IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
NORTHERN DIVISION

SHARPE HOLDINGS, INC., *et al.*, **Plaintiffs,** **v.** **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,** **Defendants.**	**Case No. 2:12-cv-00092-DDN**

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

INTRODUCTION

Plaintiffs CNS International Ministries, Inc. ("CNS") and Heartland Christian College ("Heartland") seek to temporarily restrain regulations related to the provision of contraceptive coverage that do not burden plaintiffs' religious exercise and, indeed, require plaintiffs only to take the *de minimis* step that they would have to take in the absence of such regulations: convey to their third-party administrator ("TPA") that they object to providing contraceptive services. Plaintiffs are eligible for a regulatory accommodation that relieves them from having to contract, arrange, pay or refer for contraceptive coverage, and that in no way prevents plaintiffs from continuing to voice their disapproval of contraceptive use or even from encouraging their employees to refrain from such use. To avail themselves of this significant accommodation, plaintiffs need do nothing more than provide their TPA with a copy of a self-certification that they are eligible for the accommodation and do not wish to provide contraception. Such a minimal requirement is no "burden" at all, let alone one sufficient to invalidate the regulations.

Indeed, although defendants respectfully disagree with this Court's December 2012 entry of a temporary restraining order (TRO) pertaining to the for-profit company plaintiff (Sharpe Holdings, Inc.) in this case, *see* Mem. & Order, ECF No. 20 ("TRO Order"), the Court's order is inapposite here because for-profit corporations—unlike plaintiffs CNS and Heartland, both non-profit organizations—do *not* qualify for the accommodation for eligible organizations and must contract and pay for contraceptive coverage. The lone factor identified by the Court to support its finding of a substantial burden as to the for-profit plaintiffs in this case—*i.e.*, that the prior regulations "would force them to *subsidize* coverage for drugs and devices" to which they object on religious grounds, *id.* at 6 (emphasis added)—is *entirely absent* from the regulatory accommodation the non-profit plaintiffs challenge now. In fact, the regulatory accommodation at issue here, far from requiring plaintiffs CNS and Heartland to contract or pay for contraceptive coverage, relieves them of the obligation to do so and *expressly prohibit* plaintiffs' TPA from charging *any* premium or otherwise passing on any costs to the non-profit plaintiffs with respect

to the TPA's payments for contraceptive services. *See, e.g.*, 29 C.F.R. § 2590.715-2713A(b)(2)(i)-(ii); *see also* 78 Fed. Reg. 39,870, 39,880 (July 2, 2013).

Specifically, plaintiffs 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, as discussed below, 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.

When the contraceptive-coverage requirement was first established, in August 2011, certain non-profit religious organizations objected on religious grounds to having to provide contraceptive coverage in the group health plans they offer to their employees. Although, in the government's view, these organizations were mistaken to claim that an accommodation was required under the First Amendment or the Religious Freedom Restoration Act (RFRA), the defendant Departments decided to accommodate the concerns expressed by these organizations. First, they established an exemption for the group health plans of houses of worship and their integrated auxiliaries (and any associated group health insurance coverage). In addition, defendants established accommodations for the group health plans of eligible non-profit religious organizations, like plaintiffs (and any associated group health insurance coverage), that relieve them of responsibility to contract, arrange, pay, or refer for contraceptive coverage or services, but that also ensure that the women who participate in these plans are not denied access to contraceptive coverage without cost-sharing. To be eligible for an accommodation, the organization merely needs to certify that it meets the eligibility criteria, *i.e.*, that it is a non-profit organization that holds itself out as religious and has a religious objection to providing coverage

for some or all contraceptives. Once the organization certifies that it meets these criteria, it need not contract, arrange, pay, or refer for contraceptive coverage or services. For those organizations with a self-insured group health plan—like plaintiffs—the TPA takes on the responsibility to provide contraceptive coverage to the organization's employees and covered dependents. The objecting employer does not bear the cost (if any) of providing contraceptive coverage; nor does it administer such coverage; nor does it contract or otherwise arrange for such coverage; nor does it refer for such coverage.

Yet, plaintiffs CNS and Heartland now claim that these accommodations themselves violate their rights under RFRA and the First Amendment. Plaintiffs appear to allege that even the mere act of certifying that they are eligible for an accommodation is a substantial burden on their religious exercise because, once they make the certification, their employees will be able to obtain contraceptive coverage through other parties. At bottom, plaintiffs' position seems to be that any asserted burden, no matter how *de minimis*, amounts to a substantial burden under RFRA. That is not the law. Congress amended the initial version of RFRA to add the word "substantially," and thus made clear that "any burden" would not suffice. Although their requirements are *de minimis*, plaintiffs claim that the regulations run afoul of their religious beliefs prohibiting them from providing or facilitating health coverage for certain contraceptive services. Plaintiffs move for a TRO and preliminary injunction on their RFRA and Free Exercise Clause claims, which should be denied because plaintiffs have not shown that they are likely to succeed on the merits of those claims.[1]

With respect to plaintiffs' RFRA claim, plaintiffs cannot establish a substantial burden on their religious exercise—as they must—because the regulations do 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

[1] Plaintiffs CNS and Heartland have not moved for preliminary relief on Counts III thru VI of the Second Amended Complaint ("SAC"). *See* SAC, ECF No. 61.

so, to voice their disapproval of contraception, and to encourage their employees to refrain from using contraceptive services. Plaintiffs allege 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 plaintiffs *only* to self-certify that they have a religious objection to providing contraceptive coverage and otherwise meet the criteria for an eligible organization, and to share that self-certification with their TPA. In other words, plaintiffs are required only to inform their TPA that they object to providing contraceptive services, which they have done or would have to do voluntarily anyway even absent these regulations in order to ensure that they are 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 provision by a TPA of payments for contraceptive services to which plaintiffs 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' Free Exercise claim also should fail. Indeed, nearly every court to consider similar First Amendment challenges to the prior version of the regulations rejected the claims, and their analysis applies here. For these reasons, and those explained below, plaintiffs' motion for a TRO and preliminary injunction should be denied.

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 to stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce health care costs. 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."), *available at* http://www.nap.edu/catalog.php?record_id=13181. Section 1001 of the ACA—which includes the preventive services coverage provision relevant here—seeks to cure this problem 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 group or individual 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 [(HRSA)]." 42 U.S.C. § 300gg-13(a)(4).[2]

Because there were no existing HRSA guidelines relating to preventive care and screening for women, the Department of Health and Human Services (HHS) requested that the Institute of Medicine (IOM) develop recommendations to implement the requirement to provide

[2] This provision also applies to immunizations, cholesterol screening, blood pressure screening, mammography, cervical cancer screening, screening and counseling for sexually transmitted infections, domestic violence counseling, depression screening, obesity screening and counseling, diet counseling, hearing loss screening for newborns, autism screening for children, developmental screening for children, alcohol misuse counseling, tobacco use counseling and interventions, well-woman visits, breastfeeding support and supplies, and many other preventive services. *See, e.g.*, U.S. Preventive Services Task Force A and B Recommendations, http://www.uspreventiveservicestaskforce.org/uspstf/uspsabrecs.htm (last visited Sept. 11, 2013).

coverage, without cost-sharing, of preventive services for women. IOM REP. at 2.[3] After conducting an extensive science-based review, IOM recommended that HRSA guidelines include, among other things, well-woman visits; breastfeeding support; domestic violence screening; and, 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. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices ("IUDs"). *See id.* at 105. 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 unintended pregnancies) and promote healthy birth spacing. *See id.* at 102-03.[4]

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").[5] Group health plans established or maintained by these religious employers (and associated group health insurance coverage) are exempt from any requirement to cover contraceptive services consistent with HRSA's guidelines. *See id.*; 45 C.F.R. § 147.131(a).

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[3] IOM, which was established by the National Academy of Sciences in 1970, is funded by Congress to provide expert advice to the federal government on matters of public health. IOM REP. at iv.

[4] At least twenty-eight states have laws requiring health insurance policies that cover prescription drugs to also provide coverage for FDA-approved contraceptives. *See* Guttmacher Institute, State Policies in Brief: Insurance Coverage of Contraceptives (Dec. 2013), *available at* http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf.

[5] 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
(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).

In 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). 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. The regulations challenged here (the "2013 final rules") represent the culmination of that process. *See* 78 Fed. Reg. 39,870; *see also* 77 Fed. Reg. 16,501 (Mar. 21, 2012) (Advance Notice of Proposed Rulemaking (ANPRM)); 78 Fed. Reg. 8456 (Feb. 6, 2013) (Notice of Proposed Rulemaking (NPRM)).

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 compelling government interests in safeguarding public health and ensuring that women have equal access to health care. The regulations advance these interests in a narrowly tailored fashion that does not require non-profit religious organizations with religious objections to providing contraceptive coverage to contract, pay, arrange, or refer for that coverage.

First, the 2013 final rules simplify and clarify the religious employer exemption by eliminating the first three criteria and clarifying the fourth criterion. *See supra* note 5. 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 changes made to the definition of religious employer in the

2013 final rules are intended to ensure "that an otherwise exempt plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths." 78 Fed. Reg. at 39,874.

Second, the 2013 final rules establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by "eligible organizations" (and group health insurance coverage provided in connection with such plans). *Id.* at 39,875-80; 45 C.F.R. § 147.131(b). 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.

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. 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. Its participants and beneficiaries, however, will still benefit from separate payments for contraceptive services without cost sharing or other charge. *Id.* at 39,874. In the case of an organization with a self-insured group health plan—such as plaintiffs—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. Any costs incurred by the TPA will be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See id.* at 39,880.[6]

The 2013 final rules generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, *see id.* at 39,872, except that 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 id.* at 39,871.

STANDARD OF REVIEW

A motion for a TRO is evaluated under the same standards as a motion for a preliminary injunction. *See S.B. McLaughlin & Co. v. Tudor Oaks Condo. Project*, 877 F.2d 707, 708 (8th Cir.1989). 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, Inc.*, 555 U.S. 7, 22 (2008). A plaintiff "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.

I. PLAINTIFFS HAVE NOT SHOWN A LIKELIHOOD OF SUCCESS ON THE MERITS

A. Plaintiffs' Religious Freedom Restoration Act Claims Are Without Merit

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

[6] Although not at issue in this case (because plaintiffs CNS and Heartland both are self-insured), in the case of an organization with an insured group health plan, the organization's health insurance issuer, upon receipt of the self-certification, must provide separate payments to plan participants and beneficiaries for contraceptive services without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. *See id.* at 39,875-77.

trigger the compelling interest requirement." *Henderson v. Kennedy*, 253 F.3d 12, 17 (D.C. Cir. 2001) (emphasis added). "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)); *Garner v. Kennedy*, 713 F.3d 237, 241-42 (5th Cir. 2013) (noting, in the RLUIPA context, that, "[i]n 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'"). "An inconsequential or *de minimis* burden on religious practice does not rise to this level, nor does a burden on activity unimportant to the adherent's religious scheme." *Kaemmerling*, 553 F.3d at 678; *see also Braunfeld v. Brown*, 366 U.S. 599, 606 (1961) ("To strike down, without the most careful scrutiny, legislation which imposes only an indirect burden on the exercise of religion, *i.e.*, legislation which does not make unlawful the religious practice itself, would radically restrict the operating latitude of the legislature."); *Combs v. Homer-Center Sch. Dist.*, 540 F.3d 231, 262 (3d Cir. 2008) (Scirica, C.J., concurring) ("In our modern regulatory state, virtually all legislation (including neutral laws of general applicability) imposes an incidental burden at some level by placing indirect costs on an individual's activity. Recognizing this . . . [t]he federal government . . . ha[s] identified a substantiality threshold as the tipping point for requiring heightened justifications for governmental action.").

For two reasons, plaintiffs cannot show that the challenged regulations substantially burden their religious exercise.[7] First, because the regulations require virtually nothing of

[7] Plaintiffs repeatedly refer to cases involving *for-profit* companies that object to the contraceptive coverage regulations. *See, e.g.*, Mem. of CNS Int'l Ministries, Inc. & Heartland Christian College in Support of Mot. for Temp. Restraining Order & Prelim. Inj. ("Pls.' Mem.") at 3 n.2, 17, 18, ECF No. 64 (citing, e.g., *Hobby Lobby v. Sebelius*, 723 F.3d 1114 (10th Cir. 2013) (en banc), *cert. granted*, No. 13-354; *O'Brien v. HHS*, No. 12-3357, Order (8th Cir. Nov. 28, 2012) (motions panel); *Annex Medical, Inc. v. Sebelius*, No. 13-1118, Order (8th Cir. Feb. 1, 2012) (motions panel)). But those cases are inapposite because for-profit corporations—unlike plaintiffs CNS and Heartland—do *not* qualify for the accommodations for eligible organizations. *See* 78 Fed. Reg. at 39,875. 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 plan. Plaintiffs, by contrast, are in a markedly different position: As previously explained, in order to be relieved of the obligation to contract or otherwise arrange

(footnote continued on next page…)

plaintiffs, and certainly do not require plaintiffs to modify their behavior in any meaningful way, the regulations do not impose any more than a *de minimis* burden on plaintiffs—let alone a substantial one. Second, even if this Court were to find 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. Plaintiffs, as eligible organizations, are not required to contract, arrange, pay, or refer for contraceptive coverage. To the contrary, they 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 need only fulfill the self-certification requirement and provide the completed self-certification to their TPA. They need not provide payments for contraceptive services to their employees. Instead, a third party—plaintiffs' TPA—provides payments for contraceptive services at no cost to plaintiffs. *See, e.g.*, *Bowen v. Roy*, 476 U.S. 693, 701 n.6 ("[Plaintiff]'s religious views may not accept this distinction between individual and [third party] conduct. It is clear, however, that the Free Exercise Clause, and the Constitution generally, recognize such a distinction; for the adjudication of a constitutional claim, the Constitution, rather than an individual's religion, must supply the frame of reference."). In short, with respect to contraceptive coverage, plaintiffs need not do anything more than they did prior to the

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and pay for contraceptive coverage, plaintiffs must take the simple step of completing the self-certification—which reiterates what they have already stated repeatedly in this case; that they are non-profit religious with religious objections to providing contraceptive coverage—and provide a copy of the self-certification to their TPA.

Similarly, the district court in *Zubik v. Sebelius*, Nos. 13cv1459, 13cv0303, 2013 WL 6118696 (W.D. Pa. Nov. 21, 2013), was wrong to rely on cases involving claims of for-profit employers. 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. Likewise, the recent ruling by the district court in *Archdiocese of New York v. Sebelius*, No. 12 Civ. 2542 (BMC) (E.D.N.Y. Dec. 16, 2013), ECF No. 116, glossed over the animating question of this case, which is whether a substantial burden may be said to exist because a plaintiff objects to the consequences of actions it does not independently object to taking. For the reasons set out here, it may not.

promulgation of the challenged regulations—that is, to inform their TPA that they object to providing contraceptive coverage in order to ensure that they are not responsible for contracting, arranging, paying, or referring for such coverage. Thus, the regulations do not require plaintiffs "to significant modify [their] religious behavior." *Kaemmerling*, 553 F.3d at 679; *Garner*, 713 F.3d at 241. 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 religious act in which [plaintiffs] engage[]." *Kaemmerling*, 553 F.3d at 679; *see also Love v. Reed*, 216 F.3d 682, 689 (8th Cir. 2000) (holding that a rule imposes a substantial burden on the free exercise of religion when it provides "no consistent and dependable way" to observe a religious practice); *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 assertion that RFRA is violated whenever they "set[] in motion a chain of events that results in their employees receiving free" products and services to which plaintiffs object. Pls.' Mem. at 17. This theory would mean, for example, that even the government would not realistically be able to provide contraceptive coverage to plaintiffs' employees, because such coverage would be "set[] in motion," *id.*, 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.),[8] 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 reasoned 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.*

Plaintiffs—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—attempt to circumvent this problem by advancing the novel theory that the regulations require them to somehow "facilitate . . . access" to contraception, Pls.' Mem. at 13, or become

[8] Plaintiffs incorrectly assert that the Eighth Circuit motions panel orders in *O'Brien* and *Annex Medical* "control here." Pls.' Mem. at 3 n2. Far from it. As explained above, cases involving for-profit companies that are not eligible for the accommodation are inapposite to the extent those cases find a substantial burden on for-profit plaintiffs. *See supra* at 1, 10 n.7. Nor, in any event, do motions panel decisions bind this Court. *See In re Rodriquez*, 258 F.3d 757, 759 (8th Cir. 2001) ("Decisions by motions panels are summary in character, made often on a scanty record, and not entitled to the weight of a decision made after plenary submission." (quotations omitted)); *United States v. Henderson*, 536 F.3d 776, 778 (7th Cir. 2008); *Lambert v. Blackwell*, 134 F.3d 506, 513 n.17 (3d Cir. 1997).

"part of the mechanism" that provides contraception, *id.* at 2, and that it is this "facilitation" that violates plaintiffs' religious beliefs. *See, e.g., id.* at 13. But under the challenged regulations plaintiffs need *only* to self-certify that they object to providing coverage for contraceptive services and that they otherwise meet the criteria for an eligible organization, and to share that self-certification with their TPA. In other words, plaintiffs must inform their TPA that they do not intend to cover or pay for contraceptive services, which they have done or would have to do voluntarily anyway even absent these regulations in order to ensure that they are not responsible for contracting, arranging, paying, or referring for contraceptive coverage. *See, e.g.*, SAC ¶ 49. The sole difference is that they must inform their TPA that their intention not to include contraceptive coverage is due to their religious objections—a statement which they have already made repeatedly in this litigation and elsewhere.[9]

Furthermore, any burden imposed by the purely administrative self-certification requirement—which should take plaintiffs a matter of minutes—is, at most, *de minimis*, and thus cannot be "substantial" under RFRA. The substantial burden hurdle is a high one. *Living Water Church of God v. Charter Twp. of Meridian*, 258 Fed. App'x 729, 736 (6th Cir. 2007); *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 federal government should somehow expand Medicaid or some other public program so as to provide contraceptive coverage to the women who participate in

[9] Plaintiffs point to other activities—"identify[ing] their employees" to, and otherwise "coordinat[ing]" with, their TPA—that would allegedly be required by the challenged regulations. Pls.' Mem. at 1, 14-15 But these are undoubtedly activities that plaintiffs must already engage in as part of the working relationship with their TPA—including so that the TPA provides *any* health coverage to their employees—and they have nothing to do with these regulations. Indeed, plaintiffs cite no regulatory language that requires such activities.

plaintiffs' 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* at 28. 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 that they are eligible for an accommodation and that they therefore do not intend to provide contraceptive coverage, 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 status with the eligible organization. The current accommodations are thus likely to require less of plaintiffs' involvement than would be required under a government program that would separately provide contraceptive coverage for their employees and dependents.

Contrary to plaintiffs' suggestion, the mere fact that plaintiffs claim that the self-certification requirement imposes a substantial burden on their religious exercise 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."). 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. *Cf. Bowen*, 476 U.S. at 701 n.6. 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 objection to the challenged 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 (reviewing cases); *see also, e.g., Garner*, 713 F.3d at 241; *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). This test does not require the Court to "delve into the theological merit of the belief in question," as plaintiffs incorrectly assert, Pls.' Mem. at 19 (internal quotation marks and citation omitted), but instead requires the Court to examine the operation of the regulations and their impact on plaintiffs' religious practice as a legal matter, outside the context of their religious beliefs—that is, from the perspective of an objective observer. "This is an objective test." Pls.' Mem. at 18.[10]

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. *See* Pls.' Mem. at 18-19. 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 Autocam*, 2012 WL 6845677, 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.

[10] 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; *see also* Pls.' Mem. at 18-19 (citing *Hobby Lobby*). 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 must require some actual change in religious behavior—either forced participation in conduct or forced abstention from conduct. *See Hobby Lobby*, 723 F.3d 1114 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. *See supra* at nn. 7 & 8. For similar reasons, the Seventh Circuit's substantial burden analysis in *Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 2013)—which followed *Hobby Lobby*—is unpersuasive.

Supp. 2d at 413-14; *see also Autocam*, 2012 WL 6845677, at *7; *Mersino*, 2013 WL 3546702, at *16.[11] The result would be to subject every act of Congress to strict scrutiny every time any plaintiff could articulate a sincerely held religious objection to compliance with that law. The "most demanding test known to constitutional law," *City of Boerne v. Flores*, 521 U.S. 507, 534 (1997), would thus be transformed into a norm against which Congress must always legislate.

Finally, plaintiffs seem to suggest that the regulations will actually require them to fund or subsidize access to contraceptive coverage because their TPA will find a way to pass on the costs of such coverage to plaintiffs. *See* Pls.' Mem. at 15. But the regulations specifically *prohibit* plaintiffs' TPA from charging any premium or otherwise passing on any costs to plaintiffs with respect to the TPA's payments for contraceptive services. *See* 78 Fed. Reg. at 39,880. Any suggestion that plaintiffs' TPA will violate the law is purely speculative, and boils down to the baseless argument that the regulations impose a substantial burden under RFRA because a third party might violate those same regulations. This contention has no merit.[12]

In sum, the regulations do not impose a substantial burden on plaintiffs' religious exercise, and thus plaintiffs' motion for a TRO and preliminary injunction should be denied.

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

[11] 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).

[12] To the extent plaintiffs reference defendants' cost-neutrality assumptions as to issuers of insurance, *see* Pls.' Mem. at 10, these assumptions are irrelevant to plaintiffs, both of whom are *self*-insured, not third-party insured.

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, when making use of their benefits. Those employees have a legitimate interest in access to the preventive services coverage made available under the challenged regulations.

Indeed, courts have held that claims raised by for-profit companies challenging the contraceptive coverage regulations, which require them to provide the relevant coverage themselves, are too attenuated to amount to a substantial burden under RFRA. Any burden on plaintiffs, which are eligible for 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* district 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 id.* at 415. Other courts, too, have relied on similar reasoning to reject similar plaintiffs' RFRA claims. *See, e.g.*, *Autocam*, 2012 WL 6845677, at *6 ("The incremental difference between providing the benefit directly, rather than indirectly, is unlikely to qualify as a substantial burden on the Autocam Plaintiffs."); *O'Brien*, 894 F. Supp. 2d at 1158-60 ("[RFRA] is not a means to force one's religious practices upon others." RFRA does not protect against the slight burden on religious exercise that arises when one's money circuitously flows to support the conduct of other free-exercise-wielding individuals who hold religious beliefs that differ from one's own.").[13]

[13] *See Eden Foods, Inc. v. Sebelius*, No. CIV.A. 13-11229, 2013 WL 1190001, *4 (E.D. Mich. Mar. 22, 2013); (footnote continued on next page…)

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—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/TPAs, 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 TPA.

But a burden simply cannot be "substantial" under RFRA when it is attenuated. 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 plaintiff cannot establish a substantial burden on his religious exercise by invoking this type of trickle-down theory; to constitute a substantial burden within the meaning of 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.[14] Here, of course, there is no such direct burden. In fact, given that any payment for

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Annex Medical, Inc. v. Sebelius, No. 12–2804, 2013 WL 101927, *4-5 (D. Minn. Jan. 8, 2013).

[14] *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 11, in *Hobby Lobby*, 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,

(footnote continued on next page…)

contraceptive services is made by plaintiffs' issuers/TPAs, 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; *see also Conestoga*, 917 F. Supp. 2d at 414 ("The fact that Conestoga's employees are free to look outside of their insurance coverage and pay for and use any contraception . . . through the salary they receive from Conestoga, amply illustrates this point."); *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 preventive services coverage regulations therefore affect plaintiffs' religious practice, if at all, in a highly attenuated way. In short, because the regulations "are several degrees removed from imposing a substantial burden on [plaintiffs]," *O'Brien*, 894 F. Supp. 2d at 1160, the Court should deny plaintiffs' motion, 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

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

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if any, on a plaintiff's religious exercise. 723 F.3d 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 F. App'x at 734; *McEachin*, 357 F.3d at 203 n.6; *Civil Liberties for Urban Believers*, 342 F.3d at 761. The district court's ruling *Archdiocese of New York* was built on this erroneous interpretation of RFRA, which that court adopted from *Hobby Lobby*. Slip op. at 22. Under this theory, the mere fact that a plaintiff sincerely believes that a law violates his religious beliefs would be sufficient to amount to a substantial burden under RFRA so long as there is an adverse consequence attached to violating the law. Courts would play virtually no role in determining whether an alleged burden is "substantial." This expansive interpretation of RFRA has no limiting principle and is not supported by the case law.

compelling governmental interests, and are the least restrictive means to achieve those interests.[15] First, the promotion of public health is unquestionably a compelling governmental 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 regulations further this compelling interest by "expanding access to and utilization of recommended preventive services for women." 78 Fed. Reg. at 39,887.[16]

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); *see also* 77 Fed. Reg. at 8728; 78 Fed. Reg. at 39,872, 39,887. "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; 78 Fed. Reg. at 39,873 ("Research [ ] shows that cost sharing can be a significant barrier to access to contraception." (citation omitted)).[17]

Increased access to the full range of 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. As IOM concluded in identifying services recommended to "prevent conditions harmful to women's

[15] In the Court's December 2012 TRO Order, the Court stated that the question of whether the prior regulations satisfied strict scrutiny "require[d] further hearing and consideration." TRO Order at 6-7. Defendants respectfully submit that the regulations do satisfy strict scrutiny and that the Court's preliminary ruling in its prior order does not require the same result for the current plaintiffs (CNS and Heartland) now.

[16] Plaintiffs argue, incorrectly, that the regulations do not further the government's compelling interests because—if required to comply—plaintiffs will drop health coverage for their employees. Pls.' Mem. at 25. It cannot be that a plaintiff's own deliberate steps to thwart the effects of a law undermine the government's interest in creating it.

[17] Plaintiffs miss the point, therefore, when they attempt to minimize the magnitude of these interests by arguing that the contraceptive methods to which they object are "widely available." *See* Pls.' Mem. at 23. Although a majority of employers cover FDA-approved contraceptives, *see* IOM REP. at 109, many women forgo preventive services because of cost-sharing imposed by their health plans, *see id.* at 19-20, 109. The challenged regulations eliminate that cost-sharing. 78 Fed. Reg. at 39,873.

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. Contraceptive coverage further helps to avoid "the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id.* at 103; *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). And "[c]ontraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrative 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; *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.").

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. 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 gender-specific 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); 78 Fed. Reg. at 39,887; IOM REP. at 19. 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; IOM REP. at 20. 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).[18]

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 23-24. 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.*

[18] 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 22-23. But this level of specificity would be impossible to establish and would render this regulatory scheme—and potentially every regulatory scheme that is 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 expanded the inquiry 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 (2006), is not to the contrary. To be sure, the Court rejected "slippery-slope" arguments for refusing to accommodate a particular claimant. *See id.* 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*, 374 U.S. 398, 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.

City of Hialeah, 508 U.S. 520, 546-47 (1993). Many of 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 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) (rejecting the plaintiff's argument that the existence of exemptions indicates that a law is not the least restrictive means of achieving a compelling interest where the exemptions do not undermine that interest); *see also* 78 Fed. Reg. at 39,887.

For example, the grandfathering of certain health plans with respect to certain provisions of the ACA is not specifically 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. 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. 34,540, 34,546 (June 17, 2010).

This incremental transition does nothing to 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 as time goes on. Defendants have estimated that a majority of group health plans lost their grandfather status by 2013. *See* 75 Fed. Reg. 34,538, 34,552 (June 17, 2010); *see also* Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2012 Annual Survey at 7-8, 190 (indicating that 58 percent of firms had at least one grandfathered health plan in 2012, down from 72 percent in 2011, and that 48 percent of covered workers were in grandfathered health plans in 2012, down from 56 percent in 2011), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/03/8345-employer-health-benefits-annual-survey-full-report-0912.pdf. Thus, any purported damage to 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 such an 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.").

Moreover, 26 U.S.C. § 4980H(c)(2) does *not*, as plaintiffs claim, exempt small employers from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. at 39,887 n.49. Instead, it excludes employers with fewer than fifty full-time equivalent employees from the employer responsibility provision, meaning that, starting in 2015, such employers are not subject to the possibility of assessable payments if they do not provide health coverage to their full-time employees and their dependents. *See* 26 U.S.C. § 4980H(c)(2). Small businesses that *do* offer non-grandfathered health coverage to their employees are required to provide

coverage for recommended preventive services, including contraceptive services, without cost-sharing. 78 Fed. Reg. at 39,887 n.49. And there is reason to believe that small employers will continue to offer health coverage to their employees, because the ACA, among other things, provides tax incentives for small businesses to encourage the purchase of health insurance. *See* 26 U.S.C. § 45R. But even if a small business were to choose not to offer health coverage, employees of such business could get health insurance coverage that is facilitated by other ACA provisions—primarily those establishing both small group market and individual market health insurance exchanges and those establishing tax credits to make the purchase of coverage through such exchanges more affordable—and the coverage they receive through such exchanges will include coverage of all recommended preventive services, including contraception. 78 Fed. Reg. at 39,887 n.49.

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 to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. *See* 78 Fed. Reg. at 39,874. By contrast, individuals in plans of eligible organizations that qualify for the accommodations are less likely than individuals in plans of religious employers to share their employer's faith and object to contraceptive coverage on religious grounds. *See* 78 Fed. Reg. at 39,874, 39,887. 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 exact opposite of what Congress intended to accomplish in enacting RFRA.

Granting plaintiffs the much broader exemption they request would undermine defendants' ability to enforce the regulations in a rational manner. *See Gonzales v. O Centro Espirita Beneficente Uniao Do Vegetal*, 546 U.S. 418, 435 (2006). We are a "cosmopolitan nation made up of people of almost every conceivable religious preference," *Braunfeld*, 366 U.S. at 606; *see also S. Ridge Baptist Church*, 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, administered, and otherwise provided by a third party. *See id.* (noting consequences "for the public and the government"); 77 Fed. Reg. at 8728; 78 Fed. Reg. at 39,887.

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) (describing the least restrictive means test as "the extent to which accommodation of defendant would impede the state's objectives"); *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." *Id.* 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 26-27. 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). 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.

Moreover, 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) ("A judge would be unimaginative indeed if he could not come up with something a little less 'drastic' or a little less 'restrictive' in almost any situation, and thereby enable himself to vote to strike legislation down.'" (quotations omitted)), 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 they would impose considerable new costs and other burdens on the government and would otherwise be impractical. *See* 78 Fed. Reg. at 39,888; *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; *see also, e.g.*, *Kaemmerling*, 53 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 an existing one, 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. 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 put forth viable less restrictive alternatives that would achieve the government's compelling interests, the Court should reject plaintiffs' argument that the regulations fail strict scrutiny.

B. The Regulations Do Not Violate the Free Exercise Clause

The Supreme Court has made clear that 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*.

Unlike such selective laws, the preventive services coverage regulations are neutral and generally applicable. Indeed, virtually every other court to have considered a free exercise challenge to the prior version of the regulations rejected it, concluding that the regulations are neutral and generally applicable.[19] "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.

[19] *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*, 2013 WL 1190001, at *4-5; *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 sub nom, Korte v. Sebelius*, 735 F.3d 654 (7th Cir. 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*, *Korte*, 735 F.3d 654; *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*, 85 P.3d at 81-87 (same). *But see* TRO Order at 7-8; *Geneva Coll. v. Sebelius*, 929 F.Supp.2d 402 (W.D. Penn. 2013).

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."); *Grote*, 914 F. Supp. 2d at 952-53 ("[T]he purpose of the regulations is a secular one, to wit, 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 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); *see O'Brien*, 894 F. Supp. 2d at 1162; *Autocam*, 2012 WL 6845677, at *5; *Grote*, 914 F. Supp. 2d at 953.

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. As this circuit has explained, "[g]eneral 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). "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*. 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 non-neutral 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 rendered unlawful "merely because the [religious employer exemption] does not extend as far as Plaintiffs wish." *Grote*, 914 F. Supp. 2d at 953.

Although defendants respectfully disagree with this Court's preliminary ruling regarding the regulations that apply to for-profit corporations, TRO Order at 6-7, the concerns expressed in the Court's order do not apply to the accommodation. In its order, the Court appeared to conclude that the prior regulations "imposed" burdens "only on conduct motivated by religious belief." *Id.* at 8. The accommodation challenged by these plaintiffs, however, does just the opposite—it *relieves* eligible non-profit religious organizations, like plaintiffs, of the responsibility to contract, arrange, pay, or refer for contraceptive coverage or services.

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.[20] 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.[21]

For these reasons, plaintiffs' free exercise claim—Count II—fails.

II. 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 McNeilly v. Land*, 684 F.3d 611, 621 (6th Cir. 2012).

As 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

[20] *Fraternal Order of Police v. City of Newark*, 170 F.3d 359 (3d Cir. 1999), on which plaintiffs rely, addressed a policy that created a secular exemption but refused all religious exemptions. The preventive services coverage regulations, in contrast, contain an exemption for houses of worship and accommodations for other non-profit religious organizations that specifically seek to accommodate religion. Thus, there is simply no basis in this case to infer a discriminatory purpose behind the regulations. *See Conestoga*, 917 F. Supp. 2d at 409-10.

[21] 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*.

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.[22]

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 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, 407; 77 Fed. Reg. at 8727; 78 Fed. Reg. at 39,887. As a result, in many cases, both women and developing fetuses suffer negative health consequences. *See* IOM REP. at 20, 102-04; 77 Fed. Reg. at 8728. 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.[23]

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[22] Plaintiffs note that defendants consented to preliminary injunctions in a few cases involving for-profit companies, *see* Pls.' Mem. at 34, but defendants' consent in those cases—including this one, to the extent it involves *for-profit* plaintiffs—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 preliminary 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 similar cases (i.e. cases involving for-profit plaintiffs) in other circuits and, in every circuit, opposes preliminary injunctions sought by *non-profit* plaintiffs, such as those before the Court now.

[23] Contrary to plaintiffs' assertions, Pls.' Mem. at 34, that plaintiffs object to some but not all contraceptive methods should not be an important consideration in the Court's overall determination of whether to issue a preliminary injunction. The guidelines adopted by HRSA, which are based on the recommendations made by the IOM,

(footnote continued on next page…)

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; *see also* 77 Fed. Reg. at 8728,—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' motions for a TRO and preliminary injunction.

Respectfully submitted on this 18th day of December, 2013,

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encompass coverage for *all* FDA-approved contraceptive methods "as prescribed by a provider." 77 Fed. Reg. 8725 (Feb. 15, 2012). The decision about which form of contraceptive to use, if any, is a personal medical decision that is made by a woman in consultation with her doctor. "For women with certain medical conditions or risk factors, some contraceptive methods may be contraindicated." IOM REP. at 105, AR 403. For example, for some women, hormonal contraceptives (like birth control pills) may be contraindicated because of certain risk factors, such as uncontrolled hypertension or coronary artery disease, so the doctor may instead prescribe a copper IUD, which does not contain hormones. The guidelines thus ensure that the decision about which contraceptive method (if any) to use is made by a woman and her doctor—not by her employer—and it would be contrary to the public interest to deny plaintiffs' employees (and their dependents) the use of specific methods to which plaintiffs object.

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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2013, I caused a true and correct copy of this filing to be served on counsel by means of the Court's ECF system.

/s/ Jacek Pruski
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