UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ERIC D. HARGAN, in his official capacity as Acting Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF THE TREASURY; STEVEN T. MNUCHIN, in his official capacity as Secretary of the Treasury; UNITED STATES DEPARTMENT OF LABOR; and R. ALEXANDER ACOSTA, in his official capacity as Secretary of Labor,

Defendants.

Case No. 17-cv-11930-NMG

MEMORANDUM IN SUPPORT OF THE COMMONWEALTH OF MASSACHUSETTS' MOTION FOR SUMMARY JUDGMENT

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Carey v. Population Servs., Int'l,
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Catholic Health Care Sys. v. Burwell,
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Chevron, USA, Inc. v. Natural Resource Defense Council, Inc.,
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Coalition for Parity, Inc. v. Sebelius,
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Encino Motorcars, LLC v. Navarro,
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Eternal Word Television Network, Inc. v. Sec'y of HHS,
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Freedom from Religion Fund v. Hanover Sch. Dist.,
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Geneva Coll. v. Sebelius,
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Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC,
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Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.,
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Jifry v. Fed. Aviation Admin.,
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Public Citizen v. FTC,
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Real Alternatives, Inc. v. Sec'y of HHS,
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Robinson v. Children's Hospital Boston,
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Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd.,
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Sessions v. Morales-Santana,
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Sharpe Holdings, Inc. v. HHS,
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Shaw v. Hunt,
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Sig Sauer, Inc. v. Brandon,
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Sierra Club v. EPA,
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Texas Monthly, Inc. v. Bullock,
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United States v. Virginia,
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Univ. of Notre Dame v. Burwell,
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Waterkeeper Alliance v. EPA,
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42 U.S.C. § 2000bb-3(b) 29

42 U.S.C. § 2000cc-5(7)(A) 33

42 U.S.C. § 2000e-2(a) 33

42 U.S.C. § 2000e(k) 33

Patient Protection and Affordable Care Act,
Pub. L. No. 111–48, 124 Stat. 119 .... *passim*

Women's Health Amendment, S. Amdt. 2791, 111th Congress (2009–2010)........3

Federal Regulations

45 C.F.R. 147.132(a)(1)(i)–(iii) 9

45 C.F.R. 147.132(a)(2) 9

45 C.F.R. 147.133(a)(1)(i)–(iii) 9

45 C.F.R. 147.133(a)(2) 9

Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to
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Group Health Plans and Health Insurance Issuers Relating to Coverage of
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Group Health Plans and Health Insurance Issuers Relating to Coverage of
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Coverage of Certain Preventive Services Under the Affordable Care Act,
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Coverage of Certain Preventive Services Under the Affordable Care Act,
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Coverage of Certain Preventive Services Under the Affordable Care Act,
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Interim Final Rules, Religious Exemptions and Accommodations for
Coverage of Certain Preventative Services Under the
Affordable Care Act (Oct. 6, 2017) .... *passim*

Interim Final Rules, Moral Exemptions and Accommodations for
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Massachusetts Statutes

G.L. c. 71, § 32A..39

G.L. c. 111, § 110A..39

G.L. c. 175, § 47W...11

G.L. c. 175, § 47W(c) 30

G.L. c. 176A, § 8W...11

G.L. c. 176B, § 4W 11

G.L. c. 176G, § 4O..11

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130 C.M.R. 450.316–321..12

130 C.M.R. 503.007...12

130 C.M.R. 505.000...12

Congressional Record

155 Cong. Rec. S11987 (Nov. 30, 2009) 25

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155 Cong. Rec. S12026 (Dec. 1, 2009) 2, 26

155 Cong. Rec. S12027 (Dec. 1, 2009) 25

155 Cong. Rec. S12028 (Dec. 1, 2009) 25

155 Cong. Rec. S12114 (Dec. 2, 2009) 25, 26

155 Cong. Rec. S12271 (Dec. 3, 2009) 25

155 Cong. Rec. S12274 (Dec. 3, 2009) 25

155 Cong. Rec. S12277 (Dec. 3, 2009) 25

155 Cong. Rec. S12671 (Dec. 8, 2009) 25

158 Cong. Rec. S539 (Feb. 9, 2012)..26

158 Cong. Rec. S1115 (Feb. 29, 2012)..5, 26

158 Cong. Rec. S1116 (Feb. 29, 2012)..5

158 Cong. Rec. S1166 (March 1, 2012) 26-27

Miscellaneous

Br. of Respondents, *Zubik v. Burwell*,
136 S. Ct. 1557 (2016) (No. 14–1418) 32

Ctr. for Health Information & Analysis, *Enrollment Trends* (Aug. 2017) 11

Equal Employment Opportunity Comm'n, Decision (Dec. 14, 2010),
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L. Finer & M. Zolna, *Shifts in Intended and Unintended Pregnancies in the United States, 2001 – 2008*, 104 Am. J. Pub. Health S43 (2014)...............3

A. Gariepy et al., *The Impact of Out-of-Pocket Expense on IUD Utilization Among Women with Private Insurance*, 84 Contraception e39 (2011) 14

J. Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Found. (Oct. 2006) 4

H. 4009, §§ 3(e)(1), 4(e)(1), 5(e)(1), 6(e)(1) 11

HRSA, *Women's Preventative Services Guidelines* 4

Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps (2011) 3, 4, 26

T. Jost, *Is There Justification For The Contraceptive Rule To Go Into Effect Immediately Upon Issuance?* Health Affairs Blog (July 7, 2017)............20

Kaiser Family Found., *Employer Health Benefits, 2015 Annual Survey* 58 (2015) 2

Kaiser Family Found., *Employer Health Benefits, 2017 Annual Survey* 204 (2017) 2

Kaiser Family Found., *Health Care Expenditures per Capita by State of Residence* (2014)....................14

S. Long, *On the Road to Universal Coverage: Impacts of Reform in Massachusetts At One Year*, 27 Health Affairs, No. 4 (June 2008)............4

Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120 Obstetrics & Gynecology 1291 (2012)......................14

D. Postlethwaite et al., *A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change*, 76 Contraception 360 (2007).....................4

R. Seifert et al., *The Basics of MassHealth*, Massachusetts Medicaid Policy Inst. 3 (Feb. 2011)....................12

A. Sonfield A & K. Kost, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, Guttmacher Institute (2015)....................15

U.S. Dept. of Labor, *FAQs About Affordable Care Act Implementation Part 36* (Jan. 9, 2017)..8

The Commonwealth of Massachusetts seeks to protect itself, and thousands of Massachusetts women, from the harms that will result from the Defendants' attempt to nullify the provisions of the Patient Protection and Affordable Care Act ("ACA") that guarantee women equal access to preventive medical care—specifically contraceptive care and services. On October 6, 2017, the Defendants, the Secretaries of the U.S. Departments of Health and Human Services ("HHS"), Labor, and the Treasury, as well as their respective Departments (hereinafter "Departments"), issued two Interim Final Rules ("IFRs") authorizing employers with religious or moral objections to contraception to block their employees, and their employees' dependents, from receiving health insurance coverage for contraceptive care and services. The IFRs, which became effective immediately, are flatly inconsistent with the ACA's requirement that employer-sponsored group health plans provide women with coverage for preventative care services, including contraception. They amount to an endorsement of religion in violation of the Establishment Clause of the First Amendment, they discriminate against women in violation of the Equal Protection guarantee implicit in the Fifth Amendment, and they were issued before completion of the required notice and comment rulemaking process, in violation of the Administrative Procedure Act.

A wealth of research demonstrates the critical importance of contraceptive coverage for women's health. By creating ten broad new exemptions from the ACA's contraception mandate, the IFRs jeopardize the health care of women in Massachusetts and leave the State to assume additional costs related to contraception and services associated with unintended pregnancies. The Commonwealth seeks to enjoin implementation of, and invalidate, the IFRs so that no individual or family in Massachusetts, or across the country, is harmed.

BACKGROUND

I. The Affordable Care Act and Implementation of the Contraception Mandate.

A. Preventive Services Requirement and the Women's Health Amendment.

Congress enacted the ACA, 124 Stat. 119, to ensure that all Americans have access to affordable, quality health care. Among other reforms, the ACA requires employer-sponsored group health plans to provide coverage for a broad range of preventive medical services on a no-cost basis—meaning that plan participants cannot be charged cost-sharing payments like copays or deductibles. *See* 42 U.S.C. § 300gg-13.[1] This preventative services requirement recognizes that most Americans receive health care coverage through their employers,[2] and that preventive care is a fundamental part of "basic health care" that leads to healthier populations and lower health care costs. *See* 78 Fed. Reg. 39,870, 39,872 (July 2, 2013).

As originally drafted, the preventive services requirement mandated that health plans cover three categories of care at no added cost to plan participants. *See* 42 U.S.C. § 300gg-13(a)(1)–(3). These categories, however, did not ensure adequate coverage for medically necessary preventive care services specifically for women. Prior to the ACA, gender-based disparities in health plan coverage and health care markets made it more difficult and expensive for women, relative to men, to access a range of preventive care services.[3]

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[1] Employers providing "grandfathered health plans"—that is, health plans that existed prior to March 23, 2010 and that have not made certain changes after that date—are not subject to this requirement. *See* 42 U.S.C. § 18011(a), (e). Only 17% of the 150 million nonelderly people in America with employer-sponsored health coverage are in grandfathered plans. *See* Kaiser Family Found., *Employer Health Benefits, 2017 Annual Survey* 204 (2017) (Salera Decl. Ex. A). That number will keep decreasing as modifications are made to group health plans. *See, e.g.*, *id.*; *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1161 n. 5 (10th Cir. 2015) ("The exemption for grandfathered plans is temporary and transitional.").

[2] *See* Kaiser Family Found., *Employer Health Benefits, 2015 Annual Survey* 58 (2015) (Salera Decl. Ex. B).

[3] *See, e.g.*, 155 Cong. Rec. S12025 (Dec. 1, 2009) (Sen. Boxer); 155 Cong. Rec. S12026 (Dec. 1, 2009) (Sen. Mikulski).

To redress these disparities, and to guarantee women equal access to preventive medicine, Congress passed the Women's Health Amendment. *See* S. Amdt. 2791, 111th Congress (2009–2010). The Amendment added a fourth category to the preventive services requirement mandating no-cost coverage for, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4).

The Women's Health Amendment did not mandate coverage for specific preventive care services. *Id.* Instead, Congress delegated authority to the Health Resources and Services Administration ("HRSA"), an agency within HHS, to determine which services must be covered. *Id.* HRSA, in turn, enlisted the Institute of Medicine ("IOM") (now known as the National Academy of Medicine) to convene a committee of experts to assess what preventive care services were necessary to protect women's health and wellbeing. *See* IOM, Clinical Preventive Services for Women: Closing the Gaps, at 1–2 (2011) ("IOM Report") (Salera Decl. Ex. C).

Access to contraception, the IOM found, reduces unintended pregnancies, adverse pregnancy outcomes, and other negative health consequences for women and children, as well as the number of women seeking abortions. *Id.* at 105. Unintended pregnancy is prevalent in the U.S., accounting for approximately half all pregnancies.[4] Women experiencing unintended pregnancies are more likely than women with planned pregnancies to receive late or no prenatal care, to smoke or consume alcohol during pregnancy, and to be depressed during pregnancy. *Id.* at 103. Children born as the result of unintended pregnancy have significantly increased odds of preterm birth and low birth weight compared with children born of planned pregnancies, and are less likely to be

[4] *See* L. Finer & M. Zolna, *Shifts in Intended and Unintended Pregnancies in the United States, 2001 – 2008*, 104 AM. J. PUB. HEALTH S43, S44 (2014) (Salera Decl. Ex. D).

breastfed. *Id.* The IOM also found that contraception provides women with important health benefits apart from avoiding unintended pregnancies, including decreasing the risk of certain cancers, treating menstrual disorders, and protecting against pelvic inflammatory disease and some benign breast diseases. *Id.* at 107.

The IOM recognized that there are many methods of FDA-approved contraception, the effectiveness and appropriateness of which vary depending on age, sexual practices, and health conditions. *Id.* at 104–07. And it determined that access to contraception—particularly more effective, long-lasting methods like intrauterine devices—can be significantly improved when cost-sharing requirements are eliminated. *Id.* at 109.[5] In light of its review of medical research, the IOM recommended that the HRSA Guidelines on preventative care for women include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." *Id.* at 109–10.

In accordance with the IOM's recommendation, HRSA's Women's Preventive Services Guidelines, promulgated in August 2011, required employers to provide "coverage, without cost sharing," for "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" (hereinafter "the contraception mandate"). HRSA, *Women's Preventative Services Guidelines*, at https://www.hrsa.gov/womens-guidelines/index.html. These Guidelines, including the contraception mandate, went into effect in August 2012 and were reaffirmed in 2016.

[5] Studies show that cost-sharing requirements can be a significant barrier to access to contraception, and that as copays and deductibles decline and coverage increases, more preventative services are utilized. *See, e.g.*, D. Postlethwaite et al., *A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change*, 76 CONTRACEPTION 360 (2007) (Salera Decl. Ex. E); S. Long, *On the Road to Universal Coverage: Impacts of Reform in Massachusetts At One Year*, 27 HEALTH AFFAIRS, No. 4 (June 2008) (Salera Decl. Ex. F); J. Gruber, *The Role of Consumer Copayments for Health Care: Lessons from the RAND Health Insurance Experiment and Beyond*, Kaiser Family Found. (Oct. 2006) (Salera Decl. Ex. G).

B. The Church Exemption and The Accommodation for Religious Objections to Contraceptive Coverage.

When Congress enacted the preventative services requirement in the ACA, it did not include a conscience amendment that would have permitted employer-sponsored health plans to deny coverage based upon religious beliefs or moral convictions. *See* 158 Cong. Rec. S1115–S1116 (Feb. 29, 2012) (Sen. Blunt). Recognizing that some Americans have religious objections to contraception, however, the Departments undertook a series of regulatory actions from 2011 to 2015 that sought to balance employees' statutory right to coverage for contraception with employers' religious objections to contraception, to the extent required by federal law, including the Religious Freedom Restoration Act ("RFRA"). *See, e.g.*, 75 Fed. Reg. 41,726 (July 19, 2010); 76 Fed. Reg. 46,621 (Aug. 3, 2011); 77 Fed. Reg. 8725 (Feb. 15, 2012); 78 Fed. Reg. 39,870 (July 2, 2013); 79 Fed. Reg. 51,092 (Aug. 27, 2014); 80 Fed. Reg. 41,318 (July 14, 2015).

The Church Exemption. First, in 2011 and 2012, the Departments issued regulations that created a narrow exemption—hereinafter the "Church Exemption"—that exempted churches and their integrated auxiliaries, a category of employers defined in the Internal Revenue Code,[6] from the contraception mandate. *See* 76 Fed. Reg. 46,621 (Interim Final Rules); 77 Fed. Reg. 8725 (Final Rules). In effect, this permitted employers covered by the Church Exemption to decline to provide their employees with coverage for contraception. The Exemption, the Departments explained, respects the "particular sphere of autonomy" legally afforded to internal church decisions, including those concerning church employees. 80 Fed. Reg. at 41,325. The Church Exemption therefore "complie[d] with the Religious Freedom Restoration Act." 77 Fed. Reg. at 8729. The Departments explained that their "discretion to establish an exemption applies *only* to

[6] *See* 26 U.S.C. § 6033(a)(3)(A)(i) and (iii).

group health plans sponsored by [those] religious employers and group health insurance offered in connection with such plans." 76 Fed. Reg. at 46,623–24 (emphasis added).

The Departments recognized that "certain non-exempted, non-profit organizations" also had religious objections to covering contraceptive services. 77 Fed. Reg. at 8728. Extending the Church Exemption to cover these employers, however, was not required by RFRA and was inconsistent with the ACA because it would improperly "subject . . . employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventative care," the Departments explained. *Id.* Nevertheless, the Departments pledged to work with these employers to develop an alternative mechanism for providing contraceptive coverage to their employees. *Id.*

The Accommodation. In 2013, the Departments issued regulations that honored that pledge. The regulations created a new process—called the "Accommodation"—for nonprofit organizations and institutions of higher education that held themselves out as religious and objected to providing contraceptive coverage on religious grounds. *See* 78 Fed. Reg. 39,870. Under the Accommodation, these nonprofits and universities can self-certify that they qualify as "eligible organizations" by submitting a two-page form, known as the EBSA Form 700, to their group health insurance issuer or third party administrator. 78 Fed. Reg. at 39,874–77.[7] Upon receiving the form, the insurer or third party administrator is independently responsible for removing contraceptive coverage from the employer's plan and for making payments for contraception and contraceptive services used by plan participants, without imposing cost-sharing expenses on plan participants.

[7] In response to the Supreme Court's interim order in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014), the Departments issued a separate set of regulations that alternatively permitted employers claiming the Accommodation to notify HHS, rather than the health insurance issuer or third party administrator through an EBSA Form 700, of their status as an eligible organization. *See* 79 Fed. Reg. 51,092. The EBSA Form 700 is attached as Exhibit H to the Declaration of Kristen Salera.

Id. Through this process, objecting employers and universities are relieved of the requirement to provide contraceptive coverage—and pay no costs associated with the provision of such coverage—while employees and students continue to receive seamless coverage for contraceptive care, as required by the ACA.

In *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Supreme Court considered a challenge from closely held, for-profit employers who contended that the contraception mandate violated their rights to religious liberty under the Religious Freedom Restoration Act. The Supreme Court ruled that RFRA protects those employers, and it upheld the employers' challenge on the ground that the Accommodation provided an alternative, less burdensome method for providing contraceptive coverage to employees of employers with religious objections. 134 S. Ct. at 2775, 2782–83. In response to *Hobby Lobby*, the Departments expanded the Accommodation to cover closely held, for-profit corporations with religious objections to contraception. *See* 80 Fed. Reg. 41,318.

Challenges to the Accommodation. Some religious nonprofit organizations remained dissatisfied with the Accommodation and demanded that the Departments provide them with an exemption, like the Church Exemption, that would not contain a mechanism to ensure that their employees retained coverage for contraception. These employers contended that the Accommodation made them complicit in the provision of contraception to their employees, in violation of their religious beliefs and their rights under RFRA. Eight out of nine Courts of Appeals rejected the claim, concluding that the Accommodation is consistent with RFRA because, among other reasons, the act of notifying a health insurer or HHS of an employer's status as an eligible organization does not impose a substantial burden on the religious exercise of the employer.[8]

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[8] *See Eternal Word Television Network, Inc. v. Sec'y of HHS*, 818 F.3d 1122, 1148 (11th Cir. 2016); *Mich. Catholic Conf. & Catholic Family Servs. v. Burwell*, 807 F.3d 738, 749–55 (6th Cir. 2015);

The Supreme Court consolidated several of these cases for review in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). In a short *per curiam* decision, the Court remanded the cases for further consideration, with instructions to the parties to continue working toward a mutually acceptable approach that "accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id.* at 1560 (internal quotation marks omitted). The Court "expresse[d] no view on the merits" of the RFRA claim. *Id.*

In July 2016, the Departments published a Request for Information, seeking comment from interested parties as to whether the regulations could be modified to "resolve the objections asserted by the plaintiffs in [*Zubik*], while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage."[9] In January 2017, after review of the comments submitted, the Departments announced that they were unable to identify a feasible, less burdensome alternative that would satisfy employers' religious objections while still ensuring that "women receive full and equal health coverage, including contraceptive coverage."[10]

C. The Interim Final Rules.

On October 6, 2017, the Departments issued two interim final rules—hereinafter the "Religious IFR" and the "Moral IFR"—that abandoned their prior effort to balance the religious liberty of employers with the right of women to seamless, no-cost contraception coverage. *See*

Catholic Health Care Sys. v. Burwell, 796 F.3d 207, 218 (2d Cir. 2015); *Little Sisters of the Poor Home for the Aged v. Burwell*, 794 F.3d 1151, 1180 (10th Cir. 2015); *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449, 463 (5th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 615 (7th Cir. 2015) (*Notre Dame II*); *Geneva Coll. v. Sec'y of HHS*, 778 F.3d 422, 442 (3d Cir. 2015); *Priests for Life v. HHS*, 772 F.3d 229, 252 (D.C. Cir. 2014); *Mich. Catholic Conf. & Catholic Family Servs. v. Burwell*, 755 F.3d 372, 390 (6th Cir. 2014); *Univ. of Notre Dame v. Sebelius*, 743 F.3d 547, 559 (7th Cir. 2014) (*Notre Dame I*); *but Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 942 (8th Cir. 2015).

[9] U.S. Dept. of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (Jan. 9, 2017) (Salera Decl., Ex. I).

[10] *Id.*

Salera Decl., Ex. J (Religious IFR), K (Moral IFR). The IFRs, which became effective upon their release, did not go through the Administrative Procedure Act's ("APA") notice and comment rulemaking process. *See* 5 U.S.C. § 553(b)–(c); Religious IFR 2, 79–80; Moral IFR 2, 66.

Together, the IFRs create ten new "expanded exemptions" from the contraception mandate. Religious IFR 61; Moral IFR 11. In addition to houses of worship already exempted, the Religious IFR exempts any (1) "nonprofit organization"; (2) "closely held for-profit entity"; (3) "for-profit entity that is not closely held"; (4) "other non-governmental employer"; (5) "institution of higher education"; and (6) "health insurance issuer offering group or individual insurance coverage." Religious IFR 61–74, 161–62; 45 C.F.R. 147.132(a)(1)(i)–(iii). These entities are no longer required to include contraceptive coverage in their health care plans "to the extent that" they object "based on [their] sincerely held religious beliefs." Religious IFR 162; 45 C.F.R. 147.132(a)(2). Similarly, the Moral IFR exempts any (1) "nonprofit organization"; (2) "for-profit entity that has no publicly traded ownership interests"; (3) "institution of higher education"; and (4) "health insurance issuer offering group or individual insurance coverage." Moral IFR 47–59, 98–99; 45 C.F.R. 147.133(a)(1)(i)–(iii). These entities are no longer required to include contraceptive coverage in their health plans "to the extent that" they object "based on [their] sincerely held moral convictions." Moral IFR 99; 45 C.F.R. 147.133(a)(2). The term "moral convictions" is not defined.

The IFRs also grant employers and universities control over whether their employees and students can receive independent coverage through the Accommodation. Under the new rules, which leave the Accommodation in place, an objecting employer or university can choose to: (a) claim the exemption, and simply stop providing contraceptive coverage for their employees or students, or (b) participate in the Accommodation, which still ensures that employees and students maintain independent coverage for contraception. Religious IFR 76–78, Moral IFR 64.

The Departments acknowledge that the IFRs will result in approximately 257,000 employees and their dependents losing access to the comprehensive, cost-free contraceptive coverage guaranteed by the ACA. Religious IFR 106. More specifically, they estimate that between 31,715 and 120,015 women of child-bearing age who are currently using contraception will lose coverage. *See* Religious IFR 89, 105–08, 113; Moral IFR 73, 78. They also estimate that the increased out-of-pocket cost of contraceptive care for those who lose coverage will be approximately $584 per woman per year, or between $18.5 and $63.8 million annually nationwide. Religious IFR 108, 115; Moral IFR 79. Many of these women who lose coverage will be forced to seek contraceptive care from sources other than their usual health care providers. *See* Religious IFR 42–43. Others will forgo contraception altogether, leading to an increase in unintended pregnancies and negative health consequences for women and children. *See supra*, at 3–4. As detailed further below, an increase in negative health consequences will impose additional costs and burdens on women, their families, and the Commonwealth.[11]

II. Massachusetts' Commitment to Ensuring Access to Contraception.

Massachusetts has long recognized the critical role that access to contraceptive care and services plays in the health and wellbeing of women, children, and families. The Commonwealth supports access to contraceptive care and services through an interrelated system composed of: (a) a contraceptive coverage law that requires health plans to cover contraception and family

[11] The Departments likely underestimate the impact of the IFRs. For example, they assume, based upon what they acknowledge is insufficient evidence, that employers—and particularly large employers—will make limited use the expanded exemptions created by the IFRs, which permit employers to end contraception coverage for women. They assume, therefore, that the vast majority of the approximately 1,027,000 people they estimate were receiving contraceptive coverage through the Accommodation under the prior regulations will continue to receive coverage through that Accommodation. *See* Religious IFR 89, 105–08, 113; Moral IFR 73, 78. They also assume that no significant number of newly eligible employers—employers that did not already qualify for the Accommodation under the prior regulations—will claim the expanded exemptions. *Id.*

planning services; (b) direct coverage of family planning services for individuals eligible for the Commonwealth's Medicaid program, called MassHealth; and (c) a network of family planning program providers that receive reimbursement from the Massachusetts Department of Public Health's ("DPH") Sexual and Reproductive Health Program ("SRHP").

Contraceptive Equity Law and ACCESS Act. In 2002, the Legislature expanded coverage for contraceptive services, drugs, and devices ("Contraceptive Equity Law"). *See* Mass. St. 2002, c. 49, §§ 1–4. The Contraceptive Equity Law required employer-sponsored health plans that cover outpatient services, prescriptions, or devices to provide the same level of coverage for all FDA-approved contraceptive services, prescriptions, and devices. *See* G.L. c. 175, § 47W; G.L. c. 176A, § 8W; G.L. c. 176B, § 4W; G.L. c. 176G, § 4O. Unlike the ACA, however, the law did not mandate no-cost contraceptive coverage. Women covered by the law were still responsible for cost-sharing payments, like deductibles and copays, to access contraceptive care. To remedy that gap, the Legislature recently passed an "Act relative to advancing contraceptive coverage and economic security in our state," or the "ACCESS Act." If signed into law by the Governor, the ACCESS Act would prohibit certain employer-sponsored health plans from imposing cost-sharing fees, like deductibles and copays, in connection with the provision of contraception. *See* H. 4009, §§ 3(e)(1), 4(e)(1), 5(e)(1), 6(e)(1), https://malegislature.gov/Bills/190/H4009/BillHistory.

The ACCESS Act and Contraceptive Equity Law do not apply to self-insured employer plans, which are governed solely by federal law—the Employee Retirement Income Security Act ("ERISA"). *See* 29 U.S.C. §§ 1144(a), (b)(2)(A); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740–47 (1985). Approximately 56% of Massachusetts residents who have private commercial health insurance receive coverage through a self-insured plan.[12] Women covered by

[12] *See* Ctr. for Health Information & Analysis, *Enrollment Trends* 3 (Aug. 2017) (Salera Decl. Ex. M).

these plans who lose contraceptive coverage because of the IFRs will not be protected by the ACCESS Act or Contraceptive Equity Law.

MassHealth Program. MassHealth provides access to integrated health care services that promote health, wellbeing, and quality of life for almost two million Massachusetts residents. *See* Boyle Decl. ¶ 4. As part of that mission, MassHealth guarantees its members access to all FDA-approved contraceptives. *See id.*; 130 Code Mass. Regs. ("C.M.R.") 450.105. Eligibility for MassHealth is determined by a combination of income, household composition, age, and medical status. *See* 130 C.M.R. 505.000 *et seq*.

When a Massachusetts resident with employer-sponsored insurance or student health insurance also satisfies MassHealth's eligibility criteria, "MassHealth will 'wrap around' that coverage as a secondary payer to cover a MassHealth level of services and cost sharing not covered by the primary insurance." R. Seifert et al., *The Basics of MassHealth*, MASSACHUSETTS MEDICAID POLICY INST. 3 (Feb. 2011) (Salera Decl. Ex. L); *see also* 130 C.M.R. 450.316–321, 503.007 (MassHealth third-party liability regulations); Boyle Decl. ¶ 4. Currently, MassHealth provides coverage for approximately 150,000 residents who have commercial coverage, including employer-sponsored insurance and student health insurance. *See* Boyle Decl. ¶ 4. Should these residents, or any of the thousands of other residents who meet eligibility requirements, lose comprehensive, no-cost contraceptive coverage from their employer-sponsored plans or student health plans because of the IFRs, they will be entitled to receive replacement coverage through MassHealth. *Id.* ¶ 6. Under Medicaid rules, Massachusetts is responsible for paying 10% of all family planning services covered by MassHealth. *See* 42 U.S.C. § 1396b(a)(5).

DPH-Funded Clinics. Women may also access contraceptive care through DPH-funded family planning programs. Among other things, the SRHP funds contraceptive care and related

services provided by a statewide network of family planning program providers. *See* 101 C.M.R. 312.000; Cooke Decl. ¶ 5; Childs-Roshak Decl. ¶ 11. Funded services include gynecological and breast exams, diagnosis and treatment of sexually transmitted diseases, emergency contraception, counseling, and birth control, including all FDA-approved contraceptives. Cooke Decl. ¶ 5.

Services funded by SRHP are available to a broad range of Massachusetts residents, including (a) uninsured Massachusetts residents who make less than 300% of the federal poverty level, (b) Massachusetts residents of any insurance status who need confidential care, and (c) Massachusetts residents who make less than 300% of the federal poverty level and have a health plan that does not cover all contraception methods and services. *Id.* ¶ 6. Some women who lose contraceptive coverage from their employer-sponsored plans or student health plans because of the IFRs will be eligible for contraceptive care funded by SRHP, and some of those women will likely seek and receive care at SRHP-funded clinics. *See id.* ¶ 8; Childs-Roshak Decl. ¶ 18.

III. The IFRs Will Harm the Commonwealth.

The IFRs undermine the Commonwealth's commitment to protecting the health and wellbeing of its residents through contraceptive care. In the short and the long term, the IFRs will also inflict significant financial harm on the Commonwealth, which will be legally obligated to assume the costs of contraceptive, prenatal, and postnatal care for many women who lose coverage.

Based upon the Departments' estimates in the IFRs, between 666 and 2,520 Massachusetts women who are currently using contraception will lose comprehensive, employer-sponsored contraceptive coverage.[13] The direct cost of providing replacement contraceptive coverage and

[13] These figures are calculated by multiplying the Departments' nationwide estimates by Massachusetts' share of the national population (2.1%). *See* U.S. Census Bureau, *Quick Facts: Massachusetts*, https://www.census.gov/quickfacts/MA; U.S. Census Bureau, *U.S. and World Population Clock*, https://www.census.gov/popclock/.

care for these women will be between $388,944 and $1,471,680 per year.[14]

The Commonwealth will be responsible for a significant share of these costs. The Departments acknowledge that many women who lose coverage as a result of the IFRs will receive "free or subsidized care" through state programs. *See* Religious IFR 42–43. In Massachusetts, women who lose coverage may be eligible for and receive[15] State-funded care (1) by utilizing the "wrap around" insurance coverage for contraceptive care guaranteed by MassHealth; (2) by receiving contraceptive care and services from a DPH-funded clinic or provider; or, (3) if they are students at State universities, by accessing contraceptive care at student health clinics. *See supra*, at 12–13; Cooke Decl. ¶ 8; Boyle Decl. ¶ 6; Pomales Decl. ¶ 10. Approximately one in four Massachusetts women with employer-sponsored insurance would qualify for these programs if they lost coverage as a result of the IFRs. *See* Frost Decl. ¶¶ 6–8. The Commonwealth will bear the costs of providing these services as long as each woman who loses coverage continues to use contraception and remains eligible for State-funded care.

In addition, some women who lose coverage for contraceptive care because of the IFRs will be deterred from using contraception, or will no longer be able to afford the most effective forms of contraception.[16] These women will be at an increased risk for unintended pregnancies,[17]

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[14] These figures likely underestimate the true cost for women in Massachusetts. They are based on the Departments' estimate of the average cost of coverage nationwide: $584 per year. Health care costs in Massachusetts are significantly higher than the national average. *See* Kaiser Family Found., *Health Care Expenditures per Capita by State of Residence* (2014), available at https://goo.gl/JR3Z1i.

[15] The Commonwealth's experience shows that residents turn to State-funded sources to fill gaps in their employer-sponsored insurance. MassHealth already provides secondary coverage for more than 150,000 residents who have commercial insurance. *See* Boyle Decl. ¶ 4.

[16] Cost plays an important role in women's access to contraception. For example, women with private insurance were significantly more likely to use an intrauterine device when their out-of-pocket expenses were $50 or less. A. Gariepy et al., *The Impact of Out-of-Pocket Expense on IUD Utilization Among Women with Private Insurance*, 84 CONTRACEPTION e39, e40 (2011) (Salera Decl. Ex. N).

[17] Cost-free access to the most effective forms of contraception decreases the risk of unintended pregnancy. *See, e.g.*, Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120 OBSTETRICS & GYNECOLOGY 1291 (2012) (Salera Decl. Ex. O).

which in turn will put their babies at higher risk of costly medical complications. The Commonwealth will shoulder many of these medical costs; indeed, in 2010 alone, Massachusetts spent $138.3 million on unintended pregnancies.[18]

STANDARD OF REVIEW

In a case, such as this, challenging federal regulatory action under the Administrative Procedure Act, "a motion for summary judgment is simply a vehicle to tee up a case for judicial review." *Boston Redevelopment Auth. v. Nat'l Park Serv.*, 838 F.3d 42, 47 (1st Cir. 2016). The Court does not "determine whether a dispute of fact remains," *id.*, but rather asks whether the challenged regulatory action is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "contrary to [a] constitutional right," or "in excess of statutory . . . authority," or "without observance of procedure required by law." 5 U.S.C. §§ 706(2)(A), (B), (C), (D). *See Sig Sauer, Inc. v. Brandon*, 826 F.3d 598, 601 (1st Cir. 2016).

ARGUMENT

The Departments' IFRs—empowering virtually any employer, university, or health insurer to drop coverage for contraceptive services for women—are manifestly unlawful. First, the IFRs deprived the public of its right to notice and a meaningful opportunity to comment, in violation of the procedural safeguards of the Administrative Procedure Act. Second, the Departments do not have the authority to exempt regulated entities from the Affordable Care Act's preventative services requirement. The Departments' effort to create ten new exemptions from that requirement is inconsistent with the ACA's command that employer-sponsored group health plans provide women with coverage for preventative care services, including contraception. Third, by promoting

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[18] *See* A. Sonfield A & K. Kost, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, Guttmacher Institute, at 13 (2015) (Salera Decl. Ex. P).

the religious beliefs of employers at the expense of the rights of employees and their dependents, the Religious IFR endorses religion, in violation of the Establishment Clause. Finally, by authorizing employers to deny critical health insurance coverage for women alone, the IFRs discriminate against women in violation of the Fifth Amendment's equal protection guarantee.

I. The IFRs Violate the APA Because the Departments Did Not Have Good Cause or Statutory Authorization to Forgo Notice and Comment Rulemaking.

The IFRs must be set aside because they were not promulgated in compliance with the APA's rulemaking procedures. The APA requires federal agencies to follow a three-step procedure before promulgating a rule. *See Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 752 (D.C. Cir. 2001). The agency must first publish a "[g]eneral notice of proposed rule making," then "give interested persons an opportunity to participate in the rulemaking," and finally provide "a concise and general statement of [the rule's] basis and purpose" upon announcing the final rule. 5 U.S.C. § 553(b), (c). These procedures "are designed (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005).

The APA recognizes an exception to notice and comment rulemaking, known as the "good cause" exception, when notice and comment would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). That exception "excuses notice and comment in emergency situations, or where delay could result in serious harm." *Jifry v. Fed. Aviation Admin.*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (internal citation omitted). The exception is therefore "narrowly construed and only reluctantly countenanced." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012); *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992).

Rather than comply with the notice and comment procedures required by the APA, the Departments issued interim final rules that became effective upon their release. Religious IFR 2; Moral IFR 2. The Departments offered two justifications for their failure to provide notice and accept comments. First, they contended that three substantially identical provisions of the Internal Revenue Code, ERISA, and the Public Health Service Act ("PHSA") authorize them to promulgate the rules as interim final regulations. Religious IFR 79–80; Moral IFR 66. Second, they invoked the good cause exception to the APA's rulemaking requirements. *Id.*

Neither justification excuses the Departments' noncompliance with the APA. With respect to the first, in order for a statute to supersede the notice and comment procedures in § 553, it must do so expressly. *See* 5 U.S.C. § 559 (a "[s]ubsequent statute may not be held to supersede or modify [§ 553] . . . except to the extent that it does so expressly"); *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors*, 745 F.2d 677, 686 (D.C. Cir. 1984) ("[T]he import of the § 559 instruction is that Congress's intent to make a substantive change [should] be clear."). The statutory provisions cited by the Departments are generic grants of rulemaking authority, under which the Secretaries "may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part" and "may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part." 29 U.S.C. § 1191c; 26 U.S.C. § 9833 (replacing "part" with "chapter"); 42 U.S.C. § 300gg-92 (replacing "part" with "subchapter"). While these delegations authorize the Departments to promulgate interim final rules where "appropriate," they do not expressly authorize them to disregard notice and comment rulemaking procedures whenever they choose. *See Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 18–19 (D.D.C. 2010). Courts have therefore construed the statutes to authorize the Departments to depart from notice and comment procedures only where they have separately established "good cause" to forgo notice

and comment. *See id.*; *see also Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 444 (W.D. Pa. 2013) (the "kind of permissive language [in the Internal Revenue Code, ERISA, and Public Health Service Act provisions] is not sufficient, on its own, to supersede the notice and comment requirements").

Because the generic delegations of rulemaking authority do not by themselves justify the Departments' promulgation of interim final rules, this Court must determine whether the good cause exception to the APA applies. 5 U.S.C. § 553(b)(B). The Departments rely only on the "public interest" and "impracticable" prongs of the test. Religious IFR 80; Moral IFR 66. With respect to the public interest prong, "any time one can expect real interest from the public in the content of the proposed regulation, notice-and-comment rulemaking will not be contrary to the public interest." *Levesque v. Block*, 723 F.2d 175, 185 (1st Cir. 1983). The D.C. Circuit has also explained that the public interest prong is "appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal—if, for example, 'announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent.'" *Mack Trucks*, 682 F.3d at 95 (quoting *Util. Solid Waste Activities Grp.*, 236 F.3d at 755). The Departments do not claim, nor could they claim, that it is necessary to dispense with notice and comment procedures "in order to prevent the [IFRs] from being evaded." *Util. Solid Waste Activities Grp.*, 236 F.3d at 755. Nor could they possibly claim that the rule will generate no real interest from the public, *see Levesque*, 723 F.2d at 185; instead, they note the "more than 100,000 public comments" submitted on prior iterations of the rule. Religious IFR 83, Moral IFR 69. There is therefore no basis to conclude that proper notice and comment procedures would be contrary to the public interest.

The second prong—the impracticability ground—may only be invoked when "the due and

required execution of the agency functions would be unavoidably prevented by its undertaking public rulemaking proceedings." *Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980). Put otherwise, it applies when "the agency [can]not both follow section 553 and execute its statutory duties." *Levesque*, 723 F.2d at 184. An agency action may be sustained on that ground if, "for example, air travel security agencies would be unable to address threats posing a possible imminent hazard to aircraft, persons, and property within the United States[;] . . . or if a safety investigation shows that a new safety rule must be put in place immediately[;] . . . or if a rule was of life saving importance to mine workers in the event of a mine explosion." *Mack Trucks*, 682 F.3d at 93 (internal quotation marks and citations omitted).

The Departments have no basis to claim that the execution of their agencies' functions "would be unavoidably prevented" if they promulgated the IFRs with notice and comment procedures. *Kollett*, 619 F.2d at 145. Indeed, they do not even attempt to meet that standard: They contend only that notice and comment would be impracticable because there were pending lawsuits brought by entities challenging the Accommodation, and that in 2016, the Supreme Court remanded the *Zubik* cases with instructions to work towards a mutually agreeable accommodation. Religious IFR 80; Moral IFR 67. But nothing about that ongoing litigation and consultation with *Zubik* stakeholders would have prevented the agencies from complying with the APA. If ongoing litigation were a sufficient justification for dispensing with notice and comment rulemaking, the good cause exception would swallow the rule. Moreover, the federal Government's own conduct belies the Departments' claim that the need for relief is so "urgent" that they cannot comply with the APA. Moral IFR 67; *see* Religious IFR 82. As the Departments admit, they submitted a draft of the IFRs to the Office of Information and Regulatory Affairs ("OIRA") for review before June

1, 2017. *See* Religious IFR 81.[19] The draft of the IFRs remained with OIRA for more than four months before the rules were issued on October 6, 2017—far longer than OIRA's typical turnaround of 12 days for interim final rules issued by HHS.[20] OIRA's lengthy delay further demonstrates that there is no emergency justifying the issuance of interim final regulations.

The Departments rely on *Priests for Life v. HHS*, 772 F.3d 229, 276–77 (D.C. Cir. 2014), which upheld their promulgation of interim final regulations following the Supreme Court's remand in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014). Before *Wheaton College*, the Accommodation allowed religious nonprofits to notify their insurance issuer or third party administrator of their objection to the contraception mandate. *See* 79 Fed. Reg. at 51,094. *Wheaton College* allowed those nonprofits to alternatively notify HHS of their objection. *See* 134 S. Ct. at 2807. *Priests for Life* concluded that the interim final regulations implementing that alternative were "minor, meant only to 'augment current regulations in light of'" *Wheaton College*. *Priests for Life*, 772 F.3d at 276 (quoting 79 Fed. Reg. 51,092). Here, in contrast, no one could plausibly claim that the IFRs are minor or meant merely to augment current regulations. Instead, the IFRs create ten new exemptions for nearly any employer, university, or health insurance issuer with religious or moral objections to contraception. That represents an enormous expansion of the only preexisting exemption, the Church Exemption. *See supra* at, 5–6, 8–9.

In addition, in *Priests for Life*, "[t]he government reasonably interpreted the Supreme Court's order in *Wheaton College* as obligating it to take action to further alleviate any burden on the religious liberty of objecting religious organizations." *Priests for Life*, 772 F.3d at 276. In

[19] The actual date of submission to OIRA was May 23, 2017. *See* T. Jost, *Is There Justification For The Contraceptive Rule To Go Into Effect Immediately Upon Issuance?* HEALTH AFFAIRS BLOG (July 7, 2017), available at http://www.healthaffairs.org/do/10.1377/hblog20170707.060977/full/.

[20] *See id.*

contrast, the Court's order in *Zubik* had no such urgency: It merely "anticipate[d] that the Courts of Appeals w[ould] allow the parties sufficient time to resolve any outstanding issues between them." 136 S. Ct. at 1560. Nor did the status report deadlines from the Seventh Circuit referenced in the Religious IFR create an obligation to take immediate action. *See* Religious IFR 81. Those deadlines merely ordered the parties to report on their "respective positions" or proceed to oral argument; they did not order the Departments to provide any parties with immediate relief. *Id.*

Finally, the Departments seek to justify their issuance of interim final regulations by citing the "more than 100,000 public comments" on earlier versions of the regulations. Religious IFR 83; Moral IFR 68. There is no basis in the APA's good cause exception for disregarding notice and comment on a regulation because an agency has already accepted comments on prior versions of the regulation. But even if there were, the comments that the Departments previously received were particular to the regulatory actions taken at the time—most notably, the creation of an Accommodation for religious nonprofits and closely-held for-profit corporations. The IFRs represent a stark departure from that prior effort both to ensure that women retain seamless access to contraceptive coverage and to accommodate sincerely held religious beliefs. *See supra*, at 5–9.

For all of these reasons, the Departments' failure to comply with the APA's notice and comment procedures cannot be justified by generic grants of rulemaking authority or the APA's good cause exception. The IFRs must be declared unlawful and set aside. *See* 5 U.S.C. § 706(2)(D).

II. The Departments Have No Statutory Authority to Exempt Employers, Universities, and Insurers from the Affordable Care Act's Contraception Mandate.

The IFRs must also be declared unlawful and set aside because they are "in excess of [the Departments'] statutory . . . authority" and "not in accordance with law." 5 U.S.C. § 706(2)(A), (C). The Departments claim that the ACA gives them authority to categorically exempt employers, universities, and health insurance issuers from the ACA's preventative services requirement, as it

relates to contraception coverage. That is not a permissible construction of the statute. The ACA delegates HRSA authority to determine *what* preventative care services must be covered, but it does not authorize HRSA to determine *who* may opt out of providing those services. Absent authorization from Congress, the Departments do not have authority to exempt regulated entities from validly enacted statutes, like the ACA.

A. The Affordable Care Act Requires All Employer-Sponsored Group Health Plans to Provide Women with Coverage for Preventative Care Services, Including Contraception.

Section 2713(a)(4) of the PHSA, as added by the Women's Health Amendment of the ACA, provides that "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for . . . with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). In *Hobby Lobby*, the Supreme Court construed that provision to authorize HRSA to determine what preventative care services are covered. "Congress," the Court explained, "did not specify *what* types of preventative care must be covered. Instead, Congress authorized the [HRSA]. . . to make that important and sensitive decision. The HRSA in turn consulted the Institute of Medicine . . . in determining *which* preventative services to require." *Hobby Lobby*, 134 S. Ct. at 2762 (emphasis added and internal citations omitted). After HRSA has determined which preventative care services must be covered, the Court continued, the "ACA *requires* an employer's group health plan or group-health-insurance coverage to furnish [those] 'preventative care and screenings' for women without 'any cost sharing requirements.'" *Id.* (quoting 42 U.S.C. § 300gg-13(a)(4)) (emphasis added).

In the IFRs, the Departments depart from that construction of Section 2713(a)(4) and advance a much broader interpretation of HRSA's authority under the ACA. Not only does the statute delegate HRSA the authority to specify what types of preventative care services must be covered, they claim, but it also delegates them "broad discretion . . . to exempt entities from coverage requirements announced in HRSA's Guidelines." Religious IFR 9. That construction of Section 2713(a)(4) is flatly inconsistent with the text of the statute.

First, the statute instructs that group health plans "*shall* . . . provide coverage for and *shall not* impose any cost sharing requirements for" preventive care and screenings for women. 42 U.S.C. § 300gg-13(a)(4). "Shall" is a mandatory term that "normally creates an obligation impervious to judicial discretion" or administrative discretion. *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). By directing that group health plans "shall" provide coverage for preventative care services, Congress made clear that no group health plans would be exempt from that requirement, unless specified in the ACA or required by another federal statute. *See Sierra Club v. EPA*, 705 F.3d 458, 467 (D.C. Cir. 2013) (*Sierra Club I*) (agency lacks authority to exempt regulated entities from statute because "Congress's use of the word 'shall' in each sentence of the Act evidences a clear legislative mandate").

Second, the ACA itself included only one exemption from the requirement that employer-sponsored group health plans cover preventative care for women. Specifically, it exempted employers providing "grandfathered health plans." 42 U.S.C. § 18011(e). The fact that Congress included one specific exemption from the coverage mandate indicates that Congress did not intend to give HRSA authority to devise additional exemptions. *See Sierra Club I*, 705 F.3d at 467 ("That Congress provided only one exception to this monitoring requirement . . . suggests that Congress did not intend any other exceptions."); *Sierra Club v. EPA*, 294 F.3d 155, 160 (D.C. Cir. 2002)

(*Sierra Club II*) ("We cannot but infer from the presence of these specific exemptions that the absence of any other exemption . . . was deliberate, and that the Agency's attempt to grant such a dispensation is contrary to the intent of the Congress.").

Third, the ACA states that HRSA guidelines should identify, "with respect to women, such *additional* preventive care and screenings not described in paragraph (1)" that must be covered. 42 U.S.C. § 300gg-13(a)(4) (emphasis added). In specifying that HRSA may identify "additional" forms of preventative care for women, the ACA makes clear that HRSA's charge is to identify other *types* of preventative care services, aside from those services covered by Paragraph 1,[21] that must be covered. It does not suggest that HRSA may also exempt employer-sponsored group health plans from the obligation to provide coverage for those services.

Fourth, Congress' selection of HRSA as the agency responsible for promulgating the Guidelines aligns with the agency's narrow charge. HRSA, an agency within HHS, has expertise in the provision of medical care. It is the "primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable," and has programs to "help those in need of high quality primary health care, people living with HIV/AIDS, pregnant women and mothers."[22] Consistent with that expertise, HRSA houses the Office of Women's Health, an office created by the ACA. *See* 42 U.S.C. § 914. HRSA does not, however, have expertise in determining whether employers with objections to contraception should be entitled to withhold contraception coverage from their employees.

Fifth, the ACA instructs HRSA to develop its preventative care guidelines "for purposes

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[21] Paragraph 1 requires coverage for "evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force." 42 U.S.C. § 300gg-13(a)(1).

[22] HRSA, *About the HRSA*, https://www.hrsa.gov/about/index.html.

of this paragraph." 42 U.S.C. § 300gg-13(a)(4). That textual command makes plain that, in developing the Guidelines, HRSA must honor the purposes of the Women's Health Amendment. As the statutory text makes clear, the purpose of the Amendment was to ensure that *all* health plans cover cost-free preventative care services for women. *See id.*; 155 Cong. Rec. S12025 (Dec. 1, 2009) (Sen. Boxer) (purpose of the Amendment was to "require that *all* health plans cover comprehensive women's preventative care and screenings—and cover these recommended services at little or no cost to women" (emphasis added)). Proponents of the Amendment did not intend to limit women's access to preventative care based on the identity of their employers. *See* 155 Cong. Rec. S11987 (Nov. 30, 2009) (Sen. Mikulski) ("[M]y amendment . . . *guarantees* women access to lifesaving preventative services and screenings." (emphasis added)). And while the Amendment delegated HRSA authority to develop the Guidelines, Congress expected that contraception and family planning counseling would be included. Senator Mikulski, the sponsor of the Amendment, stated that it "provides family planning." 155 Cong. Rec. S12028 (Dec. 1, 2009). Many other Senators echoed this understanding.[23]

Another purpose of the Women's Health Amendment was to ensure that all women have

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[23] *See, e.g.*, 155 Cong. Rec. S12025 (Dec. 1, 2009) (Sen. Boxer) (preventative care "include[s] . . . family planning services"); *id.* at S12027 (Sen. Shaheen) ("Women must have access to vitally important preventative services such as . . . preconception counseling that promotes healthier pregnancies and optimal birth outcomes."); *id.* (Sen. Gillibrand) (under the Amendment, "even more preventative screenings will be covered, including . . . family planning"); 155 Cong. Rec. S12114 (Dec. 2, 2009) (Sen. Feinstein) ("The amendment . . . will require insurance plans to cover at no cost basic preventive services" including "family planning."); 155 Cong. Rec. S12271 (Dec. 3, 2009) (Sen. Franken) ("Under [the] amendment, the [HRSA] will be able to include other important services at no cost, such as . . . family planning."); *id.* at 12274 (Sen. Murray) (the "amendment will make sure this bill provides coverage for important preventive services for women at no cost," including "family planning services"); *id.* at 12277 (Sen. Nelson) ("I strongly support the underlying goal of furthering preventive care for women, including . . . family planning."); 155 Cong. Rec. S12671 (Dec. 8, 2009) (Sen. Durbin) (under the ACA "millions more women will have access to affordable birth control and other contraceptive services"); *id.* (the Amendment "provide[s] for more preventative services for women across the board," which "would result in more counseling, more contraception, and fewer unintended pregnancies").

access to the same package of preventative care benefits enjoyed by members of Congress. Senator Mikulski explained that the HRSA Guidelines "will be based on the benefit package available to Federal employees." 155 Cong. Rec. S12026 (Dec. 1, 2009). "What is good enough for a United States Senator," she affirmed, "should be good enough for any woman in the United States of America." *Id.*; *see also* 155 Cong. Rec. S12114 (Dec. 2, 2009) (Sen. Feinstein) ("[W]e believe all women—all women—should have access to the same affordable preventive health care services as women who serve in Congress."). At the time, contraception was among the preventative care benefits covered in the health plan for federal employees, including members of Congress. *See* IOM Report 108.

Finally, subsequent legislative efforts confirm that Congress did not authorize HRSA to exempt employers from the contraception mandate. In 2012, the Senate considered and rejected a bid to add to the ACA a "conscience amendment," which would have authorized employers and insurers to deny coverage for preventative care services based on their "religious beliefs or moral convictions." 158 Cong. Rec. S539 (Feb. 9, 2012) (S. Amdt. 1520, Section (b)(1)). The proposed amendment stated that "[w]hile PPACA provides an exemption for some religious groups that object to participation in Government health programs generally, it does not allow purchasers, plan sponsors, and other stakeholders with religious or moral objections to specific items or services to decline providing or obtaining coverage of such items or services." *Id.* (S. Amdt. 1520, § (a)(1)(E)). Senator Blunt, the amendment's sponsor, confirmed that it would change the ACA by "allow[ing] religious belief or moral conviction to be an important factor in whether people comply with new health care mandates," including the contraception mandate. 158 Cong. Rec. S1115 (Feb. 29, 2012). "Supplying respect for religious beliefs and moral convictions is already part of Federal health programs of all kinds[;] it just does not happen to be in the [ACA]," he

explained. 158 Cong. Rec. S1166 (March 1, 2012) (Sen. Blunt). In voting down Senator Blunt's proposed conscience amendment, Congress reaffirmed its decision *not* to include in the ACA a provision authorizing exemptions from the contraception mandate.

B. The Departments' Justifications for Creating Ten New Exemptions from the Contraception Mandate Are Meritless.

All of these factors demonstrate that while Section 2713(a)(4) delegates HRSA authority to determine what preventative care services must be covered by group health plans, it does not give HRSA discretion to create new exemptions from the ACA's coverage mandate. In claiming otherwise, the Departments do not point to any textual provision in the ACA that authorizes HRSA to exempt employers from the mandate. They do not claim, and could not claim, that Section 2713(a)(4) is ambiguous and that their construction of the statute is therefore entitled to deference under *Chevron, USA, Inc. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837 (1984). And, having failed to justify their claim of authority with these arguments, the Departments are foreclosed from making them in this Court. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (a court "'may not supply a reasoned basis for the agency's action that the agency itself has not given'" (quoting *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983))).

Instead, the Departments say that they consider it appropriate to issue the IFRs because Congress did not "prohibi[t] them from providing conscience protections." Moral IFR 25. But courts "'will not presume a delegation of power based solely on the fact that there is not an express withholding of such power.'" *Michigan v. EPA*, 268 F.3d 1075, 1082 (D.C. Cir. 2001) (quoting *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995)). Indeed, courts have stressed that the Departments' position—that they can create ten new exemptions from the contraception mandate because Section 2713(a)(4) "does not expressly *negate*" that authority—"is both flatly

unfaithful to the principles of administrative law . . . and refuted by precedent." *Am. Petroleum Inst.*, 52 F.3d at 1120 (citing *Ry. Labor Executives' Ass'n v. Nat'l Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (en banc)); *see also Am. Library Ass'n v. FCC*, 406 F.3d 689, 708 (D.C. Cir. 2005) ("The [agency's] position in this case amounts to the bare suggestion that it possesses *plenary* authority to act within a given area simply because Congress has endowed it with *some* authority to act in that area. We categorically reject that suggestion."); *Michigan*, 268 F.3d at 1082 ("Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony.").

The Departments next point out that "many Federal healthcare laws and regulations provide exemptions for objections based on religious beliefs" and moral convictions. Religious IFR 63; *see also* Moral IFR 5–6 & n. 1, 27–28, 52–53. But that only underscores that Section 2713(a)(4) does *not* provide such exemptions, and that Congress deliberately rejected an effort to create such exemptions when it voted down a proposed conscience amendment for the preventative services requirement. *See supra*, at 26–27.

The Departments claim that because they have "repeatedly exercised their discretion to create and modify various exemptions within the Guidelines," they must have authority to do so. Religious IFR 63; *see also* Moral IFR 9–10, 25. Not so. Before these IFRs, the Departments only exempted houses of worship from the coverage mandate via the Church Exemption. *See supra*, at 5–6. The only basis for that exemption is RFRA, not the ACA itself. *See infra*, at 30 n. 24. In any event, there is no adverse possession in administrative law; past assertions of agency authority cannot give rise to authority not otherwise delegated by Congress in a statute.

Finally, the Departments contend that the contraception mandate "imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that

have [religious and] moral convictions opposed to providing contraception coverage." Moral IFR 40. That argument runs up against the settled rule that "'there exists no general administrative power to create exemptions to statutory requirements based upon the agency's perception of costs and benefits.'" *Public Citizen v. FTC*, 869 F.2d 1541, 1556–57 (D.C. Cir. 1989) (internal quotation marks omitted) (rejecting FTC's attempt to exempt products made by tobacco producers from statutory labeling requirement); *see also Waterkeeper Alliance v. EPA*, 853 F.3d 527, 534–37 (D.C. Cir. 2017) (rejecting EPA's attempt to exempt farms from statutory requirement to notify authorities when pollutants are emitted); *Sierra Club I*, 705 F.3d at 467–69 (rejecting EPA's attempt to exempt operators of pollution-emitting facilities from their statutory obligation to conduct an air quality analysis). The IFRs are contrary to the ACA's command that employer-sponsored group health plans provide all women coverage for preventative care services.

C. The IFRs Cannot Be Justified by the Religious Freedom Restoration Act.

The ACA's requirement that employer-sponsored group health plans provide coverage for preventative care services can be limited only to the extent it is inconsistent with the Constitution or with another federal statute. In general, when two federal statutes conflict, a court must "analy[ze] both, to see if they are indeed incompatible or if they can be harmonized, and if they are incompatible to decide which one Congress meant to take precedence." *Boston & Maine Corp. v. Mass. Bay Transp. Auth.*, 587 F.3d 89, 98 n. 1 (1st Cir. 2009) (internal quotation marks omitted). Here, another federal statute, RFRA, applies to the ACA and takes precedence to the extent the two statutes conflict. *See* 42 U.S.C. §§ 2000bb-3(a), (b).

RFRA prohibits the "Government [from] substantially burden[ing] a person's exercise of religion even if the burden results from a rule of general applicability," unless the Government "demonstrates that application of the burden to the person—(1) is in furtherance of a compelling

government interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. §§ 2000bb-1(a), (b). Thus, under RFRA, the government cannot, through Section 2713(a)(4) or implementing regulations, substantially burden a person's exercise of religion except in furtherance of a compelling government interest and through the least restrictive means of achieving that interest. RFRA does not, however, give the Departments unfettered discretion to grant exemptions from the ACA's coverage mandate in the name of religion. Because agencies and courts must harmonize federal statutes in order to honor Congress's intent, see *Boston & Maine Corp.*, 587 F.3d at 98 n. 1, the ACA's coverage mandate can only be limited to the extent required by RFRA's accommodation of religious exercise. *See Hobby Lobby*, 134 S. Ct. at 2786–87 (Kennedy, J., concurring) (exercise of religion cannot "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling").

To harmonize RFRA and the ACA's mandate to cover all preventative care services, including contraception, the Departments have previously taken several regulatory actions. First, through the Church Exemption, they determined that houses of worship must be exempted from the contraception mandate. *See supra*, at 5–6.[24] Second, they created the Accommodation, which relieves objecting nonprofit organizations and closely held for-profit corporations of their obligation to provide contraception coverage, while still ensuring that employees of those

[24] Here and throughout, the Commonwealth does not challenge the validity of the Church Exemption, which is consistent with RFRA, the principle of non-interference enshrined in the First Amendment, and similar exemptions provided in Massachusetts' Contraceptive Equity Law and ACCESS Act. *See* G.L. c. 175, § 47W(c) (providing an exemption if the employer is a "church or qualified church-controlled organization"). Churches are simply different than other employers. *See* 80 Fed. Reg. at 41,325; *Hosanna-Tabor Evangelical Lutheran Church & Sch. v. EEOC*, 565 U.S. 171, 189 (2012) (the First Amendment provides "special solicitude" to the rights of churches); *Real Alternatives, Inc. v. Sec'y of HHS*, 867 F.3d 338, 350–53 (3d Cir. 2017) (noting that churches and non-religious employers are different, and that "respecting church autonomy" is protected both by federal law and the First Amendment). As the Departments have explained, the Exemption was created to respect the "particular sphere of autonomy" that protects churches from government interference. 80 Fed. Reg. at 41,325.

organizations have seamless coverage for contraception. *See supra*, at 6–7. In *Hobby Lobby*, the Supreme Court approved of the Accommodation, calling it "an alternative that achieves all of the Government's aims while providing greater respect for religious liberty." 134 S. Ct. at 2759; *see id.* at 2786 (Kennedy, J., concurring) (the "[A]ccommodation equally furthers the Government's interest but does not impinge on the plaintiffs' religious beliefs"). The Court also stressed that under the Accommodation, employees of objecting employers "would continue to receive contraceptive coverage without cost sharing for all FDA-approved contraceptives." *Id.* at 2782; *see also id.* at 2760 ("The effect of the HHS-created [A]ccommodation on the women employed by Hobby Lobby and the other companies involved in these cases would be precisely zero.").

After *Hobby Lobby*, eight Courts of Appeals concluded that the Accommodation is consistent with RFRA.[25] These courts did not question the sincerity of religious employers' beliefs that they may not provide, pay for, or facilitate access to contraception and related counseling. *See, e.g.*, *Priests for Life*, 772 F.3d at 246–47. But, the courts explained, the Accommodation does not require them to take any of those actions. *See, e.g.*, *id.* at 246–47, 249. Instead, it simply requires an objecting employer to "send a single sheet of paper honestly communicating its eligibility and sincere religious objection in order to be excused from the contraceptive coverage requirement." *Id.* at 249; *see also Notre Dame I*, 743 F.3d at 554. Once an employer has mailed in the form, "all action taken to pay for or provide its employees with contraceptive services is taken by a third party." *Priests for Life*, 772 F.3d at 249. These courts also rejected the argument that signing the form makes an employer complicit in the provision of contraceptive coverage to women by third parties, and therefore qualifies as a substantial burden. As Judge Posner explained for the Seventh Circuit, it is "[f]ederal law, not the religious organization's signing and mailing the form, [that]

[25] *See supra*, at 7–8 n. 8. The First Circuit has not addressed the issue.

requires health-care insurers, along with third party administrators of self-insured plans, to cover contraceptive services." *Notre Dame I*, 743 F.3d at 554; *see also Priests for Life*, 772 F.3d at 252. The Accommodation, these courts therefore concluded, does not impose a substantial burden under RFRA. *See supra*, at 7–8 n. 8.[26]

The Departments acknowledge that "a majority of Federal appeals courts have held that the [A]ccommodation does not impose a substantial burden on . . . religious nonprofit entities." Religious IFR 31. Indeed, for years, the Departments themselves explained in litigation why the Accommodation does not impose a substantial burden under RFRA. *See, e.g.*, Br. of Respondents at 32–53, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14–1418). In the IFRs, the Departments retreat from that position, concluding, without explanation, that they now believe the Accommodation does impose a substantial burden on religious exercise. Religious IFR 31–33. But they have not justified that reversal with any reasoned analysis; their discussion of substantial burden barely fills a page. *See id.* Moreover, they have not adequately accounted for the burdens that will be imposed on all the women who will lose contraceptive coverage under the IFRs, contrary to *Hobby Lobby*. *See* 134 S. Ct. at 2781 n. 37 (an agency seeking to create a RFRA accommodation "must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries'" (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005))).[27]

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[26] Even if the Accommodation did impose a substantial burden on employers' exercise of religion, it advances compelling government interests using the least restrictive means. As the D.C. Circuit explained, it advances two compelling government interests: improving public health by promoting seamless access to affordable healthcare appropriate to women's needs, and promoting women's social and economic equality. *Priests for Life*, 772 F.3d at 259–64. The mechanism it uses—authorizing employers to provide notice that they wish to opt out, while requiring third parties to cover contraceptive costs for women—is the least restrictive means of achieving those objectives. *See id.* at 264–67.

[27] The Departments have previously explained that an exemption broader than the Church Exemption "would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives." 77 Fed. Reg. at 8728. That, in turn, would undermine the benefits of contraception coverage—namely, lower rates of unintended pregnancies, fewer babies born

Because the Accommodation does not impose a substantial burden on employers' exercise of religion, it is consistent with RFRA. *See Priests for Life*, 772 F.3d at 244 ("if the law's requirements do not amount to a substantial burden under RFRA, that is the end of the matter"). Thus, the Departments have no authority to violate the ACA's coverage mandate by going beyond what RFRA demands and adopting any of the ten exemptions in the IFRs.

In addition, the four new exemptions contained in the Moral IFR are unlawful for a second and independent reason. By its plain terms, RFRA applies only to the "exercise of religion," and therefore does not provide protection for nonreligious, moral objections to contraceptive coverage. 42 U.S.C. §§ 2000bb-1(b), 2000cc-5(7)(A) (defining "exercise of religion"). Indeed, the Supreme Court explained in *Hobby Lobby* that an exemption for moral objectors "extend[s] more broadly than the pre-existing protections of RFRA." 134 S. Ct. at 2775 n. 30. Thus, the Departments did not have authority to create the four new exemptions in the Moral IFR, and those exemptions, which have nothing to do with religion, cannot be justified by RFRA.[28]

III. <u>The Religious IFR Has the Purpose and Effect of Endorsing Religion, In Violation of the Establishment Clause.</u>

Compounding these legal infirmities, the IFRs also violate the Constitution. By nullifying the statutory rights of thousands of women in order to advance the religious interests of employers,

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prematurely, higher birth weights for babies, cost savings to employers, and improved social and economic status for women. *Id.* at 8727–28.

[28] Not only are the IFRs not required by RFRA, but they also run afoul of Title VII, as amended by the Pregnancy Discrimination Act, which makes clear that discrimination "on the basis of pregnancy, childbirth, or related medical conditions" is unlawful discrimination on the basis of sex. *See* 42 U.S.C. §§ 2000e-2(a), 2000e(k); Equal Employment Opportunity Comm'n, Decision (Dec. 14, 2010), https://www.eeoc.gov/policy/docs/decision-contraception.html ("failing to offer insurance coverage for the cost of prescription contraceptive drugs and devices" for women constitutes unlawful discrimination under Title VII). In addition, the IFRs violate the non-discrimination provision of the ACA, which prohibits discrimination on the basis of sex in certain health programs. *See* 42 U.S.C. § 18116. For these additional reasons, the Departments failed in their obligation to "harmoniz[e]" the ACA with other federal statutes. *See Boston & Maine Corp.*, 587 F.3d at 98 n. 1.

the new exemptions created by the Religious IFR, in particular, violate the Establishment Clause.[29] Through the new exemptions, the Departments have restructured Section 2713(a)(4) of the ACA, as enacted by Congress, "to conform with a particular religious viewpoint." *Edwards v. Aguillard*, 482 U.S. 578, 593 (1987). In so doing, they have crossed the tipping point at which permissible religious exemptions become an unconstitutional endorsement of religion. *See Bd. of Educ. of Kiryas Joel Village Sch. Dist. v. Grumet*, 512 U.S. 687, 725 (1994) (Kennedy, J., concurring in the judgment); *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 708–10 (1985).

The Establishment Clause places "fundamental limitations" on the Departments' authority to create religious exemptions that are not required by the Free Exercise Clause. *Lee v. Weisman*, 505 U.S. 577, 586–87 (1992). The new exemptions for employers clearly fall into this category: the Free Exercise Clause does not require the provision of such exemptions to neutral, generally applicable statutes, like the ACA. *See Employment Div. v. Smith*, 494 U.S. 872, 878 (1990). The Departments do not claim otherwise. Furthermore, the limits imposed by the Establishment Clause apply regardless of whether the Religious IFR is "required" by RFRA.[30] Religious exemptions created pursuant to statutes like RFRA are subject to full Establishment Clause scrutiny. *See Hobby Lobby*, 134 S. Ct. at 2781 n. 37; *Cutter*, 544 U.S at 721–22 (the Establishment Clause limits accommodations under RFRA's sister statute, the Religious Land Use and Institutionalized Persons Act).

The new exemptions violate the Establishment Clause because they have the primary purpose and effect of advancing the religious interests of employers over the interests and autonomy of employees and their dependents. The exemptions therefore fail both the *Lemon* test

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[29] This Establishment Clause claim only challenges exemptions (1) through (5) in the Religious IFR. *See supra*, at 9.

[30] As discussed, the exemptions in the Religious IFR are not required by RFRA. *See supra*, at 29–33.

and the related "endorsement analysis," which are used to enforce the limits on religious exemptions imposed by the Establishment Clause. *See ACLU of Mass. v. Sebelius*, 821 F. Supp. 2d 474, 483–84 (D. Mass. 2012), *rev'd on other grounds*, 705 F.3d 44. As relevant here, under the *Lemon* Test, a religious exemption is valid only if (1) it was put in place for a legitimate "secular . . . purpose"; and (2) it does not have the "principal or primary effect" of advancing religion.[31] *Id.* (quoting *Lemon v. Kurtzman*, 403 U.S. 602, 612–13 (1971)). The endorsement analysis prohibits any exemption that "has the purpose or effect of endorsing, favoring, or promoting religion." *Freedom from Religion Fund v. Hanover Sch. Dist.*, 626 F.3d 1, 10 (1st Cir. 2010).

By using their rulemaking authority to empower employers with religious objections to contraception to deny employees access to statutorily mandated contraceptive coverage, the Departments have endorsed those religious objections. *See Estate of Thornton*, 472 U.S. at 710 ("The First Amendment . . . gives no one the right to insist that in pursuit of their own interests others must conform their conduct to his own religious necessities." (internal quotation marks omitted)); *ACLU of Mass.*, 821 F. Supp. 2d at 484–85 (permitting the Conference of Catholic Bishops to impose a "religiously motivated restriction" on abortion and contraceptive services under a government grant program violated the Establishment Clause); *see also Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 343 (1987) (Brennan, J., concurring in the judgment) (creating exemptions for for-profit businesses risks "furthering religion in violation of the Establishment Clause"). The new exemptions created by the Departments are particularly problematic given the continued existence of the Accommodation, which the Religious IFR leaves in place. As discussed, the Accommodation

[31] The *Lemon* test also bars exemptions that "foster an excessive government entanglement with religion." 403 U.S. at 613 (internal quotation marks omitted).

relieves objecting employers of their obligation to comply with the ACA's contraceptive mandate and sets up a separate system (involving the government, insurers, and other third parties) to independently provide coverage to employees and their dependents. *See, e.g., Priests for Life*, 772 F.3d at 250–51. Through the Religious IFR, the Departments have granted employers a "religious veto" over access to coverage through this separate system. *Id.* at 251. In doing so, the Departments have not only denied women a vital statutory right, they have compelled employees (and insurers and the government) to conform their independent activities to the religious beliefs of employers. *See Hobby Lobby*, 134 S. Ct. at 2786–87 (Kennedy, J., concurring) (exercise of religion may not "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling"); *Bowen v. Roy*, 476 U.S. 693, 699–700 (1986) (the First Amendment does not empower citizens to "demand that the Government join in their chosen religious practices"); *Estate of Thornton*, 472 U.S. at 709 (laws that compel employers to "conform their business practices to the particular religious practices of the employee[s]" violate Establishment Clause).

The Departments' endorsement of religious objections to contraception comes at "the detriment of those who do not share [them]." *Estate of Thornton*, 472 U.S. at 711 (O'Connor, J., concurring). Religious exemptions that impose significant burdens on third parties in order to permit "others to act according to their religious beliefs" advance religion in violation of the Establishment Clause. *See Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 14–15, 18 n. 8 (1989); *see also Hobby Lobby*, 134 S. Ct. at 2760 ("[W]e certainly do not hold or suggest that RFRA demands accommodation of a for-profit corporation's religious beliefs no matter the impact that accommodation may have on . . . thousands of women." (internal quotation marks omitted)); *Kiryas Joel*, 512 U.S. at 722 (Kennedy, J., concurring in the judgment) ("[A] religious accommodation demands careful scrutiny to ensure that it does not so burden nonadherents . . . as

to become an establishment.”).[32] The Departments acknowledge that the Religious IFR will deprive tens of thousands of women of contraceptive coverage and impose tens of millions of dollars in out-of-pocket costs annually. Religious IFR 108, 115. Although the Departments now stress that women may be able to acquire free or subsidized contraceptive care through various federal, state, and local programs, *see* Religious IFR 42–43, they have repeatedly acknowledged that these sources of care cannot substitute for the “seamless,” no-cost coverage guaranteed by the ACA. *See, e.g.*, 78 Fed. Reg. at 39,888 (the ACA “contemplates providing coverage of recommended preventive services through the existing employer-based system of health coverage so that women face minimal logistical and administrative obstacles”). The medical research underpinning the contraception mandate shows that even “minor obstacles”—like having to find, access, and pay for alternative sources of care, distinct from a woman’s regular doctor—significantly deters use of contraception. *Priests for Life*, 373 F.3d at 235. By re-imposing logistical, administrative, and financial obstacles through the new exemptions, the Departments will not only impose significant burdens on employees and their families, but will also “block many women from obtaining needed care at all.” *Hobby Lobby*, 134 S. Ct. at 2788 (Ginsburg, J., dissenting).

IV. <u>The IFRs Discriminate Against Women, In Violation of Equal Protection.</u>

Finally, the Religious and Moral IFRs violate the equal protection guarantee implicit in the Fifth Amendment to the Constitution. *See Sessions v. Morales-Santana*, 137 S. Ct. 1678, 1686 n. 1 (2017) (equal protection claims under the Fifth and Fourteenth Amendments treated identically). The Departments’ narrow focus on weakening provisions of the ACA related to women’s

[32] As discussed, see *supra*, at 34, this is not a case where the burden imposed by the new exemptions is necessary to “remove a demonstrated and possibly grave imposition on religious activity sheltered by the Free Exercise Clause.” *Texas Monthly*, 489 U.S. at 18 n. 8.

preventive care has resulted in regulations that impermissibly single out women for unfavorable treatment. By selectively empowering employers to use their religious and moral beliefs to limit access to women's contraception, the IFRs unconstitutionally interfere with the ability of women to "participate fully in the economic and social life of the Nation," and serve to "perpetuate the legal, social, and economic inferiority of women." *See United States v. Virginia*, 518 U.S. 515, 533–34 (1996) (the government may use gender-based classification to "compensate women for particular economic disabilities they have suffered" but not to "create or perpetuate the legal, social, and economic inferiority of women" (quotation marks omitted)); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992) (recognizing that access to contraceptive is necessary for women to fully and equally participate in public life); *see also Carey v. Population Servs., Int'l*, 431 U.S. 678, 685 (1977) (the constitutional right to privacy protects access to contraception).

Laws and regulations, like the IFRs, that distribute benefits or burdens unequally on the basis of gender are presumptively unconstitutional and subject to heightened scrutiny. *See Morales-Santana*, 137 S. Ct. at 1700–01 (subjecting a "gender-based distinction infecting [immigration law]" to heightened scrutiny); *Orr v. Orr*, 440 U.S. 268, 283 (1979) ("Legislative classifications which distribute benefits and burdens on the basis of gender . . . must be carefully tailored."). The IFRs insert gender-based exemptions into the preventive services requirement of the ACA. *See supra*, at 8–10. Although the IFRs ostensibly concern the preventive services requirement generally, *see* Religious IFR 8, they create exemptions only for "women's preventive care"—specifically the contraception mandate imposed pursuant to Section 2713(a)(4). Section 2713(a)(4) was inserted into the ACA to ensure that women receive full and equal access to medically necessary preventive care, including contraceptive care. *See supra*, at 2, 25. By creating an exemption specific to this requirement, the IFRs undermine a statutory benefit "necessary to

protect the health of female employees," while leaving coverage for male employees untouched. *See Hobby Lobby*, 134 S. Ct. at 2785–86 (Kennedy, J., concurring).

The IFRs do not provide the type of "exceedingly persuasive justification" necessary to survive heightened scrutiny. *See Morales-Santana*, 137 S. Ct. at 1690; *Virginia*, 518 U.S. at 531, 533 (the justification for a gender-based distinction must be "genuine, not hypothesized or invented *post hoc* in response to litigation"). Contrary to the Departments' claims, the IFRs are not supported by a general governmental interest in accommodating moral and religious objections to "sensitive" medical procedures and services. *See* Religious IFR 1, 30. Even assuming there were such an interest, it would be better served by a broad, gender-neutral exemption than by the gender-specific exemption for "women's preventive care" created by the IFRs. *See Orr*, 440 U.S. at 282–83 (a gender-based distinction is unconstitutional if the proffered state interest would be "as well served by a gender-neutral classification"). Contraceptive care is hardly the only "sensitive" procedure or service covered by the ACA. The preventive care requirement alone requires coverage for immunizations for children and adults, *see Robinson v. Children's Hospital Boston*, 2016 WL 1337255 (D. Mass. 2016) (Slip Op.) (religious objections to influenza vaccination); mental health screenings for children and adults, *see Haines v. New Hampshire Dept. of Health and Human Servs.*, 2009 WL 1307203 (D.N.H. 2009) (Slip Op.) (religious objections to mental health screening); newborn blood screening, *see* G.L. c. 111, § 110A (requiring religious exemptions for newborn blood screening requirements); and sexually transmitted infection prevention counseling and screening for children, *see* G.L. c. 71, § 32A (requiring parental notice and exemption for sex education classes). The list is not exhaustive; significant numbers of Americans have sincerely held religious and moral objections to most modern medical services and practices. *See Children's Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084,

1088 (8th Cir. 2000) (Christian Scientists and other religious groups object to all medical care and consider religion to be the "sole means of healing"). The IFRs, then, are fatally underinclusive. *See Orr*, 440 U.S. at 272, 282–83.

Moreover, Congress did not intend for women's access to necessary medical care to be dependent upon the religious or moral beliefs of their employers—and the Departments cannot substitute their judgment for that of Congress. *See Campbell v. U.S. Dept. of Ag.*, 515 F. Supp. 1239, 1249 (D.D.C. 1981) ("[J]ust as the Court cannot substitute its judgment for that of the . . . Departments . . . [the Departments] cannot substitute their judgment for that of Congress."). The Departments are correct that Congress has included moral and religious exemptions in many health care related laws. *See* Religious IFR 5 n. 1. But it declined to include such an exemption in the ACA. *See supra*, at 26–27. As discussed, the Departments' legitimate interest in accommodating moral and religious objections to the ACA is limited to what is required by the Free Exercise Clause and RFRA—requirements already met by the prior regulations. *See supra*, at 29–33.

Finally, the Departments' claim that the IFRs are necessary to end litigation over the contraception mandate is misguided. An agency's "desire to resolve pending litigation and prevent future litigation," Religious IFR 28, is not a sufficiently important interest to satisfy heightened scrutiny. *See Shaw v. Hunt*, 517 U.S. 899, 908 n. 4 (1996). In this case, the Departments' interest in avoiding litigation "rings hollow," given that the IFRs have predictably led to additional litigation. *See Cotter v. City of Boston*, 323 F.3d 160, 172 n. 10 (1st Cir. 2003).

CONCLUSION

For the foregoing reasons, this Court should grant this motion for summary judgment, declare that the Religious and Moral IFRs are unlawful, permanently enjoin implementation of both IFRs, and enter judgment in favor of the Commonwealth.

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS,

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CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be sent electronically to registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 17, 2017.

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