2012) (Advance Notice of Proposed Rulem aking (ANPRM)), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013) (Notice of Proposed Rulemaking (NPRM)), AR at 165-85.

13. Under the 2013 final 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).

14. The changes made to the definition of religious employer in the 2013 final rules 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.

15. The 2013 final rules 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).

16. 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.

17. 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.

18. 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 third party administrator (TPA). *Id.* at 39,878-79, AR at 10-11.

19. Its participants and beneficiaries, however, will still benefit from separate payments for contraceptive services made by the issuer or TPA, without cost sharing or other charge. *Id.* at 39,874, AR at 6.

20. 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.

21. In the case of an organization with a self-insured group health plan, 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.

22. Any costs incurred by TPAs will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See id.* at 39,880, AR at 12.

23. 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 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.

24. The primary predicted benefit of the preventive services coverage 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. 41,726, 41,733 (July 19, 2010), AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19.

25. "By expanding coverage and eliminating cost sharing for recommended preventive services, [the regulations are] expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733, AR at 233; *see also* 78 Fed. Reg. at 39,873 ("Research [ ] shows that cost sharing can be a significant barrier to access to contraception." (citation omitted)), AR at 5.

26. Although a majority of employers cover FDA-approved contraceptives, *see* IOM Rep. at 109, AR at 407, many women forgo preventive services because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109, AR at 317-18, 407.

27. Unintended pregnancies have proven in many cases to have negative health consequences for women and developing fetuses. *See* 78 Fed. Reg. at 39,872, AR at 4.

28. 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, 103-04, AR at 318, 401-02.

29. Contraceptive coverage further helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103, AR at 401; *see also* 78 Fed. Reg. at 39,872 ("Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-gestational age births.") (citing studies), AR at 4.

30. "Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrative preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne)." 78 Fed. Reg. at 39,872, AR at 4; *see also* IOM Rep. at 103-04 ("[P]regnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome."), AR at 401-02.

31. "[W]omen 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." 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 19, AR at 317.

32. These costs result in women often forgoing preventive care and place women in the workforce at a disadvantage compared to their male coworkers. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274 (daily ed. Dec. 3, 2009) (statement of Sen. Murray); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 20, AR at 318.

33. The grandfathering of certain health plans with respect to certain provisions of the ACA is not specifically limited to the preventive services coverage regulations. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140.

34. The effect of grandfathering is not really 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.

35. A majority of group health plans will have lost their grandfather status by the end of 2013. *See* 75 Fed. Reg. 34,538, 34,552 (June 17, 2010); *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.

36. 26 U.S.C. § 4980H(c)(2) does not exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. at 39,887 n.49, AR at 19.

37. Instead, it excludes employers with fewer than fifty full-time equivalent employees from the employer responsibility provision, meaning that, starting in 2015, such employers are not subject to the possibility of assessable payments if they do not provide health coverage to their full-time employees and their dependents. *See* 26 U.S.C. § 4980H(c)(2).

38. Small businesses that do offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive services, including contraceptive services, without cost-sharing. 78 Fed. Reg. at 39,887 n.49, AR at 19.

39. The ACA provides tax incentives for small businesses to encourage the purchase of health insurance. *See* 26 U.S.C. § 45R.

40. Even if a small business were to choose not to offer health coverage, employees of such business could get health insurance coverage that is facilitated by other ACA

provisions—primarily those establishing both small group market and individual market health insurance exchanges and those establishing tax credits to make the purchase of coverage through such exchanges more affordable—and the coverage they receive through such exchanges will include coverage of all recommended preventive services, including contraception. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19.

41. The only exemption from the preventive services coverage regulations is the exemption for the group health plans of religious employers. 45 C.F.R. § 147.131(a).

42. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are, as a group, more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. *See* 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19.

43. Congress did not adopt a single (government) payer system financed through taxes and instead opted to build on the existing system of employment-based coverage. *See* H.R. Rep. No. 111-443, pt. II, at 984-86 (2010).

44. Defendants are constrained by statute from adopting the alternative administrative schemes proposed by plaintiffs. *See* 78 Fed. Reg. at 39,888, AR at 20.

45. Plaintiffs' proposed alternatives are not feasible because they would also impose considerable new costs and other burdens on the government and would otherwise be impractical. *See* 78 Fed. Reg. at 39,888, AR at 20.

46. Nor would the proposed alternatives be equally effective in advancing the government's compelling interests. *See* 78 Fed. Reg. at 39,888, AR at 20.

47. Plaintiffs' alternatives would require establishing entirely new governm ent programs and infrastructures or fundam entally altering an existing one, and would require women to take burdensom e steps to find out a bout the availability of and sign up for a new benefit, thereby ensuring that fewe r women would take advantage of it. *See* 78 Fed. Reg. at 39,888, AR at 20.

48. The regulations explicitly prohibit issuers and TPAs from im posing any cost-sharing, premium, fee, or other ch arge on plaintiffs or their plan s with respect to the separate payments for contraceptive services made by the issuers and TPAs. *See* 78 Fed. Reg. at 39,880, AR at 12.

49. The regulations simply require coverage of "education and counseling for wom en with reproductive capacity." HRSA Guidelines, AR at 130-31.

50. Defendants issued the ANPRM on March 21, 2012 and solicited comments on it. 77 Fed. Reg. at 16,501, AR at 186.

51. 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.

52. Defendants received over 400,000 comm ents, 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.

53. The ACA requires only that there be a m inimum interval of not less than one year between the date on which a recomm endation or guideline is issued and the plan year for which the coverage of the services included in that recommendation or guideline must take effect. *See* 42 U.S.C. § 300gg-13(b); 75 Fed. Reg. at 41,729, AR at 229.

54. The HRSA Guidelines were published on August 1, 2011, and these regulations apply for plan years beginning on or after January 1, 2014. HRSA Guidelines, AR 283-84; 78 Fed. Reg. at 39,870, AR at 2.

55. 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).

56. 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.

57. Plaintiffs are neither health insurance issuers nor purchasers of qualified health plans.

58. The Weldon Amendment denies funds made available in the Consolidated Appropriations Act of 2012 to any federal, state, or local agency, program, or government that "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. No. 112-74, §§ 506, 507, 125 Stat. 786, 1111-12 (Dec. 23, 2011).

59. Plaintiffs are not institutional or individual health care entities. *See id.* at § 507(d)(2).

60. 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).

61. The preventive services covered by the regulations do not include abortifacient drugs. 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 Sept. 27, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320.

62. The list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See* IOM REP. at 105, AR at 403.

63. 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.").

64. 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, except under limited circumstances, may not offer abortion—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 Sept. 27, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

65. Representative Weldon, the sponsor of the Weldon Amendment, 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.").

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2013, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which sent notice of such filing to all parties.

/s/ Michael C. Pollack
MICHAEL C. POLLACK