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

SOUTHERN NAZARENE UNIVERSITY, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 5:13-cv-01015-F

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

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants move to dismiss this action for lack of subject matter jurisdiction and for failure to state a claim upon which relief may be granted. In the alternative, defendants move for summary judgment on all of plaintiffs' claims pursuant to Rule 56. The grounds for these motions are set forth in the accompanying memorandum, which also responds to plaintiffs' motion for preliminary injunction.

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INTRODUCTION

Plaintiffs Southern Nazarene University (SNU), Oklahoma Wesleyan University (OKWU), Oklahoma Baptist University (OBU), and Mid-America Christian University (MACU) ask this Court to 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, 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.

The regulations are the product of a decision by defendants to accommodate concerns expressed by non-profit religious organizations, like plaintiffs, by relieving them of responsibility to contract, arrange, pay, or refer for contraceptive coverage or services. The regulations also ensure that women who participate in the group health plans of such organizations are not denied access to contraceptive coverage without cost-sharing. To be eligible for the accommodations, an 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 OKWU, OBU, and MACU—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 SNU[1]—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 the Religious Freedom Restoration Act (RFRA). Plaintiffs 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 and students will be able to obtain contraceptive coverage through other parties. This extraordinary contention suggests that plaintiffs not only seek to avoid contracting, arranging, paying, or referring for contraceptive coverage themselves, but also seek to prevent the women who work for, and attend, the universities from obtaining such coverage, even if through other parties.

[1] SNU alleges that "its health plan is partially self-insured." Compl. ¶ 39. It is not entirely clear on the facts in the Complaint precisely how SNU's health plan operates—among other things, there are two options in that plan, *id.* ¶ 38—but because SNU describes the accommodation available to it as the one available to self-insured eligible organizations, *see id.* ¶ 175, defendants assume for the purposes of this brief that this is so.

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 have moved 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 and students to refrain from using contraceptive services. Plaintiffs are required only to inform their issuers/third-party administrators 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 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.

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 or Equal Protection Clauses. Plaintiffs also cannot succeed on their APA claims. Plaintiffs 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. [2]

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

Section 1001 of the ACA—which includes the preventive services coverage provision relevant here—seeks to cure this problem by making preventive care accessible and affordable for many more Americans. Specifically, the provision requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing, including, "[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).[3]

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

[3] 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 Dec. 17, 2013).

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. *Id*. at 102-03, AR at 400-01.

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.[4] 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

[4] 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.

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.[5]

The 2013 final rules represent a significant accommodation by the government of the religious objections of certain non-profit religious organizations while promoting two important policy goals. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the government's compelling 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.

[5] The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, 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* 78 Fed. Reg. at 39,871-72, AR at 3-4.

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 4. 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 2013 final rules also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations." 78 Fed. Reg. at 39,875-80, AR at 7-12. 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 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—like OKWU, OBU, and MACU—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. *Id*. at 39,875-77, AR at 7-9. In the case of an organization with a self-insured group health plan—like SNU—the organization's TPA, upon receipt of the self-certification, will 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.

MOVANT'S STATEMENT OF MATERIAL FACTS

1. 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. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), AR at 317-18, 407.

2. Due largely to cost, Americans used preventive services at about half the recommended rate. *See id.* at 19-20, 109, AR at 317-18, 407.

3. Section 1001 of the ACA seeks to cure this problem by making preventive care accessible and affordable for many more Americans. 42 U.S.C. § 300gg-13(a)(4).

4. Specifically, the provision requires all group health plans and health insurance issuers that offer non-grandfathered 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)]." *Id.*

5. Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services 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.

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

7. 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.

8. 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 them) and promote healthy birth spacing. *See id.* at 102-03, AR at 400-01.

9. 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.

10. 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.

11. 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 Guidelines, AR at 283-84; 45 C.F.R. § 147.131(a).

12. 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.

13. 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. 77 Fed. Reg. at 8728, AR at 215.

14. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,870 (July 2, 2013), AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012) (Advance Notice of Proposed Rulemaking), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013) (Notice of Proposed Rulemaking), AR at 165-85.

15. The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, 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* 78 Fed. Reg. at 39,871-72, AR at 3-4.

16. 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. *See* 78 Fed. Reg. 39,870, AR at 1-31.

17. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the government's interests in safeguarding public health and ensuring that women have equal access to health care. *See id.*

18. The regulations do so in a way that does not require non-profit religious organizations with religious objections to contract, arrange, pay, or refer for that coverage. *See id.*

19. The 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth. *See id.* at 39,874, AR at 6.

20. 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).

21. 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.

22. 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.

23. 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.

24. 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.

25. 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. *See id.* at 39,878-79, AR at 10-11.

26. 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.

27. 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.

28. 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.

29. 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.

30. By contrast, individuals in plans of eligible organizations that qualify for the accommodations are less likely than individuals in plans of religious employers to share their employer's faith and object to contraceptive coverage on religious grounds. *See id.* at 39,874, 39,887, AR at 6, 19.

31. "Nothing in the[] final regulations prohibits an eligible organization from expressing its opposition to the use of contraception." *Id.* at 39,880 n.41, AR at 12.

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

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

34. 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.

35. 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.

36. The ACA 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 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.

37. 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.

38. 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).

39. 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 or HHS or states no later than January 1, 2014. *Id.* § 18031.

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

41. 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).

42. 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).

43. 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 Dec. 17, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320.

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

45. 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.").

46. 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 Dec. 17, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

47. 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.").

STANDARD OF REVIEW

Defendants move to dismiss one of plaintiffs' claims in part under Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. *See infra* pp. 43-44. 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). Defendants also move to dismiss the case in its entirety for failure to state a claim upon which relief may be granted under Rule 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).

To the extent that the Court must consider the administrative record in addition to the face of the complaint, defendants move, in the alternative, for summary judgment

under Rule 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 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*, 555 U.S. 7, 22 (2008). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id*. at 20.

ARGUMENT

I. PLAINTIFFS' RELIGIOUS FREEDOM RESTORATION ACT CLAIM IS WITHOUT MERIT

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). "A substantial burden exists when government action puts 'substantial pressure on an adherent to modify his behavior and to violate his beliefs.'" *Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008) (citing *Thomas v. Review Bd. of the Ind. Emp't Sec. Div.*, 450 U.S. 707, 718 (1981)). "An

inconsequential or *de minimis* burden on religious practice does not rise to this level, nor does a burden on activity unimportant to the adherent's religious scheme." *Kaemmerling*, 553 F.3d at 678; *see Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) ("In order to show a substantial burden, the plaintiff must show that the challenged action 'truly pressures the adherent to significantly modify his religious behavior and significantly violate his religious beliefs.'").

Plaintiffs cannot show—as they must—that the challenged regulations substantially burden their religious exercise. Plaintiffs rely heavily on the Tenth Circuit's decision in *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc) as if it were dispositive of this issue, but it is not. *Hobby Lobby* addressed the RFRA claim of for-profit corporations, which, unlike plaintiffs here, are not eligible for the accommodations and thus are required by the regulations to contract, arrange, and pay for contraceptive coverage for their employees. The court had no occasion to consider whether these regulations' accommodations, which relieve eligible non-profit religious organizations like plaintiffs of any obligation to contract, arrange, pay, or refer for contraceptive coverage, impose a substantial burden on religious exercise. They do not for the reasons discussed below.[6]

[6] Similarly, the district court in *Zubik v. Sebelius*, __ F. Supp. 2d __, 2013 WL 6118696 (W.D. Pa. Nov. 21, 2013), was wrong to rely on cases involving claims of for-profit employers. For all the reasons set out in this brief, the *Zubik* court's conclusion that the regulations at issue in that case (and in this one) impose a substantial burden on the plaintiffs in that case—a conclusion that was rendered without citation to any legal authority, *id.* at *24-27—is simply unpersuasive. Likewise, the recent ruling by the district court in *Archdiocese of New York*, No. 12 Civ. 2542 (BMC) (E.D.N.Y. Dec. 16, 2013), ECF No. 116, glossed over the animating question of this case, which is whether a

The regulations do not impose a substantial burden on plaintiffs because they do not require plaintiffs to modify their behavior in any meaningful way. 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 and students 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 or students. 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 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 significantly modify [their] religious behavior." *Garner*, 713 F.3d at 241. 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.

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substantial burden may be said to exist because a plaintiff objects to the consequences of actions it does not independently object to taking. For the reasons set out here, it may not.

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 coverage for their employees and students—which, under these regulations, they are—but plaintiffs would also prevent *anyone else* from providing such coverage to their employees and students, 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 plaintiffs "trigger" a third party's provision to plaintiffs' employees of services to which plaintiffs object. Compl. ¶¶ 176, 178; *see* Pls.' Br. at 3 (stating that RFRA is violated because plaintiffs' decision to offer a group health plan "results in" the provision to plaintiffs' employees of services to which plaintiffs object). 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]" by, or would be the "result" of, plaintiffs' objection to providing such coverage themselves. But RFRA is a shield, not a sword, *see O'Brien v. HHS*, 894 F. Supp. 2d 1149, 1158-60 (E.D. Mo. 2012), and accordingly it does not prevent the government from providing alternative means of achieving important statutory objectives once it has provided a religious accommodation. *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 [plaintiff] plays no role." *Id*. As in *Kaemmerling*, "[a]lthough the [third party]'s activities . . . may offend [plaintiff's] religious beliefs, they cannot be said to hamper [its] 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 "facilitat[e]" access to contraception coverage, Pl.'s Br. at 6, 8, and that it is this facilitation that violates plaintiffs' religious beliefs. 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 must 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 plaintiffs 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. 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.[7]

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."). 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

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

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 v. Charter Twp. of Meridian*, 258 Fed. App'x 729, 734-36 (6th Cir. 2007) (reviewing cases); *see also, e.g.*, *Garner*, 713 F.3d at 241; *Westchester Day Sch. v. Vill. of Mamaroneck*, 504 F.3d 338, 348-49 (2d Cir. 2007).

The Tenth Circuit's decision in *Hobby Lobby* is not to the contrary. There, the court observed that, in determining whether an alleged burden is substantial, the court's "only task is to determine whether the claimant's belief is sincere, and if so, whether the government has applied substantial pressure on the claimant to violate that belief." 723 F.3d at 1137. But, because the for-profit corporation plaintiffs in that case were not eligible for the accommodations (and thus were required to contract, arrange, and pay for contraceptive coverage), the court did not address whether an accommodation that requires a plaintiff to do nothing beyond satisfying a purely administrative self-certification requirement imposes a substantial burden on religious exercise. Indeed, the *Hobby Lobby* court relied heavily on *Abdulhaseeb v. Calbone*, 600 F.3d 1301 (10th Cir. 2010), which makes clear that, for a law to impose a substantial burden, it must require

some actual change in religious behavior —either forced participation in conduct or forced abstention from conduct. *See Hobby Lobby*, 723 F.3d at 1138 ("[A] government act imposes a 'substantial burden' on religious exercise if it: (1) '*requires participation* in an activity prohibited by a sincerely held religious belief,' (2) '*prevents participation in conduct* motivated by a sincerely held religious belief,' or (3) 'places substantial pressure on an adherent . . . *to engage in conduct* contrary to a sincerely held religious belief." (emphasis added) (citing *Abdulhaseeb*, 600 F.3d at 1315)).

Because the challenged regulations require that plaintiffs take the *de minimis* step that they would have to take even in the absence of the regulations, the regulations do not impose a substantial burden on plaintiffs' religious exercise. Plaintiffs' RFRA claim should therefore be dismissed, or summary judgment should be granted to defendants.

The challenged regulations also do not impose a substantial burden on plaintiffs' religious exercise because any burden is indirect and too attenuated to be substantial. The ultimate decision of whether to use contraception "rests not with [the employers], but with [the] employees" in consultation with their health care providers. *Conestoga*, 917 F. Supp. 2d at 414-15; *see e.g.*, *Autocam Corp. v. Sebelius*, 2012 WL 6845677, at *6 (W.D. Mich. Dec. 24, 2012) ("The incremental difference between providing the benefit directly, rather than indirectly, is unlikely to qualify as a substantial burden on the Autocam Plaintiffs."). Moreover, even if the challenged regulations were deemed to impose a substantial burden on plaintiffs' religious exercise, the regulations satisfy strict scrutiny because they are narrowly tailored to serve compelling governmental interests in public health and gender equality. Defendants recognize that a majority of the en banc

Tenth Circuit rejected these arguments in *Hobby Lobby*, and that this Court is bound by that decision. The Supreme Court recently granted defendants' petition for a writ of certiorari, in which defendants asked the Supreme Court to review the Tenth Circuit's decision in that case. *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354, 2013 WL 5297798 (U.S. Nov. 26, 2013). Defendants raise the arguments here merely to preserve them for appeal.

II. THE REGULATIONS DO NOT VIOLATE THE FREE EXERCISE CLAUSE

A law that is neutral and generally applicable does not run afoul of the Free Exercise Clause even if it prescribes conduct that an individual's religion proscribes or has the incidental effect of burdening a particular religious practice. *Emp't Div. v. Smith*, 494 U.S. 872, 879 (1990). "Neutrality and general applicability are interrelated." *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 531 (1993). 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.[8] "The regulations were passed, not with the object of interfering with religious practices, but instead to improve women's access to health care and lessen the disparity between men's and women's healthcare costs." *O'Brien*, 894 F. Supp. 2d at 1161. 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

[8] *See MK Chambers Co. v. U.S. Dep't of Health & Human Servs.*, 2013 WL 1340719, at *5 (E.D. Mich. Apr. 3, 2013); *Eden Foods, Inc. v. Sebelius*, 2013 WL 1190001, at *4-5 (E.D. Mich. Mar. 22, 2013); *Conestoga*, 917 F. Supp. 2d at 409-10; *Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943, 952-53 (S.D. Ind. 2012), *rev'd on other grounds sub nom. Korte v. Sebelius*, __ F.3d __, 2013 WL 5960692 (7th Cir. Nov. 8, 2013); *Autocam*, 2012 WL 6845677, at *5; *Korte v. U.S. Dep't of Health & Human Servs.*, 912 F. Supp. 2d 735, 744-47 (S.D. Ill. 2012), *rev'd on other grounds sub nom. Korte v. Sebelius*, __ F.3d __, 2013 WL 5960692 (7th Cir. Nov. 8, 2013); *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp. 2d 1278, 1289-90 (W.D. Okla. 2012), *rev'd on other grounds*, 723 F.3d 1114 (10th Cir. 2013); *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, Inc. v. Superior Court*, 85 P.3d 67, 81-87 (Cal. 2004) (same).

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).

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

"[C]arving out an exemption for defined religious entities [also] does not make a law non-neutral as to others." *Grote*, 914 F. Supp. 2d at 953 (quotation omitted). Indeed, the religious employer exemption "presents a strong argument in favor of neutrality" by

"demonstrating that the object of the law was not to infringe upon or restrict practices because of their religious motivation." *O'Brien*, 894 F. Supp. 2d at 1161 (quotations omitted); *see Conestoga*, 917 F. Supp. 2d at 410 ("The fact that exemptions were made for religious employers . . . . shows that the government made efforts to accommodate religious beliefs, which counsels in favor of the regulations' neutrality."). The regulations are not rendered unlawful "merely because the [religious employer exemption] does not extend as far as Plaintiff[] wish[es]." *Grote*, 914 F. Supp. 2d at 953.

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. ¶ 256-57, 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, e.g.*, *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.

III. 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 preferen ce"). 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 "particul ar religious denominations" to comply with registration and reporting requirem ents while excluding other religious denom inations. *Larson*, 456 U.S. at 254; *see also Bd. of Educ. of Kiry as Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that "single[d] out a particular religious sect for special treatment"). The Co urt, on the other ha nd, has upheld a statute that provided an exemption from military service for pers ons who had a conscientious objection to all wars, but not those wh o objected to onl y a particular war. *Gillette v. United States*, 401 U .S. 437 (1971). The Court e xplained 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 because it did not "conf er[] . . . 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 s ervices 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.

Finally, plaintiffs' allegation that the accommodations "require[] ongoing, comprehensive government surveillance" of an entangling nature, Compl. ¶ 263, is

simply incorrect. The accommodations neither contemplate nor require *any* government surveillance of religious organizations: to avail itself of the accommodations, eligible organizations like plaintiffs simply must self-certify that they meet the criteria to be eligible organizations and deliver that self-certification to their issuers/TPAs. In any event, any incidental interaction between the government and religious organizations would not be so "comprehensive," *Lemon v. Kurtzman*, 403 U.S. 602, 619 (1971), or "pervasive," *Agostini v. Felton*, 521 U.S. 203, 233 (1997), as to result in excessive entanglement. The Supreme Court has upheld laws that require government monitoring more onerous than any that could be conceived regarding the accommodations. *See Bowen v. Kendrick*, 487 U.S. 589, 615-617 (1988) (concluding there was no excessive entanglement where the government reviewed adolescent counseling programs set up by the religious institution grantees, reviewed the materials used by such grantees, and monitored the programs by periodic visits); *Roemer v. Board of Public Works of Md.*, 426 U.S. 736, 764–765 (1976) (rejecting excessive entanglement challenge where the State conducted annual audits to ensure that grants to religious colleges were not used to teach religion); *see also United States v. Corum*, 362 F.3d 489, 496 (8th Cir. 2004) (concluding statute did not foster excessive entanglement; "Although the government, in its role as the [statute's] enforcer, may interact with religious organizations, it is not required to engage in per[v]asive monitoring of or intrusion into the activities of these organizations").

Indeed, every court to have considered an Establishment Clause challenge to the prior version of the regulations has rejected it. *See, e.g.*, *O'Brien*, 894 F. Supp. 2d at 1162; *Conestoga*, 917 F. Supp. 2d at 416-17; *Grote*, 914 F. Supp. 2d at 954; *see also*

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"); *Liberty Univ., Inc. v. Lew*, 2013 WL 3470532, at *17-18 (4th Cir. July 11, 2013) (upholding another religious exemption in ACA where it made "no explicit and deliberate distinctions between sects" (quotation omitted)).

IV. 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 other health care services) as well as their views about the regulations. Plaintiffs, moreover, may encourage their employees and students 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, e.g.*, *MK Chambers*, 2013 WL 1340719, at *6; *Briscoe v. Sebelius*, 927 F. Supp. 2d 1109 (D. Colo. 2013); *Conestoga*, 917 F. Supp. 2d at 418; *Autocam*, 2012 WL 6845677, *8; *O'Brien*, 894 F. Supp. 2d at 1165-67. 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. The requirement that plaintiffs must self-certify their eligibility for an accommodation is "plainly incidental . . . to the regulation of conduct," *FAIR*, 547 U.S. at 62, not speech.

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, A R 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 6725 905, 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 college s' support for, or sponsorship of, recruiters' message).

Furthermore, plaintiffs are wrong whe n they contend that the regul ations require plaintiffs to "facilitate access to gover nment-dictated education and counseling related to abortion." Compl. ¶ 271. The r egulations simply require covera ge of "education and counseling for women with re productive capacity." HRSA Gu idelines, AR at 130-31. The conversations that may take place between a patient and her doc tor 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 objectiona ble because some of the conversations between a doctor and one of plaintiffs' em ployees *might* be supportive of something to which they object, accepting this theory would mean that the First Amendment is violated by the mere po ssibility of an employer's disagreement with a potential subject of discussion between an employee and her doctor, and w ould extend to all such interactions, not just those that are the subject of the challenge d regulations. The First Amendment does not re quire such a drastic result. *See, e.g., Conestoga*, 917 F. Supp. 2d at 418-19.

Finally, the regulations do not violate the right to expr essive association. To be sure, "[t]he right to speak is ofte n exercised most effectively by combining one's voice with the voices of othe rs." *FAIR*, 547 U.S. at 68. "If the government were free to restrict individuals' ability to join to gether and speak, it could essentially silence views that the First Amendment is intended to protect." *Id*. The Suprem e Court, therefore, has

recognized a First Amendment right to associate for the purpose of speaking. *Roberts v. U.S. Jaycees*, 468 U.S. 609, 618 (1984).

But the preventive services coverage regulations do not interfere with plaintiffs' 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 v. U.S. Dep't of Health & Human Servs.*, No. 13-cv-11379-BPH-MJH, Order Denying Mot. for Prelim. Inj. at 12-13, ECF No. 46 (Sept. 13, 2013) (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").

V. 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. ¶¶ 278-79. 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. ¶ 281. 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.[9] Similarly, there is no merit to plaintiffs' allegation that the regulations—which contain specific criteria—will lead to discriminatory enforcement.

VI. PLAINTIFFS' APA CLAIMS FAIL

A. The regulations were promulgated in accordance with the APA

Plaintiffs assert that defendants failed to comply with the APA's notice and comment procedures and the ACA's timing provisions. These allegations are baseless. The APA's rulemaking provisions generally require that agencies provide notice of a

[9] 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.

proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Defendants complied with these requirements.[10]

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 plaintiffs refer, 42 U.S.C. § 300gg-13(b), requires only that there be a minimum interval of not less than one year between the date on which a *recommendation*

[10] 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.

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

B. The regulations are neither arbitrary nor capricious

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

record, which explicitly discusses that very issue. *See* 78 Fed. Reg. at 39,886-88, AR at 18-20.

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

C. The regulations do not violate restrictions relating to abortion

Plaintiffs contend the regulations violate the APA because they conflict with three federal statutes dealing with abortion: section 1303(b)(1) of the ACA, the Weldon Amendment, and the Church Amendment. Plaintiffs appear to reason that, because the preventive services coverage regulations require group health plans to cover emergency contraception, such as Plan B, they in effect require plaintiffs to provide coverage for abortions in violation of federal law.

Some of these arguments should be rejected at the outset because plaintiffs lack prudential standing to assert them. The doctrine of prudential standing requires that a plaintiffs' claim fall within "the zone of interests to be protected or regulated by the statute or constitutional guarantee in question." *Ass'n of Data Processing Serv. Orgs.,*

Inc. v. Camp, 397 U.S. 150, 153 (1970). But the necessary link between plaintiffs and two of these statutes is missing here. *See Dialysis Ctrs., Ltd. v. Schweiker*, 657 F.2d 135, 138 (7th Cir. 1981); *O'Brien*, 894 F. Supp. 2d at 1167-68 (holding that plaintiff lacked prudential standing to raise similar claims). Section 1303(b)(1) of the ACA provides that "nothing in this title . . . shall be construed to require a qualified health plan to provide coverage of [abortion services]," 42 U.S.C. § 18023(b)(1)(A)(i), but plaintiffs are neither health insurance issuers nor purchasers of a qualified health plan.[11] They therefore do not fall within the zone of interests to be protected by the statute in question. Similarly, the Church Amendment protects individuals from being required to "perform or assist in the performance of any part of a health service program or research activity funded . . . by the Secretary of Health and Human Services if his performance or assistance . . . would be contrary to his religious beliefs or moral convictions." 42 U.S.C. § 300a-7(d). By merely providing a health plan to their 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.

[11] 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."

Even if the Court were to reach the merits of these claims, and on the merits of plaintiffs' Weldon Amendment claim, 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.[12] 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

[12] 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 Dec. 17, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of permissible recommendations), AR at 320.

approved by the FDA as safe and effective. *See* IOM REP. at 10, AR at 308. And the list of FDA-approved 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 Dec. 17, 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.[13] *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)).

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

Plaintiffs have not established that they are likely to suffer irreparable harm in the absence of preliminary relief because, as explained above, they have not shown a likelihood of success on the merits of their RFRA or First Amendment claims. *See Hobby Lobby*, 723 F.3d at 1146 (explaining that, in the RFRA and First Amendment context, 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).

Plaintiffs' motion for preliminary injunctive relief suffers from an additional, critical flaw: The harm that SNU and OKWU allege is in no way imminent. *See Bedrossian v. Northwestern Memorial Hosp.*, 409 F.3d 840, 844 (7th Cir. 2005) (noting

[13] 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).

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 SNU and OKWU until July 1, 2014, when their next plan years begin. Am. Compl. ¶¶ 40, 63, 175, 177. There is ample time between now and then for the parties to litigate the merits of SNU's and OKWU'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 12. There is no uncertainty—the regulations have been issued in final form, and 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 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.[14]

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 women and

[14] Plaintiffs note that defendants consented to preliminary injunctions in some cases involving for-profit corporations, *see* Pls.' Br. at 14, 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 Mgmt. Co. v. Sebelius*, 2013 WL 3546702 at *16 (E.D. Mich. July 11, 2013) ("[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.

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 preliminary injunction, and grant defendants' motion to dismiss or, in the alternative, for summary judgment on all of plaintiffs' claims.

Respectfully submitted this 17th day of December, 2013,

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CERTIFICATE OF SERVICE

I hereby certify that on December 17, 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