

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

**MICHIGAN CATHOLIC
CONFERENCE, *et al.***

Plaintiffs,

v.

KATHLEEN SEBELIUS, *et al.*

Defendants.

Case No. 1:13-cv-01247-GJQ

**DEFENDANTS' COMBINED MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION, AND IN SUPPORT OF
MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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INTRODUCTION

Plaintiffs—Michigan Catholic Conference (MCC) and Catholic Family Services d/b/a Catholic Charities Diocese of Kalamazoo (“Catholic Charities”)—ask this Court to enjoin regulations that are intended to accommodate religious exercise while helping to ensure that women have access to health coverage, without cost-sharing, for preventive services that medical experts deem necessary for women’s health and well-being. Subject to an exemption for houses of worship and their integrated auxiliaries, and accommodations for certain other non-profit religious organizations, the regulations that plaintiffs challenge require certain group health plans and health insurance issuers to provide coverage, without cost-sharing (such as a copayment, coinsurance, or a deductible), for, among other things, all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

The regulations are the product of a decision by defendants to attempt to accommodate concerns expressed by some non-profit religious organizations by relieving those with religious objections to contraceptive coverage of any responsibility to contract, arrange, pay, or refer for contraceptive coverage or services. MCC is entirely exempt from the contraceptive coverage requirement. And Catholic Charities is eligible for a regulatory accommodation that relieves it from having to contract, arrange, pay or refer for contraceptive coverage, and that in no way prevents it from continuing to voice its disapproval of contraception or from encouraging its employees to refrain from using contraception. To avail itself of this significant accommodation, Catholic Charities need do nothing more than provide its third-party administrator(s) (TPA(s)) with a copy of a self-certification that it is eligible for the accommodation. Catholic Charities’ TPA has no obligation to provide contraceptive coverage, either. It is hard to fathom how the mere act of requiring Catholic Charities to complete this self-certification could amount to a

“substantial” burden, especially where—as here—the certification requires noting of Catholic Charities’ TPA or anyone else with respect to contraceptive coverage.

Notably, both plaintiffs offer employees health coverage through the MCC Second Amended and Restated Group Health Benefit Plan for Employees (“MCC Plan”), a self-insured “church plan” generally exempt from the Employee Retirement Income Security Act (“ERISA’).” Compl. ¶ 16, ECF No. 1; *see id.* ¶¶ 11, 30-31, 50. While defendants continue to consider potential options to fully and appropriately extend the consumer protections provided by the regulations to self-insured church plans, they acknowledge that, under current law, they lack authority to require the TPAs of self-insured church plans to make the separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation.

For this and several other reasons, plaintiffs’ motion for preliminary injunction should be denied and this case should be dismissed or summary judgment should be granted in favor of the government. At the outset, plaintiffs lack standing to assert their claims. As noted above, because the MCC Plan is a self-insured church plan, the government lacks authority to require any TPA of the MCC Plan to make the separate payments for contraceptive services for participants and beneficiaries in the plan under the accommodation. Because both plaintiffs offer coverage to their employees through the MCC Plan, the injury of which plaintiffs complain—that the regulations somehow require them to facilitate access to contraceptive services to which they object on religious grounds or to contract, arrange, or pay for such services—simply does not apply to plaintiffs here and, as a result, plaintiffs lack standing.

Even if plaintiffs had standing, however, their assertion that these accommodations themselves violate their rights under RFRA, the First Amendment, and the Administrative Procedure Act (APA) would fail. With respect to plaintiffs’ RFRA claim, plaintiffs cannot establish a substantial burden on their religious exercise—as they must— because, as noted

above, the government cannot require any TPA of the MCC Plan to provide separate payments for contraceptive services to the participants and beneficiaries of the MCC Plan. Thus, the regulations impose absolutely no burden on plaintiffs' religious exercise, much less a substantial burden as required under RFRA. Furthermore, even if the government *could* require any TPA of the MCC Plan to make the separate payments, the regulations would not require *plaintiffs* to change their behavior in any significant way. Plaintiffs are not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, plaintiffs are free to continue to refuse to do so, to voice their disapproval of contraception, and to encourage their employees to refrain from using contraceptive services. Plaintiffs contend that the need to self-certify in order to obtain the accommodation is itself a burden on their religious exercise. But the challenged regulations require Catholic Charities only to self-certify that it has a religious objection to providing contraceptive coverage and otherwise meets the criteria for an eligible organization, and to share that self-certification with its TPAs. In other words, Catholic Charities is required only to convey to its TPAs that it is a non-profit religious organization that objects to providing contraceptive services, which it has done or would have to do voluntarily anyway even absent these regulations in order to ensure that it is not responsible for contracting, arranging, paying, or referring for such coverage. Plaintiffs can hardly claim that it is a violation of RFRA to require them to do almost exactly what they would do in the ordinary course, absent the regulations.

Further, plaintiffs' challenge rests largely on the theory that even the extremely attenuated connection between them and the independent and wholly voluntary provision by TPAs of payments for contraceptive services to which they object on religious grounds—but for which plaintiffs pay nothing—amounts to a substantial burden on their religious exercise. This cannot be. Regardless of how plaintiffs frame their religious beliefs, courts must independently consider whether a given law imposes a substantial burden on those beliefs. *See Autocam Corp.*

v. Sebelius, No. 1:12-CV-1096, 2012 WL 6845677, at *6 (W.D. Mich. Dec. 24, 2012), *aff'd*, 730 F.3d 618 (6th Cir. 2013). The regulations impose, at most, only the most *de minimis* burden on plaintiffs' religious exercise, too slight and attenuated to be "substantial" under RFRA, and little different from plaintiffs' payment of salaries to their employees, which those employees can also use to buy contraceptive services if they so choose.

Moreover, even if the challenged regulations were deemed to impose a substantial burden on plaintiffs' religious exercise, the regulations would not violate RFRA because they are narrowly tailored to serve two compelling interests: improving the health of women and newborn children, and equalizing the provision of preventive care for women and men so that women can participate in the workforce, and society more generally, on an equal playing field with men.

Plaintiffs' First Amendment claims are equally meritless. Indeed, nearly every court to consider similar First Amendment challenges to the prior version of the regulations—including Judge Jonker in *Autocam*—rejected the claims, and their analysis applies here. Plaintiffs' APA claims also fail. The regulations are in accordance with federal law, and defendants' interpretation of the regulations is not erroneous.

For these reasons, and those explained below, defendants' motion to dismiss or, in the alternative, for summary judgment should be granted.

BACKGROUND

Before the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), many Americans did not receive the preventive health care they needed. Due largely to cost, Americans used preventive services at about half the recommended rate. *See* INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 19-20, 109 (2011) ("IOM REP."), AR at 317-18, 407.¹ Section 1001 of the ACA seeks to cure this problem

¹ Where appropriate, defendants have provided parallel citations to the Administrative Record (AR), on file with the Court.

by making preventive care accessible and affordable for many more Americans. Specifically, the provision requires all group health plans and health insurance issuers that offer non-grandfathered health coverage to provide coverage for certain preventive services without cost-sharing, including, “[for] women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.” 42 U.S.C. § 300gg-13(a)(4).

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services requested that the Institute of Medicine (IOM) develop recommendations to implement the requirement to provide coverage, without cost-sharing, of preventive services for women. IOM REP. at 2, AR at 300. After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, as relevant here, “the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.” *Id.* at 10-12, AR at 308-10. IOM determined that coverage, without cost-sharing, for these services is necessary to increase access to such services, and thereby reduce unintended pregnancies (and the negative health outcomes that disproportionately accompany them) and promote healthy birth spacing. *Id.* at 102-03, AR at 400-01.

On August 1, 2011, HRSA adopted guidelines consistent with IOM’s recommendations, subject to an exemption relating to certain religious employers authorized by regulations issued that same day (the “2011 amended interim final regulations”). *See* HRSA, Women’s Preventive Services: Required Health Plan Coverage Guidelines (“HRSA Guidelines”), AR at 283-84.² In

² To qualify for the religious employer exemption contained in the 2011 amended interim final regulations, an employer had to meet the following criteria:

- (1) The inculcation of religious values is the purpose of the organization;
- (2) the organization primarily employs persons who share the religious tenets of the organization;
- (3) the organization serves primarily persons who share the religious tenets of the organization; and

(Footnote continued on next page)

February 2012, the government adopted in final regulations the definition of “religious employer” contained in the 2011 amended interim final regulations while also creating a temporary enforcement safe harbor for non-grandfathered group health plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage (and any associated group health insurance coverage). *See* 77 Fed. Reg. 8725, 8726-27 (Feb. 15, 2012), AR at 213-14. The government committed to undertake a new rulemaking during the safe harbor period to adopt new regulations to further accommodate non-grandfathered non-profit religious organizations’ religious objections to covering contraceptive services. *Id.* at 8728, AR at 215. The regulations challenged here (the “2013 final rules”) represent the culmination of that process. *See* 78 Fed. Reg. 39,870 (July 2, 2013), AR at 1-31; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012), AR at 186-93; 78 Fed. Reg. 8456 (Feb. 6, 2013), AR at 165-85.³

The 2013 final rules represent a significant accommodation by the government of the religious objections of certain non-profit religious organizations while promoting two important policy goals. The regulations provide women who work for non-profit religious organizations with access to contraceptive coverage without cost sharing, thereby advancing the government’s compelling interests in safeguarding public health and ensuring that women have equal access to health care. The regulations do so in a narrowly tailored way that does not require non-profit religious organizations with religious objections to contract, arrange, pay, or refer for that coverage.

(4) the organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

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

³ The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, except the amendments to the religious employer exemption apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013. *See* 78 Fed. Reg. at 39,871-72, AR at 3-4.

The 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth. Under the 2013 final rules, a “religious employer” is “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended,” which refers to churches, their integrated auxiliaries, and conventions or associations of churches, and the exclusively religious activities of any religious order. 45 C.F.R. § 147.131(a).

The 2013 final rules also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by “eligible organizations.” 78 Fed. Reg. at 39,875-80, AR at 7-12. An “eligible organization” is an organization that satisfies the following criteria:

- (1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.
- (2) The organization is organized and operates as a nonprofit entity.
- (3) The organization holds itself out as a religious organization.
- (4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies.

45 C.F.R. § 147.131(b); *see also* 78 Fed. Reg. at 39,874-75, AR at 6-7.

Under the 2013 final rules, an eligible organization is not required “to contract, arrange, pay, or refer for contraceptive coverage” to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6. To be relieved of any such obligations, the 2013 final rules require only that an eligible organization complete a self-certification form stating that it is an eligible organization and provide a copy of that self-certification to its issuer or TPA. *Id.* at 39,878-79, AR at 10-11.

In the case of a self-insured group health plan that is not a self-insured church plan, the organization's TPA, upon receipt of the self-certification, must provide or arrange separate payments for contraceptive services for participants and beneficiaries in the plan without cost-sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See id.* at 39,879-80, AR at 11-12. Any costs incurred by the TPA will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See id.* at 39,880, AR at 12. The regulations do not require the TPAs of self-insured church plans—like the MCC Plan—to make separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation. *See* 78 Fed. Reg. at 39,879-80, AR at 11-12; 29 U.S.C. § 1003(b)(2).

STANDARD OF REVIEW

Defendants move to dismiss this case for lack of subject matter jurisdiction and failure to state a claim upon which relief may be granted under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively. The party invoking federal jurisdiction bears the burden of establishing its existence, and the Court must determine whether it has subject matter jurisdiction before addressing the merits of a claim. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95, 104 (1998). Under Rule 12(b)(6), “the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

To the extent that the Court must consider the administrative record in addition to the face of the complaint, defendants move, in the alternative, for summary judgment under Rule 56. A party is entitled to summary judgment where the administrative record demonstrates “that

there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a).

This memorandum also responds to plaintiffs’ motion for preliminary injunction. A preliminary injunction is an “extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Id.* at 20; *Autocam Corp. v. Sebelius*, No. 1:12-cv-1096, 2012 WL 6845677, at *4 (W.D. Mich. Dec. 24, 2012), *aff’d*, 730 F.3d 618 (6th Cir. 2013).⁴

ARGUMENT

I. THIS CASE SHOULD BE DISMISSED BECAUSE THE COURT LACKS SUBJECT MATTER JURISDICTION

Plaintiffs’ motion for preliminary injunction, and their entire case, should be dismissed at the outset for lack of standing. “[T]he irreducible constitutional minimum of standing” requires that a plaintiff (1) have suffered an injury in fact, (2) that is caused by the defendant’s conduct, and (3) that is likely to be redressed by a favorable ruling. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). As to the injury prong, a plaintiff must demonstrate that it has “suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical.” *Id.* at 560 (quotations omitted).

⁴ Plaintiffs’ suggestion that they need not show a likelihood of success on the merits if the Court determines that the remaining factors strongly favor plaintiffs, *see* Pls.’ Mem. of Law in Supp. of Pls.’ Mot. for Prelim. Inj. (“Pls.’ Mem.”) at 12-13, ECF No. 15, is in significant tension with the Supreme Court’s requirement that “[a] plaintiff seeking a preliminary injunction *must* establish that he is *likely* to succeed on the merits,” *Winter*, 555 U.S. at 20 (emphasis added); *Obama for Am. v. Husted*, 697 F.3d 423, 428 (6th Cir. 2012); *Autocam*, 2012 WL 6845677, at *4. Further, where a plaintiff’s alleged harm is a deprivation of RFRA or First Amendment rights, as here, the merits and irreparable harm prongs merge. *See Am. Freedom Def. Initiative v. Suburban Mobility Auth. for Reg’l Transp.*, No. 11-1538, 2012 WL 5258999, at *2 (6th Cir. Oct. 25, 2012). In this respect, plaintiffs cannot show irreparable harm without also showing a likelihood of success on the merits. *See id.*; *McNeilly v. Land*, 684 F.3d 611, 621 (6th Cir. 2012); *Autocam*, 730 F.3d at 624.

Allegations of possible future injury do not suffice; rather, “[a] threatened injury must be certainly impending to constitute injury in fact.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990) (quotation omitted).

The harm alleged by plaintiffs is that, to avail themselves of the accommodations, the challenged regulations require them to engage in actions that “facilitate” and/or make them the “trigger” for the provision of payments for contraceptive services by a third party. *See* Pls.’ Mem. at 9. The MCC Plan, however, is a self-insured “‘church plan’ generally exempt from . . . ERISA.” Compl. ¶ 16. Defendants lack regulatory authority to require the TPAs of such self-insured church plans to make the separate payments for contraceptive services for participants and beneficiaries in such plans under the accommodation.

In general, under the challenged regulations, when a TPA receives a copy of the self-certification from an eligible employer that sponsors a self-insured group health plan, that TPA becomes an ERISA Section 3(16), 29 U.S.C. § 1002(16), plan administrator and claims administrator for the purpose of providing the separate payments for contraceptive services. *See* 29 C.F.R. § 2510.3-16(b). Thus, the contraceptive coverage requirements can be enforced against such TPAs through defendant Department of Labor’s ERISA enforcement authority. *See* 78 Fed. Reg. at 39,879-39,880, AR at 11-12. But church plans are specifically excluded from the ambit of ERISA. *See* 29 U.S.C. § 1003(b)(2). Thus, ERISA enforcement authority is not available with respect to the TPAs of self-insured church plans under the accommodation, and the government cannot compel such TPAs under such authority to provide contraceptive coverage to self-insured church plan participants and beneficiaries under the accommodation, including the plaintiffs’ employees and their covered dependents.

MCC is entirely exempt from the regulations, and Catholic Charities remains eligible for the accommodations under the final regulation promulgated by defendant Department of the

Treasury, 26 C.F.R. § 54.9815-2713A, and therefore need not contract, arrange, pay, or refer for contraceptive coverage.⁵ And neither the MCC Plan nor any TPA of the MCC Plan is required under the regulations to provide separate payments for contraceptive services or to contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the MCC Plan. In short, under the challenged regulations, there is absolutely no connection between plaintiffs and contraceptive coverage. Thus, the injury of which plaintiffs complain—that the regulations somehow require them to facilitate access to contraceptive services to which they object on religious grounds—simply does not apply to plaintiffs here. Because plaintiffs lack standing to assert their claims, this case should be dismissed in its entirety.

II. PLAINTIFFS' CLAIMS LACK MERIT

A. Plaintiffs' Religious Freedom Restoration Act Claim Fails

1. The regulations do not substantially burden plaintiffs' exercise of religion

Under RFRA, Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified at 42 U.S.C. § 2000bb-1 et seq.), the federal government “shall not substantially burden a person’s exercise of religion” unless that burden is the least restrictive means to further a compelling governmental interest. 42 U.S.C. 2000bb-1. Importantly, “only substantial burdens on the exercise of religion trigger the compelling interest requirement.” *Henderson v. Kennedy*, 253 F.3d 12, 17 (D.C. Cir. 2001). “A substantial burden exists when government action puts ‘substantial pressure on an adherent to modify his behavior and to violate his beliefs.’” *Kaemmerling v. Lappin*, 553 F.3d 669, 678 (D.C. Cir. 2008) (citing *Thomas v. Review Bd. of the Ind. Emp’t Sec. Div.*, 450 U.S. 707, 718 (1981)). “An inconsequential or *de minimis* burden on religious practice does not rise to

⁵ The same can be said of any other entity that qualifies as an “eligible organization” under the accommodations, whether or not that organization is a plaintiff in this action.

this level, nor does a burden on activity unimportant to the adherent’s religious scheme.” *Kaemmerling*, 553 F.3d at 678; *see Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) (“In order to show a substantial burden, the plaintiff must show that the challenged action ‘truly pressures the adherent to significantly modify his religious behavior and significantly violate his religious beliefs.’”).

For three reasons, plaintiffs cannot show that the challenged regulations substantially burden their religious exercise. First, as explained above, because the MCC Plan is a self-insured church plan, the challenged regulations do not require the MCC Plan nor its TPAs to provide separate payments for contraceptive services, or to contract or otherwise arrange with a third party for such payments to be made with respect to the participants and beneficiaries of the MCC Plan. The regulations, therefore, impose absolutely no burden on plaintiffs’ religious exercise, let alone a substantial burden. *See supra* Section I.⁶ Second, even assuming the regulations *do* require the MCC Plan or its TPA to provide separate payments for contraceptive services—which the regulations do not⁷—the regulations require virtually nothing of plaintiffs, and certainly do not require plaintiffs to modify their behavior in any meaningful way. Thus, the

⁶ Plaintiffs’ heavy reliance on out-of-circuit cases involving for-profit companies (*Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc), *cert. granted*, No. 13-354; *Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013); and *Gilardi v. HHS*, 733 F.3d 1208 (D.C. Cir. 2013)), as well as the district court ruling in *Zubik v. Sebelius*, 2013 WL 6118696 (W.D. Pa. Nov. 21, 2013), is misplaced. None of those cases involved eligible organizations that offer health coverage through a self-insured church plan, and thus, the courts had no occasion to address the arguments defendants raise here. Furthermore, those out-of-circuit for-profit company cases—which conflict with the Sixth Circuit’s *Autocam* decision—are inapposite because for-profit corporations—unlike plaintiffs—do *not* qualify for the religious employer exemption or the accommodations for eligible organizations. *See* 78 Fed. Reg. at 39,875, AR at 7. Thus, for example, the regulations require for-profit companies to contract or otherwise arrange and pay for contraceptive coverage for the participants and beneficiaries of their group health plans. Plaintiffs, by contrast, are in a markedly different position. As previously explained, MCC is exempt, and in order to be relieved of the obligation to contract or otherwise arrange and pay for contraceptive coverage, Catholic Charities must only fulfill the self-certification requirement. Similarly, the district court in *Zubik* was wrong to rely on those for-profit company cases. The *Zubik* court’s conclusion that the regulations at issue in that case (and in this one) impose a substantial burden on the plaintiffs in that case—which was rendered without citation to any legal authority, *id.* at *24-27—is unpersuasive.

⁷ Defendants will make this assumption in the remainder of their RFRA argument because plaintiffs’ claims fail regardless of whether the challenged regulations require anything of their third-party TPAs.

regulations cannot be deemed to impose any more than a *de minimis* burden on plaintiffs—let alone a substantial one. Third, even if this Court finds that the regulations impose some burden on plaintiffs’ religious exercise, any such burden would be far too attenuated to be substantial.

a. The regulations impose no more than a de minimis burden on plaintiffs’ exercise of religion because the regulations require virtually nothing of plaintiffs

To put this case in its simplest terms, plaintiffs challenge regulations that require them to do next to nothing, except what they would have to do even in the absence of the regulations. MCC is entirely exempt from the contraceptive coverage requirement.⁸ And Catholic Charities, as an eligible organization, is not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, Catholic Charities is free to continue to refuse to do so, to voice its disapproval of contraception, and to encourage its employees to refrain from using contraceptive services. Catholic Charities need only fulfill the self-certification requirement and provide the completed self-certification to its TPA(s). Catholic Charities need not pay for contraceptive services to their employees. Instead, third parties—plaintiff’s TPA(s)—provide payments for contraceptive services, at no cost to plaintiff. In short, with respect to contraceptive coverage, the non-exempt plaintiff, Catholic Charities, need not do anything more than it did prior to the promulgation of the challenged regulations—that is, to inform its TPA(s) that it objects to providing contraceptive coverage in order to ensure that it is not responsible for contracting, arranging, paying, or referring for such coverage. Thus, the regulations do not require plaintiffs “to modify [their] religious behavior in any way.” *Kaemmerling*, 553 F.3d at 679. The Court’s inquiry should end here. A law cannot be a substantial burden on religious exercise when “it involves no action or forbearance on [plaintiffs’] part, nor . . . otherwise interfere[s] with any

⁸ Plaintiffs repeatedly suggest, without support, that the religious employer exemption adopted in the 2013 final rules is narrower than that contemplated in the ANPRM. *See, e.g.*, Compl. ¶ 15. This contention is not only false, 78 Fed. Reg. at 39,886, AR at 18, but irrelevant: Even if the scope of the exemption in the final rules were different from what was set forth in the ANPRM—which it is not—plaintiffs have not indicated why that would be improper. In fact, it is the very purpose of the rulemaking process to subject a proposal to public comment and potentially alter the proposal accordingly. *See, e.g., Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004).

religious act in which [plaintiffs] engage[.]” *Id.*; see also *Civil Liberties for Urban Believers v. City of Chi.*, 342 F.3d 752, 761 (7th Cir. 2003) (holding, in the context of RLUIPA, that “a substantial burden on religious exercise is one that necessarily bears direct, primary, and fundamental responsibility for rendering religious exercise . . . effectively impracticable”).

Because the regulations place no burden *at all* on plaintiffs, they plainly place no cognizable burden on their religious exercise. Plaintiffs’ contrary argument rests on an unprecedented and sweeping theory of what it means for religious exercise to be burdened. Not only do plaintiffs want to be free from contracting, arranging, paying, or referring for contraceptive services for their employees—which, under these regulations, they are—but plaintiffs would also prevent *anyone else* from providing such coverage to their employees, who might not subscribe to plaintiffs’ religious beliefs. That this is the *de facto* impact of plaintiffs’ stated objections is made clear by their suggestion that RFRA is violated whenever they are a “but-for cause” of the provision of the objectionable products and services. See, e.g., Compl. ¶ 30. This theory would mean, for example, that even the government would not realistically be able to provide contraceptive coverage to plaintiffs’ employees (as plaintiffs elsewhere suggest), because it would be “trigger[ed],” *id.*; Pls.’ Mem. at 9, by plaintiffs’ refusal to provide such coverage themselves. But RFRA is a shield, not a sword, see *O’Brien v. U.S. Dep’t of Health & Human Servs.*, 894 F. Supp. 2d 1149, 1158-60 (E.D. Mo. 2012), *appeal pending*, No. 12-3357 (8th Cir.), and accordingly it does not prevent the government from providing alternative means of achieving important statutory objectives once it has provided a religious accommodation. *Cf. Bowen v. Roy*, 476 U.S. 693, 699 (1986) (“The Free Exercise Clause simply cannot be understood to require the Government to conduct its own internal affairs in ways that comport with the religious beliefs of particular citizens.”).

Plaintiffs’ RFRA challenge is similar to the claim that the D.C. Circuit rejected in *Kaemmerling*. There, a federal prisoner objected to the FBI’s collection of his DNA profile. 553 F.3d at 678. In concluding that this collection did not substantially burden the prisoner’s religious exercise, the court concluded that “[t]he extraction and storage of DNA information are

entirely activities of the FBI, in which Kaemmerling plays no role and which occur after the BOP has taken his fluid or tissue sample (to which he does not object).” *Id.* at 679. In the court’s view, “[a]lthough the government’s activities with his fluid or tissue sample after the BOP takes it may offend Kaemmerling’s religious beliefs, they cannot be said to hamper his religious exercise because they do not pressure [him] to modify his behavior and to violate his beliefs.” *Id.* (internal citation and quotation marks omitted). The same is true here, where the provision of contraceptive services is “entirely [an] activit[y] of [a third party], in which [plaintiffs] play[] no role.” *Id.* As in *Kaemmerling*, “[a]lthough the [third party]’s activities . . . may offend [plaintiffs’] religious beliefs, they cannot be said to hamper [their] religious exercise.” *Id.*

Perhaps understanding the tenuous ground on which their RFRA claim rests, given that the regulations do not require them to contract, arrange, pay, or refer for contraceptive services, plaintiffs attempt to circumvent this problem by advancing the novel theory that the regulations require them to somehow “facilitate access” to contraceptive coverage, and that it is this “facilitation” that violates plaintiffs’ religious beliefs. *See, e.g.*, Compl. ¶¶ 8, 152; Pls.’ Mem at 11. But the challenged regulations do not require MCC to do anything, and require Catholic Charities *only* to self-certify that it objects to providing coverage for contraceptive services and that it otherwise meets the criteria for an eligible organization, and to share that self-certification with its TPA(s). In other words, Catholic Charities is required to inform its TPA(s) that it objects to providing contraceptive coverage, which it has done or would have to do voluntarily anyway even absent these regulations in order to ensure that it is not responsible for contracting, arranging, paying, or referring for contraceptive coverage. The sole difference is that it must inform its TPA(s) that its objection is for religious reasons—a statement it has already made repeatedly in this litigation and elsewhere.

Furthermore, any burden imposed by the purely administrative self-certification requirement—which should take Catholic Charities a matter of minutes—is, at most, *de minimis*, and thus cannot be “substantial” under RFRA. The Sixth Circuit and other courts have made clear that the substantial burden hurdle is a high one. *Living Water Church of God v. Charter*

Twp. of Meridian, 258 F. App'x 729, 734 (6th Cir. 2007); *Autocam*, 2012 WL 6845677, at *6 (“[A] ‘substantial burden’ is a difficult threshold to cross,” and Plaintiffs are unlikely to cross it.” (quoting *Living Water Church of God*, 258 F. App'x at 736)); see also *Kaemmerling*, 553 F.3d at 678 (“An inconsequential or *de minimis* burden on religious practice does not rise to this level [of a substantial burden.]”); *Washington v. Klem*, 497 F.3d 272, 279-81 (3d Cir. 2007); *McEachin v. McGuinnis*, 357 F.3d 197, 203 n.6 (2d Cir. 2004); *Civil Liberties for Urban Believers*, 342 F.3d at 761. Indeed, if this is not a *de minimis* burden, it is hard to see what would be. In fact, plaintiffs’ alternative proposals only confirm that the alleged “burden” of self-certification is *de minimis*. They contend that, as an alternative to the accommodations developed by the Departments, the government should somehow expand or create other public programs so as to provide contraceptive coverage to the women who participate in their group health plans. RFRA plainly does not require defendants to expand or create government programs, particularly where, as here, there is no statutory authority to do so. See *infra* Section II.A.2.b. But, in any event, plaintiffs’ own proposals would entail the same putative “burden” as the existing accommodations, or an even greater burden: One way or another, plaintiffs would have to certify their eligibility for an accommodation, and the result would be that the women who participate in their plan would get contraceptive coverage through another source such as Medicaid. The government would of course, as it does with Medicaid, have to verify employment and/or dependent beneficiary status with the eligible organization. The current accommodations are thus likely to require less of plaintiffs’ involvement than would a government program to separately provide contraceptive coverage for their employees and dependents.

Contrary to plaintiffs’ suggestion, the mere fact that Catholic Charities claims that the self-certification requirement imposes a substantial burden on its religious exercise by requiring it to “facilitate” access to contraception does not make it so. See *Conestoga Wood Specialties Corp. v. Sebelius*, 917 F. Supp. 2d 394, 413 (E.D. Pa. 2013) (“[W]e reject the notion . . . that a plaintiff shows a burden to be substantial simply by claiming that it is.”), *aff’d*, 724 F.3d 377 (3d Cir. 2013). Under RFRA, plaintiffs are entitled to their sincere religious beliefs, but they are not

entitled to decide what does and does not impose a substantial burden on such beliefs. Although “[c]ourts are not arbiters of scriptural interpretation,” *Thomas*, 450 U.S. at 716, “RFRA still requires the court to determine whether the burden a law imposes on a plaintiff’s stated religious belief is ‘substantial,’” *Conestoga*, 917 F. Supp. 2d at 413. Plaintiffs would limit the Court’s inquiry to two prongs: first, whether plaintiffs’ religious objections to the regulations are sincere, and second, whether the regulations apply significant pressure to plaintiffs to comply. But plaintiffs ignore a critical third criterion of the “substantial burden” test, which gives meaning to the term “substantial”: whether the challenged regulations actually require plaintiffs to modify their behavior in a significant—or more than *de minimis*—way. See *Living Water Church of God*, 258 Fed. App’x at 734-36; see also, e.g., *Vision Church v. Vill. of Long Grove*, 468 F.3d 975, 997 (7th Cir. 2006) (noting, in the RLUIPA context, that “the Supreme Court has found a ‘substantial burden’ to exist when the government puts ‘substantial pressure on an adherent to modify his behavior and to violate his beliefs’” (quoting *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 141 (1987))) (emphasis added); *Westchester Day Sch. v. Vill. of Mamaroneck*, 504 F.3d 338, 348-49 (2d Cir. 2007); *Church of Scientology of Ga., Inc. v. City of Sandy Springs, Ga.*, 843 F. Supp. 2d 1328, 1353-54 (N.D. Ga. 2012). As plaintiffs themselves appear to recognize, a “law ‘substantially burdens’ an exercise of religion if it compels one “to perform acts undeniably at odds with fundamental tenets of [one’s] religious beliefs,” Pls.’ Mem. at 23 (quoting *Wisconsin v. Yoder*, 406 U.S. 205, 218 (1972)) (emphasis added), “or ‘put[s] substantial pressure on an adherent to modify his behavior and violate his beliefs.’” *Id.* (quoting *Thomas*, 450 U.S. at 717-18) (emphasis added). This test does not require the Court to delve into the theological merits of a belief, but instead to examine the operation of the regulations and their impact on plaintiffs’ religious practice. See *Autocam*, 2012 WL 6845677 at *7-8.⁹

⁹ In *Hobby Lobby*, a bare majority of the en banc Tenth Circuit concluded that, in determining whether a burden is substantial, a court’s “only task is to determine whether the claimant’s belief is sincere, and if so, whether the government has applied substantial pressure on the claimant to violate that belief.” 723 F.3d at 1137. The government believes that the majority’s ruling in *Hobby Lobby* was wrong on this and many other points. However, even if this Court were inclined to agree with the Tenth Circuit, the majority proceeded to rely on *Abdulhaseeb v. Calbone*, 600 F.3d 1301 (10th Cir. 2010), which makes clear that in order for a law to impose a substantial burden, it

(Footnote continued on next page)

Under plaintiffs' alternative interpretation of RFRA, courts would play virtually no role in determining whether an alleged burden is "substantial"—as long as a plaintiff's religious belief is sincere, that would be the end of the inquiry. Plaintiffs would thus be allowed to evade RFRA's threshold by simply asserting that the burden on their religious exercise is "substantial," thereby paradoxically reading the term "substantial" out of RFRA. *See id.* at *6 ("The Court does not doubt the sincerity of Plaintiff Kennedy's decision to draw the line he does, but the Court still has a duty to assess whether the claimed burden—no matter how sincerely felt—really amounts to a substantial burden on a person's exercise of religion."). "If every plaintiff were permitted to unilaterally determine that a law burdened their religious beliefs, and courts were required to assume that such burden was substantial, simply because the plaintiff claimed that it was the case, then the standard expressed by Congress under the RFRA would convert to an 'any burden' standard." *Conestoga*, 917 F. Supp. 2d at 413-14; *see also Autocam*, 2012 WL 6845677, at *7; *Mersino Mgmt. Co. v. Sebelius*, No. 13-CV-11296, 2013 WL 3546702, at *16 (E.D. Mich. July 11, 2013).¹⁰ The result would be to subject every act of Congress to strict scrutiny every time a plaintiff could articulate a sincerely held religious objection to compliance with that law.

Finally, plaintiffs seem to suggest that the regulations will actually require them to fund or subsidize access to contraceptive coverage because their issuers will find a way to pass on the costs of such coverage to plaintiffs. *See, e.g.,* Pls.' Mem. at 22. But the regulations specifically prohibit plaintiffs' TPA(s) from charging any premium or otherwise passing on any costs to plaintiffs with respect to the issuers' payments for contraceptive services. *See* 78 Fed. Reg. at

must require some actual change in religious behavior—either forced participation in conduct or forced abstention from conduct. *See Hobby Lobby*, 723 F.3d at 1138 (citing *Abdulhaseeb*, 600 F.3d at 1315). The *Hobby Lobby* substantial burden analysis is also inapposite because for-profit corporations are not eligible for the accommodations. For similar reasons, the Seventh Circuit's substantial burden analysis in *Korte*—which followed *Hobby Lobby*—is unpersuasive. *See Korte*, 735 F.3d at 687.

¹⁰ RFRA's legislative history makes clear that Congress did not intend such a relaxed standard. The initial version of RFRA prohibited the government from imposing *any* "burden" on free exercise, substantial or otherwise. Congress amended the bill to add the word "substantially," "to make it clear that the compelling interest standards set forth in the act" apply "only to Government actions [that] place a substantial burden on the exercise of" religious liberty. 139 Cong. Rec. S14350-01, S14352 (daily ed. Oct. 26, 1993) (statement of Sen. Kennedy); *see also id.* (text of Amendment No. 1082).

39,880, AR at 12. Any suggestion that plaintiffs' TPA(s) will violate the law is purely speculative, and boils down to the baseless argument that the regulations impose a substantial burden because a third party might violate those same regulations. This contention has no merit.

In sum, the regulations do not impose a substantial burden on plaintiffs' religious exercise, and thus Count I should be dismissed or summary judgment granted to defendants.

b. Even if the regulations were found to impose some more than de minimis burden on plaintiffs' exercise of religion, any such burden would be far too attenuated to be "substantial" under RFRA

Although the regulations do not require plaintiffs to contract, arrange, pay, or refer for contraceptive coverage, plaintiffs' complaint appears to be that the regulations require plaintiffs to indirectly facilitate conduct on the part of their employees that they find objectionable (*i.e.*, the use of certain contraceptives). But this complaint has no limits. An employer provides numerous benefits, including a salary and other fringe benefits, to its employees and by doing so in some sense facilitates whatever use its employees make of those benefits. Plaintiffs not only seek to be free from the requirement to contract, arrange, pay, or refer for contraceptive coverage themselves—which they are under these regulations—but also seek to prevent anyone else from providing such coverage to their employees. But an employer has no right to control the choices of its employees, who may not share its religious beliefs, and who have a legitimate interest in access to the preventive services coverage made available under the challenged regulations.

Indeed, courts—including in this district—have held that claims raised by for-profit companies challenging the contraceptive coverage regulations, which—unlike here—actually require employers to contract, arrange, pay, or refer for the relevant coverage *themselves*, are too attenuated to amount to a substantial burden under RFRA. *See, e.g., Autocam*, 2012 WL 6845677, at *6-7. Any burden on plaintiffs, which are eligible for the religious employer exemption or the accommodations, is *a fortiori* too attenuated to be substantial. For example, the district court in *Conestoga* reasoned that the ultimate decision of whether to use contraception “rests not with [the employer], but with [the] employees” and that “any burden imposed by the

regulations is too attenuated to be considered substantial.” 917 F. Supp. 2d at 414-15. The *Conestoga* court further explained that the indirect nature of any burden imposed by the regulations distinguished them from the statutes challenged in *Yoder*, *Sherbert*, *Thomas*, and *Gonzales*. See *Conestoga*, 917 F. Supp. 2d at 415; see also, e.g., *Autocam*, 2012 WL 6845677, at *6; *O’Brien*, 894 F. Supp. 2d at 1158-60.¹¹

As these courts concluded, the preventive services coverage regulations result in only an indirect impact on for-profit companies, which must provide contraceptive coverage themselves. Any burden on plaintiffs and similar eligible organizations that qualify for the accommodations is even more attenuated. Not only are plaintiffs separated from the use of contraception by “[a] series of events” that must occur before the use of contraceptive services to which plaintiffs object would “come into play,” *Conestoga*, 917 F. Supp. 2d at 414-15, but they are also further insulated by the fact that a third party—plaintiffs’ TPA(s)—and *not* plaintiffs, will actually contract, arrange, pay, and refer for such services, and thus plaintiffs are in no way subsidizing—even indirectly—the use of preventive services that they find objectionable. Under plaintiffs’ theory, their religious exercise is substantially burdened when one of their employees and her health care provider make an independent determination that the use of certain contraceptive services is appropriate, and such services are paid for exclusively by plaintiffs’ issuers, with none of the cost being passed on to plaintiffs, and no administration of the payments by plaintiffs, solely because plaintiffs self-certified that they have religious objections to providing contraceptive coverage and so informed their issuers.

But a burden cannot be “substantial” under RFRA when it is attenuated. See *Autocam*, 2012 WL 6845677, at *6-7. Cases that find a substantial burden uniformly involve a direct burden on the plaintiff rather than a burden imposed on another entity. See, e.g., *Potter v. Dist. of Columbia*, 558 F.3d 542, 546 (D.C. Cir. 2009); see also *Conestoga*, 917 F. Supp. 2d at 413-14. A

¹¹ See also *Korte*, 735 F.3d at 705-15 (Rovner, J., dissenting); *Eden Foods*, 2013 WL 1190001; *Annex Medical, Inc. v. Sebelius*, No. 12–2804, 2013 WL 101927, *4-5 (D. Minn. Jan. 8, 2013).

plaintiff cannot establish a substantial burden on his religious exercise by invoking this type of trickle-down theory; to constitute a substantial burden under RFRA, the burden must be imposed on the plaintiff himself. *See Conestoga*, 917 F. Supp. 2d at 411, 413; *Autocam*, 2012 WL 6845677, at *7.¹² Here, of course, there is no such direct burden. In fact, given that any payment for contraceptive services is made by plaintiffs' issuers, the regulations have even less impact on plaintiffs' religious exercise than plaintiffs' payment of salaries to their employees, which those employees can use to purchase contraceptives. *See O'Brien*, 894 F. Supp. 2d at 1160; *Conestoga*, 917 F. Supp. 2d at 414; *Korte*, 735 F.3d at 715-16 (Rovner, J., dissenting); *Autocam*, 2012 WL 6845677, at *6.

Plaintiffs remain free to refuse to contract, arrange, pay, or refer for contraceptive coverage; to voice their disapproval of contraception; and to encourage their employees to refrain from using contraceptive services. The regulations therefore affect plaintiffs' religious practice, if at all, in a most attenuated way. In short, because the preventive services coverage regulations "are several degrees removed from imposing a substantial burden on [plaintiffs]," *O'Brien*, 894 F. Supp. 2d at 1160, the Court should dismiss plaintiffs' RFRA claim, or grant summary judgment to defendants, even if it finds—contrary to the government's argument—that the challenged regulations impose some burden on plaintiffs' religious exercise.

2. Even if there were a substantial burden on religious exercise, the regulations serve compelling governmental interests and are the least restrictive means to achieve those interests

¹² *Thomas* is not to the contrary. In *Thomas*, the Supreme Court recognized that "a *compulsion* may certainly be indirect and still constitute a substantial burden, such as the denial of a benefit found in *Thomas*." *Conestoga*, 917 F. Supp. 2d at 415 n.15. But that is not so where the *burden* itself is indirect, as it is here. *See id.* As previously explained, *see supra* note 9, in *Hobby Lobby*, 723 F.3d 1114, a bare majority of the en banc Tenth Circuit concluded that the word "substantial" in RFRA refers to the "intensity of coercion" rather than to the directness or indirectness of the burden, if any, on a plaintiff's religious exercise. *Id.* at 1137-40. The Tenth Circuit's conclusion that the substantial burden requirement relates to the intensity of the coercion, however, is inconsistent with *Kaemmerling*, discussed above, as well as other decisions that have analyzed "substantial burden" in terms of the degree to which the challenged law directly imposes a requirement or prohibition on religious practice. *See* 553 F.3d at 678-79; *Living Water Church of God*, 258 Fed. App'x at 734; *McEachin*, 357 F.3d at 203 n.6; *Civil Liberties for Urban Believers*, 342 F.3d at 761. And, again, the substantial burden analysis in *Hobby Lobby* and *Korte* are inapplicable to this case. *See supra* notes 7 & 9.

a. The regulations significantly advance compelling governmental interests in public health and gender equality

Even if plaintiffs were able to demonstrate a substantial burden on their religious exercise, they would not prevail because the challenged regulations are justified by two compelling interests, and are the least restrictive means to achieve those interests. First, the promotion of public health is unquestionably a compelling interest. *Mead v. Holder*, 766 F. Supp. 2d 16, 43 (D.D.C. 2011); *see also, e.g., Buchwald v. Univ. of N.M. Sch. of Med.*, 159 F.3d 487, 498 (10th Cir. 1998); *Dickerson v. Stuart*, 877 F. Supp. 1556, 1559 (M.D. Fla. 1995). And the challenged regulations further this compelling interest by “expanding access to and utilization of recommended preventive services for women.” 78 Fed. Reg. at 39,887, AR at 19.

The primary predicted benefit of the preventive services coverage regulations is that “individuals will experience improved health as a result of reduced transmission, prevention or delayed onset, and earlier treatment of disease.” 75 Fed. Reg. 41,726, 41,733 (July 19, 2010), AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19. “By expanding coverage and eliminating cost sharing for recommended preventive services, [the regulations are] expected to increase access to and utilization of these services, which are not used at optimal levels today.” 75 Fed. Reg. at 41,733, AR at 233; *see also* 78 Fed. Reg. at 39,873 (“Research [] shows that cost sharing can be a significant barrier to access to contraception.” (citation omitted)), AR at 5.

Increased access to FDA-approved contraceptive services is a key part of these predicted health outcomes, as unintended pregnancies have proven in many cases to have negative health consequences for women and developing fetuses. *See* 78 Fed. Reg. at 39,872, AR at 4. As IOM concluded in identifying services recommended to “prevent conditions harmful to women’s health and well-being,” unintended pregnancy may delay “entry into prenatal care,” prolong “behaviors that present risks for the developing fetus,” and cause “depression, anxiety, or other conditions.” IOM REP. at 20, 103-04, AR at 318, 401-02. Contraceptive coverage further helps to avoid “the increased risk of adverse pregnancy outcomes for pregnancies that are too closely

spaced.” *Id.* at 103, AR at 401; *see also* 78 Fed. Reg. at 39,872 (“Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-gestational age births.”) (citing studies), AR at 4. And “[c]ontraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne).” 78 Fed. Reg. at 39,872, AR at 4; *see also* IOM REP. at 103-04 (“[P]regnancy may be contraindicated for women with serious medical conditions such as pulmonary hypertension . . . and cyanotic heart disease, and for women with the Marfan Syndrome.”), AR at 401-02.

Closely tied to this interest is a related, but separate, compelling interest that is furthered by the regulations: assuring that women have equal access to health care services. 78 Fed. Reg. at 39,872, 39,887, AR at 4, 19. As the Supreme Court explained in *Roberts v. U.S. Jaycees*, 468 U.S. 609 (1984), there is a fundamental “importance, both to the individual and to society, of removing the barriers to economic advancement and political and social integration that have historically plagued certain disadvantaged groups, including women.” *Id.* at 626. Thus, “[a]ssuring women equal access to . . . goods, privileges, and advantages clearly furthers compelling state interests.” *Id.* By including in the ACA preventive health services for women, Congress made clear that the goals and benefits of effective preventive health care apply equally to women, who might otherwise be excluded from such benefits if their unique health care needs were not taken into account in the ACA. As explained by members of Congress, “women have different health needs than men, and these needs often generate additional costs. Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men.” 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009) (statement of Sen. Mikulski); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 19, AR at 317. These costs result in women often forgoing preventive care and place women in the workforce at a disadvantage compared to their male coworkers. *See, e.g.*, 155 Cong. Rec. S12265-02, S12274 (daily ed. Dec. 3, 2009); 78 Fed. Reg. at 39,887, AR at 19; IOM REP. at 20, AR at 318. Congress’s attempt to equalize the provision of

preventive health care services, with the resulting benefit of women being able to contribute to the same degree as men as healthy and productive members of society, furthers a compelling governmental interest. *Cf. Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 92-93 (Cal. 2004).¹³

Although the challenged regulations further these two compelling governmental interests, while simultaneously accommodating the religious objections of eligible organizations, plaintiffs maintain that the interests underlying the regulations cannot be considered compelling when millions of people are not protected by the regulations at the moment. Pls.' Mem. at 27. But this is not a case where underinclusive enforcement of a law suggests that the government's "supposedly vital interest" is not really compelling. *Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546-47 (1993). For the most part, the "exemptions" referred to by plaintiffs are not exemptions from the preventive services coverage regulations at all, but are instead provisions of the ACA that exclude individuals and entities from other requirements imposed by the ACA. Or they reflect the government's attempts to balance the compelling

¹³ In arguing that the government's interests are not compelling, plaintiffs suggest the government must separately analyze the impact of and need for the regulations as to each and every employer and employee in America. *See* Pls.' Mem. at 26. But this level of specificity would be impossible to establish and would render this regulatory scheme—and potentially every regulatory scheme challenged due to religious objections—completely unworkable. *See United States v. Lee*, 455 U.S. 252, 259-60 (1982). In practice, courts have not required the government to analyze the impact of a regulation on the single entity seeking an exemption, but have conducted the inquiry with respect to all similarly situated individuals or organizations. *See, e.g., id.* at 260 (considering the impact on the tax system if all religious adherents—not just the plaintiff—could opt out); *United States v. Oliver*, 255 F.3d 588, 589 (8th Cir. 2001) (per curiam) ("Oliver has argued a one-man exemption should be made, however, there is nothing so peculiar or special with Oliver's situation which warrants an exception. There are no safeguards to prevent similarly situated individuals from asserting the same privilege and leading to uncontrolled eagle harvesting."); *Dole v. Shenandoah Baptist Church*, 899 F.2d 1389, 1398 (4th Cir. 1990) ("There is no principled way of exempting the school without exempting all other sectarian schools and thereby the thousands of lay teachers and staff members on their payrolls."); *see also, e.g., Graham v. Comm'r*, 822 F.2d 844, 853 (9th Cir. 1987), *overruled in part on other grounds by Navajo Nation v. U.S. Forest Serv.*, 479 F.3d 1024, 1033 (9th Cir. 2007) (en banc); *United States v. Winddancer*, 435 F. Supp. 2d 687, 697 (M.D. Tenn. 2006). *Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 435 (2006), is not to the contrary. To be sure, the Court rejected "slippery-slope" arguments for refusing to accommodate a particular claimant. *See* 546 U.S. at 435-36. But it construed the scope of the requested exemption as encompassing all members of the plaintiff religious sect. *See id.* at 433. Similarly, the exemption in *Yoder*, 406 U.S. 205, encompassed *all* Amish children; and the exemption in *Sherbert v. Verner*, 374 U.S. 398 (1963), encompassed *all* individuals who had a religious objection to working on Saturdays. *See O Centro*, 546 U.S. at 431. The Court's warning in *O Centro* against "slippery-slope" arguments was a rejection of arguments by analogy—that is, speculation that providing an exemption to one group will lead to exemptions for other *non*-similarly situated groups. It was not an invitation to ignore the reality that an exemption for a particular claimant might necessarily lead to an exemption for an entire category of similarly situated entities.

interests underlying the challenged regulations against other significant interests supporting the complex administrative scheme created by the ACA. *See Lee*, 455 U.S. at 259 (“The Court has long recognized that balance must be struck between the values of the comprehensive social security system, which rests on a complex of actuarial factors, and the consequences of allowing religiously based exemptions.”); *Winddancer*, 435 F. Supp. 2d at 695-98 (recognizing that the regulations governing access to eagle parts “strike a delicate balance” between competing interests). And, unlike the exemption plaintiffs seek for employers that object to the regulations on religious grounds, the existing exceptions do not undermine the government’s interests in a significant way. *See Lukumi*, 508 U.S. at 547; *S. Ridge Baptist Church v. Indus. Comm’n of Ohio*, 911 F.2d 1203, 1208-09 (6th Cir. 1990); *see also* 78 Fed. Reg. at 39,887, AR at 19.

For example, the grandfathering of certain health plans with respect to certain ACA provisions is not limited to the preventive services coverage regulations. *See* 42 U.S.C. § 18011; 45 C.F.R. § 147.140. In fact, the effect of grandfathering is not really a permanent “exemption,” but rather, over the long term, a transition in the marketplace with respect to several provisions of the ACA, including the preventive services coverage provision. *See* 78 Fed. Reg. at 39,887 n.49, AR at 19. The grandfathering provision reflects Congress’s attempts to balance competing interests—specifically, the interest in spreading the benefits of the ACA, including those provided by the preventive services coverage provision, and the interest in maintaining existing coverage and easing the transition into the new regulatory regime established by the ACA—in the context of a complex statutory scheme. *See* 75 Fed. Reg. 34,538, 34,546 (June 17, 2010).

This incremental transition does not call into question the compelling interests furthered by the preventive services coverage regulations. Even under the grandfathering provision, it is projected that more group health plans will transition to the requirements under the regulations over time. Defendants have estimated that a majority of group health plans will have lost their grandfather status by the end of 2013. *See id.* at 34,552; *see also* Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits 2012 Annual Survey* at 7-8, 190, AR at 663-64, 846. Thus, any purported adverse effect on the compelling interests

underlying the regulations will be quickly mitigated, which is in stark contrast to the *permanent* exemption plaintiffs seek. Plaintiffs would have this Court believe that an interest cannot truly be “compelling” unless Congress is willing to impose it on everyone all at once despite competing interests, but plaintiffs offer no support for that untenable proposition. *See Legatus v. Sebelius*, 901 F. Supp. 2d 980, 994 (E.D. Mich. 2012) (“[T]he grandfathering rule seems to be a reasonable plan for instituting an incredibly complex health care law while balancing competing interests.”).¹⁴

The only true exemption from the preventive services coverage regulations is the exemption for the group health plans of religious employers. 45 C.F.R. § 147.131(a). But there is a rational distinction between this narrow exception and the expansion plaintiffs seek. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers, including organizations eligible for the accommodations, to employ people of the same faith who share the same objection, and who would therefore be less likely to use contraceptive services even if such services were covered under their plan. *See* 78 Fed. Reg. at 39,874, 39,887, AR at 6, 19. In any event, it would be perverse to hold that the government’s provision of a limited religious exemption eliminates its compelling interest in the regulation, thus effectively extending the same exemption to anyone else who wants it under RFRA. Such a reading of RFRA would *discourage* the government from accommodating religion, the opposite of what Congress intended in enacting RFRA.

Granting plaintiffs the much broader exemption they request would undermine defendants’ ability to enforce the regulations in a rational manner. *See O Centro*, 546 U.S. at 435. We are a “cosmopolitan nation made up of people of almost every conceivable religious preference,” *Braunfeld v. Brown*, 366 U.S. 599, 606 (1961); *see also S. Ridge Baptist Church*,

¹⁴ Plaintiffs also allude to a “small-employer exemption[.]” Pls.’ Mem. at 27. But 26 U.S.C. § 4980H(c)(2) does *not*, as plaintiffs suggest, exempt small employers from the challenged regulations. Small businesses that elect to offer non-grandfathered health coverage to their employees are required to provide coverage for recommended preventive health services without cost sharing. *See* 42 U.S.C. § 300gg-13. And, small employers have business incentives to offer health coverage to their employees; an otherwise eligible small employer would lose eligibility for certain tax benefits if it did not do so. *See* 26 U.S.C. § 45R.

911 F.2d at 1211, and many people object to various medical services. If any organization with a religious objection were able to claim an exemption from the operation of the preventive services coverage regulations—even where the regulations require virtually nothing of the organization—it is difficult to see how defendants could administer the regulations in a manner that would achieve Congress’s goals of improving the health of women and newborn children and equalizing the coverage of preventive services for women. *See United States v. Israel*, 317 F.3d 768, 772 (7th Cir. 2003) (recognizing that granting plaintiff’s RFRA claim “would lead to significant administrative problems for the [government] and open the door to a . . . proliferation of claims”). Indeed, women who receive their health coverage through employers like plaintiffs would face negative health and other outcomes because they had obtained employment with an organization that objects to its employees’ use of contraceptive services, even when those services are paid for and administered by a third party. *See id.* (noting consequences “for the public and the government”); 77 Fed. Reg. at 8728, AR at 215; 78 Fed. Reg. at 39,887, AR at 19.

b. The regulations are the least restrictive means of advancing the government’s compelling interests

When determining whether a particular regulatory scheme is the “least restrictive,” the appropriate inquiry is whether the individual or organization with religious objections, and those similarly situated, can be exempted from the scheme—or whether the scheme can otherwise be modified—without undermining the government’s compelling interests. *See, e.g., United States v. Schmucker*, 815 F.2d 413, 417 (6th Cir. 1987); *United States v. Wilgus*, 638 F.3d 1274, 1289-95 (10th Cir. 2011). The government is not required “to do the impossible—refute each and every conceivable alternative regulation scheme.” *Wilgus*, 638 F.3d at 1289. Instead, the government need only “refute the alternative schemes offered by the challenger.” *Id.*

Instead of explaining how plaintiffs and similarly situated eligible organizations could be exempted from the regulations without significant damage to the government’s compelling interests, plaintiffs conjure up, without any statutory support, several brand new statutory and regulatory schemes—most of which would require the government to pay for contraceptive

coverage—that they claim would be less restrictive. *See* Pls.’ Mem. at 32. Yet plaintiffs fail to recognize that such alternatives would be incompatible with the fundamental statutory scheme set forth in the ACA, which plaintiffs do not challenge in this lawsuit. Congress did not adopt a single (government) payer system financed through taxes and instead opted to build on the existing system of employment-based coverage. *See* H.R. Rep. No. 111-443, pt. II, at 984-86 (2010). Plaintiffs point to no statutory authority for any of their proffered less restrictive alternatives. Nor is there any indication that Congress would have contemplated that agency action could be invalidated under RFRA because the agency in discharging its statutorily delegated authority failed to adopt an alternative scheme absent any statutory authority for doing so. Thus, even if defendants wanted to adopt one of plaintiffs’ non-employer-based alternatives, they would be constrained by the statute from doing so. *See* 78 Fed. Reg. at 39,888, AR at 20.

Furthermore, plaintiffs themselves indicate that they would “oppose many of” the alternatives that they put forth. Pls.’ Mem. at 32. Indeed, as noted above, it is not clear why the government’s provision of contraceptive coverage to women based upon their employer’s objection to providing it would not be subject to exactly the same RFRA claim that plaintiffs advance here. By their own admission then, plaintiffs’ proposals would do little—if anything—to satisfy their religious objections, and therefore should not be considered viable less restrictive alternatives. *See New Life Baptist Church Acad. v. Town of E. Longmeadow*, 885 F.2d 940, 950-51 (1st Cir. 1989) (Breyer, J.) (considering the limited extent to which an alternative would alleviate a religious burden in rejecting it as a “less restrictive alternative,” even though the plaintiff had expressed a preference for the alternative over the challenged requirements). An eligible organization’s religious objection to contraceptive coverage would still “facilitate” the availability of such coverage—in this case, by the government—and the eligible organization would likely be called upon to verify or certify matters such as the religious objection to contraceptive coverage, and employment or plan beneficiary status. Plaintiffs cannot plausibly contend that the regulations are not the least restrictive means while simultaneously asserting that they would oppose their own suggested alternatives.

Finally, even if plaintiffs would be satisfied by their proposed alternative schemes, just because plaintiffs can devise an entirely new legislative and administrative scheme does not make that scheme a feasible less restrictive means, *see Wilgus*, 638 F.3d at 1289; *Adams v. Comm’r of Internal Revenue*, 170 F.3d 173, 180 n.8 (3d Cir. 1999), particularly where such alternatives would come at enormous administrative and financial cost to the government. A proposed alternative scheme is not an adequate alternative—and thus not a viable less restrictive means to achieve a compelling interest—if it is not feasible. *See, e.g., New Life Baptist*, 885 F.2d at 947; *Graham*, 822 F.2d at 852. In determining whether a proposed alternative scheme is feasible, courts often consider the additional administrative and fiscal costs of the scheme. *See, e.g., S. Ridge Baptist Church*, 911 F.2d at 1206; *Fegans v. Norris*, 537 F.3d 897, 905-06 (8th Cir. 2008); *United States v. Lafley*, 656 F.3d 936, 942 (9th Cir. 2011); *New Life Baptist*, 885 F.2d at 947. Defendants considered plaintiffs’ alternatives and determined that they were not feasible because the agencies lacked statutory authority to implement them; they would impose considerable new costs and other burdens on the government; and they would otherwise be impractical. *See* 78 Fed. Reg. at 39,888, AR at 20; *see also, e.g., Lafley*, 656 F.3d at 942; *Gooden v. Crain*, 353 F. App’x 885, 888 (5th Cir. 2009); *Adams*, 170 F.3d at 180 n.8.

Nor would the proposed alternatives be equally effective in advancing the government’s compelling interests. *See* 78 Fed. Reg. at 39,888, AR at 20; *see also, e.g., Kaemmerling*, 553 F.3d at 684 (finding that means was least restrictive where no alternative means would achieve compelling interests); *Murphy v. State of Ark.*, 852 F.2d 1039, 1042-43 (8th Cir. 1988) (same). As discussed above, Congress determined that the best way to achieve the goals of the ACA, including expanding preventive services coverage, was to build on the existing employer-based system. The anticipated benefits of the preventive services coverage regulations are attributable not only to the fact that recommended contraceptive services will be available to women with no cost-sharing, but also to the fact that these services will be available through the existing employer-based system of health coverage through which women will face minimal logistical and administrative obstacles to receiving coverage of their care. Plaintiffs’ alternatives, by

contrast, have none of these advantages. They would require establishing entirely new government programs and infrastructures or fundamentally altering existing ones, and would almost certainly require women to take burdensome steps to find out about the availability of and sign up for a new benefit, thereby ensuring that fewer women would take advantage of it. *See* 78 Fed. Reg. at 39,888, AR at 20. Nor do plaintiffs offer any suggestion as to how these programs could be integrated with the employer-based system or how women would obtain government-provided preventive services in practice. Thus, plaintiffs' proposals—in addition to raising myriad administrative and logistical difficulties and being unauthorized by any statute and not funded by any appropriation—are less likely to achieve the compelling interests furthered by the regulations, and therefore do not represent reasonable less restrictive means. *Id.*

Because plaintiffs have failed to offer viable less restrictive alternatives, the Court should reject plaintiffs' argument that the regulations fail strict scrutiny.¹⁵

B. The Regulations Do Not Violate the Free Exercise Clause

A law that is neutral and generally applicable does not run afoul of the Free Exercise Clause even if it prescribes conduct that an individual's religion proscribes or has the incidental effect of burdening a particular religious practice. *Emp't Div. v. Smith*, 494 U.S. 872, 879 (1990). "Neutrality and general applicability are interrelated." *Lukumi*, 508 U.S. at 531. A law is neutral if it does not target religiously motivated conduct either on its face or as applied. *Id.* at 533. A neutral law has as its purpose something other than the disapproval of a particular religion, or of religion in general. *Id.* at 545. A law is generally applicable so long as it does not selectively impose burdens only on conduct motivated by religious belief. *Id.*

¹⁵ Plaintiffs cite extra-record evidence in support of many of their arguments. For example, they cite a law review article for the proposition that the challenged regulations "are unlikely to significantly impact contraceptive use." *See* Pls.' Mem. at 30. The introduction of this and other extra-record evidence is inappropriate and should not be considered by the Court. Plaintiffs are challenging agency regulations, and thus this Court's review is limited to the administrative record. *See, e.g., United States v. Carlo Bianchi & Co.*, 373 U.S. 709, 715 (1963).

Unlike such selective laws, the preventive services coverage regulations are neutral and generally applicable. Indeed, nearly every court to have considered a free exercise challenge to the prior version of the regulations—including in this district—has rejected it, concluding that the regulations are neutral and generally applicable.¹⁶ See *Autocam*, 2012 WL 6845677, at *5 (“The ACA’s contraceptive coverage requirement is neutral and generally applicable. It does not target a particular religion or religious practice or have as its objective the interference with a particular religion or religious practice.”). “The regulations were passed, not with the object of interfering with religious practices, but instead to improve women’s access to health care and lessen the disparity between men’s and women’s healthcare costs.” *O’Brien*, 894 F. Supp. 2d at 1161. The regulations reflect expert medical recommendations about the medical necessity of contraceptive services, without regard to any religious motivations for or against such services. See, e.g., *Conestoga*, 917 F. Supp. 2d at 410 (“It is clear from the history of the regulations and the report published by the Institute of Medicine that the purpose of the [regulations] is not to target religion, but instead to promote public health and gender equality.”).

The regulations, moreover, do not pursue their purpose “only against conduct motivated by religious belief.” *Lukumi*, 508 U.S. at 545; see *United States v. Amer*, 110 F.3d 873, 879 (2d Cir. 1997) (concluding law that “punishe[d] conduct within its reach without regard to whether the conduct was religiously motivated” was generally applicable). The regulations apply to all non-grandfathered health plans that do not qualify for the religious employer exemption or the

¹⁶ See *MK Chambers Co. v. U.S. Dep’t of Health & Human Servs.*, No. 13-11379, 2013 WL 1340719, at *5 (E.D. Mich. Apr. 3, 2013); *Eden Foods, Inc. v. Sebelius*, No. 13-cv-11229, 2013 WL 1190001, at *4-*5 (E.D. Mich. Mar. 22, 2013); *Conestoga*, 917 F. Supp. 2d at 409-10; *Grote Indus., LLC v. Sebelius*, 914 F. Supp. 2d 943, 952-53 (S.D. Ind. 2012), *rev’d on other grounds*, No. 13-1077 (7th Cir. Nov. 8, 2013); *Autocam*, 2012 WL 6845677 at *5; *Korte v. U.S. Dep’t of Health & Human Servs.*, 912 F. Supp. 2d 735, 744-47 (S.D. Ill. 2012), *rev’d on other grounds*, No. 12-3841 (7th Cir. Nov. 8, 2013); *Hobby Lobby Stores, Inc. v. Sebelius*, 870 F. Supp. 2d 1278, 1289-90 (W.D. Okla. 2012), *rev’d on other grounds*, 723 F.3d 1114; *O’Brien*, 894 F. Supp. 2d at 1160-62; see also *Catholic Charities of Diocese of Albany v. Serio*, 859 N.E.2d 459, 468-69 (N.Y. 2006) (rejecting similar challenge to state law); *Catholic Charities of Sacramento, Inc. v. Superior Court*, 85 P.3d 67, 81-87 (Cal. 2004) (same). But see *Sharpe Holdings, Inc. v. HHS*, 2012 WL 6738489, at *5 (E.D. Mo. Dec. 31, 2012); *Geneva Coll. v. Sebelius*, 929 F.Supp.2d 402 (W.D. Penn. 2013).

accommodations for eligible organizations. Thus, “it is just not true . . . that the burdens of the [regulations] fall on religious organizations ‘but almost no others.’” *Am. Family Ass’n v. FCC*, 365 F.3d 1156, 1171 (D.C. Cir. 2004) (quoting *Lukumi*, 508 U.S. at 536).

The existence of express exceptions or accommodations for objectively defined categories of entities, like grandfathered plans, religious employers, and eligible organizations, “does not mean that [the regulations do] not apply generally.” *Autocam*, 2012 WL 6845677, at *5 (citing *Lee*, 455 U.S. at 261). “General applicability does not mean absolute universality.” *Olsen v. Mukasey*, 541 F.3d 827, 832 (8th Cir. 2008); accord *Axson-Flynn v. Johnson*, 356 F.3d 1277, 1298 (10th Cir. 2004); *Am. Friends Serv. Comm. Corp. v. Thornburgh*, 951 F.2d 957, 960-61 (9th Cir. 1991) (concluding employer verification statute was generally applicable even though it exempted independent contractors, household employees, and employees hired prior to November 1986 because exemptions “exclude[d] entire, objectively-defined categories of employees”); *Intercommunity Ctr. for Justice & Peace v. INS*, 910 F.2d 42, 44 (2d Cir. 1990) (same); *Ungar v. N.Y.C. Hous. Auth.*, 363 F. App’x 53, 56 (2d Cir. 2010). “Instead, exemptions undermining ‘general applicability’ are those tending to suggest disfavor of religion.” *O’Brien*, 894 F. Supp. 2d at 1162. The exception for grandfathered plans is available on equal terms to all employers, whether religious or secular. And the religious employer exemption and eligible organization accommodations serve to accommodate religion, not to disfavor it. *Id.*; see also *Conestoga*, 917 F. Supp. 2d at 410; *Grote*, 914 F. Supp. 2d at 953. Thus, these categorical exceptions and accommodations do not trigger strict scrutiny.

“[C]arving out an exemption for defined religious entities [also] does not make a law nonneutral as to others.” *Grote*, 914 F. Supp. 2d at 953 (quotation omitted). Indeed, the religious employer exemption “presents a strong argument in favor of neutrality” by “demonstrating that the object of the law was not to infringe upon or restrict practices because of their religious motivation.” *O’Brien*, 894 F. Supp. 2d at 1161 (quotations omitted); see *Conestoga*, 917 F. Supp.

2d at 410 (“The fact that exemptions were made for religious employers . . . shows that the government made efforts to accommodate religious beliefs, which counsels in favor of the regulations’ neutrality.”). The regulations are not unlawful “merely because the [religious employer exemption] does not extend as far as Plaintiffs wish.” *Grote*, 914 F. Supp. 2d at 953.

Plaintiffs’ reliance on *Lukumi*, 508 U.S. 520, is of no help, as this case is a far cry from *Lukumi*, where the legislature specifically targeted the religious exercise of members of a single church (Santeria) by enacting ordinances that used terms such as “sacrifice” and “ritual,” *id.* at 533-34, and prohibited few, if any, animal killings other than Santeria sacrifices, *id.* at 535-36. Here, there is no indication that the regulations are anything other than an effort to increase women’s access to and utilization of recommended preventive services. *See O’Brien*, 894 F. Supp. 2d at 1161; *Conestoga*, 917 F. Supp. 2d at 410; *Grote*, 914 F. Supp. 2d at 952-53. Plaintiffs’ unsupported assertion that the regulations are “part of a conscious political strategy to marginalize and delegitimize Plaintiffs’ religious views by holding them up for ridicule on the national stage,” Pls.’ Mem. at 34, is mere rhetorical bluster. And it cannot be disputed that defendants have made extensive efforts—through the religious employer exemption and the eligible organization accommodations—to accommodate religion in ways that will not undermine the goal of ensuring that women have access to coverage for recommended preventive services without cost sharing.¹⁷

Plaintiffs also posit that the regulations must have been designed to target plaintiffs’ religious practice of refusing to facilitate access to contraception because, prior to the promulgation of the regulations, “85 percent of health plans already cover[ed] contraception.” Pls.’ Mem. at 34. As an initial matter, this 85 percent figure represents only large employers, not small employers (only 62 percent of which covered contraception prior to issuance of the

¹⁷ *Fraternal Order of Police v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), an out-of-circuit case on which plaintiffs also rely (Pls.’ Mem. at 33), addressed a policy that created a secular exemption but refused all religious exemptions. The preventive services coverage regulations, in contrast, contain an exemption and accommodations that specifically seek to accommodate religion. Thus, unlike in *Fraternal Order*, there is simply no basis here to infer a discriminatory object behind the regulations. *See Conestoga*, 917 F. Supp. 2d at 409-10.

regulations) or plans on the individual market. IOM REP. at 109, AR at 407. More importantly, many of the plans that covered contraceptive services imposed cost-sharing requirements that often resulted in women forgoing preventive care. *Id.* at 19-20, 109. The regulations eliminate that cost-sharing. Finally, even if plaintiffs could show that the regulations have a disproportionate effect on them (and they have not), it would not destroy the regulations' neutrality. *See O'Brien*, 894 F. Supp. 2d at 1161 (rejecting identical argument). "[A] neutral and perfectly constitutional law may have a disproportionate impact upon religiously inspired behavior The Free Exercise Clause is not violated even though a group motivated by religious reasons may be more likely to engage in the proscribed conduct." *Id.* (citing cases). Indeed, by plaintiffs' logic, the government also was "target[ing]," Pls.' Mem. at 34, those with religious objections to vaccinations, as a similar or even greater percentage of health plans covered vaccinations prior to promulgation of the challenged regulations. *See* 75 Fed. Reg. 41,726, 41,732 (July 19, 2010), AR at 232.¹⁸

Finally, plaintiffs maintain that the challenged regulations are subject to strict scrutiny under a "hybrid rights" theory because they also infringe on plaintiffs' freedom of speech and association. The Sixth Circuit, however, has specifically rejected the theory. *See Kissinger v. Bd. of Trs. of Ohio State Univ.*, 5 F.3d 177, 180 (6th Cir. 1993). Indeed, the Supreme Court, however, has never invoked this so-called "hybrid rights theory" to justify applying strict scrutiny to a free exercise claim. *See Lukumi*, 508 U.S. at 567 (Souter, J., concurring in part and concurring in the judgment) (noting the hybrid rights exception would either swallow the *Smith* rule or be entirely unnecessary).¹⁹

¹⁸ Plaintiffs' assertion that the regulations were "directly modeled on a California statute," Pls.' Mem. at 35, is incorrect. Defendants considered the laws of multiple states. *See* 77 Fed. Reg. at 8,728, AR at 215.

¹⁹ Nevertheless, assuming arguendo that the hybrid rights theory is valid, it applies only where the plaintiff's non-free-exercise claims are "independently viable." *Mahoney v. Dist. of Columbia*, 662 F. Supp. 2d 74, 95 n.12 (D.D.C. 2009). Here, plaintiffs assert in their brief that the preventive services coverage provision violates both the right to free exercise of religion and their "rights of free speech and association." Pls.' Mem. at 35-36. But plaintiffs do not even raise a separate free association claim and, as explained next, their free speech claims are meritless. "[T]he combination of two untenable claims" does not "equal[] a tenable one." *Henderson*, 253 F.3d at 19; *see also Civil* (Footnote continued on next page)

For these reasons, plaintiffs' free exercise claim—Count II of the Complaint—fails.²⁰

C. The Regulations Do Not Violate the Free Speech Clause

Plaintiffs' free speech claims fare no better. The right to freedom of speech “prohibits the government from telling people what they must say.” *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* (“FAIR”), 547 U.S. 47, 61 (2006). But the preventive services coverage regulations do not compel speech—by plaintiffs or any other person, employer, or entity—in violation of the First Amendment. Nor do they limit what plaintiffs may say. Plaintiffs remain free under the regulations to express whatever views they may have on the use of contraceptive services (or any other health care services) as well as their views about the regulations. Plaintiffs, moreover, may encourage their employees not to use contraceptive services.

Plaintiffs contend that the regulations violate their free speech rights in three ways, none of which has merit. First, plaintiffs are wrong to contend that the regulations require plaintiffs to “support ‘counseling’ in favor of” preventive services to which they object. Pls.’ Mem. at 36. The regulations simply require coverage of “education and counseling for all women with reproductive capacity.” HRSA Guidelines, AR at 283-84. There is no requirement that such education and counseling be “in favor of” any particular contraceptive service, or even in support of contraception in general. The conversations that may take place between a patient and her doctor cannot be known or screened in advance and may cover any number of options. To the extent that plaintiffs intend to argue that the covered education and counseling is objectionable because some of the conversations between a doctor and one of plaintiffs' employees *might* be supportive of contraception, accepting this theory would mean that the First Amendment is violated by the mere possibility of an employer's disagreement with a potential subject of discussion between an employee and her doctor, and would extend to all such interactions, not

Liberties for Urban Believers, 342 F.3d at 765 (“[A] plaintiff does not allege a hybrid rights claim entitled to strict scrutiny analysis merely by combining a free exercise claim with an utterly meritless claim of the violation of another alleged fundamental right.” (quoting *Miller v. Reed*, 176 F.3d 1202, 1207-08 (9th Cir. 1999))). Thus, even if the hybrid rights theory were valid, it would not trigger strict scrutiny.

²⁰ Even if the regulations were not neutral or generally applicable, plaintiffs' free exercise challenge still would fail because the regulations satisfy strict scrutiny. *See supra*.

just those that are the subject of the challenged regulations. The First Amendment does not require such a drastic result. *See, e.g., Conestoga*, 917 F.Supp.2d at 418-19.

Second, plaintiffs note that, in order to avail itself of an accommodation, an organization must self-certify that it meets the definition of “eligible organization.” Pls.’ Mem. at 37. But, contrary to plaintiffs’ assertion, the self-certification does not in any sense “trigger” payments for contraceptive services, Pls.’ Mem. at 37, as the government cannot require any TPA of the MCC Plan, which is a self-insured church plan, to provide payments for contraceptive services. Moreover, completion of the simple self-certification form is “plainly incidental to the . . . regulation of conduct,” *FAIR*, 547 U.S. at 62, not speech. Indeed, every court to review a Free Speech challenge to the prior contraceptive-coverage regulations has rejected it, in part, because the regulations deal with conduct. *See Autocam*, 2012 WL 6845677, *8; *see also MK Chambers*, 2013 WL 1340719 at *6 (“Like the [law at issue in *FAIR*], the contraceptive requirement regulates conduct, not speech.” (quotations omitted)); *Briscoe v. Sebelius*, 927 F. Supp. 2d 1109, 1120 (D. Colo. 2013) (“The plaintiffs cite no authority and I am not aware of any authority holding that such conduct qualifies as speech so as to trigger First Amendment protection.”); *Conestoga*, 917 F. Supp. 2d at 418; *Grote*, 914 F. Supp. at 955; *O’Brien*, 894 F. Supp. 2d at 1165-67; *see also Catholic Charities of Sacramento*, 85 P.3d at 89 (rejecting similar claim); *Catholic Charities of the Diocese of Albany*, 859 N.E.2d at 465 (same). The accommodations likewise regulate conduct by relieving an eligible organization of the obligation “to contract, arrange, pay, or refer for contraceptive coverage” to which it has religious objections. 78 Fed. Reg. at 39,874, AR at 6.²¹ Plaintiffs’ suggestion that self-certifying their eligibility for an accommodation, which is incidental to the regulation of conduct, violates their speech rights lacks merit. *See FAIR*, 547 U.S. at 61-63.

²¹ Indeed, self-certifying eligibility for a religious accommodation is a far cry from the laws at issue in the cases plaintiffs cite, which mandated the posting of specific written messages throughout an organization’s building and advertisements, as well as speaking oral messages to the organization’s clients. *See* Pls.’ Mem. at 37 (citing *Evergreen Ass’n v. City of New York*, 801 F. Supp. 2d 197 (S.D.N.Y. 2011) and *Centro Tepeyac v. Montgomery Cnty.*, 779 F. Supp. 2d 456 (D. Md. 2011)).

The regulations also do not require plaintiffs to subsidize any conduct that is “inherently expressive.” *FAIR*, 547 U.S. at 66; *see also United States v. O’Brien*, 391 U.S. 367, 376 (1968) (recognizing that some forms of “symbolic speech” are protected by the First Amendment). As an initial matter, the regulations explicitly prohibit plaintiffs’ issuers and TPAs from imposing any cost sharing, premium, fee, or other charge on plaintiffs with respect to the separate payments for contraceptive services made by the issuers or TPAs. Plaintiffs, therefore, are not funding or subsidizing anything pertaining to contraceptive coverage. Moreover, even if plaintiffs played some role in an issuer’s or TPA’s provision of payments for contraceptive services (and they do not), making payments for health care services is not the sort of conduct the Supreme Court has recognized as inherently expressive. *See Conestoga*, 917 F. Supp. 2d at 418; *Grote*, 2012 WL 6725905, at *10; *Autocam*, 2012 WL 6845677, at *8; *O’Brien*, 894 F. Supp. 2d at 1166-67; *Catholic Charities of Sacramento*, 85 P.3d at 89; *Diocese of Albany*, 859 N.E.2d at 465; *see also FAIR*, 547 U.S. at 65-66 (making space for military recruiters on campus is not conduct that indicates colleges’ support for, or sponsorship of, recruiters’ message).

Finally, plaintiffs’ claim that the regulations impose a so-called “gag order” that interferes with their free-speech rights, *see* Pls.’ Mem. at 37, is wholly without merit. Defendants have been clear that “[n]othing in these final regulations prohibits an eligible organization from expressing its opposition to the use of contraception.” 78 Fed. Reg. at 39,880 n.41, AR at 12. What the regulations prohibit is an employer’s improper attempt to interfere with its employees’ ability to obtain contraceptive coverage from a third party by, for example, threatening the TPA with a termination of its relationship with the employer because of the TPA’s “arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries.” *See* 26 C.F.R. § 54.9815-2713A(b)(1)(iii); 29 C.F.R. § 2590.715-2713A(b)(1)(iii). Addressing an analogous argument in the context of the National Labor Relations Act, the Supreme Court concluded that an employer’s threatening statements to its employees regarding the effects of unionization fell outside the protection of the First Amendment because they interfered with employee rights. *NLRB v. Gissel Packing Co.*, 395 U.S. 575, 618 (1969). The Court explained

that there was no First Amendment violation because the employer was “free to communicate . . . any of his general views . . . so long as the communications do not contain a ‘threat of reprisal or force or promise of benefit.’” *Id.*; *see also Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 456 (1978) (“[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.” (quotation omitted)). The same is true here. Because the regulations do not prevent plaintiffs from expressing their views regarding the use of contraceptive services, but, rather, protect employees’ right to obtain payments for contraceptive services through TPAs, there is no infringement of plaintiffs’ right to free speech.

Accordingly, the regulations do not violate the Free Speech Clause, and Counts III and IV of the Complaint should be dismissed or summary judgment granted to the government.

D. The Regulations Do Not Violate the Establishment Clause

“The clearest command of the Establishment Clause is that one religious *denomination* cannot be officially preferred over another.” *Larson v. Valente*, 456 U.S. 228, 244 (1982) (emphasis added). A law that discriminates among religions by “aid[ing] one religion” or “prefer[ring] one religion over another” is subject to strict scrutiny. *Id.* at 246; *see also Olsen v. DEA*, 878 F.2d 1458, 1461 (D.C. Cir. 1989). Thus, for example, the Supreme Court has struck down on Establishment Clause grounds a state statute that was “drafted with the explicit intention” of requiring “particular religious denominations” to comply with registration and reporting requirements while excluding other religious denominations. *Larson*, 456 U.S. at 254; *see also Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 703-07 (1994) (striking down statute that created special school district for religious enclave of Satmar Hasidim because it “single[d] out a particular religious sect for special treatment”). The Court, on the other hand, has upheld a statute that provided an exemption from military service for persons who had a conscientious objection to all wars, but not those who objected to only a particular war. *Gillette v. United States*, 401 U.S. 437 (1971). The Court explained that the statute did not discriminate among religions because “no particular sectarian affiliation” was required to qualify

for conscientious objector status. *Id.* at 450-51. “[C]onscientious objector status was available on an equal basis to both the Quaker and the Roman Catholic.” *Larson*, 456 U.S. at 247 n.23; *see also Cutter v. Wilkinson*, 544 U.S. 709, 724 (2005) (upholding RLUIPA against Establishment Clause challenge because it did not “confer[] . . . privileged status on any particular religious sect” or “single[] out [any] bona fide faith for disadvantageous treatment”).

Like the statutes at issue in *Gillette* and *Cutter*, the preventive services coverage regulations do not grant any denominational preference or otherwise discriminate among religions. It is of no moment that the religious employer exemption and accommodations for eligible organizations apply to some employers but not others. “[T]he Establishment Clause does not prohibit the government from [differentiating between organizations based on their structure and purpose] when granting religious accommodations as long as the distinction[s] drawn by the regulations . . . [are] not based on religious affiliation.” *Grote*, 914 F. Supp. 2d at 954; *accord O’Brien*, 894 F. Supp. 2d at 1163; *see also, e.g., Children’s Healthcare Is a Legal Duty, Inc. v. Min De Parle*, 212 F.3d 1084, 1090-93 (8th Cir. 2000); *Droz v. Comm’r of IRS*, 48 F.3d 1120, 1124 (9th Cir. 1995); *Diocese of Albany*, 859 N.E.2d at 468-69. Here, the distinctions established by the regulations are not so drawn.

The regulations’ definitions of religious employer and eligible organization “do[] not refer to any particular denomination.” *Grote*, 914 F. Supp. 2d at 954. The exemption and accommodations are available on an equal basis to organizations affiliated with any and all religions. The regulations, therefore, do not discriminate among religions in violation of the Establishment Clause. Indeed, every court to have considered an Establishment Clause challenge to the prior version of the regulations has rejected it. *See, e.g., O’Brien*, 894 F. Supp. 2d at 1162 (upholding prior version of religious employer exemption because it did “not differentiate between religions, but applie[d] equally to all denominations”); *Conestoga*, 917 F. Supp. 2d at 416-17 (same); *Grote*, 914 F. Supp. 2d at 954 (same); *see also Liberty Univ., Inc. v. Lew*, 733

F.3d 72, 100-03 (4th Cir. 2013) (upholding another religious exemption contained in the ACA against an Establishment Clause challenge), *cert. denied*, No. 13-306 (Dec. 2, 2013).²²

“As the Supreme Court has frequently articulated, there is space between the religion clauses, in which there is ‘room for play in the joints;’ government may encourage the free exercise of religion by granting religious accommodations, even if not required by the Free Exercise Clause, without running afoul of the Establishment Clause.” *O’Brien*, 894 F. Supp. 2d at 1163 (citations omitted). Accommodations of religion are possible because the type of legislative line-drawing to which the plaintiffs object in this case is constitutionally permissible. *Id.*; *Conestoga*, 917 F. Supp. 2d at 417; *see, e.g., Walz v. Tax Comm’n of NY*, 397 U.S. 664, 666 (1970); *Amos*, 483 U.S. at 334 (upholding Title VII’s exemption for religious organizations).²³

Plaintiffs also claim that the regulations’ definition of religious employer violates the Establishment Clause because, more than thirty-five years ago, the Internal Revenue Service (IRS) developed a non-exhaustive list of fourteen facts and circumstances that may be considered, in addition to “any other facts and circumstances which may bear upon the organization’s claim for church status,” in assessing whether an organization is a church. *See*

²² Plaintiffs stretch *Colorado Christian University v. Weaver*, 534 F.3d 1245 (10th Cir. 2008), well beyond its facts in suggesting that the case stands for the proposition that the Establishment Clause prohibits the government from distinguishing among different types of organizations that adhere to the same religion. Pls.’ Mem. at 39. *Weaver* was limited to “laws that facially regulate religious issues,” 534 F.3d at 1257, and, particularly, those that do so in a way that denies certain religious institutions public benefits that are afforded to all other institutions, secular or religious. The court in *Weaver* said nothing about the constitutionality of exemptions from generally applicable laws that are designed to accommodate religion, as opposed to discriminate against religion. A requirement that any religious exemption that the government creates must extend to all organizations—no matter their structure or purpose—would hamper the government’s ability to accommodate religion. *See Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334 (1987) (“There is ample room under the Establishment Clause for ‘benevolent’ neutrality which will permit religious exercise to exist without sponsorship and without interference.”); *Diocese of Albany*, 859 N.E.2d at 464 (“To hold that any religious exemption that is not all-inclusive renders a statute non-neutral would be to discourage the enactment of any such exemptions – and thus to restrict, rather than promote, freedom of religion.”). And, the manner in which the law at issue in *Weaver* was administered required the government to make intrusive inquiries into a school’s religious beliefs and practices by, for example, reading syllabi to determine if a school’s theology courses were likely to convince students of religious truths. *See* 534 F.3d at 1261-62. The religious employer exemption requires no such inquiry: Qualification for the exemption does not require the government to make any determination, much less an unconstitutionally intrusive one.

²³ Even if the regulations discriminate among religions (and they do not), they are valid under the Establishment Clause, because they satisfy strict scrutiny. *See supra; Larson*, 456 U.S. at 251-52.

Found. of Human Understanding v. Comm’r of IRS, 88 T.C. 1341, 1357-58 (1987); Internal Revenue Manual (IRM) 7.26.2.2.4. Although plaintiffs do not appear to have ever before challenged the constitutionality of this non-exhaustive list, they now contend that it acts to require the government to make impermissible “judgments regarding beliefs, practices, and organizational structure.” Pls.’ Mem. at 42. This claim fails for numerous reasons.

As an initial matter, the claim is not ripe and therefore should be dismissed for lack of jurisdiction. The non-exhaustive list that plaintiffs seek to challenge is not set out in any statute, regulation, or other binding source of law. It is instead contained in the IRM, which serves as a source of guidance for the internal administration of the IRS and is not binding on the IRS or courts. *United States v. Will*, 671 F.2d 963, 967 (6th Cir. 1982); *Capital Fed. Sav. & Loan Ass’n v. Comm’r of Internal Revenue*, 96 T.C. 204, 216-17 (1991). A party can challenge such guidance “only if and when the directive has been applied specifically to them.” *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987); *see also, e.g., Home Builders Ass’n of Greater Chicago v. U.S. Army Corps of Eng’rs*, 335 F.3d 607, 619 (7th Cir. 2003) (concluding general statement of policy was not ripe for review). Plaintiffs do not challenge any determination by the IRS that was based on this IRM provision. Because defendants have not applied a similar non-exhaustive list of facts and circumstances to plaintiffs, plaintiffs’ challenge is not ripe.

Indeed, qualification for the religious employer exemption does not require the government to make any determination, whether as a result of the application of the non-exhaustive list or otherwise. If an organization “is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended,” it qualifies for the exemption, without any government action whatsoever. 45 C.F.R. § 147.131(a). Plaintiffs, moreover, have no difficulty determining whether they qualify for the exemption. MCC alleges that it qualifies for the exemption, Compl. ¶¶ 9, 120, and Catholic Charities allege that it does not, *id.* ¶ 11. Any claim—which plaintiffs do not in fact make—that the government will dispute these allegations and therefore need to undertake any

sort of intrusive inquiry into whether plaintiffs qualify for the exemption is entirely speculative and thus unripe for this reason as well.

Finally, even assuming plaintiffs could mount a facial challenge to a non-exhaustive list of facts and circumstances that the defendant agencies have never applied to plaintiffs, any such challenge would be meritless. Any interaction between the government and religious organizations that may be necessary to enforce the religious employer exemption is not so “comprehensive,” *Lemon v. Kurtzman*, 403 U.S. 602, 619 (1971), or “pervasive,” *Agostini v. Felton*, 521 U.S. 203, 233 (1997) (quotations omitted), as to result in excessive entanglement. The Supreme Court has upheld laws that require government monitoring that is more onerous than any monitoring that may be required to enforce the religious employer exemption. *See Bowen v. Kendrick*, 487 U.S. 589, 615-617 (1988) (no excessive entanglement where the government reviewed and monitored programs and materials); *Roemer v. Bd. of Pub. Works of Md.*, 426 U.S. 736, 764–765 (1976) (no excessive entanglement where the state conducted annual audits); *see also United States v. Corum*, 362 F.3d 489, 496 (8th Cir. 2004). And every court to address the issue upheld the prior version of the religious employer exemption, which contained the same requirement that the organization be one that is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended, against an entanglement challenge. *See Conestoga*, 917 F. Supp. 2d at 417; *O’Brien*, 894 F. Supp. 2d at 1164-65; *Geneva Coll.*, 929 F. Supp. 2d at 439-40.²⁴

Thus, plaintiffs’ Establishment Clause claim—Count V of the Complaint—fails.

²⁴ Even if this Court were to conclude that it had jurisdiction to adjudicate a facial challenge to the non-exhaustive list of facts and circumstances set forth in IRM 7.26.2.2.4 and that such nonbinding guidance violates the Establishment Clause, the remedy would be invalidation of the list, not invalidation of the contraceptive coverage requirement or the religious employer exemption. The regulations would survive, with the religious employer exemption being available to any organization that is organized and operates as a nonprofit entity and is a church, integrated auxiliary of a church, convention or association of churches, or the exclusively religious activities of any religious order, as those terms are specifically defined under section 6033 or commonly understood.

E. The Regulations Do Not Interfere With Church Governance

Plaintiffs also assert that, by allegedly requiring plaintiffs to facilitate practices in violation of their religious beliefs, the regulations interfere with plaintiffs’ “internal church governance” in violation of the Religion Clauses. *See* Pls.’ Mem. at 42. But that is merely a restatement of plaintiffs’ substantial burden theory,²⁵ which fails for reasons explained already. Indeed, the main case cited by plaintiffs on this point, *Hosanna-Tabor Evangelical Lutheran Church & School v. E.E.O.C.*, 132 S. Ct. 694 (2012), is inapposite. In *Hosanna-Tabor*, the Supreme Court held that allowing a minister employee to sue her church employer under the Americans with Disabilities Act—thereby interfering with “a church’s ability to select its own ministers”—violates the Free Exercise and Establishment Clauses. *Id.* at 704, 706. But this case is not about the selection of clergy, nor any other matters of church governance apart from plaintiffs’ religious objection to providing contraceptive coverage (which, again, is subsumed by plaintiffs’ substantial burden argument). Nor is this case about any law that regulates the structure of the church—plaintiffs may choose whatever organizational structure they wish. Thus, Count VI should be dismissed or summary judgment granted to defendants.

F. Plaintiffs’ APA Claims Fail

1. The regulations are not contrary to law

Plaintiffs contend the regulations violate the APA because they conflict with the Weldon Amendment to the Consolidated Appropriations Act of 2012. They are incorrect. Plaintiffs appear to reason that, because the preventive services coverage regulations require group health plans to cover emergency contraception, such as Plan B, they require plaintiffs to provide coverage for abortions in violation of federal law. The Weldon Amendment denies funds made available in the Consolidated Appropriations Act of 2012 to any federal, state, or local agency, program, or government that “subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage

²⁵ While the *Zubik* ruling was incorrect for reasons explained already, *supra* note 7, that court analyzed arguments about interference with the church under RFRA’s “substantial burden” test. *See* 2013 WL 6118696 at *27.

of, or refer for abortions.” Pub. L. No. 112-74, §§ 506, 507, 125 Stat. 786, 1111-12 (Dec. 23, 2011). The regulations, however, do not require that any health plan cover abortion at all, much less as a preventive service. The government has made clear that the preventive services covered by the regulations do not include abortifacient drugs.²⁶ Although plaintiffs are certainly entitled to believe that emergency contraceptives and certain IUDs are abortifacient drugs or cause abortions, neither the government nor this Court is required to accept that characterization, which is inconsistent with the FDA’s scientific assessment and with federal law. While plaintiffs’ religious beliefs may define abortion more broadly than federal law, statutory interpretation requires that terms be construed as a matter of law and not in accordance with any individual’s personal views or beliefs. *E.g.*, *GEICO v. Benton*, 859 F.2d 1147, 1149 (3d Cir. 1988).

In recommending what contraceptive services should be covered by health plans without cost-sharing, the IOM Report identified the contraceptives that have been approved by the FDA as safe and effective. *See* IOM REP. at 10, AR at 308. And the list of FDA-approved contraceptives includes emergency contraceptives such as Plan B. *See id.* at 105, AR at 403. The basis for the inclusion of such drugs among safe and effective means of contraception dates back to 1997, when the FDA first explained why Plan B and similar drugs act as contraceptives rather than abortifacients. *See* Prescription Drug Products; Certain Combined Oral Contraceptives for Use as Postcoital Emergency Contraception, 62 Fed. Reg. 8610, 8611 (Feb. 25, 1997); 45 C.F.R. § 46.202(f). In light of this conclusion by the FDA, HHS informed Title X grantees, which are required to offer a range of acceptable and effective family planning methods—and, except under limited circumstances, may not offer abortion—that they “should consider the availability of emergency contraception the same as any other method which has been established as safe and effective.” Office of Population Affairs, Memorandum (Apr. 23, 1997), <http://www.hhs.gov/opa/pdfs/opa-97-02.pdf> (last visited Dec. 11, 2013); *see also* 42 U.S.C.

²⁶ HealthCare.gov, Affordable Care Act Rules on Expanding Access to Preventive Services for Women (August 1, 2011), *available at* <http://www.hhs.gov/healthcare/facts/factsheets/2011/08/womensprevention08012011a.html> (last visited Dec. 11, 2013); *see also* IOM REP. at 22 (recognizing that abortion services are outside the scope of recommendations), AR at 320.

§§ 300, 300a-6. The regulations are consistent with over a decade of regulatory policy and practice and thus cannot be deemed contrary to any law dealing with abortion. *See Bhd. of R.R. Signalmen v. Surface Transp. Bd.*, 638 F.3d 807, 815 (D.C. Cir. 2011) (giving particular deference to an agency's longstanding interpretation).²⁷

Thus, because the challenged regulations are not contrary to law, Count VI of the Complaint should be dismissed or summary judgment granted to defendants.

2. The regulations were promulgated in accordance with the APA

In Count VII (the only count not raised in their preliminary injunction motion), plaintiffs assert that defendants failed to comply with the APA's notice and comment procedures in relation to challenged regulations and the HRSA Guidelines. Plaintiffs also appear to allege that defendants improperly delegated their authority when they sought the expertise of the IOM. All of these allegations are baseless. The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). Defendants complied with these requirements.

As to the challenged regulations, defendants issued the ANPRM on March 21, 2012, and solicited comments on it. 77 Fed. Reg. 16,501. Defendants then considered those comments and issued the NPRM on February 6, 2013, requesting comments on the proposals contained in it. 78 Fed. Reg. 8456, 8457. Defendants received over 400,000 comments, and the preamble to the 2013 final rules contains a detailed discussion both of the comments defendants received and of defendants' responses to those comments. *See* 78 Fed. Reg. at 39,871-39,888. The mere fact that the regulations as ultimately issued may not satisfy the preferences of each and every commenter is certainly not evidence that those comments were not considered. Given the range of interests

²⁷ Representative Weldon, the sponsor of the Weldon Amendment, himself did not consider the word "abortion" in the statute to include FDA-approved emergency contraceptives. *See* 148 Cong. Rec. H6566, H6580 (daily ed. Sept. 25, 2002) ("The provision of contraceptive services has never been defined as abortion in Federal statute, nor has emergency contraception, what has commonly been interpreted as the morning-after pill. . . . [U]nder the current FDA policy[,] that is considered contraception, and it is not affected at all by this statute.").

and views among commenters, it is unlikely—if not impossible—that any regulation will be fully in line with the comments made by every commenter.

As to the HRSA Guidelines, because there were no existing HRSA guidelines relating to preventive care and screening for women, HRSA sought the scientific and medical expertise of the IOM. IOM conducted a science-based review and made recommendations as to what the HRSA guidelines should include.²⁸ This is not at all unusual, as entities like HRSA frequently contract with non-governmental entities, including the IOM, for this type of technical input. Seeking such input is not a delegation of HRSA's authority, but rather a consultation. After considering the IOM's recommendations, HRSA independently made the decision to adopt guidelines based on those recommendations, subject to the religious employer exemption. Moreover, nothing in the APA, or any other statute, requires HRSA to have subjected IOM's recommendations to notice and comment procedures before adopting them in the guidelines. The APA's notice-and-comment requirements apply only to rulemaking, 5 U.S.C. § 553(b), and a "rule" is defined in the APA, in relevant part, as being "designed to implement, interpret, or prescribe law or policy," *id.* § 551(4). The guidelines neither do nor are designed to do any such thing, and as such they do not constitute a "rule" within the meaning of the APA; they are simply the clinical recommendations of a scientific body. The substantive obligations that are imposed on group health plans and health insurance issuers were imposed by Congress, in 42 U.S.C. § 300gg-13(a) and in corresponding provisions of ERISA and the Internal Revenue Code, which expressly and automatically imported the content of various guidelines (including the HRSA Guidelines), including new content after a specified period of time. Indeed, in the same provision, Congress also imported by reference clinical recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices of the

²⁸ To the extent plaintiffs question the process that IOM used to develop its recommendations, *see* Compl. ¶ 219, they have not offered any support for the notion that the APA requires IOM to have provided the public with an opportunity to comment. IOM is an entity that gives expert advice to the federal government, and it issues recommendations that plainly do not have the force of law of their own accord. In any event, IOM did invite the public to speak at three public meetings and/or to submit written comments. *See* IOM REP. at 22-23, AR at 320-21.

Centers for Disease Control and Prevention. *Id.* The clinical recommendations of these entities are not generally required to be subject to notice and comment, and there is no suggestion that Congress intended otherwise here for any of the referenced recommendations.²⁹

For the above reasons, plaintiffs' APA claims—Counts VI and VII—should be dismissed, or summary judgment should be entered in the government's favor on those claims.

III. PLAINTIFFS CANNOT ESTABLISH IRREPARABLE HARM, AND AN INJUNCTION WOULD INJURE THE GOVERNMENT AND THE PUBLIC

“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976). Even assuming *arguendo* that same rule applies to a statutory claim under RFRA, plaintiffs have not shown that the challenged regulations violate their First Amendment or RFRA rights, so there has been no “loss of First Amendment freedoms” for any period of time. *Id.* In this respect, the merits and irreparable injury prongs of the preliminary injunction analysis merge together, and plaintiffs cannot show irreparable injury without also showing a likelihood of success on the merits, which they cannot do. *See supra* note 4.

Furthermore, plaintiffs' claim to irreparable harm is further undermined by their own delay in filing suit. Although the challenged regulations were published in the Federal Register in early July, 78 Fed. Reg. 39,870, these plaintiffs waited roughly five months—until mid-November—to file suit and even longer—until early December—to seek expedition of their request for the extraordinary remedy of preliminary injunctive relief. Such a substantial and unexplained delay seriously undermines these plaintiffs' claim of irreparable harm. *See, e.g., Autocam*, 2012 WL 6845677, at *9 (noting, in a challenge to the prior contraceptive-coverage regulations, that “the immediacy of the dilemma Plaintiffs face is in no small part of their own

²⁹ In contrast, other provisions of the ACA use clear language when referring to the promulgation of substantive rules. *See, e.g.*, 42 U.S.C. § 300gg-1(b)(3) (“The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).”); *id.* § 300gg-14(b) (“The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).”); *id.* § 300gg-17(d) (“Not later than 2 years after March 23, 2010, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).”). That Congress explicitly did not use such language here indicates that it did not intend the HRSA Guidelines to be “rules” within the meaning of the APA.

making,” because plaintiffs filed suit “less than two months before the deadline Plaintiffs say is critical”); *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975) (denying preliminary injunctive relief and noting that a delay of forty-four days after final regulations were issued was “inexcusable”).

Turning to the final two preliminary injunction factors—the balance of equities and the public interest—“there is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop and enforce.” *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *see also Connection Distrib. Co. v. Reno*, 154 F.3d 281, 296 (6th Cir. 1998) (indicating that granting an injunction against the enforcement of a likely constitutional statute would harm the government). Enjoining the preventive services coverage regulations as to plaintiffs would undermine the government’s ability to achieve Congress’s goals of improving the health of women and newborn children and equalizing the coverage of preventive services for women and men.³⁰

It would also be contrary to the public interest to deny plaintiffs’ employees (and their families) the benefits of the preventive services coverage regulations. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982) (“[C]ourts . . . should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.”). Many of the plaintiffs’ employees may not share plaintiffs’ objections to the challenged regulations. Those employees should not be deprived of the benefits of payments provided by a third party that is not their employer for the full range of FDA-approved contraceptive services, as prescribed by a health care provider, on the basis of their employers’ religious objection. Many women do not

³⁰ Plaintiffs note that defendants consented to preliminary injunctions in a few cases involving for-profit companies, *see* Pls.’ Mem. at 48-49, but defendants’ consent in those cases was nothing more than an effort to conserve judicial and governmental resources. Those cases were in the Seventh, Eighth, and D.C. Circuits, and they were filed after motions panels in those circuits had preliminarily enjoined the regulations pending appeal in similar cases. *See Mersino*, 2013 WL 3546702 at *16 (“[W]here the government has conceded to injunctive relief, it appears that it has generally done so in jurisdictions where the legal landscape has been set against them, and continuing to litigate the claims in those jurisdictions would be a waste of both judicial and client resources.”). The government continues to oppose preliminary injunctions in other circuits regarding for-profit plaintiffs, and opposes in *all* circuits injunctive relief sought by non-profit plaintiffs like plaintiffs here.

use contraceptive services because they are not covered by their health plan or require costly copayments, coinsurance, or deductibles. IOM REP. at 19-20, 109, AR at 317-18, 407; 77 Fed. Reg. at 8727, AR at 214; 78 Fed. Reg. at 39,887, AR at 19. As a result, in many cases, both women and developing fetuses suffer negative health consequences. *See* IOM REP. at 20, 102-04, AR at 318, 400-02; 77 Fed. Reg. at 8728, AR at 215. And women are put at a competitive disadvantage due to their lost productivity and the disproportionate financial burden they bear in regard to preventive health services. 155 Cong. Rec. S12106-02, S12114 (daily ed. Dec. 2, 2009); *see also* IOM REP. at 20, AR at 318.

Enjoining defendants from enforcing, as to plaintiffs, the preventive services coverage regulations—the purpose of which is to eliminate these burdens, 75 Fed. Reg. at 41,733, AR at 233; *see also* 77 Fed. Reg. at 8728, AR at 215—would thus inflict a very real harm on the public and, in particular, a readily identifiable group of individuals. *See Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1139 (9th Cir. 2009) (vacating preliminary injunction entered by district court and noting that “[t]here is a general public interest in ensuring that all citizens have timely access to lawfully prescribed medications”). Accordingly, even assuming plaintiffs were likely to succeed on the merits (which they are not for the reasons explained above), any potential harm to plaintiffs resulting from their offense at a third party providing payment for contraceptive services at no cost to, and with no administration by, plaintiffs’ would be outweighed by the significant harm an injunction would cause these employees and their families.

CONCLUSION

For the foregoing reasons, defendants respectfully ask that the Court deny plaintiffs’ motion for a preliminary injunction, and grant defendants’ motion to dismiss or, in the alternative, for summary judgment on all of plaintiffs’ claims.

Respectfully submitted this 16th day of December, 2013,

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