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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 November 15, 2018, 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 Final Rules 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.<sup>1</sup> The Rules are flatly inconsistent with the ACA’s requirement that employer-sponsored group health plans provide women with coverage for preventive 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 without 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 broad new exemptions from the ACA’s contraceptive mandate, the Rules jeopardize the health and well-being of women in Massachusetts and leave the State to assume additional costs related to contraception and services associated with unintended pregnancies. The Commonwealth seeks an order from this Court vacating the Rules and declaring them unlawful so that no individual or family in Massachusetts, or across the country, is harmed.

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<sup>1</sup> The Rules also apply to colleges, universities, and student health plans. *See* 83 Fed. Reg. 57536, 57593 (Nov. 15, 2018). For ease of reference, this brief will refer generally to “employers” and “employees” except where the distinction is relevant.

## **BACKGROUND**

### **I. The Affordable Care Act and Implementation of the Contraceptive 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 significant reforms, the ACA requires employer-sponsored 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.<sup>2</sup> This requirement recognizes that most Americans receive health care coverage through their employers,<sup>3</sup> and that preventive care is a fundamental part of “basic health care” that improves public health and lowers health care costs. *See* 78 Fed. Reg. 39872 (July 2, 2013).

Through a provision called the Women’s Health Amendment, the preventive services requirement mandates 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 [(“HRSA”)] for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a)(4). HRSA—an agency within HHS—issued these “Women’s Preventive Services Guidelines” in 2011. Among other services, the Guidelines require “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”

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<sup>2</sup> 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).

<sup>3</sup> *See* Kaiser Family Found., *Employer Health Benefits: 2018 Annual Survey* 61 (2018) (Administrative Record: Disk 12, Page 804791) (hereinafter “D12, 804791”).



(hereinafter “the contraceptive mandate”).<sup>4</sup>

HRSA based the Guidelines on recommendations from an expert panel from the Institute (“IOM”) (now known as the National Academy of Medicine).<sup>5</sup> Based on its comprehensive review of the medical research and evidence, the IOM found that access to contraception reduces unintended pregnancies, adverse pregnancy outcomes, and other negative health consequences for women and children, as well as the number of women seeking abortions.<sup>6</sup> Unintended pregnancy is prevalent in the United States, accounting for approximately half all pregnancies.<sup>7</sup> 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.<sup>8</sup> 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 breastfed.<sup>9</sup> The IOM also recognized that the effectiveness and appropriateness of different contraceptive methods vary depending on age, sexual practices, and health conditions.<sup>10</sup> And it determined that cost-sharing requirements were a significant barrier to access to contraception—particularly more effective, long-lasting methods

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<sup>4</sup> HRSA, *Women’s Preventive Services Guidelines*, <https://www.hrsa.gov/womens-guidelines/index.html>.

<sup>5</sup> See IOM, *Clinical Preventive Services for Women: Closing the Gaps 1-2* (2011) (“IOM Report”) (D1, 328-29)

<sup>6</sup> *Id.* at 105 (D1, 432).

<sup>7</sup> *Id.* at 102-03 (D1, 429-30).

<sup>8</sup> *Id.*

<sup>9</sup> *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 (D1, 434).

<sup>10</sup> *Id.* at 104-07 (D1, 431-34)

like intrauterine devices.<sup>11</sup> As a result, the IOM recommended that HRSA’s Guidelines include no-cost coverage for all FDA-approved “contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.”<sup>12</sup>

In 2016, HRSA subjected the Guidelines, including the contraceptive mandate, to a “scientifically rigorous review” led by the American College of Obstetricians and Gynecologists as part of the Women’s Preventive Services Initiative (“WPSI”) program.<sup>13</sup> The review accepted IOM’s findings and concluded that the “effectiveness of the full range of FDA-approved contraceptive methods for preventing or delaying pregnancy is well established.”<sup>14</sup> Based on this conclusion, HRSA included the contraceptive mandate in updated Guidelines issued the same year. The mandate remains in effect to date.

As a result of the contraceptive mandate, more than 45 million women now receive comprehensive, no-cost coverage for contraceptive care and services through an employer-sponsored plan. *See* 82 Fed. Reg. 47792, 47821 (Oct. 13, 2017). Out-of-pocket expenditures for contraception have fallen by more than 70%. *Id.* at 47805. And in Massachusetts, the contraceptive mandate has led to a significant decrease in the number of women without contraceptive coverage seeking care through state-funded programs, and to a significant increase in the number of women using more effective forms of contraception. *See* Childs-Roshak Decl. ¶¶ 13, 24, 25.

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<sup>11</sup> *Id.* at 108-09 (D1, 435-36).

<sup>12</sup> *Id.* at 109-10 (D1, 436-37).

<sup>13</sup> *See* U.S. Dep’t of Health and Human Servs., *HRSA Takes Next Step in Updating the Women’s Preventive Services Guidelines* (Dec. 2016), <https://www.hrsa.gov/about/news/press-releases/2016-12-20-womens-guidelines-updates.html>.

<sup>14</sup> WPSI, *Recommendations for Preventive Services for Women* 64 (2016) (D9, 2017 Religious IFR Supp. Docs., No. 39, 668965)

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

When Congress enacted the Women’s Health Amendment, it decided not to include a “conscience” provision that would have permitted employer-sponsored health plans to deny coverage based upon religious beliefs or moral convictions. *See* 158 Cong. Rec. S1116 (Feb. 29, 2012) (Sen. Johanns) (explaining that a conscience provision was removed from the ACA prior to passage); 158 Cong. Rec. S1115-S1116 (Feb. 29, 2012) (Sen. Blunt) (discussing an unsuccessful attempt to amend the ACA to insert a conscience provision in response to the contraceptive mandate). Recognizing that some Americans have religious objections to contraception, however, beginning in 2011 the Departments undertook a series of regulatory actions that sought to balance employees’ statutory right to coverage with employers’ religious objections, to the extent required by federal law, including the Religious Freedom Restoration Act (“RFRA”), 42 U.S.C. § 2000bb *et seq.* *See, e.g.,* 75 Fed. Reg. 41726 (July 19, 2010); 76 Fed. Reg. 46621 (Aug. 3, 2011); 77 Fed. Reg. 8725 (Feb. 15, 2012); 78 Fed. Reg. 39870 (July 2, 2013); 79 Fed. Reg. 51092 (Aug. 27, 2014); 80 Fed. Reg. 41318 (July 14, 2015).

First, the Departments issued regulations that exempted houses of worship and their integrated auxiliaries—a category of employers defined in the Internal Revenue Code<sup>15</sup>—from the contraceptive mandate (hereinafter “Church Exemption”). *See* 76 Fed. Reg. 46623; 77 Fed. Reg. 8729; 80 Fed. Reg. 41325. The Departments explained that the Church Exemption was necessary to respect the “special status” and “particular sphere of autonomy” afforded to houses of worship “under longstanding tradition in our society and under federal law.” 80 Fed. Reg. 41325. Second, the Departments created an alternative process, called the “Accommodation,” to deliver

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<sup>15</sup> *See* 26 U.S.C. § 6033(a)(3)(A)(i) and (iii).

contraceptive coverage to employees of nonprofit organizations, institutions of higher education, and closely held for-profit companies with religious objections to contraception.<sup>16</sup> See 78 Fed. Reg. 39870. The Departments declined to simply exempt these non-Church organizations because doing so was inconsistent with the ACA, was not required by RFRA, and would have improperly “subject[ed] . . . employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care.” 77 Fed. Reg. 8728. Under the Accommodation, a qualifying objecting employer can self-certify its objection to providing contraceptive coverage by submitting a two-page form to its health insurer or third-party administrator or by notifying HHS. See 78 Fed. Reg. 39874-77; 79 Fed. Reg. 51092.<sup>17</sup> Contraceptive coverage is then removed from the employer’s health plan, and the insurer or third-party administrator becomes responsible for independently making payments for contraception used by plan participants. *Id.* As a result, objecting employers do not have to “contract, arrange, pay, or refer for [contraceptive] coverage,” while employees continue to receive seamless coverage as required by the ACA. 79 Fed. Reg. 51093.

While the Accommodation “effectively exempted” objecting employers from the contraceptive mandate, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 698 (2014), certain religious nonprofit organizations remained dissatisfied and filed lawsuits demanding that the Departments provide them with the same exemption created for houses of worship. These

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<sup>16</sup> The Accommodation was originally available to religious non-profits and institutions of higher education. In response to *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014), the Departments expanded the Accommodation to cover closely held, for-profit corporations with religious objections to contraception. See 80 Fed. Reg. 41318.

<sup>17</sup> Regulations permitting objecting employer to claim the Accommodation by notifying HHS of their objection were issued in response to an interim order issued by Supreme Court in *Wheaton College v. Burwell*, 573 U.S. 958 (2014). The two-page form that employers can use to self-certify, called EBSA Form 700, is included in the administrative record at Disk 9, 2017 Moral IFR Supp. Docs., No. 5, pages 666635-36.

organizations claimed 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 this claim. *See Eternal Word Television Network, Inc. v. Sec’y of HHS*, 818 F.3d 1122, 1141-42, 1148 (11th Cir. 2016) (collecting cases). The Supreme Court subsequently consolidated several of these cases for review in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). In a *per curiam* decision, the Court remanded the cases for further consideration, with instructions to the parties to continue working toward an 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 (quotation marks omitted). The Court “expresse[d] no view on the merits” of the RFRA claim. *Id.*

In July 2016, the Departments sought public comment on 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.”<sup>18</sup> 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.”<sup>19</sup>

### **C. The Interim Final Rules.**

On October 6, 2017, the Departments issued two interim final rules—hereinafter the “Religious IFR” and the “Moral IFR” (collectively “IFRs”)—that abandoned their prior effort to balance the religious liberty of employers with the right of women to seamless, no-cost

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<sup>18</sup> U.S. Dept. of Labor, *FAQs About Affordable Care Act Implementation Part 36*, at 4 (Jan. 9, 2017) (D9, 2017 Moral IFR Supp. Docs., No. 8, 666650).

<sup>19</sup> *Id.*

contraception coverage. *See* 82 Fed. Reg. 47792; 82 Fed. Reg. 47838. The IFRs created many new “expanded exemptions” from the contraceptive mandate. 82 Fed. Reg. 47794; 82 Fed. Reg. 47840. In addition to houses of worship already exempted by the Church Exemption, the Religious IFR exempted any nonprofit organization, closely held for-profit entity, for-profit entity that is not closely held, other non-governmental employer, institution of higher education, and health insurance issuer offering group or individual insurance coverage that objects based on sincerely held religious beliefs. *See* 82 Fed. Reg. 47809-12. The Moral IFR exempted any nonprofit organization, for-profit entity that has no publicly traded ownership interests, institution of higher education, and health insurance issuer offering group or individual insurance coverage that objects based on sincerely held moral beliefs. *See* 82 Fed. Reg. 47850-53. The IFRs also retained the Accommodation as an “optional process” that exempted agencies could “voluntarily” choose to make available to their employees. 82 Fed. Reg. 47792, 47812-13; 82 Fed. Reg. 47854.

The IFRs, which became effective upon their release, did not go through the Administrative Procedure Act’s (“APA”) notice and comment rulemaking process. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56. Instead, the Departments solicited post-promulgation comments on whether the expanded exemptions should be kept in place and codified in a final rule.

In December 2017, district courts in Pennsylvania and California issued preliminary injunctions barring the Departments from enforcing the IFRs anywhere in the United States. *See California v. Health & Human Servs.*, 281 F. Supp. 3d 806 (N.D. Cal. 2017) (“*California I*”); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017) (“*Pennsylvania I*”). The Ninth Circuit subsequently affirmed the California district court’s decision on the merits. *California v. Azar*, 911 F.3d 558 (9th Cir. 2018) (“*California II*”). It held that the plaintiff States had standing to challenge the IFRs and that the Departments likely did not have statutory authority or good cause to bypass

notice-and-comment rulemaking procedures required by the APA. *See id.* at 578-80. The Third Circuit stayed the appeal of the Pennsylvania district court's decision pending resolution of a subsequent motion for a preliminary injunction, and later consolidated it with the appeal of that second preliminary injunction. *See infra*, at 10.

#### **D. The Final Rules.**

On November 15, 2018, the Departments issued Final Rules that “finaliz[ed] the provisions of the Religious [IFR and Moral IFR] without contracting the scope of the exemptions.” 83 Fed. Reg. 57536, 57542 (hereinafter “Religious Exemption Rule”); *see* 83 Fed. Reg. 57592 (hereinafter “Moral Exemption Rule”). Thus, the Rules maintain the IFRs’ expanded exemptions without material change and continue to give objecting employers the option of permitting their employees to access contraceptive coverage through the Accommodation. *See* 83 Fed. Reg. 57556-71; 83 Fed. Reg. 57614-24.

In January 2019, the California and Pennsylvania district courts issued preliminarily injunctions barring enforcement of the Final Rules immediately before they were scheduled to go into effect. *See California v. Health and Human Servs.*, 351 F. Supp. 3d 1267 (N.D. Cal. 2019) (“*California III*”), *appeal pending*, Nos. 19-15072, 19-15118, 19-15150 (granting preliminary injunction applicable to plaintiff States); *Pennsylvania v. Trump*, 351 F. Supp. 3d 791 (E.D. Pa. 2019) (“*Pennsylvania II*”) (granting nationwide preliminary injunction). Both courts found that the Rules are likely invalid because they are inconsistent with the ACA and are not required or authorized by RFRA. *See California III*, 351 F. Supp. 3d at 1284-97; *Pennsylvania II*, 351 F. Supp. 3d at 816-27. The Pennsylvania court additionally held that the rulemaking process the Departments utilized—promulgating the expanded exemptions in IFRs without prior notice, then providing a post-promulgation comment period, before codifying the exemptions without change

in the Final Rules—likely violated the notice-and-comment rulemaking requirement of the APA. *See Pennsylvania II*, 351 F. Supp. 3d at 812-15. In July 2019, the Third Circuit affirmed the Pennsylvania court’s ruling in its entirety. *Pennsylvania v. President United States*, --- F.3d ---, 2019 WL 3057657 (3d Cir. 2019) (“*Pennsylvania III*”). It held that the States have Article III standing to challenge the Final Rules, that the Final Rules are likely procedurally deficient because the Departments bypassed notice-and-comment rulemaking before issuing the IFRs, that the Final Rules likely conflict with the ACA and are not authorized by RFRA, and that the district court did not abuse its discretion in issuing nationwide injunctive relief. *See id.* at \*5-\*18.

## **II. Massachusetts’ Lawsuit Challenging the Rules.**

Shortly after the IFRs were issued, in October 2017, the Commonwealth filed this action seeking to have the Rules declared unlawful and set aside. The Commonwealth asserted that the Rules violate the APA’s notice-and-comment requirement; are inconsistent with the ACA’s requirement that employer-sponsored health plans provide women with coverage for preventive care services, including contraception; amount to an endorsement of religion, in violation of the Establishment Clause of the First Amendment; and discriminate against women, in violation of the equal protection guarantee implicit in the Fifth Amendment. The parties thereafter filed cross-motions for summary judgment. Holding that the Commonwealth did not have standing under Article III to advance its claims, this Court granted judgment to the Departments. The Commonwealth filed a timely notice of appeal.

On May 2, 2019, the First Circuit vacated this Court’s judgment and remanded the case. *Massachusetts v. U.S. Dept. of Health & Human Servs.*, 923 F.3d 209 (1st Cir. 2019). The First Circuit held that the Commonwealth has Article III standing to challenge the Rules because it faces an imminent risk of financial injury that is fairly traceable to the Rules and likely to be redressed



by a decision in the Commonwealth's favor. *Id.* at 221-28. Specifically, the First Circuit ruled that there is a substantial risk that women in Massachusetts will lose contraceptive coverage because of the Rules and a substantial likelihood that the Commonwealth will incur costs providing replacement contraceptive care and services, or prenatal and postnatal care, to some of those women. *Id.* at 221-27; *see also* Boyle Decl. ¶¶ 4-6; Childs-Roshak Decl. ¶¶ 18-26; Cooke Decl. ¶¶ 6-8; Dutton Decl. ¶¶ 27-30; Frost Decl. ¶¶ 6-8; Pomales Decl. ¶¶ 10-11. And while the court held that the Commonwealth's procedural challenge to the *IFRs* had been mooted by the issuance of the Final Rules, it emphasized that this ruling would "not preclude the Commonwealth from asserting any procedural challenges to the Final Rules." *Massachusetts*, 923 F.3d at 228.

This Court thereafter granted the Commonwealth leave to file a Second Amended Complaint, which was filed on July 8, 2019.

### **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**

As every court to review the Final Rules has concluded, the Final Rules are manifestly unlawful. First, in issuing the Rules, the Departments 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 preventive services requirement. The Departments' effort to create new exemptions from that requirement is inconsistent with the ACA's command that employer-sponsored group health plans provide women with coverage for preventive care services, including contraception, and it is not required or authorized by RFRA. Third, by exclusively promoting the religious beliefs of employers at the expense of the rights, health, and well-being of employees and their dependents, the Religious Exemption Rule endorses religion in violation of the Establishment Clause. Finally, by authorizing employers to deny critical health insurance coverage for women alone, the Rules discriminate against women in violation of the Fifth Amendment's equal protection guarantee.

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

The Rules must be set aside because they were not promulgated in compliance with the APA's rulemaking procedures. Agencies must provide advance notice and an opportunity to comment on proposed regulatory action "before implementation, when the agenc[ies] [are] more likely to be receptive to argument." *Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980). The Departments did not comply with this requirement. Instead, they promulgated expanded religious and moral exemptions through interim final rules issued without advance notice, then solicited post-promulgation comments on whether the exemptions should be kept in place, before predictably finalizing the exemptions without substantive change. This attempted end-run around the APA is unlawful. *See Pennsylvania III*, 2019 WL 3057657, at \*9-\*13; *cf. New Jersey v. EPA*, 626 F.2d 1038, 1049-50 (D.C. Cir. 1980) ("Were we to allow [an agency] to prevail on this point we would make [the APA] virtually unenforceable. An agency that wished to dispense with pre-

promulgation notice and comment could simply do so, invite post-promulgation comment, and republish the regulation before a reviewing court could act.” (quoting *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214-15 (5th Cir. 1979)).

**A. The IFRs Were Procedurally Invalid When They Were Promulgated.**

The APA requires federal agencies to follow a three-step procedure before promulgating a rule. *See Utility 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). Rather than comply with these procedures, the Departments issued interim final rules that became effective upon their release. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56. The Departments offered two justifications for their failure to provide notice and accept comments. First, they contended that provisions of the Health Insurance Portability and Accountability Act of 1996 (“HIPPA”), 110 Stat. 1936, authorize them to promulgate the regulations as interim final rules. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56. Second, they invoked the good cause exception to the APA’s rulemaking requirements. *See id.* Neither justification suffices.

The Departments’ claim that HIPPA gives them statutory authority to dispense with notice-and-comment rulemaking has been repeatedly considered, analyzed, and rejected. *See, e.g., Pennsylvania III*, 2019 WL 3057657, at \*10; *California II*, 911 F.3d at 578-81; *Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 444 (W.D. Pa. 2013); *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 17-19 (D.D.C. 2010). Under the APA, 5 U.S.C. § 559, an agency may bypass the notice-and-comment process only “when a subsequent statute ‘plainly expresses a congressional intent to depart from normal APA procedures.’” *Lake Carriers’ Ass’n v. EPA*, 652 F.3d 1, 6 (D.C.

Cir. 2011) (quoting *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998)). Statutes that satisfy this standard use mandatory language—“shall” rather than “may”—and expressly direct agencies to follow “procedures [and timelines] so clearly different from those required by the APA that [Congress] must have intended to displace the norm.” *Asiana Airlines*, 134 F.3d at 397-98; see also *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994). The HIPPA provisions, in contrast, are general grants of rulemaking authority commonly included in statutes, under which the Departments “may promulgate” interim final rules where “appropriate.” 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. The provisions use permissive rather than mandatory language and do not supply the plain statement necessary to supersede the APA’s notice and comment provisions. See *Pennsylvania III*, 2019 WL 3057657, at \*10; *California II*, 911 F.3d at 578-80; *Geneva Coll.*, 929 F. Supp. 2d at 444; *Coalition for Parity*, 709 F. Supp. 2d at 18-19.

The Department’s “good cause” argument fares no better. The APA permits agencies to dispense with notice-and-comment rulemaking only for good cause—when doing so would be “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B). The First Circuit interprets this “good cause” exception narrowly and restricts its use to emergency situations. See *Levesque v. Block*, 723 F.2d 175, 184-85 (1st Cir. 1983) (good cause exception is “narrowly construed”); *Kollett*, 619 F.2d at 145 (same).

The Departments incorrectly contend that the “public interest” and “impracticable” prongs of the exception justified issuing the IFRs without notice and the opportunity to comment. See 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47855. But with respect to the “public interest” prong, the First Circuit has made clear that “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” unless it would “prevent an agency from operating.” *Levesque*, 723 F.2d at 184-85. The Departments cannot—and have not—maintained that there was a lack of interest in the Rules; indeed, they affirmatively highlighted the public’s interest in the contraceptive mandate rulemakings. *See* 82 Fed. Reg. 47814. Nor could the Departments represent, or have they represented, that following notice-and-comment procedures before issuing the IFRs would have “prevent[ed] [them] from operating.” *Levesque*, 723 F.2d at 184.

As to the “impracticable” prong, an agency may only invoke impracticability when it “[can]not both follow [notice-and-comment rulemaking] and execute its statutory duties.” *Id.* Again, the Departments cannot—and have not attempted—to meet this standard. The Departments have argued that following notice-and-comment procedures would have been complicated by ongoing litigation. *See* 82 Fed. Reg. 47814; 82 Fed. Reg. 47855. But it is well established that “an agency’s desire to eliminate more quickly legal and regulatory uncertainty is not by itself good cause.” *California II*, 911 F.3d at 576. And, even acknowledging the ongoing litigation, there is no basis to suggest that compliance with the APA would have “unavoidably prevented” “due and required execution of the agenc[ies’] functions”—a necessary showing for impracticability. *Kollett*, 619 F.2d at 145. Thus, the IFRs were procedurally invalid when they were issued.

**B. The Final Rules Remain Procedurally Invalid and Were Not Cured by the Department’s Post-Promulgation Notice-and-Comment Period.**

The Departments’ failure to engage in the APA’s required notice-and-comment rulemaking not only rendered the IFRs procedurally defective, *see California II*, 911 F.3d at 575-81, but also renders the Final Rules invalid. In general, a regulation “found invalid for failure to provide for notice and comment cannot be saved by providing for comment after promulgation.” *Levesque*, 723 F.2d at 187. This rule “reflects the concerns that underlie section 553” of the APA. *Id.* “[T]he purpose of *prior* notice and comment,” the First Circuit has explained, “is to afford persons an

opportunity to influence agency action in the formulative stage, before implementation, when the agency is more likely to be receptive to argument.” *Kollett*, 619 F.2d at 145 (emphasis added); *accord Levesque*, 723 F.2d at 187-88. Indeed, “citizens will recognize that the agency is less likely to pay attention to their views after a rule is in place.” *Levesque*, 723 F.2d at 187-88.

That rule directly controls this case: the post-implementation comment period provided by the Departments after issuance of the IFRs did not cure the procedural defect that has tainted the Rules from the outset. As the Departments conceded in the First Circuit, the “substance of the [Final] [R]ules remains largely the same” as the substance of the IFRs. Appellees’ Mot. to Govern Further Proceedings, at 4 (1st Cir. No. 18-1514); *accord Massachusetts*, 923 F.3d at 220-21. The Final Rules simply “finaliz[e]” the expanded exemptions without substantive change, 83 Fed. Reg. 57542, and do “not reflect any real open-mindedness toward the position set forth in the IFRs,” *Pennsylvania III*, 2019 WL 3057657, at \*12. Moreover, during the post-implementation comment period, the Departments engaged in conduct—including stipulating to resolve the *Zubik* cases and other litigation—that demonstrated that they had already decided to finalize the expanded exemptions without change. *See* 83 Fed. Reg. 57578 (noting that “since the Religious IF[R] was issued, additional entities have received permanent injunctions”). Since the Final Rules are “virtually identical” to the IFRs, *Pennsylvania III*, 2019 WL 3057657, at \*12, and do not reflect “a degree of agency receptivity that demonstrate[s] that a real public reconsideration of the issued rule has taken place,” the Final Rules must be set aside as inconsistent with the APA. *Levesque*, 723 F.2d at 188 (internal quotation marks omitted); *see also Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005) (“It is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later.”); *Nat. Resources Def. Council, Inc. v. EPA*, 683 F.2d 752, 768 (3d Cir. 1982) (agencies may not take regulatory “action without complying

with the APA, and then establis[h] a notice and comment procedure on the question of whether that action should be continued”).

**II. The Departments Have No Statutory Authority to Adopt the Expanded Exemptions in the Final Rules.**

The Final Rules must also be declared unlawful and set aside because they are “in excess of [the Departments’] statutory . . . authority” and “arbitrary, capricious, [and] . . . not in accordance with law.” 5 U.S.C. § 706(2)(A), (C). The Departments’ contention that the ACA gives them authority to categorically exempt employers from the ACA’s preventive services requirement, as it relates to contraceptive coverage, is entirely inconsistent with the statute. The ACA delegates HRSA authority to determine *what* preventive 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 a validly enacted statute like the ACA. And because the Accommodation satisfies religious objectors’ rights under RFRA, the Religious Exemption Rule is not separately compelled or authorized by RFRA.

**A. The Affordable Care Act Requires All Employer-Sponsored Group Health Plans to Provide Women with Coverage for Preventive 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 preventive care services are covered. “Congress,” the Court explained, “did not specify *what* types of preventive 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* preventive services to require.” *Hobby Lobby*, 573 U.S. at 697 (emphasis added and internal citations omitted). After HRSA has determined which preventive 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] ‘preventive care and screenings’ for women without ‘any cost sharing requirements.’” *Id.* (quoting 42 U.S.C. § 300gg-13(a)(4)) (emphasis added). In the Final Rules, the Departments depart from that construction 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 preventive care services must be covered, they claim, but it also delegates them “broad discretion” to set rules on “the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.” 83 Fed. Reg. 57541; *see generally* 83 Fed. Reg. 57540-44; 83 Fed. Reg. 57596-98.

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); *see also Claudio-De Leon v. Sistema Universitario Ana G. Mendez*, 775 F.3d 41, 46 (1st Cir. 2014) (“[I]t is axiomatic that the word ‘shall’ has a mandatory connotation.”). By directing that group health plans “shall” provide coverage for preventive care services for women, 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 Pennsylvania III*, 2019 WL 3057657, at \*13 (“The term ‘shall’ denotes a requirement . . . and HRSA’s authority to issue the guidelines does not empower it to ignore that requirement.”); *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 preventive 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 manufacture additional exemptions. *See Pennsylvania III*, 2019 WL 3057657, at \*14. Indeed, “[w]hen Congress provides exceptions in a statute, . . . [t]he proper inference . . . is that Congress considered the issue of exceptions and, in the end, limited the statute to the ones set forth.” *United States v. Johnson*, 529 U.S. 53, 58 (2000); *see also 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 preventive care for women, the ACA makes clear that HRSA’s charge is to identify other

*types* of preventive care services, aside from those services covered by Paragraph 1,<sup>20</sup> 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's 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 health care to people who are geographically isolated, economically 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."<sup>21</sup> 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 expressly instructs HRSA to develop its preventive care guidelines "for purposes 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 preventive 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 preventive 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

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<sup>20</sup> 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).

<sup>21</sup> HRSA, *About the HRSA* (March 2019), <https://www.hrsa.gov/about/index.html>.

access to preventive 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 preventive 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.<sup>22</sup>

Another purpose of the Women’s Health Amendment was to ensure that all women have access to the same package of preventive 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

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<sup>22</sup> *See, e.g.*, 155 Cong. Rec. S12025 (Dec. 1, 2009) (Sen. Boxer) (preventive care “include[s] . . . family planning services”); *id.* at S12027 (Sen. Shaheen) (“Women must have access to vitally important preventive services such as . . . preconception counseling that promotes healthier pregnancies and optimal birth outcomes.”); *id.* (Sen. Gillibrand) (under the Amendment, “even more preventive 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 preventive services for women across the board,” which “would result in more counseling, more contraception, and fewer unintended pregnancies”).

as women who serve in Congress.”). At the time, contraception was among the preventive care benefits covered in the health plan for federal employees, including members of Congress. *See* IOM Report 108 (D1, 405).

Finally, subsequent legislative efforts confirm that Congress did not authorize HRSA to exempt employers from the contraceptive 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 preventive 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 contraceptive 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 contraceptive mandate.

**B. The Departments’ Justifications for Creating Broad New Exemptions from the Contraceptive Mandate Are Meritless.**

All of these factors demonstrate that while Section 2713(a)(4) delegates HRSA authority to determine what preventive 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 identify any textual provision in the ACA that authorizes HRSA to exempt employers from the mandate. Instead, they point out that while the preventive services requirement for children requires coverage of "evidence-informed preventive care and screenings *provided for* in the comprehensive guidelines supported by" HRSA, 42 U.S.C. § 300gg-13(a)(3) (emphasis added), the preventive services requirement for women requires coverage of "such additional preventive care and screenings not described in paragraph (1) *as provided for* in comprehensive guidelines supported by the [HRSA] for purposes of this paragraph," *id.* § 300gg-13(a)(4) (emphasis added). *See* 83 Fed. Reg. 57540-41. The use of the word "as" in the women's provision, the Departments contend, suggests that Congress gave them authority to exempt employers from the requirement. *Id.* It is not at all clear how the Departments derive this meaning from the word "as," but in any event, the use of the word "as" in the women's requirement has an obvious explanation. When the ACA was enacted, the children's preventive services guidelines were in existence, while the women's guidelines were not. *See Pennsylvania III*, 2019 WL 3057657, at \*14. The word "as" was used in anticipation of HRSA issuing guidelines for women. *See id.* Everyone agrees that Congress gave the Departments authority to issue guidelines on *what* preventive services must be covered for women, but there is no conceivable way to construe the word "as" to confer additional authority to exempt employers from the statutory mandate.

The Departments also point out that adjacent preventive services requirements use the terms "evidence-based" or "evidence-informed," while the women's preventive services requirement does not. *Compare* 42 U.S.C. §§ 300gg-13(a)(1) and (3), with *id.* § 300gg-13(a)(4). From this, the Departments contend that Congress empowered them to develop the Women's Guidelines in light of policy-based concerns. *See* 83 Fed. Reg. 57541. Even if that were true, at

most it would allow them to consider non-evidence-based factors in determining *what* preventive services for women must be covered. It cannot be construed to authorize the Departments to create out of whole cloth new exemptions to the Guidelines, particularly in light of the clear statutory command that the services identified in the Guidelines “shall” be covered by employers’ plans. *See Public Citizen v. FTC*, 869 F.2d 1541, 1556-57 (D.C. Cir. 1989) (“there exists no general administrative power to create exemptions to statutory requirements based upon the agency’s perception of costs and benefits” (internal quotation marks omitted)).

The Departments maintain that they have authority to issue the Final Rules because Congress did not “prohibi[t] them from providing conscience protections.” 82 Fed. Reg. 47844; *accord* 83 Fed. Reg. 57543. 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 broad exemptions from the contraceptive 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 ACA plainly does not grant the Departments authority to create the expanded exemptions codified in the

Final Rules.<sup>23</sup>

**C. The Religious Exemption Rule Cannot Be Justified by the Religious Freedom Restoration Act.**

As an alternative to the ACA, the Departments invoke another federal statute—RFRA—as a possible source of authority for the expanded exemptions in the Religious Exemption Rule.<sup>24</sup> See 83 Fed. Reg. 57544-52. RFRA prohibits the federal “Government [from] substantially burden[ing] a person’s exercise of religion” unless the “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). Even assuming RFRA gives federal agencies authority to alleviate substantial burdens on religious exercise by regulation, it does not 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. v. Mass. Bay Transp. Auth.*, 587 F.3d 89, 98 n. 1 (1st Cir. 2009), the ACA’s coverage mandate can only be limited to the extent required by RFRA’s accommodation of religious exercise. See *Hobby Lobby*, 573 U.S. at 739 (Kennedy, J., concurring) (exercise of religion cannot “unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling”). And because “it is the obligation of *the courts* to consider whether exceptions are required” under

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<sup>23</sup> Because Section 2713(a)(4) is unambiguous, the Departments’ interpretation of that statute is not entitled to deference under *Chevron U.S.A. Inc. v. Nat. Resources Def. Council Inc.*, 467 U.S. 837 (1984). See *Michigan v. EPA*, 135 S. Ct. 2699, 2708 (2015) (*Chevron* deference “does not license interpretive gerrymanders under which an agency keeps parts of statutory context it likes while throwing away parts it does not”).

<sup>24</sup> RFRA applies only to the “exercise of religion,” and therefore provides no authority for the nonreligious exemptions created by the Moral Exemption Rule. See 42 U.S.C. §§ 2000bb-1(b), 2000cc-5(7)(A); *Hobby Lobby*, 573 U.S. at 719 n.30 (an exemption for moral objectors would “exten[d] more broadly than the pre-existing protections of RFRA”).

RFRA, *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 434 (2006) (emphasis added), the Departments are entitled to no deference in their application of RFRA to the ACA. *See Pennsylvania III*, 2019 WL 3057657, at \*15 (citing *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 649 (1990)).

To harmonize RFRA and the ACA’s mandate to cover all preventive care services, including contraception, the Departments previously exempted houses of worship from the contraceptive mandate<sup>25</sup> and 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 organizations have seamless coverage for contraception. *See supra*, at 5-6. 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.” 573 U.S. at 692; *see id.* at 738 (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 732; *see also id.* at 693

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<sup>25</sup> 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 law. *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. 41325; *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. 41325.



(“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.”).

The existence of the Accommodation—which fully satisfies RFRA’s protections for employers’ religious exercise without harming women—prevents the Departments from now insisting that the Religious Exemption Rule is necessary to satisfy RFRA. For the reasons that follow, the Religious Exemption Rule is neither required nor authorized by RFRA.

1. The Religious Exemption Rule Is Not Required or Authorized by RFRA Because the Accommodation Does Not Impose a Substantial Burden on Objecting Employers’ Exercise of Religion.

For years, the Departments correctly explained, in courts across the country and in the Supreme Court, that the Accommodation does not impose a substantial burden on religious exercise cognizable under RFRA. *See, e.g.*, Br. of Respondents at 32-53, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418) (“*Zubik Br.*”). And, after *Hobby Lobby*, eight federal Courts of Appeals agreed with that conclusion.<sup>26</sup> Specifically, these courts ruled that the act of opting out of the contraceptive mandate—accomplished by submitting a two-page notice to HHS or an insurer or third-party administrator—does not substantially burden the exercise of religion. *See, e.g.*, *Eternal Word Television*, 818 F.3d at 1141-42 (collecting cases). In the Religious Exemption Rule, however, the Departments have abandoned their prior position and now argue that the Rule is necessary because the Accommodation imposes a substantial burden on religion. *See* 83 Fed. Reg.

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<sup>26</sup> *See Eternal Word Television*, 818 F.3d at 1148; *Mich. Catholic Conf. & Catholic Family Servs. v. Burwell*, 807 F.3d 738, 749-55 (6th Cir. 2015); *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); *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); *but Sharpe Holdings, Inc. v. HHS*, 801 F.3d 927, 942 (8th Cir. 2015).

57546. The Departments' about-face is wrong as a matter of law and must be rejected.

Under RFRA, while courts may not question the sincerity of an objecting employers' religious beliefs regarding contraception, the question whether the Accommodation imposes a "substantial burden" is "a question of law" for courts to review "de novo." *Roman Catholic Bishop of Springfield v. City of Springfield*, 724 F.3d 78, 93 (1st Cir. 2013)<sup>27</sup>; accord, e.g., *Eternal Word Television*, 818 F.3d at 1142,1144-47; *Priests for Life v. HHS*, 772 F.3d 229, 247 (D.C. Cir. 2014) ("*Priests for Life I*"). A regulation like the Accommodation may impose a substantial burden if it "appears to target a religion, religious practice, or members of a religious organization because of hostility to that religion itself," if "local regulators have subjected [the objecting] religious organization to a process . . . designed to reach a predetermined outcome contrary to the group's interest," or if the regulation "was imposed on the religious institution arbitrarily, capriciously, or unlawfully." *Roman Catholic Bishop*, 724 F.3d at 96-97 (internal quotation marks omitted). The Departments have never contended, nor could they contend, that the Accommodation falters on any of these shoals. The Accommodation only 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." *Priests for Life I*, 772 F.3d at 249; see also *Eternal Word Television*, 818 F.3d at 1148; *Univ. of Notre Dame v. Sebelius*, 743 F.3d 547, 554 (7th Cir. 2014) ("*Notre Dame I*"). This modest requirement—which is common to most if not all

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<sup>27</sup> The *Roman Catholic Bishop* case involved the Religious Land Use and Institutionalized Persons Act of 2000 ("RLUIPA"), which is RFRA's "sister statute." *Holt v. Hobbs*, 135 S. Ct. 853, 859 (2015); see *Roman Catholic Bishop of Springfield*, 724 F.3d at 93-100. RLUIPA "allows federal and state prisoners to seek religious accommodations pursuant to the same standard as set forth in RFRA." *Gonzales*, 546 U.S. at 436. Because the two statutes adopt the "same standard," *id.*, "RLUIPA and RFRA 'are analogous for the purpose of the substantial burden test.'" *Pennsylvania III*, 2019 WL 3057657, at \*15 n.29 (quoting *Mack v. Warden Loretto FCI*, 839 F.3d 286, 304 n.103 (3d Cir. 2016)).

accommodations—imposes no serious burden on religious exercise. *See id.* After notice is provided, the government arranges for third parties to independently provide seamless coverage as required by the ACA and HRSA guidelines. *Eternal Word Television*, 818 F.3d at 1149; *see also Priests for Life I*, 772 F.3d at 249 (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”).

The Departments have previously claimed that this process makes employers “complicit” in third parties’ provision of contraceptive coverage to employees. *See* Defts’ Cross-Mot. to Dismiss Mem., at 31-32 (ECF No. 33).<sup>28</sup> But RFRA provides no right to object to the independent activities of third parties. *See Priests for Life I*, 772 F.3d at 246 (“[Employers] have no RFRA right to be free from the unease, or even anguish, of knowing that third parties are legally privileged or obligated to act in ways their religion abhors.”).<sup>29</sup> And it is “[f]ederal law, not the religious organization’s signing and mailing the form, [that] 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 I*, 772 F.3d at 252. Indeed, if the Departments’ complicity theory were right, the Government would impose a substantial burden on religious exercise every

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<sup>28</sup> Only *some* employers that object to directly providing contraceptive coverage also have this type of complicity objection to the Accommodation. The Rule, however, exempts *all* objecting employers and makes participation in the Accommodation entirely voluntary. *See* 83 Fed. Reg. 57537 (“These rules also finalize provisions from the Religious IF[R] that maintain an accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation.”). As the Departments appear to concede, because the Rule extends exemptions to employers that are not substantially burdened by the Accommodation, it goes beyond what is required by RFRA. *See id.* at 57545 (“[W]ith respect to *at least some objecting entities*, an expanded exemption, as opposed to the existing accommodation, is required by RFRA.”). The scope of the Rule is therefore clearly unlawful and, as discussed below, *see infra*, at 35-39, violates the Establishment Clause.

<sup>29</sup> As discussed below, *see infra*, at 35-39, such a right to enlist the government in compelling third parties to conform their behavior to the objector’s religious beliefs would be inconsistent with the Establishment Clause.

time it replaced a sincere religious objector who had opted out of compulsory military service with a new draftee, because the act of opting out could make the religious objector complicit in war. *See Eternal Word Television*, 818 F.3d at 1150; *E. Tex. Baptist Univ. v. Burwell*, 793 F.3d 449, 461 (5th Cir. 2015); *Univ. of Notre Dame v. Burwell*, 786 F.3d 606, 623 (7th Cir. 2015) (“*Notre Dame II*”). Just as no court would countenance that interpretation of RFRA, the complicity theory cannot be invoked to claim that the Accommodation imposes a substantial burden under RFRA.

Because the Accommodation does not impose a substantial burden on employers’ exercise of religion, it is consistent with RFRA. *See Priests for Life I*, 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 exemptions in the Religious Exemption Rule.

2. Even If the Accommodation Did Impose a Substantial Burden on Employers’ Religious Exercise, It Is the Least Restrictive Means of Achieving the Government’s Compelling Interest in Ensuring that Women Receive Full and Equal Health Coverage.

Nevertheless, even if this Court were to assume that the Accommodation substantially burdened employers’ exercise of religion, it is the least restrictive means of furthering Congress’s compelling interest in ensuring women receive full and equal health care coverage, including coverage for contraceptive services. *See Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring) (the Accommodation “serves the Government’s compelling interest in providing insurance coverage that is necessary to protect the health of female employees”).

The text and purpose of the Women’s Health Amendment reflect Congress’s determination that the government has a compelling interest in providing women full and equal coverage appropriate to their medical needs. *See, e.g.*, 155 Cong. Rec. S12026 (Dec. 1, 2009) (Sen. Mikulski) (explaining that the Women’s Health Amendment was part of a “Titanic battle” to

secure equal treatment and benefits for women in health care). And the conclusions reached by the IOM and WPSI confirm that seamless, no-cost contraceptive coverage is an “essential component of the full and equal coverage mandated by Congress.” *Zubik Br.* at 29; *see also supra*, at 3-4. Among other benefits, contraceptive coverage: (1) “enables women to avoid the health problems unintended pregnancies may visit on them and their children”; (2) “helps women avoid the increased risk of adverse pregnancy outcomes that comes with pregnancies that are too closely spaced”; (3) provides critical protections for women who suffer from the “many medical conditions for which pregnancy is contraindicated”; (4) “secures benefits wholly unrelated to pregnancy, [including] preventing certain cancers, menstrual disorders, and pelvic pain”; and (5) allows women “to make important decisions about their families and careers and how they will participate in the social and economic life of our nation.” *Zubik Br.* at 30, 55-56 (quotation marks omitted). Further, because even “minor obstacles” significantly reduce the use of contraception, contraceptive coverage that that imposes “financial, administrative, or logistical burdens” on women is not effective, full, or equal. *Id.* at 57, 73-75.

The Departments do not seriously challenge the overwhelming record evidence supporting the contraceptive mandate. *See* 83 Fed. Reg. 57554 (“The Departments do not take a position on the scientific . . . [or] empirical question[s]” concerning contraception). Indeed, “the Rules provide no new facts and no meaningful discussion that would discredit [the Departments’] prior factual findings establishing the beneficial and essential nature of contraceptive healthcare for women.” *California III*, 351 F. Supp. 3d at 1296.<sup>30</sup> Nor do the Departments contest that the Accommodation

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<sup>30</sup> The Departments’ position that RFRA requires the exemptions created by the Rule rests “on new *legal* assertions” that are not entitled to any deference. *California III*, 351 F. Supp. 3d at 1297 (emphasis in original); *see also Pennsylvania III*, 2019 WL 3057657, at \*15 (courts “owe the agencies no deference when reviewing determinations based on RFRA”). To the extent the Departments contend it also rests on the reversal of any prior regulatory position concerning the

is the least restrictive means of effectively providing this coverage. *See* 83 Fed. Reg. 57544 n.14 (there is “no feasible [alternative] approach” to the Accommodation).

Instead, the Departments principally contend that the government cannot show it has a compelling interest in enforcing the mandate against each individual employer exempted by the Rule. *See id.* at 57546-47 (the government must demonstrate a compelling interest “as applied to the particular adherent”). The Departments postulate that the government’s interest in enforcing the mandate could be undercut if, for example, employees shared their employer’s objections to contraception, had easy access to alternative sources of contraceptive coverage, or were otherwise at a lower risk of becoming unintentionally pregnant. *Id.* at 57547. But as the Departments appear to concede, concerns about the individualized circumstances of some employers—even if accurate—cannot justify “a blanket exemption for [all] religious . . . objectors” under RFRA. *Hobby Lobby*, 573 U.S. at 719 n.30; *see* 83 Fed. Reg. 57545 (“[A]n expanded exemption is required by RFRA *for at least some objectors.*”) (emphasis added). The Departments acknowledge that the exemptions created by the Religious Exemption Rule will lead to tens of thousands of women losing coverage for their chosen method of contraception. *See Massachusetts*, 923 F.3d at 216-17 (noting that the Departments’ analysis already “accounted for various factors that could skew the estimates”); *California II*, 911 F.3d at 572 (same). The Departments have failed to show that the government lacks a compelling interest in ensuring that these women receive the full and equal coverage guaranteed by the ACA. *See Priests for Life v. HHS*, 808 F.3d 1, 26 (D.C. Cir. 2015) (Mem.) (“*Priests for Life II*”) (Kavanaugh, J., dissenting from the denial of rehearing en

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importance or effectiveness of the mandate, that reversal is arbitrary and capricious because the Departments have “failed to provide a reasoned explanation . . . for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *California III*, 351 F. Supp. 3d at 1297 (internal quotation marks omitted).

banc) (explaining that “[i]t is not difficult to comprehend” why facilitating access to contraceptive coverage is a “compelling interest,” and that “*Hobby Lobby* strongly suggests that the Government has a compelling interest in facilitating access to contraception for the employees of these religious organizations”); *Zubik* Br. at 59 (the government’s interest is “no less compelling with respect to the women who obtain their health coverage through employers with religious objections to contraception”). And they have likewise failed to demonstrate that the “blanket exemption” created by the Rule is required by RFRA.<sup>31</sup>

3. The Religious Exemption Rule Overrides Other Significant Interests by Imposing an Undue Burden on Women and Their Families.

Finally, because the Religious Exemption Rule would impose an undue burden on women and their families, it is neither required nor permitted by RFRA. *See Pennsylvania III*, 2019 WL 3057657, at \*16-\*17. The fact that the Rule will cause significant harm underscores the government’s compelling interest in enforcing the contraceptive mandate and demonstrates that the Departments have failed to “reconcile” employers’ religious objections with employees’ rights under the ACA. *Hobby Lobby*, 573 U.S. at 739 (Kennedy, J., concurring); *see also id.* at 729 n.37 (explaining that the burden imposed by an exemption “will often inform the analysis of the Government’s compelling interest and the availability of a less restrictive means of advancing that

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<sup>31</sup> The Departments also raise the related argument that because the contraceptive mandate does not apply to all employers—for example, those with grandfathered health plans—the government cannot establish a compelling interest in enforcing the mandate against any employer. 83 Fed. Reg. 57547-58. The Departments convincingly and correctly refuted this identical argument when it was raised in the *Zubik* litigation: “[I]t is implausible to suggest that the government cannot have a compelling interest in the application of a law because that law allows for some exceptions . . . Numerous organizations are not required to pay taxes; half the country’s draft-age population is exempt from registering for the draft; and Title VII does not apply to millions of employers with fewer than 15 employees . . . Yet no one would suggest that raising tax revenue, raising an army, and combating employer discrimination are not compelling interests.” *Zubik* Br. at 62.

interest”).

In applying RFRA, this court “*must* take adequate account of the burdens [the Religious Exemption Rule] may impose on non-beneficiaries,” *Hobby Lobby*, 573 U.S. at 729 n.37 (emphasis added), to ensure that it does not “override other significant interests,” *Cutter v. Wilkinson*, 544 U.S. 709, 722 (2005).<sup>32</sup> But the Rule does exactly that. As direct result of the Rule, tens of thousands of women will lose coverage for their chosen method of contraception. *See Pennsylvania III*, 2019 WL 3057657, at \*5-\*7; *Massachusetts*, 923 F.3d at 216-17; *California II*, 911 F.3d at 571-72; *see* 83 Fed. Reg. 57578, 57581 (estimating the number of women who will lose coverage and the costs imposed as a result of the Rule). Some of these women will be able to secure effective replacement care at a cost of millions of dollars annually. *Id.* Others will be forced to switch to less expensive and less effective methods of contraception—or forgo contraception altogether—leading to an increase in unintended pregnancies. *See Pennsylvania III*, 2019 WL 3057657, at \*7; *Massachusetts*, 923 F.3d at 217. As the Departments previously explained to the Supreme Court, the “medical evidence prompting the contraceptive requirement showed that even minor obstacles to obtaining contraception”—like having to find, access, and pay for alternative sources of care, distinct from a woman’s regular doctor—“led to more unplanned and risky pregnancies, with attendant adverse effects on women and their families.” *Zubik Br.* at 74-75.

“No tradition, and no prior decision under RFRA, allows a religion-based exemption when the [exemption] would be harmful to others—here, the very persons the contraceptive coverage requirement was designed to protect.” *Pennsylvania III*, 2019 WL 3057657, at \*16 (quotation omitted). Thus, in *Hobby Lobby*, the Supreme Court endorsed the Accommodation precisely

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<sup>32</sup> This is both a statutory and a constitutional requirement. *See Cutter*, 544 U.S. at 720. The burdens imposed by the Rule also violate the Establishment Clause. *See infra*, at 35-39.



because it avoided the costs and burdens that the Rule will impose on women and their families. *See* 573 U.S. at 738-39 (Kennedy, J., concurring). And in *Zubik*, the Court directed that any resolution to employers’ objections to the contraceptive mandate must respect women’s right to “receive full and equal health coverage, including contraceptive coverage.” 136 S. Ct. at 1560 (quotation marks omitted). The Rule, which simply cancels this right, imperiling the health and well-being of thousands of women, is not the type of “appropriately balanced” accommodation required by RFRA. *Cutter*, 544 U.S. at 722. Like the Moral Exemption Rule, the Religious Exemption Rule must be declared unlawful and set aside. *See Pennsylvania*, 2019 WL 3057657, at \*16-\*17; *see also Hobby Lobby*, 573 U.S. at 693 (“We certainly do not hold or suggest that RFRA demands accommodation of . . . religious beliefs no matter the impact . . . on thousands of women.”).

### **III. The Religious Exemption Rule Has the Purpose and Effect of Endorsing Religion, In Violation of the Establishment Clause.**

Compounding these legal infirmities, the expanded exemptions created by the Religious Exemption Rule also violate the Establishment Clause.<sup>33</sup> Through the Rule, the Departments have restructured the Women’s Health Amendment “to conform with a particular religious viewpoint,” *Edwards v. Aguillard*, 482 U.S. 578, 593 (1987), privileging employers’ objections to contraception over the rights, health, and well-being of thousands of women and their families. In so doing, the Departments have crossed the tipping point at which permissible accommodation becomes 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).

The Establishment Clause places “fundamental limitations” on the Departments’ authority

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<sup>33</sup> This Establishment Clause claim only challenges exemptions for employers and institutions of higher education.

to create religious exemptions that are not required by the Free Exercise Clause. *Lee v. Weisman*, 505 U.S. 577, 587 (1992). The exemptions the Rule creates for non-church 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); *see also Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 710 (1985) (“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.”) (quotations omitted). The Departments do not claim otherwise. *See* 83 Fed. Reg. 57544. Furthermore, the limits imposed by the Establishment Clause apply regardless of whether the Religious Rule is “required” by RFRA.<sup>34</sup> Religious exemptions created pursuant to statutes like RFRA are subject to full Establishment Clause scrutiny. *See Cutter*, 544 U.S. at 721-22 (the Establishment Clause limits accommodations under RFRA’s sister statute, RLUIPA).

The exemptions created by the Rule violate the Establishment Clause because they impermissibly advance employers’ religious interests “over all other interests.” *Thornton*, 472 U.S. at 708-10. The Rule therefore fails both the *Lemon* test and the related “endorsement analysis,” which are used to enforce the limits on religious exemptions imposed by the Establishment Clause. *See id.* at 708-10; *id.* at 711-12 (O’Connor, J., concurring); *see also 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.”<sup>35</sup> *Freedom from Religion Fund v. Hanover Sch. Dist.*, 626 F.3d 1, 9 (1st Cir.

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<sup>34</sup> As discussed, the exemptions are not required or authorized by RFRA. *See supra*, at 25-35.

<sup>35</sup> The *Lemon* test also bars exemptions that “foster an excessive government entanglement with religion.” *Lemon v. Kurtzman*, 403 U.S. 602, 613 (1971) (internal quotation marks omitted).

2010). The endorsement analysis prohibits any exemption that “has the purpose or effect of endorsing, favoring, or promoting religion.” *Id.* at 10. Under both the *Lemon* and endorsement tests, the effect of a religious exemption must be judged from the perspective of a reasonable member of the public. *See Thornton*, 472 U.S. at 711 (O’Connor, J., concurring).

The Religious Exemption Rule serves no valid secular purpose and has the unconstitutional effect of “subject[ing] . . . employees to the religious views of the[ir] employer.” 77 Fed. Reg. 8728. Through the Rule, the Departments have replaced a balanced regulatory system that imposed no “cognizable burden on the . . . exercise of religion,” *see Zubik Br.* at 34-53, with one that gives objecting employers the authority to deny employees’ access to statutorily mandated contraceptive coverage, *see Pennsylvania III*, 2019 WL 3057657, at \*15-\*17. Until the Rule was promulgated, objecting employers were “effectively exempted” from the contraceptive mandate through the Accommodation. *Hobby Lobby*, 573 U.S. at 698. After an employer provided notice of its objection, the government arranged for a third party to provide contraceptive coverage as required by the ACA. *Pennsylvania III*, 2019 WL 3057657, at \*15. Through the Rule, the Departments have given employers the power to decide whether employees can access this third-party coverage.<sup>36</sup> *Id.* Granting employers a religious veto over the activities of employees, health

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<sup>36</sup> Granting employers this type of “veto power” over access to a statutory benefit can alternatively be seen as creating an unconstitutional entanglement with religion in violation of the third prong of the *Lemon* test. *Larkin v. Grendel’s Den, Inc.*, 459 U.S. 116, 125-27 (1982). And doing so without putting clear standards in place to avoid abuse is patently unconstitutional. *Id.* As discussed above, *see supra*, at 8-9, the Rule makes participation in the Accommodation entirely voluntary for objecting employers. The Rule does not require an employer to meet a “substantial burden” standard—or any other objective standard—to use an exemption rather than the Accommodation. *Id.* As a result, an employer could block its employees from participating in the Accommodation simply to deter them from engaging in behavior it sincerely believes is sinful, even though its own religious exercise is not substantially burdened. This Court need not assume that employers will act in this manner to recognize that the scope of the authority delegated by the Rule is impermissible. *Larkin*, 459 U.S. at 125-26.

insurers, and the government does not lift any burden on their religious exercise, *id.*, but instead confers official endorsement on their religious beliefs. *See Lee*, 505 U.S. at 629 (Souter, J., concurring) (“Concern for the position of religious individuals in the modern regulatory State cannot justify official solicitude for religious practice unburdened by general rules.”); *see also Hobby Lobby*, 573 U.S. at 739 (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”); *United States v. Lee*, 455 U.S. 252, 260-61 (1982) (a religious exemption must not “operate to impose the employer’s religious faith on the employee” by denying employee benefits provided by federal law).

More problematic still, this endorsement of employers’ beliefs comes at “the detriment of those who do not share [them].” *Thornton*, 472 U.S. at 711 (O’Connor, J., concurring); *see also 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.”). As discussed, the Rule will impose significant financial costs on employees and other non-beneficiaries and will harm the health and well-being of women and their families. *See supra*, at 33-35. These burdens make manifest the “unyielding weigh[t]” the Departments have given to employers’ religious beliefs. *Thornton*, 472 U.S. at 710. The Rule provides employers an “absolute and unqualified right” to exempt themselves from the contraceptive mandate “no matter what burden or inconvenience this imposes on [employees and others].” *Id.* at 708-10. The Rule does not provide any exceptions, even for “special circumstances,” *id.* at 709—for example, where losing coverage would impose severe health risks

on a woman. *See Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring) (“There are many medical conditions for which pregnancy is contraindicated.”). It simply “commands that . . . religious concerns automatically control over all other secular interests at the workplace.” *Thornton*, 472 U.S. at 709. Religious exemptions that so heavily burden nonbeneficiaries 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 Thornton*, 472 U.S. at 710.

#### **IV. The Final Rules Discriminate Against Women, In Violation of Equal Protection.**

Finally, the Religious and Moral Exemption Rules 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). Congress added the Women’s Health Amendment to the ACA to “ensure that women receive full and equal health coverage appropriate to their medical needs . . . including [for] contraceptive services prescribed . . . by their doctors.” *Zubik* Br. at 5. By creating exemptions specific to the Women’s Health Amendment, the Rules undermine a statutory provision “necessary to protect the health of female employees,” while leaving coverage for male employees untouched. *See Hobby Lobby*, 573 U.S. at 737 (Kennedy, J., concurring). And by selectively empowering employers to use their religious and moral beliefs to limit women’s access to preventive health care—specifically contraception—the Rules unconstitutionally interfere with their ability 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).

As amended by the Women’s Health Amendment, the ACA’s preventive services requirement guarantees that both men and women receive comprehensive coverage for preventive medical services. This does not mean that the ACA guarantees coverage of the same services for everyone. Because their medical needs differ, the ACA requires coverage of some services only for men, and of other services only for women.<sup>37</sup> Contraception is one of the services that is covered only for women. This is not because the ACA confers a special benefit on women, but primarily because women face unique medical risks associated with unintended pregnancies that make contraception a necessary part of comprehensive preventive care for women. *See supra*, at 2-3. The ACA does not require contraceptive coverage for men because they do not face equivalent medical risks.

The Rules insert a gender-based distinction into the preventive services requirement. Under the Rules, men continue to receive comprehensive coverage for preventive services responsive to their medical needs. The Departments, however, have made comprehensive coverage for women contingent on the religious and moral approval of their employers. This is not equal treatment. Because the Rules overtly single out women for disadvantageous treatment, they are presumptively unconstitutional and subject to heightened scrutiny. *See Orr v. Orr*, 440 U.S. 268, 283 (1979) (“Legislative classifications which distribute benefits and burdens on the basis of gender . . . must

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<sup>37</sup> For example, abdominal aortic aneurysm screenings are covered as a preventive service for men only. *See* U.S. Preventive Services Task Force, *A and B Recommendations*, <https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>.

be carefully tailored.”); *see also Morales-Santana*, 137 S. Ct. at 1700-01 (subjecting a “gender-based distinction infecting [immigration law]” to heightened scrutiny);

The Rules 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 Rules are not supported by a general governmental interest in accommodating moral and religious objections to “sensitive” medical procedures and services. 83 Fed. Reg. 57555. Even assuming there was such an interest, it would be better served by an inclusive gender-neutral exemption than by the gender-specific exemption created by the Rules. *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) (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) (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) (explaining that some religious groups object to all

medical care and consider religion to be the “sole means of healing”). The Rules, 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. 83 Fed. Reg. 57555. But it repeatedly declined to include such an exemption in the ACA. *See supra*, at 5, 22. 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 25-35.

Finally, the Departments’ stated desire to “bring a close” to litigation concerning the contraceptive mandate, 83 Fed. Reg. 57545, is not a sufficiently important interest to satisfy heightened scrutiny. *See Shaw v. Hunt*, 517 U.S. 899, 908 n.4 (1996). Moreover, in this case, the Departments’ interest in avoiding litigation “rings hollow,” given that the Rules (and the IFRs before them) have predictably led to additional litigation. *See Cotter v. City of Boston*, 323 F.3d 160, 172 n.10 (1st Cir. 2003).

**V. This Court Should Declare the Religious and Moral Exemption Rules Unlawful and Order that the Rules Be Vacated in Their Entirety.**

Because the Religious and Moral Exemption Rules violate the APA, the ACA, the Establishment Clause, and the equal protection component of the Fifth Amendment, this Court should enter an order that vacates the Rules and declares them unlawful. Under the APA, “vacatur is the normal remedy” for unlawful agency regulations. *Allina Health Servs. v. Sebelius*, 746 F.3d



1102, 1110 (D.C. Cir. 2014). Furthermore, “when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated” in their entirety—“not that their application to the individual petitioners is proscribed.” *Nat’l Mining Ass’n v. U.S. Army Corps of Eng’rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n. 21 (D.C. Cir. 1989)). That rule follows directly from the plain text of the APA, which empowers courts not only to “hold unlawful” but also to “set aside” legally infirm “agency action.” 5 U.S.C. § 706(2). See *Massachusetts ex rel. Div. of Marine Fisheries v. Daley*, 170 F.3d 23, 32 (1st Cir. 1999) (“Where a regulation is not adequately supported, the normal practice is to set it aside pending further proceedings.”). And, as a consequence of vacatur, the invalidated regulations have no effect anywhere in the country, and regulations previously in force are reinstated. See *Council Tree Communications, Inc. v. FCC*, 619 F.3d 235, 258 (3d Cir. 2010) (“vacating or rescinding invalidly promulgated regulations has the effect of reinstating prior regulations” (quoting *Abington Mem. Hosp. v. Heckler*, 750 F.2d 242, 244 (3d Cir. 1984))); *CropLife Am. v. EPA*, 329 F.3d 876, 884-85 (D.C. Cir. 2003) (vacating procedurally deficient agency directive and explaining that the agency’s prior practice “is reinstated and remains in effect unless and until it is replaced by a lawfully promulgated regulation”); see also *New Hampshire Hosp. Ass’n v. Azar*, 887 F.3d 62, 69, 77 (1st Cir. 2018) (affirming district court judgment that permanently enjoined HHS from implementing a procedurally deficient regulation and ordered that prior agency practice be reinstated until it is replaced by a lawfully promulgated regulations).

**CONCLUSION**

For the foregoing reasons, this Court should grant the Commonwealth's motion for summary judgment, declare that the Religious and Moral Exemption Rules are unlawful, vacate the Religious and Moral Exemption Rules, and enter judgment in favor of the Commonwealth.

Respectfully submitted,

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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 July 31, 2019.

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