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

GENEVA COLLEGE, et al.,) Coss No. 2:12 ov 00207 IEC
Plaintiff,) Case No. 2:12-cv-00207-JFC
v.)
KATHLEEN SEBELIUS, et al.,)
Defendants.)
)

<u>DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT</u>

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants hereby move to dismiss plaintiff Geneva College's claims. In the alternative, defendants move for summary judgment on all of Geneva College's claims pursuant to Rule 56. The grounds for these motions are set forth in the accompanying memorandum.

Respectfully submitted this 3rd day of December, 2013,

STUART F. DELERY Assistant Attorney General

DAVID J. HICKTON United States Attorney

JENNIFER RICKETTS
Director

SHEILA M. LIEBER Deputy Director

/s/ Bradley P. Humphreys
BRADLEY P. HUMPHREYS (VA Bar No. 83212)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue N.W., Room 7108
Washington, DC 20530
Tel: (202) 514-3367; Fax: (202) 616-8470
Email: Bradley.P.Humphreys@usdoj.gov

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2013, I caused a true and correct copy of the foregoing to be served on plaintiff's counsel by means of the Court's ECF system.

/s/ Bradley P. Humphreys BRADLEY P. HUMPHREYS

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

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

- 1. Before the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), due largely to cost, Americans used preventive services at about half the recommended rate. *See* Inst. of Med., Clinical Preventive Services for Women: Closing the Gaps 19-20, 109 (2011) ("IOM Rep."), AR at 317-18, 407.
- 2. Section 1001 of the ACA requires all group health plans and health insurance issuers that offer non-grandfathered group or individual health coverage to provide coverage for certain preventive services without cost-sharing, including, "[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).
- 3. Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services (HHS) tasked the Institute of Medicine (IOM) with developing recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300.

- 4. After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, among other things, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 10-12, AR at 308-10.
- 5. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices ("IUDs"). *See id.* at 105, AR at 403.
- 6. Coverage, without cost-sharing, for these services is necessary to increase access to such services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany unintended pregnancies) and promote healthy birth spacing. *See id.* at 102-03, AR at 400-01.
- 7. On August 1, 2011, HRSA adopted guidelines consistent with IOM's recommendations, encompassing all FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling," as prescribed by a health care provider, subject to an exemption relating to certain religious employers authorized by regulations issued that same day (the "2011 amended interim final regulations"). *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84.
- 8. To qualify for the religious employer exemption contained in the 2011 amended interim final regulations, an employer had to meet the following criteria:
 - (1) The inculcation of religious values is the purpose of the organization;
 - (2) the organization primarily employs persons who share the religious tenets of the organization;
 - (3) the organization serves primarily persons who share the religious tenets of the organization; and
 - (4) the organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

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

- 9. Group health plans established or maintained by religious employers (and associated group health insurance coverage) are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("HRSA Guidelines"), AR at 283-84; 45 C.F.R. § 147.131(a).
- 10. In February 2012, the government adopted in final regulations the definition of "religious employer" contained in the 2011 amended interim final regulations while also creating a temporary enforcement safe harbor for non-grandfathered group health plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). *See* 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012), AR at 213-14.
- 11. The government committed to undertake a new rulemaking during the safe harbor period to adopt new regulations to further accommodate non-grandfathered non-profit religious organizations' religious objections to covering contraceptive services. *Id.* at 8728, AR at 215.
- 12. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,870, AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012) (Advance Notice of Proposed 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).
- 14. The changes made to the definition of religious employer in the 2013 final rules ensure "that an otherwise exempt plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths." 78 Fed. Reg. at 39,874, AR at 6.

- 15. The 2013 final rules establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations" (and group health insurance coverage provided in connection with such plans). *Id.* at 39,875-80, AR at 7-12; 45 C.F.R. § 147.131(b).
 - 16. An "eligible organization" is an organization that satisfies the following criteria:
 - (1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.
 - (2) The organization is organized and operates as a nonprofit entity.
 - (3) The organization holds itself out as a religious organization.
 - (4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies.
- 45 C.F.R. § 147.131(b); see also 78 Fed. Reg. at 39,874-75, AR at 6-7.
- 17. Under the 2013 final rules, an eligible organization is not required "to contract, arrange, pay, or refer for contraceptive coverage" to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6.
- 18. To be relieved of any such obligations, the 2013 final rules require only that an eligible organization complete a self-certification form stating that it is an eligible organization and provide a copy of that self-certification to its issuer or third party administrator (TPA). *Id.* at 39,878-79, AR at 10-11.
- 19. Its participants and beneficiaries, however, will still benefit from separate payments for contraceptive services made by the issuer or TPA, without cost sharing or other charge. *Id.* at 39,874, AR at 6.
- 20. In the case of an organization with an insured group health plan, the organization's health insurance issuer, upon receipt of the self-certification, must provide separate payments to plan participants and beneficiaries for contraceptive services without cost

sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See id.* at 39,875-77, AR at 7-9.

- 21. The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, *see id.* at 39,872, AR at 4, except the amendments to the religious employer exemption apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013, *see id.* at 39,871, AR at 3.
- 22. The primary predicted benefit of the preventive services coverage regulations is that "individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease." 75 Fed. Reg. 41,726, 41,733 (July 19, 2010), AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19.
- 23. "By expanding coverage and eliminating cost sharing for recommended preventive services, [the regulations are] expected to increase access to and utilization of these services, which are not used at optimal levels today." 75 Fed. Reg. at 41,733, AR at 233; *see also* 78 Fed. Reg. at 39,873 ("Research [] shows that cost sharing can be a significant barrier to access to contraception." (citation omitted)), AR at 5.
- 24. Although a majority of employers cover FDA-approved contraceptives, *see* IOM Rep. at 109, AR at 407, many women forgo preventive services because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109, AR at 317-18, 407.
- 25. 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.
- 26. 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.
- 27. Contraceptive coverage further helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103, AR at 401; *see also*

- 78 Fed. Reg. at 39,872 ("Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-gestational age births.") (citing studies), AR at 4.
- 28. "Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrative preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne)." 78 Fed. Reg. at 39,872, AR at 4; *see also* IOM Rep. at 103-04 ("[P]regnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome."), AR at 401-02.
- 29. "[W]omen have different health needs than men, and these needs often generate additional costs. Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men." 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 19, AR at 317.
- 30. These costs result in women often forgoing preventive care and place women in the workforce at a disadvantage compared to their male coworkers. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274 (daily ed. Dec. 3, 2009) (statement of Sen. Murray); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 20, AR at 318.
- 31. 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.
- 32. 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.
- 33. A majority of group health plans will have lost their grandfather status by the end of 2013. *See* 75 Fed. Reg. 34,538, 34,552 (June 17, 2010); *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012 Annual Survey at 7-8, 190 (indicating that 58 percent of firms had at least one grandfathered health plan in 2012, down

from 72 percent in 2011, and that 48 percent of covered workers were in grandfathered health plans in 2012, down from 56 percent in 2011), AR at 663-64, 846.

- 34. 26 U.S.C. § 4980H(c)(2) does not exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. at 39,887 n.49, AR at 19.
- 35. 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).
- 36. 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.
- 37. The ACA provides tax incentives for small businesses to encourage the purchase of health insurance. *See* 26 U.S.C. § 45R.
- 38. Even if a small business were to choose not to offer health coverage, employees of such business could get health insurance coverage that is facilitated by other ACA provisions—primarily those establishing both small group market and individual market health insurance exchanges and those establishing tax credits to make the purchase of coverage through such exchanges more affordable—and the coverage they receive through such exchanges will include coverage of all recommended preventive services, including contraception. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19.
- 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).
- 40. 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.

- 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 Geneva College. *See* 78 Fed. Reg. at 39,888, AR at 20.
- 43. Geneva College's proposed alternatives are not feasible because they would also impose considerable new costs and other burdens on the government and would otherwise be impractical. *See* 78 Fed. Reg. at 39,888, AR at 20.
- 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.
- 45. Geneva College's 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.
- 46. The regulations explicitly prohibit issuer from imposing any cost-sharing, premium, fee, or other charge on Geneva College or its plan with respect to the separate payments for contraceptive services made by the issuer. *See* 78 Fed. Reg. at 39,880, AR at 12.
- 47. The regulations simply require coverage of "education and counseling for women with reproductive capacity." HRSA Guidelines, AR at 130-31.
- 48. Defendants issued the ANPRM on March 21, 2012 and solicited comments on it. 77 Fed. Reg. at 16,501, AR at 186.
- 49. 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.

50. 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.

Respectfully submitted this 3rd day of December, 2013,

STUART F. DELERY Assistant Attorney General

DAVID J. HICKTON United States Attorney

JENNIFER RICKETTS Director, Federal Programs Branch

SHEILA M. LIEBER Deputy Director, Federal Programs Branch

/s/ Bradley P. Humphreys
BRADLEY P. HUMPHREYS (VA Bar No. 83212)
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Avenue N.W., Room 7108
Washington, DC 20530
Telephone: (202) 514-3367
Facsimile: (202) 616-8470

Email: bradley.p.humphreys@usdoj.gov

Attorneys for Defendants

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Defendants.)
)
[PROPO	OSED] ORDER
Upon consideration of Defendants' m	otion to dismiss or, in the alternative, for summary
judgment, Geneva College's response, and an	ny reply thereto,
IT IS HEREBY ORDERED:	
Defendants' motion is GRANTED.	
BY THE COURT:	
Date	The Honorable Joy Flowers Conti Chief United States District Judge