IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

THE CATHOLIC DIOCESE OF NASHVILLE, *et al.*	)	
Plaintiffs,	)	
v.	)	**Case No. 3:13-CV-01303**
KATHLEEN SEBELIUS, *et al.*,	)	
Defendants.	)	

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

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, which also responds to plaintiffs' motion for a preliminary injunction.

Dated: December 11, 2013

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 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/ Jacek Pruski
JACEK PRUSKI

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

Pursuant to Local Civil Rule 56.01, defendants hereby submit the following statement of 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.

Response:

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).

Response:

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.

Response:

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.

Response:

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.

Response:

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).

Response:

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.

Response:

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.

Response:

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).

Response:

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.

Response:

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).

Response:

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.

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

19. In the case of an organization with an insured group health plan—such as all of the plaintiffs here—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, 39,881, AR at 7-9, 13.

Response:

20. In the case of an organization with a self-insured group health plan, the organization's TPA, upon receipt of the self-certification, will, 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).

Response:

21. 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).

Response:

22. 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).

Response:

23. The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, *see id.* at 39,872, AR at 4 (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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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.

Response:

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).

Response:

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.

Response:

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).

Response:

37. Instead, it e xcludes employers with fewer than fifty full-time equivalent employees from the employer responsibility provision, meaning that, starting in 2015, s uch 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).

Response:

38. Small businesses that do of fer 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).

Response:

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).

Response:

40. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on r eligious 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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

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).

Response:

47. 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).

Response:

48. 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).

Response:

49. "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 Dec. 11, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320 (Tab 1).

Response:

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

Response:

51. 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).

Response:

52. 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. 11, 2013); *see also* 42 U.S.C. §§ 300, 300a-6.

Response:

53. 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.").

Response:

Dated: December 11, 2013

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