



Susan Kendig

After *Hobby Lobby*: Where do women's rights fit in?

By Susan Kendig, JD, MSN, WHNP-BC, FAANP

The Affordable Care Act (ACA) seeks to improve population health outcomes by making preventive health services affordable and accessible. To achieve this aim, the ACA requires health plans to cover preventive services that have strong scientific evidence of their health benefits, with no cost sharing by patients (i.e., no co-payment, co-insurance, or deductible) when these services are delivered by a network provider. With limited exceptions, all FDA-approved contraceptive methods are covered under the Women's Preventive Services Guidelines.¹

However, on June 30, 2014, the U.S. Supreme Court issued one of its most highly anticipated rulings regarding women's health. In a 5-to-4 ruling in *Burwell v. Hobby Lobby Stores*,² the Court stated that "closely held" corporations do have religious rights and, as such, should be permitted an exemption from compliance with the contraceptive mandate issued by the U.S. Department of Health and Human Services (HHS).

How did we get here?

In accordance with the ACA, required preventive services, to be covered with no cost sharing on the patient's part, include (1) evidence-based services that have received a U.S. Preventive Services Task Force (USPSTF) rating of "A" or "B"; (2) immunizations recommended by the CDC's Advisory Committee on Immunization Practices; (3) evidence-informed screenings and guidelines for infants, children, ado-



lescents, and women supported by the Health Resources and Services Administration (HRSA, a division of HHS); and (4) USPSTF breast cancer screening, mammography, and prevention recommendations considered the most current other than those issued in or around November 2009.³

The Institute of Medicine (IOM) was then charged with convening an expert committee to review which preventive services are necessary for women's health and should be considered in the development of comprehensive guidelines for preventive services for women, as well as with identifying any gaps in the USPSTF's A- and B-rated preventive services for women.⁴ The IOM panel included recommendations for women that met the following criteria:

- The condition to be prevented affects a broad population;
- The condition to be prevented has a large potential impact on health and well-being; and
- The quality and strength of the evidence is supportive of the recommendation.

Within this framework, the IOM panel recommended that preventive services for women that are to be provided without cost sharing include the "full range of FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity."⁴ In making this recommendation, the IOM panel cited systematic evidence reviews and other peer-reviewed studies point-

ing to the efficacy of these interventions in reducing the number of unintended pregnancies, as well as their favorable effect on women's health and pregnancy outcomes.⁴ (pp102-110) Based on the IOM recommendation, HRSA issued regulations requiring inclusion of all FDA-approved contraceptive methods as a preventive health benefit.

Exempt from this contraceptive mandate were religious employers; non-profit entities, including churches, their integrated auxiliaries, and conventions or associations of churches; and the exclusively religious activities of any religious order.^{1,5} In addition, HHS rules issued in June 2013 provided an accommodation for other non-profit religious organizations that object to the contraceptive mandate. The accommodation permitted religious organizations that met certain requirements to self-certify as non-profit religious organizations. Such organizations could then avoid contracting, paying for, or otherwise making available contraceptive coverage by notifying their health insurance issuer of their self-certified status as a religious organization.⁶

Understanding *Hobby Lobby*

Burwell v. Hobby Lobby Stores arose from cases brought by three closely held, for-profit corporations.² These companies sued HHS, seeking to prohibit application of the contraceptive mandate insofar as it required them to provide coverage for four "objectionable" contraceptive methods. In particular, Conestoga Wood Companies, a woodworking company owned by the Hahn family, sought to prohibit application of the contraceptive mandate with regard to two forms of emergency contraception and two types of intrauterine devices. The Hahns, devout Mennonites, believed that because these contraceptive methods may operate after fertilization of the egg, these products are "against their moral conviction to be involved in the termination of human life."²(p12)

Likewise, Hobby Lobby, a chain of arts and crafts stores, and Mardel, an affiliated business that operates 35 Christian bookstores, brought suit to stop application of the contraceptive mandate with regard to the same four contraceptives that the Hahns found objectionable.² Hobby Lobby is owned by David Green and family and Mardel by one of David Green's sons. Like the Hahns, the Greens believe that life begins at conception. Therefore, providing access to contraceptives with potential to operate after fertilization of the ovum would violate their religious

beliefs. The owners of Conestoga, Hobby Lobby, and Mardel do not object to the other FDA-approved methods of birth control.²(p14) The decisions by lower courts in this matter differed, resulting in the matter being brought to the Supreme Court.

In a narrow 5-4 opinion, the Court held that the HHS contraceptive mandate, as it applies to closely held corporations, violates the Religious Freedom Restoration Act (RFRA). The RFRA prohibits the federal government from taking any action that substantially burdens a person's exercise of religion, unless that action constitutes the "least restrictive means" of serving a "compelling government interest."⁷ Although the RFRA does not define the term "person," the Court here applied the definition under the Dictionary Act, which defines "person" to include "corporations, companies, associations, firms ... as well as individuals."⁸ Although the Court acknowledged that the contraceptive mandate may serve a compelling government interest, requiring these closely held companies to arrange for coverage of the objectionable contraceptive methods or to suffer penalties if they refuse to do so, it also posed a "substantial burden" on their free exercise of religion.²

In an eloquent dissent, Justice Ruth Bader Ginsburg challenged the majority's assertion that the ruling was narrow in scope, and referred to the Court's holding as a decision of "startling breadth" that would allow commercial entities to "opt out of any law (save tax laws) they judge incompatible with their sincerely held beliefs."⁹ The dissent argued against the interpretation of the word "person" to include a for-profit corporation in this instance. In addition, Justice Ginsburg pointed out that the decision to claim contraceptive health benefits is a woman's decision, and that women with beliefs similar to those of the Hahns and Greens would not be compelled by the plan to access the objectionable methods. In closing, Justice Ginsburg accused the Court of "stepping onto a minefield ... by its immoderate reading of the RFRA."⁹

Where are we now?

Following the *Hobby Lobby* decision, Senators Patty Murray (D-WA) and Mark Udall (D-CO) introduced the Protect Women's Health from Corporate Interference Act.¹⁰ This bill was intended to restore the ACA's contraceptive coverage requirement and protect coverage of other health services from being denied based on an employer's beliefs by prohibiting employers

from refusing to provide health coverage guaranteed to employees under Federal law. The procedural vote to take up the bill narrowly failed in the Senate, by a vote of 56-43, just 4 votes short of the 60 votes needed to move the bill forward.¹¹

In the wake of *Hobby Lobby*, various executive departments have issued guidance and fact sheets, and have proposed rules regarding ACA implementation with regard to contraceptive coverage. In July 2014, the U.S. Department of Labor issued a Frequently Asked Questions (FAQ) response regarding health plans' disclosure of changes to contraceptive coverage.¹² According to the FAQ, a plan subject to the provisions of the Employee Retirement Income Security Act (ERISA) must disclose information relevant to coverage of preventive services. The Department of Labor regulations require that the summary plan description include an explanation of preventive services, including contraception, covered by the plan. Expedited disclosure requirements are in place for plans that reduce or eliminate aspects of preventive services coverage after having provided the services.¹³

In August 2014, HHS issued a proposed rule in response to the *Hobby Lobby* decision in an attempt to help ensure that women whose contraceptive coverage is being threatened continue to receive the coverage to which they are entitled under the ACA.¹⁴ The proposed rule expands the availability of the accommodation for non-profit religious organizations to avoid contracting, arranging, paying, or referring for contraceptive services to include a closely held, for-profit entity that has a religious objection to providing coverage for some or all contraceptive services. Under the proposed rule, the closely held, for-profit entity may not be publicly traded and must be owned by a limited number of persons or have a minimum percentage of ownership concentrated among a smaller group of people. The comment period for the proposed rule is scheduled to close prior to publication of this article.

Summary

The Supreme Court's *Hobby Lobby* decision has the potential to undermine the ACA's provision establishing a federal guarantee of coverage for a full range of FDA-approved contraceptive methods as a key preventive health service for women.¹ By limiting the ability of some women to choose among all FDA-approved contraceptive methods, based on their employer's values and belief system, this deci-

sion may create uneven access to evidence-based healthcare services shown to have a profound impact on women's overall health and well-being. ●

Susan Kendig is a teaching professor and WHNP Emphasis Area Coordinator at the University of Missouri-St. Louis; a consultant at Health Policy Advantage, LLC, in St. Louis, Missouri; and Director of Policy for the National Association of Nurse Practitioners in Women's Health (NPWH). She can be reached at 314-629-2372 or at skendig@npwh.org.

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