IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

THE ROMAN CATHOLIC ARCHDIOCESE OF ATLANTA, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services, *et al.*, Defendants.	Case No. 1:12-cv-03489-WSD

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

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants hereby move to dismiss this action. 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.

Respectfully submitted this 23rd day of September,

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 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

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DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

In their memorandum in opposition to plaintiffs' motion for preliminary injunction, ECF No. 63, defendants have already addressed five of the eight counts in plaintiffs' complaint: Count I (a violation of the Religious Freedom Restoration Act), Count II (a violation of the Free Exercise Clause), Counts III and IV (violations of the Free Speech Clause), and Count VI (an interference in internal church governance). For the same reasons set out in that brief, the Court should dismiss or grant defendants summary judgment on those Counts, and defendants incorporate by reference their arguments on those Counts.

Plaintiffs' complaint raises three additional claims. First, plaintiffs contend that the regulations violate the Establishment Clause, but nearly every court to consider a similar First Amendment challenge to the prior version of the regulations rejected such a claim, and their analysis is equally applicable here. Second, plaintiffs raise a claim of unconstitutional delegation, but the regulations themselves do not delegate any authority, and the statute under which those regulations were promulgated contains an intelligible legislative principle. Finally, plaintiffs claim the regulations are contrary to law and so violate the APA. They lack prudential standing to raise this claim, and in any event, the regulations are in accordance with federal law. The Court should therefore dismiss or grant defendants summary judgment on these Counts as well.

STANDARD OF REVIEW

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

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

ARGUMENT

I. 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. Thus, for example, the Supreme Court has struck down on Establishment Clause grounds a state statute that was "drafted with the explicit intention" of requiring "particular religious denominations" to comply with registration and reporting requirements while excluding other religious denominations. *Id.* at 254; *see also Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that created special school district because it "single[d] out a particular religious sect for special treatment"). The Court, on the other hand, has upheld a statute that provided an exemption from military service for persons who had a conscientious objection to all wars, but not those who objected to only a particular war. *Gillette v. United States*, 401 U.S. 437 (1971). The Court explained that the statute did not discriminate among religions because "no particular sectarian affiliation" was required to qualify for conscientious objector status. *Id*. at 450-51; *see Larson*, 456 U.S. at 247 n.23 (describing *Gillette*); *see also Cutter v. Wilkinson*, 544 U.S. 709,

724 (2005) (upholding RLUIPA against Establishment Clause challenge because it did not "confer[] . . . privileged status on any particular religious sect" or "single[] out [any] bona fide faith for disadvantageous treatment").

Like the statutes at issue in *Gillette* and *Cutter*, the preventive services coverage regulations do not grant any denominational preference or otherwise discriminate among religions. It is of no moment that the religious employer exemption and accommodations for eligible organizations apply to some employers but not others. "[T]he Establishment Clause does not prohibit the government from [differentiating between organizations based on their structure and purpose] when granting religious accommodations as long as the distinction[s] drawn by the regulations . . . [are] not based on religious affiliation." *Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943, 954 (S.D. Ind. 2012); *accord O'Brien v. U.S. Dep't of Health & Human Servs.*, 894 F. Supp. 2d 1149, 1163 (E.D. Mo. 2012); *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); *Catholic Charities of the Diocese of Albany v. Serio*, 859 N.E.2d 459, 468-69 (N.Y. 2006). 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. *See O'Brien*, 894 F. Supp. 2d at 1162 (upholding prior version of religious employer exemption because it did "not differentiate between religions, but applie[d] equally to all denominations"); *Conestoga Wood Specialties Corp. v. Sebelius*, 917 F. Supp. 2d 394, 416-17 (E.D. Pa. 2013) (same); *see also Liberty Univ., Inc. v. Lew*, 2013 WL 3470532, at *17-18 (4th Cir. July 11, 2013).

"As the Supreme Court has frequently articulated, there is space between the religion clauses, in which there is 'room for play in the joints;' government may encourage the free exercise of religion by granting religious accommodations, even if not required by the Free Exercise Clause, without running afoul of the Establishment Clause." *O'Brien*, 894 F. Supp. 2d at 1163 (citations omitted). Accommodations of religion are possible because the type of legislative line-drawing to which the plaintiffs object in this case is constitutionally permissible. *Id.*; *Conestoga*, 917 F. Supp. 2d at 417; *see, e.g., Walz v. Tax Commission of New York*, 397 U.S. 664, 672-73 (1970); *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334 (1987).[1]

[1] Even if the regulations discriminate among religions (and they do not), they are valid under the Establishment Clause, because they satisfy strict scrutiny, as

Plaintiffs also claim that the regulations' definition of religious employer violates the Establishment Clause because, more than thirty-five years ago, the Internal Revenue Service (IRS) developed a non-exhaustive list of fourteen facts and circumstances that may be considered, in addition to "any other facts and circumstances that may bear upon the organization's claim for church status," in assessing whether an organization is a church. *See Found. of Human Understanding v. Comm'r of Internal Rev. Serv.*, 88 T.C. 1341, 1357-58 (1987); Internal Revenue Manual (IRM) 7.26.2.2.4. Although plaintiffs do not appear to have ever before challenged the constitutionality of this non-exhaustive list, they now contend that it acts to require the government to make impermissible "judgments about [plaintiffs'] beliefs, practices and organizational features." Second Am. Compl. ¶ 196. This claim fails for numerous reasons.

As an initial matter, the claim is not ripe and therefore should be dismissed for lack of jurisdiction. The non-exhaustive list that plaintiffs seek to challenge is not set out in any statute, regulation, or other binding source of law. It is instead contained in the IRM, which serves solely as a source of guidance for the internal administration of the IRS and is not binding on the IRS or courts. *United States v. Will*, 671 F.2d 963, 967 (6th Cir. 1982); *Capital Fed. Sav. & Loan Ass'n v.*

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explained in defendants' opposition to plaintiffs' motion for preliminary injunction. *See* ECF No. 63; *Larson*, 456 U.S. at 251-52.

Comm'r of Internal Revenue, 96 T.C. 204, 216-17 (1991). A party can challenge such guidance "only if and when the directive has been applied specifically to them." *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987); *see also, e.g.*, *Home Builders Ass'n of Greater Chicago v. U.S. Army Corps of Eng'rs*, 335 F.3d 607, 619 (7th Cir. 2003) (concluding general statement of policy was not ripe for review). Plaintiffs do not challenge any determination by the IRS that was based on this IRM provision. Because the defendant agencies have not applied a similar non-exhaustive list of facts and circumstances to plaintiffs, plaintiffs' challenge is not ripe.

Indeed, qualification for the religious employer exemption does not require the government to make any determination, whether as a result of the application of the non-exhaustive list or otherwise. If an organization "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," it qualifies for the exemption, without any government action whatsoever. 45 C.F.R. § 147.131(a). Plaintiffs, moreover, do not allege any difficulty determining whether or not they qualify for the exemption. *See* Second Am. Compl. ¶ 16. Any claim—which plaintiffs do not in fact make—that the government will dispute their determination and therefore undertake an intrusive inquiry into whether plaintiffs qualify is entirely speculative and thus unripe for this reason as well.

Finally, even assuming plaintiffs could mount a facial challenge to a non-exhaustive list of facts and circumstances that the defendant agencies have never applied to plaintiffs, any such challenge would be meritless. Any interaction between the government and religious organizations that may be necessary to enforce the religious employer exemption is not so "comprehensive," *Lemon v. Kurtzman*, 403 U.S. 602, 619 (1971), or "pervasive," *Agostini v. Felton*, 521 U.S. 203, 233 (1997), as to result in excessive entanglement. The Supreme Court has upheld laws that require government monitoring that is more onerous than any monitoring that may be required to enforce the religious employer exemption. *See Bowen v. Kendrick*, 487 U.S. 589, 615-617 (1988) (no excessive entanglement where the government reviewed and monitored programs and materials); *Roemer v. Bd. of Public Works of Md.*, 426 U.S. 736, 764–765 (1976) (no excessive entanglement where the state conducted annual audits); *see also United States v. Corum*, 362 F.3d 489, 496 (8th Cir. 2004). And every court to address the issue upheld the prior version of the religious employer exemption, which contained the same requirement that the organization be one that is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended, against an entanglement challenge. *See Conestoga*, 917 F. Supp. 2d at 417; *O'Brien*, 894 F. Supp. 2d at 1164-65; *Geneva Coll. v. Sebelius*, 2013 WL

838238, at *28.[2] Count V of the Second Amended Complaint therefore fails.

II. The Regulations Do Not Unconstitutionally Delegate Authority

Plaintiffs take issue with the fact that the Affordable Care Act (ACA) delegates to the Health Resources and Services Administration (HRSA) the authority to establish "comprehensive guidelines" for the preventive services that must be covered by group health plans. 42 U.S.C. § 300gg-13(a)(4). Specifically, plaintiffs claim the ACA lacks an intelligible principle and therefore constitutes an unconstitutional delegation of legislative power. Second Am. Compl. ¶¶ 216-20. But plaintiffs do not ask the Court to strike down the ACA. Rather, plaintiffs' case is a set of challenges to what they call the "Mandate," which they define as "various rules" promulgated under the ACA. *Id.* ¶ 10. They make no argument that the regulations they challenge are somehow an improper delegation, and instead level the misdirected complaint that, in enacting them, defendants have used the authority granted to them by Congress.

[2] Even if this Court were to conclude that it had jurisdiction to adjudicate a facial challenge to the non-exhaustive list of facts and circumstances set forth in IRM 7.26.2.2.4 and that such nonbinding guidance violates the Establishment Clause, the remedy would be invalidation of the list, not invalidation of the contraceptive coverage requirement or the religious employer exemption. The regulations would survive, with the religious employer exemption being available to any organization that is organized and operates as a nonprofit entity and is a church, integrated auxiliary of a church, convention or association of churches, or the exclusively religious activities of any religious order, as those terms are specifically defined under section 6033 or commonly understood.

In any event, the ACA does not contain any unconstitutional delegation of legislative power. "So long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Mistretta v. United States*, 488 U.S. 361, 372 (1989). The government's burden to demonstrate an intelligible principle is "not . . . onerous," *United States v. Brown*, 364 F.3d 1266, 1271 (11th Cir. 2004), and examples of permissible delegations include delegations to agencies to make regulations "in the public interest," *Nat'l Broad. Co. v. United States*, 319 U.S. 190, 216-17 (1943), or to fix prices that would be "fair and equitable," *Yakus v. United States*, 321 U.S. 414, 422-23 (1944). Indeed, the Supreme Court, recognizing that "Congress simply cannot do its job absent an ability to delegate power under broad general directives," has upheld "without deviation, Congress' ability to delegate power under broad standards." *Mistretta*, 488 U.S. at 372-73.

Plaintiffs erect an impossibly high bar when they say that the Act does not contain a standard as to what constitutes "preventive care," since that is precisely the question that Congress delegated to public health experts. The doctrine plainly is not directed at that level of specificity, since there would be no room left for a delegation that could pass muster if Congress was required to answer every question it intended to delegate. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S.

457, 475 (2001) (upholding delegation to set standards "requisite to protect the public health" and noting that "we have never demanded . . . that statutes provide a determinate criterion for saying how much of the regulated harm is too much").

Instead, the relevant question is whether the ACA sets out an intelligible principle to guide the agencies in answering the technical questions delegated to them. The ACA was enacted to improve Americans' access to affordable and quality health care and health coverage. Specifically, the Women's Health Amendment, which contains the requirement to provide coverage for recommended preventive services for women without cost-sharing, was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in the ACA, and specified that "preventive care and screenings" for women shall be covered. 42 U.S.C. § 300gg-13(a)(4); *see* 155 Cong. Rec. S12021-02, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer); 155 Cong. Rec. S12265-02, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken). By requiring coverage for recommended preventive services and eliminating cost-sharing requirements, Congress sought to increase access to and utilization of recommended preventive services. These are the guiding principles, and women's "preventive care and screenings" is far more specific than a direction to act "in the public interest." Since even such a broad directive has been found not to raise any delegation problem, as discussed above, the ACA fits comfortably in

the doctrine. Count VII of the Second Amended Complaint therefore fails.

III. The Regulations Do Not Violate the APA

Plaintiffs contend the regulations violate the APA because they conflict with the Weldon Amendment to the Consolidated Appropriations Act of 2012, which is a statute that deals with abortion. 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.[3]

This argument should be rejected at the outset because plaintiffs lack prudential standing to assert it. The doctrine of prudential standing requires that a plaintiff's 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 the Weldon Amendment 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. The Weldon Amendment denies funds made available in the Consolidated

[3] Plaintiffs also allege that the regulations violate the ACA because the ACA "contains no clear expression of an affirmative intention of Congress" with respect to employers with religious objections to providing certain coverage. Second Am. Compl. ¶ 227. But Congress said all it needed to say when it required that group health plans "shall" provide coverage without cost-sharing for preventive services as recommended by HRSA, 42 U.S.C. § 300gg-13(a)(4), and did not enact any exception for employers with religious objections.

Appropriations Act of 2012 to any federal, state, or local agency, program, or government that "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. No. 112-74, §§ 506, 507, 125 Stat. 786, 1111-12 (Dec. 23, 2011). Plaintiffs are neither institutional nor individual health care entities, *see id.* at § 507(d)(2), so they are not within this statute's zone of interests.

Even if the Court were to reach the merits of these claims, plaintiffs' premise that the contraceptive coverage regulations require abortion coverage is fundamentally incorrect. The regulations do not require that any health plan cover abortion at all, much less as a preventive service. 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, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84. And the government has made clear that the preventive services covered by the regulations do not include abortifacient drugs.[4]

[4] HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at* http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html (last visited Sept. 23, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320.

Although plaintiffs are certainly entitled to 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. Statutory interpretation requires that terms be construed as a matter of law and not in accordance with any particular plaintiff's views or beliefs. *E.g.*, *Gov't Empls. Ins. Co. v. Benton*, 859 F.2d 1147, 1149 (3d Cir. 1988).

In recommending what contraceptive services should be covered by health plans without cost-sharing, the IOM Report identified the contraceptives that have been approved by the FDA as safe and effective. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 10 (2011) ("IOM REP."), 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 Plan B and similar drugs among safe and effective means of contraception dates back to 1997, when the FDA first explained why they 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); 45 C.F.R. § 46.202(f). In light of this conclusion, 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."[5] The regulations are thus consistent with over a decade of regulatory policy and practice and cannot be deemed contrary to any law dealing with abortion.[6] *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). Count VIII of the Second Amended Complaint therefore fails.

CONCLUSION

For these reasons, and those set out in defendants' opposition to plaintiffs' motion for preliminary injunction and incorporated by reference here, the Court should grant defendants' motion to dismiss or for summary judgment.

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[5] Office of Population Affairs, Memorandum (Apr. 23, 1997), http://www.hhs.gov/opa/pdfs/opa-97-02.pdf (last visited Sept. 23, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

[6] 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."); *Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (statements of legislation's sponsors deserve substantial interpretive weight).

Respectfully submitted this 23rd day of September, 2013,

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 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

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

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

1. Before the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), due largely to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), AR at 317-18, 407.

2. Section 1001 of the ACA requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing, including, "[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).

3. Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services (HHS) tasked the Institute of Medicine (IOM) with developing recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300.

4. After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, among other things, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 10-12, AR at 308-10.

5. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices ("IUDs"). *See id.* at 105, AR at 403.

6. Coverage, without cost-sharing, for these services is necessary to increase access to such services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. *See id.* at 102-03, AR at 400-01 (Tab 5).

7. On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, encompassing all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider, subject to an exemption relating to certain religious employers authorized by regulations issued that same day (the "2011 amended interim final regulations"). *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84.

8. To qualify for the religious employer exemption contained in the 2011 amended interim final regulations, an employer had to meet the following criteria:

> (1) The inculcation of religious values is the purpose of the organization;
>
> (2) the organization primarily employs persons who share the religious tenets of the organization;
>
> (3) the organization serves primarily persons who share the religious tenets of the organization; and

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

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

9. Group health plans established or maintained by religious employers, and associated coverage, are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84 (Tab 7); 45 C.F.R. § 147.131(a).

10. In February 2012, the government adopted in final regulations the definition of "religious employer" contained in the 2011 amended interim final regulations while also creating a temporary enforcement safe harbor for non-grandfathered group health plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). *See* 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012), AR at 213-14.

11. The government committed to undertake a new rulemaking during the safe harbor period to adopt new regulations to further accommodate non-grandfathered non-profit religious organizations' religious objections to covering contraceptive services. *Id.* at 8728, AR at 215 (Tab 10).

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

13. Under the 2013 final rules, a "religious employer" is "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended," which refers to churches, their integrated auxiliaries, and conventions or associations of churches, and the exclusively religious activities of any religious order. 45 C.F.R. § 147.131(a) (Tab 9).

14. The 2013 final rules establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations" (and group health insurance coverage provided in connection with such plans). *Id.* at 39,875-80, AR at 7-12 (Tab 12); 45 C.F.R. § 147.131(b) (Tab 9).

15. 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) (Tab 9); *see also* 78 Fed. Reg. at 39,874-75, AR at 6-7 (Tab 12).

16. 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 (Tab 12).

17. To be relieved of any such obligations, the 2013 final rules require only that an eligible organization complete a self-certification form stating that it is an eligible organization and provide a copy of that self-certification to its issuer or third party administrator (TPA). *Id.* at 39,878-79, AR at 10-11 (Tab 12).

18. Its participants and beneficiaries, however, will still benefit from separate payments for contraceptive services made by the issuer or TPA, without cost sharing or other charge. *Id.* at 39,874, AR at 6 (Tab 12).

19. In the case of an organization with a self-insured group health plan—such as plaintiffs here—the organization's TPA, upon receipt of the self-

certification, must, among other things, 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 (Tab 12).

20. 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 (Tab 12).

21. The government "propos[ed] to make the accommodation or the religious employer exemption available on an employer-by-employer basis" in the NPRM. 78 Fed. Reg. 8456, 8467 (Feb. 6, 2013), AR at 176 (Tab 12).

22. The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, *see id.* at 39,872, AR at 4 (Tab 12), except the amendments to the religious employer exemption apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013, *see id.* at 39,871, AR at 3 (Tab 12).

23. The regulations specifically prohibit TPAs from charging any premium or otherwise passing on any costs to eligible organizations with respect to the TPAs' payments for contraceptive services. *See* 78 Fed. Reg. at 39,880, AR at 12 (Tab 12).

24. The primary predicted benefit of the preventive services coverage regulations is that "individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease." 75 Fed. Reg. 41,726, 41,733 (July 19, 2010), AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215 (Tab 10); 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19 (Tab 12).

25. "By expanding coverage and eliminating cost sharing for recommended preventive services, [the regulations are] expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733, AR at 233 (Tab 24); *see also* 78 Fed. Reg. at 39,873 ("Research [ ] shows that cost sharing can be a significant barrier to access to contraception." (citation omitted)), AR at 5 (Tab 12).

26. Although a majority of employers cover FDA-approved contraceptives, *see* IOM Rep. at 109, AR at 407 (Tab 1), many women forgo preventive services because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109, AR at 317-18, 407 (Tab 1).

27. Unintended pregnancies have proven in many cases to have negative health consequences for women and developing fetuses. *See* 78 Fed. Reg. at 39,872, AR at 4 (Tab 12).

28. Unintended pregnancy may delay "entry into prenatal care," prolong "behaviors that present risks for the developing fetus," and cause "depression, anxiety, or other conditions." IOM REP. at 20, 103-04, AR at 318, 401-02 (Tabs 1, 5).

29. Contraceptive coverage further helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103, AR at 401 (Tab 5); *see also* 78 Fed. Reg. at 39,872, AR at 4 (Tab 12).

30. "Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrative preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne)." 78 Fed. Reg. at 39,872, AR at 4 (Tab 12); *see also* IOM Rep. at 103-04, AR at 401-02 (Tab 5).

31. "[W]omen have different health needs than men, and these needs often generate additional costs. Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men." 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein); 78 Fed. Reg. at 39,887, AR at 19 (Tab 12); IOM REP. at 19, AR at 317 (Tab 1).

32. These costs result in women often forgoing preventive care and place women in the workforce at a disadvantage compared to their male coworkers. *See,*

e.g., 155 Cong. Rec. S12265-02, S12274 (daily ed. Dec. 3, 2009) (statement of Sen. Murray); 78 Fed. Reg. at 39,887, AR at 19 (Tab 12); IOM REP. at 20, AR at 318 (Tab 1).

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

34. The effect of grandfathering is not really a permanent "exemption," but rather, over the long term, a transition in the marketplace with respect to several provisions of the ACA, including the preventive services coverage provision. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19 (Tab 12).

35. A majority of group health plans will have lost their grandfather status by the end of 2013. *See* 75 Fed. Reg. 34,538, 34,552 (June 17, 2010); *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012 Annual Survey at 7-8, 190, AR at 663-64, 846.

36. 26 U.S.C. § 4980H(c)(2) does not exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a) (Tab 2); 78 Fed. Reg. at 39,887 n.49, AR at 19 (Tab 12).

37. Instead, it excludes employers with fewer than fifty full-time equivalent employees from the employer responsibility provision, meaning that, starting in 2015, such employers are not subject to the possibility of assessable

payments if they do not provide health coverage to their full-time employees and their dependents. *See* 26 U.S.C. § 4980H(c)(2).

38. Small businesses that do offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive services, including contraceptive services, without cost-sharing. 78 Fed. Reg. at 39,887 n.49, AR at 19 (Tab 12).

39. The only exemption from the preventive services coverage regulations is the exemption for the group health plans of religious employers. 45 C.F.R. § 147.131(a) (Tab 9).

40. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are 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, AR at 6 (Tab 12).

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

42. Defendants are constrained by statute from adopting the alternative administrative schemes proposed by plaintiffs. *See* 78 Fed. Reg. at 39,888, AR at 20 (Tab 12).

43. Plaintiffs' proposed alternatives are not feasible because they would impose considerable new costs and other burdens on the government and would otherwise be impractical. *See* 78 Fed. Reg. at 39,888, AR at 20 (Tab 12).

44. Nor would the proposed alternatives be equally effective in advancing the government's compelling interests. *See* 78 Fed. Reg. at 39,888, AR at 20 (Tab 12).

45. Plaintiffs' alternatives would require establishing entirely new government programs and infrastructures or fundamentally altering an existing one, and would require women to take burdensome steps to find out about the availability of and sign up for a new benefit, thereby ensuring that fewer women would take advantage of it. *See* 78 Fed. Reg. at 39,888, AR at 20 (Tab 12).

46. "Nothing in the[] final regulations prohibits an eligible organization from expressing its opposition to the use of contraception." 78 Fed. Reg. at 39,880 n.41, AR at 12 (Tab 12).

47. The regulations only prohibit an employer's improper attempt to interfere with its employees' ability to obtain contraceptive coverage from a third party by, for example, threatening the TPA with a termination of its relationship

with the employer because of the TPA's "arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries." *See* 26 C.F.R. § 54.9815-2713A(b)(1)(iii); 29 C.F.R. § 2590.715-2713A(b)(1)(iii).

48. The Women's Health Amendment, which contained the requirement to provide coverage for recommended preventive services for women without cost-sharing, was intended to fill significant gaps relating to women's health that existed in the other preventive care guidelines identified in the Affordable Care Act. *See* 155 Cong. Rec. S12021-02, S12025 (daily ed. Dec. 1, 2009) (statement of Sen. Boxer); 155 Cong. Rec. S12265-02, S12271 (daily ed. Dec. 3, 2009) (statement of Sen. Franken).

49. 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).

50. "Abortifacient drugs are not included" in the preventive services covered by the regulations. HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at*

http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html (last visited Sept. 23, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320 (Tab 1).

51. The list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See* IOM REP. at 105, AR at 403 (Tab 5).

52. 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); 45 C.F.R. § 46.202(f).

53. In light of this conclusion by the FDA, HHS informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods—and, except under limited circumstances, may not offer abortion—that they "should consider the availability of emergency contraception the same as any other method which has been established as safe and effective." Office of Population Affairs, Memorandum (Apr. 23, 1997), http://www.hhs.gov/opa/pdfs/opa-97-02.pdf (last visited Sept. 23, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

54. Representative Weldon, the sponsor of the Weldon Amendment, did not consider the word "abortion" in the statute to include FDA-approved emergency contraceptives. *See* 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002) ("The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. . . . [U]nder the current FDA policy[,] that is considered contraception, and it is not affected at all by this statute.").

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CERTIFICATE OF SERVICE

I hereby certify that on September 23, 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