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DIVISION OF SOCIAL JUSTICE
HEALTH CARE BUREAU

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December 5, 2017

Via Federal eRulemaking Portal
Acting Secretary Eric Hargan
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW., Room 445–G
Washington, DC 20201

Re: Comments on Interim Final Rules: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act, and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act
45 C.F.R §§ 147.130-147.133

Dear Acting Secretary Hargan:

The undersigned State Attorneys General submit these comments in response to the Departments of Health and Human Services, Labor, and Treasury's (the "Departments") issuance of the proposed interim final rules ("IFRs"): the Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017), and Moral Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (filed Oct. 6, 2017). By creating broad new exemptions from the Affordable Care Act's contraceptive mandate, thereby allowing employers to deprive women of contraceptive health coverage, the IFRs will harm women and children, and the public health in general, and result in significant financial and administrative burdens to the States. As discussed more fully below, the IFRs violate the Administrative Procedure Act, the equal protection guarantee of the Fifth Amendment, and the Establishment Clause of the First Amendment, and as such, the undersigned Attorneys General urge that the IFRs be rescinded.[1]

[1] State Attorneys General have also filed lawsuits challenging the IFRs. *See* States' Notice Mot. & Mot. Prelim. Inj., with Mem. P. & A., § I.A.–E., at 11–27, California v. Eric D. Hargan, No. 4:17-cv-05783-HSG (N.D. Cal. filed Nov. 9, 2017) (*"CA Br."*) (attached as Exhibit 1); Mem. Law Support Pls.' Mot. Prelim. Inj., § I.A., C.–D., at 18–

I. Background

Before implementation of the Affordable Care Act ("ACA"), one in seven women with private health insurance, and nearly one-third of women covered by Medicaid, either postponed or went without needed health care because they could not afford it.[2] With respect to birth control in particular, women were forced to spend between 30 percent and 44 percent of their total out-of-pocket health costs.[3] These out-of-pocket costs prevented many women, not solely those with lower incomes, from accessing preventive services, including contraception.[4]

During this period before the ACA's passage, an estimated 49 percent of all pregnancies in the United States were unintended, and 42 percent of those unintended pregnancies ended in abortion.[5] Unintended pregnancies are associated with increases in maternal and child morbidity, including increased odds of preterm birth, low birth weight, and the potentially life-long negative health effects of premature birth.[6] Significantly, the risk of unintended pregnancy is greatest for the most vulnerable women: young, low-income, minority women, without high school or college education.[7]

Within this public health landscape, Congress passed the "Women's Health Amendment" ("WHA") to expand women's access to preventive health services through health plan coverage and no cost-sharing responsibilities.[8] The Department of Health and Human Services ("HHS") commissioned the Institute of Medicine ("IOM") to issue recommendations identifying the

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22, 32–38, Pennsylvania v. Donald J. Trump, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) ("*PA Br.*") (attached as Exhibit 2); Complt. Declaratory & Injunctive Relief, Massachusetts v. U.S. Dept. of Health & Human Servs., No. 17-cv-11930-NMG (D. Mass. filed Oct. 6, 2017); Complt. Declaratory & Injunctive Relief, Washington v. Trump, No. 2:17-cv-01510-RBL (W.D. Wa. filed Oct. 9, 2017). State Attorneys General have also submitted amicus briefs in support of plaintiffs in two lawsuits. *See, e.g.*, Br. for Mass. & Cal. et al. as Amici Curiae in Support of Pls.' Mot. Prelim. Inj., § II, at 18–30, Pennsylvania v. Donald J. Trump, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017) ("*Amici Br.*") (attached as Exhibit 3).

[2] Usha Ranji & Alina Salganicoff, *Women's Health Care Chartbook: Key Findings from the Kaiser Women's Health* Survey, HENRY J. KAISER FAMILY FOUND.1, 4 (2011), http://www.kaiserfamilyfoundation.files.wordpress.com/2013/01/8164.pdf.

[3] Laurie Sobel et al., *The Future of Contraceptive Coverage*, HENRY J. KAISER FAMILY FOUND. 1, 4 (2017), http://www.files.kff.org/attachment/Issue-Brief-The-Future-of-Contraceptive-Coverage.

[4] Su-Ying Liang et al., *Women's Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills between 1996 and 2006*, 83 CONTRACEPTION 491, 531 (2010); *see also* COMM. ON PREVENTIVE SERVS. FOR WOMEN & BD. ON POPULATION HEALTH & PUB. HEALTH PRACTICE, INST. OF MED. OF THE NAT'L ACADS., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19 (Nat'l Acad. Press, 2011), *available at* https://www.nap.edu/read/13181/chapter/1 ("IOM Report"). Another study of approximately 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography. Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 HEALTH SERVS. RESEARCH 1331, 1342-43 (2000), *available at* http://www.pubmedcentralcanada.ca/pmcc/articles/PMC1089084/pdf/hsresearch00023-0075.pdf; *see also* David Machledt & Jane Perkins, *Medicaid Premiums & Cost-Sharing*, NAT'L HEALTH LAW PROGRAM 2-3 (2014), http://www.healthlaw.org/component/jsfsubmit/showAttachment?tmpl=raw&id=00Pd000000ANrCpEAL.

[5] IOM Report at 102.

[6] *Id.* at 103.

[7] *Id.*

[8] *See* S. Amdt. 2791, 111th Congress (2009-2010); Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 et seq. (2010); Public Health Service Act (as amended by ACA) § 2713, 42 U.S.C. §300gg-13(a)(4).

specific preventive women's health services that should be covered under the ACA. In 2011, the IOM recommended, and the Health Resources and Services Administration ("HRSA") adopted, a list that includes all FDA-approved contraceptives, sterilization procedures, and reproductive education and counseling.[9] In 2016, the Women's Preventive Services Initiative,[10] led by the American Congress of Obstetricians and Gynecologists ("ACOG"), updated the preventive services guidelines and continued to include coverage of all FDA-approved contraceptive methods, reiterating their importance to women.

The IOM, ACOG, and other experts based their decisions to include coverage of contraception on the considerable evidence that the use of contraception has contributed to lower unintended pregnancy and abortion rates in the United States.[11] With the decrease in unintended pregnancies, there has been a corresponding decrease in the risk of maternal mortality, adverse child outcomes, behavior problems in children, and negative psychological outcomes associated with unintended pregnancies for both mothers and children.[12] Contraceptive use contributes to longer spacing between pregnancies, which decreases the risk of adverse health outcomes for pregnancies that are too closely spaced, and is especially critical for the health of women with certain medical conditions.[13]

Significantly, access to contraceptive coverage has given women the option to delay childbearing and pursue additional education, spend additional time in their careers, and increase earning power over the long-term. One-third of the wage gains women have made since the 1960s have been attributed to access to oral contraceptives.[14] Access to birth control has helped narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-year-olds between men's and women's annual incomes would have been 10 percent smaller in the 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access for women.[15]

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[9] *Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being*, HEALTH RESOURCES & SERVS. ADMIN., http://www.hrsa.gov/womens-guidelines/index.html (last reviewed Oct. 2017).

[10] The Women's Preventive Services Initiative also included the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health.

[11] IOM Report at 104–05.

[12] *See* IOM Report 103–04.

[13] IOM Report at 103–04. There are additional benefits of contraceptive use for treating medical conditions, including menstrual disorders and pelvic pain, and long-term use of oral contraceptives has been shown to reduce women's risk of endometrial cancer, pelvic inflammatory disease, and some benign breast diseases. *Id.* at 107.

[14] *Birth Control Has Expanded Opportunity for Women–in Economic Advancement, Educational Attainment, and Health Outcomes*, PLANNED PARENTHOOD 1,1 (June 2015), http://www.plannedparenthood.org/files/1614/3275/8659/BC_factsheet_may2015_updated_1.pdf.

[15] *See* Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages* 27 (Nat'l Bureau of Econ. Research, Working Paper No. 17322, 2012), http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf.

Since the ACA's requirement that health plans cover contraception benefits and services, women with employer-sponsored coverage have had increased access to contraception,[16] and have saved $1.4 billion in out-of-pocket costs on birth control pills in 2013 alone.[17] The share of women of reproductive age who had out-of-pocket spending on oral contraceptive pills fell sharply after the ACA's implementation; spending on oral contraceptive pills plummeted from 20.9 percent in 2012 to 3.6 percent in 2014, corresponding to the timing of the contraception provision.[18] Also during this time, the proportion of privately insured women who paid no out-of-pocket costs for oral contraception increased from 15 percent to 67 percent, with similar changes for injectable contraceptives, the vaginal ring and the intrauterine device.[19] To date, over 62.4 million women have benefited from ACA-mandated contraceptive coverage.[20]

Several of the undersigned States, in recognition that no-cost contraception is critical to women's health and autonomy, have enacted statutory schemes to require no-cost coverage for state-regulated plans.[21] However, the federal Employee Retirement Income Security Act of 1974 ("ERISA") preempts States from imposing coverage requirements on self-funded plans offered by employers.[22] Such plans cover about 58 percent of workers with employer-sponsored insurance.[23] The IFRs threaten this access by allowing virtually any employer with a self-insured plan to opt-out of the contraceptive-coverage requirement based on the employer's own religious or moral beliefs without offering any explanation or requiring any certification process

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[16] Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTION 44, 45-47 (2014), *available at* http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf.

[17] *Reproductive Rights & Health: The Affordable Care Act's Birth Control Benefit Is Working for Women*, NAT'L WOMEN'S LAW CTR. (Dec. 2016), http://www.nwlc.org/wp-content/uploads/2016/06/The-ACAs-Birth-Control-Benefit-1.pdf.

[18] Laurie Sobel et al., *Private Insurance Coverage of Contraception*, HENRY J. KAISER FAMILY FOUND. (2016), http://www.files.kff.org/attachment/issue-brief-private-insurance-coverage-of-contraception.

[19] Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTIVE 44, 45 (2015), *available at* http://www.contraceptionjournal.org/article/S0010-7824(14)00687-8/pdf.

[20] *Reproductive Rights & Health: New Data Estimates 62.4 Million Women Have Coverage of Birth Control Without Out-of-Pocket* Costs, NAT'L WOMEN'S LAW CTR. 1, 2 (2017), http://www.nwlc.org/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf.

[21] An overview of State laws and regulations is provided by Guttmacher Institute. *Insurance Coverage of Contraceptives*, GUTTMACHER INST., http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives (last updated Dec. 1, 2017). *See also* Cal. Ins. Code § 10123.196; Conn. Gen. Stat. § 38A-503e; Haw. Rev. Stat. § 432:1-604.5; 215 Ill. Comp. Stat. 5/356Z.4; Iowa Code § 514C.19; Me. Rev. Stat. tit. 24, § 2332-J, amended by Public Law, Chapter 190 (June 13, 2017); Md. Code, Ins. §§ 15-826, 15-826.1; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.M. Stat. Ann. §§ 59A-22-42; 59A-46-44; N.Y. Ins. Law §§ 3216, 3221, and 4303; N.C. Gen. Stat. § 58-3-178; Or. Rev. Stat. § 743A.066; R.I. Gen. Laws §§ 27-19-48, 27-18-57, 27-20-43; Vt. Stat. tit. 8, § 4099c; Wash. Admin. Code § 284-43-5150. State laws routinely include exemptions from mandatory coverage for prescription contraceptives for religious employers. *See, e.g.*, Conn. Gen. Stat. § 38A-503e; Mass. Gen. Laws. ch. 175, § 47W, amended by Chapter 120 of the Acts of 2017; N.Y. Insur. L. § 4303(cc).

[22] 29 U.S.C. § 1144(b).

[23] *Medical Expenditure Panel Survey: Percent of Private-Sector Enrollees That Are Enrolled in Self-Insured Plans at Establishments That Offer Health Insurance by Firm Size and State: United States, 2016*, U.S. DEPT. OF HEALTH & HUMAN SERVS., http://www.meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.pdf (last visited Dec. 4, 2017) ("ARHQ Database").

by regulators charged with enforcing the ACA's requirements. Moreover, some of the undersigned States do not have state laws requiring no-cost contraception coverage for state-regulated plans, and as such, the threatened harm of the IFRs extends to *all* employee insurance plans.

II. The IFRs violate the Administrative Procedure Act

(A) *The IFRs are contrary to law.*

The IFRs violate numerous requirements of the ACA. First, the IFRs stand in direct conflict with the WHA, which mandates that employers provide health plans that cover women's preventive care with no cost-sharing.[24] While the Religious Freedom Restoration Act (RFRA) requires protection of religious beliefs, the ACA already provides religious exemptions that satisfy RFRA's requirements.[25] The IFRs' vast exemptions go well beyond what is required to avoid a substantial religious burden by permitting a broad range of employers, including publicly-traded companies, to evade compliance with the contraceptive mandate, rather than the narrower class of churches, religious non-profits, and closely held for-profit corporations that the Supreme Court has held are protected by RFRA.[26] The IFRs also excuse these employers from undertaking any steps, however minimal, to ensure that their employees retain access to contraceptive coverage through other means, eviscerating any accommodation requirements.[27] As such, the IFRs allow for noncompliance with a mandatory statute so long as there is *any* religious burden, rather than a *substantial* one. Moreover, RFRA's protection of religious belief does not authorize the IFRs' exemptions for wholly expansive moral beliefs. (*See* further discussion in *CA Br.* § I.A.1.–2., at 11–14; *PA Br.* § I.A.2.i.–ii., at 23–27; *Amici Br.* § II.B.2., at 21–24.)

Second, the IFRs violate the ACA's nondiscrimination provision that prohibits an individual from being "excluded from participation in," "denied the benefits of," or "subjected to discrimination under, any health program or activity" receiving federal funds, to the extent that the grounds for such discrimination are otherwise unlawful under federal law.[28] The IFRs violate this nondiscrimination provision because they selectively authorize denial of coverage for women's preventive care benefits only. Indeed, the Equal Employment Opportunity Commission has previously held that an employer who offers coverage for preventive

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[24] *See FAQs about Affordable Care Act Implementation Part 36*, EMPLOYEE BENEFITS SEC. ADMIN., U.S. DEPT, OF LABOR, 1, 1 (2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf (explaining the effects of the Women's Health Amendment on insurance coverage of women's preventive care).

[25] *Id.* at 4-5.

[26] *See Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2768–69 (2014).

[27] The IFRs also eliminate the requirement for employers to notify the federal government if they choose to avail themselves of the exemption, thereby allowing for contraceptive coverage to be quietly eliminated without oversight or transparency.

[28] 42 U.S.C. § 18116.

prescription drugs and services but does not offer coverage for contraception violates Title VII.[29] (*See* further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § II.B., at 43–46; *Amici Br.* § II.B.2., at 21–24.)

Third, the ACA prohibits the Secretary of Health and Human Services from "promulgat[ing] any regulation that creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," or "impedes timely access to health care services."[30] The IFRs clearly violate this provision by preventing women from accessing important and often medically necessary contraceptive services. (*See* further discussion in *CA Br.* § I.A.3., at 14; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § I.A.1.–2., at 4–6.)

(B) *The IFRs are arbitrary and capricious.*

The IFRs radically depart from prior policy without adequate or reasonable justification, as required by law. First, the IFRs do not provide sufficient justification for discarding the prior regulations' finding of a compelling government interest in ensuring that women have contraceptive coverage even if their employers object to providing it. Five justices of the Supreme Court have expressly recognized such a compelling interest.[31] The IFRs cite scant evidence to support the assertion that access to contraception has little effect on unintended pregnancies, and indeed, the vast majority of studies have shown precisely the opposite.[32] Moreover, the IFRs ignore the other public health interests served by the contraceptive mandate—including the need for some women to avoid pregnancy, which can be hazardous or life-threatening to them due to a medical condition. (*See* further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Second, the IFRs provide inadequate explanation for expanding the universe of employers who are exempt from compliance with the contraceptive mandate from churches, houses of worship, religious non-profits, and closely held for-profit corporations, to *any and all* non-governmental employers and *any and all* private universities. Relatedly, the IFRs fail to justify the creation of the broader religious employer exemption, rather than the narrower eligible organization accommodation, to these employers. The offered explanations for this approach is disagreement with the former Administration; but a disagreement with the previous approach is far from the reasoned and evidence-based explanation required for the evisceration of the relied-upon accommodation requirements, which balanced religious exercise and full and equal health coverage for women. (*See* further discussion in *CA Br.* § I.C., at 19–21; *PA Br.* § I.A.2.iii., at 27–28; *Amici Br.* § II.C., at 24–26.)

Third, the IFRs extend the applicability of the religious and moral exemption to insurance companies, without reasonable explanation for this entirely new expansion. In fact, the IFRs

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[29] *See* Commission Decision on Coverage of Contraception, U.S. EQUAL EMPLOYMENT OPPORTUNITY COMM., 2000 WL 33407187 (Dec. 14, 2000), http://www.eeoc.gov/policy/docs/decision-contraception.html.
[30] 42 U.S.C. § 18114.
[31] *See Hobby Lobby*, 134 S. Ct. at 2785 (Kennedy, J., concurring); *id.* at 2799 (Ginsburg, J., dissenting).
[32] *See, e.g.*, IOM Report at 102–07 (collecting studies on effects of women's access to contraceptives).

acknowledge that the Departments are not aware of any insurance company with such an objection—it is undoubtedly arbitrary to promulgate a rule with no intended use.

III. The IFRs Violate the Equal Protection Guarantee of the Fifth Amendment

Although the ACA requires coverage for many different types of preventive services, the IFRs single out only women's health benefits and services. The President's Executive Order directed the Departments to consider allowing additional "conscience-based objections" to services mandated by the WHA specifically.[33] The IFRs create vast exemptions for contraceptive coverage only, clearly targeting women's preventive services, while leaving preventive service coverage for male employees untouched. The IFRs include a gender-based classification[34] and are thus subject to heightened scrutiny.

The government interest motivating both IFRs is articulated as providing protections for "sincerely held ['religious beliefs' or 'moral convictions'] in certain health care contexts."[35] Even if an unbounded moral conviction is found to be a compelling interest, this gender-based classification does not have an "exceedingly persuasive justification" and is not "substantially related to the achievement of those objectives."[36] The IFRs fail any "means" test as the staggering breadth of the exemptions—to virtually *any* employer for virtually *any* religious or moral objection—lacks any tailoring whatsoever, and flies in the face of any reasonable interpretation of the "substantial relationship" standard. (*See* further discussion in *CA Br.* § I.E., at 25–28; *PA Br.* § I.C., at 32–34; *Amici Br.* § II.D.2., at 29–30.)

IV. The IFRs Violate the Establishment Clause

The IFRs violate the Establishment Clause because their purpose and effect is clearly the advancement of religious beliefs.[37] The Rules do not even bother to feign a non-religious purpose. The IFRs also violate the Establishment Clause because they allow employers to obtain religious exemptions in a manner that substantially burdens female employees who may not share the employers' faith.[38] The burdens here imposed go well beyond any justified by religious exercise—they result in the potentially dramatic loss of contraceptive coverage for millions of women, with no alternative structure to obtain care. The Supreme Court relied

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[33] Exec. Order No. 13798, 82 Fed. Reg. 21,675 (May 4, 2017), http://www.gpo.gov/fdsys/pkg/FR-2017-05-09/pdf/2017-09574.pdf.

[34] The IFRs are also overtly discriminatory because they single out women's health care services, including benefits that are only used by women. Aside from the reference to only women's services, the IFRs are infused with overt references to purported "sensitive" areas of health, which all concern women's reproductive health and rely on overly-broad generalizations of women's health care. *See* 82 Fed. Reg. 47,838 (2017); 82 Fed. Reg. 47,813 (2017). The IFRs are also covertly discriminatory because they have a direct impact on women only. Women alone will be forced to struggle to pay for contraception themselves, forgo contraceptives, or to try to seek out services from some entity other than their employer.

[35] 82 Fed. Reg. 47,845 (2017); 82 Fed. Reg. 47,800 (2017).

[36] *Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1690 (2017).

[37] *See Lemon v. Kurtzman*, 403 U.S. 602, 612–13 (1971).

[38] *See* 42 U.S.C. § 2000bb–1(a) (the "government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability").

heavily on the notification and accommodation mechanisms previously in place as necessary protections of women's ability to access contraception.[39] Without such accommodation, notice, and justification requirements, the burdens on women have grown dramatically, resulting in a clear violation of the Establishment Clause. (*See* further discussion in *CA Br.* § I.D., at 21–24; *PA Br.* § I.D., at 34–38; *Amici Br.* § II. D.1., at 27–28.)

V. Conclusion

The IFRs at issue will result in harms that are both direct and indirect, tangible and intangible. Access to contraception is fundamental to women's rights to bodily freedom and to emotional autonomy. It is a public health issue, with effects on unintended pregnancy, maternal health, and infant morbidity. It also implicates economic mobility and wage parity, educational opportunity and social equality. These far-reaching effects are too great to ignore, and are protected by the Constitution, our laws and regulations. Accordingly, we urge the Secretary to rescind the IFRs.

Respectfully submitted,
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[39] In *Hobby Lobby*, for example, the Court explained that the accommodation sought by closely held for-profit corporations would not violate the Establishment Clause because it has "precisely zero" effect on the women employed by Hobby Lobby. The Court noted that "these women would still be entitled to all FDA-approved contraceptives without cost sharing." 134 S. Ct. at 2760. In his concurrence, Justice Kennedy underscored that an accommodation of religious exercise must not "unduly restrict other persons, such as employees, in protecting their own interests." *Id*. at 2786–87 (Kennedy, J., concurring). Similarly, the Court in *Wheaton College v. Burwell* expressly noted that its order allowing employers to notify the government rather than their insurer about a religious objection would not "affect[] the ability of [Wheaton's] employees and students to obtain, without cost, the full range of FDA approved contraceptives." 134 S. Ct. 2806, 2807 (2014).

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