IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF OKLAHOMA

CATHOLIC BENEFITS ASSOCIATION, LCA, *et al.*

Plaintiffs,

v.

SYLVIA M. BURWELL, in her official capacity as Secretary of the Department of Health and Human Services, *et al.*,

Defendants.

No. 5:14-cv-00685

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs seek to preliminary enjoin application of the preventive services coverage regulations as to new members that joined the Catholic Benefits Association ("CBA") after June 4, 2014. The Court should deny plaintiffs' motion. As an initial matter, CBA's "Group I" members are entirely exempt from the challenged regulations, and—as this Court has held—are therefore not likely to succeed on the merits of their claims. *See Catholic Benefits Ass'n v. Burwell*, --- F. Supp. 2d ----, 2014 WL 2522357, at *7 (W.D. Okla. 2014) ("*CBA I*"). Moreover, although defendants recognize that this Court has already granted preliminary injunctive relief to some of CBA's "Group II" members,[1] defendants respectfully submit that further injunctive relief is unwarranted in light of the Supreme Court's decision in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), and in light of the interim final rules issued by defendants on August 22, 2014.

In *Hobby Lobby*, the Supreme Court held that the contraceptive coverage requirement violated RFRA with respect to closely held for-profit corporations that, unlike CBA's Group II members, could not opt out of the requirement.[2] The existence of the opt-out regulations that plaintiffs challenge here was crucial to the Court's reasoning. The Court observed that the opt-out regulations "effectively exempt[]" organizations that are eligible for an accommodation, such as CBA's Group II members. *Id.* at 2763. The Court expressly

[1] Defendants respectfully submit that the Court erred in granting the plaintiffs' motion for a preliminary injunction in *CBA I* and note that defendants are currently pursuing an appeal of the Court's decision. *See Catholic Benefits Ass'n v. Burwell*, No. 14-6163 (10th Cir.).

[2] Accordingly, defendants do not oppose preliminary injunctive relief as to "Group III" members that are closely held for-profit corporations, provided that any preliminary injunction makes clear that nothing prevents defendants from enforcing the contraceptive coverage requirement against them and/or their health insurance issuers and/or third-party administrators if religious accommodations regarding the contraceptive coverage are made available to for-profit entities with religious objections.

stated that the regulations "seek[] to respect the religious liberty of religious nonprofit corporations while ensuring that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage." *Id*. at 2759.

The Supreme Court concluded that the opt-out regulations demonstrated that HHS "ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." *Id.* at 2782. The Court reasoned that the accommodations allowed under the regulations "serve[] HHS's stated interests equally well" because "female employees would continue to receive contraceptive coverage without cost sharing for all FDA-approved contraceptives, and they would continue to 'face minimal logistical and administrative obstacles'" in obtaining the coverage. *Id.* at 2782 (citation omitted). Indeed, "[t]he effect of the HHS-created accommodation on the women employed by Hobby Lobby and the other companies involved in these cases would be *precisely zero*." 134 S. Ct. at 2760 (emphasis added); *see also id.* at 2759 (explaining that the accommodation "ensur[es] that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage").

Moreover, on August 22, 2014, the Departments augmented the regulatory accommodation process available to non-profit entities like CBA's Group II members in light of the Supreme Court's interim order in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014). *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,092 (Aug. 27, 2014) (interim final regulations). In its *Wheaton College* order, the Supreme Court identified an alternative form of accommodation that would neither affect "the ability of [Wheaton College's] employees and students to obtain, without cost, the full range of FDA approved contraceptives," nor preclude the government from relying

on the notice it receives from Wheaton College "to facilitate the provision of full contraceptive coverage under the [Affordable Care] Act." 134 S. Ct. at 2807. The accommodation, as originally challenged in *Wheaton College* and in this case, contemplated that an eligible organization would notify its insurer or third-party administrator of its decision to opt out. Under the interim final regulations, an organization may also opt out by notifying HHS directly of its decision rather than by notifying its insurance issuer or third-party administrator. 79 Fed. Reg. at 51,094-95. This provides CBA's Group II members with an alternative mechanism for opting out of the contraceptive coverage requirement.

Because CBA's Group II members are eligible for the accommodations, they are—in the words of the Supreme Court—"effectively exempt[]" from the contraceptive coverage requirement. *Hobby Lobby*, 134 S. Ct. at 2763. But plaintiffs' argument goes beyond the Group II members' own exemption from providing contraceptive coverage and would preclude the government from independently ensuring that their employees have the "same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage." *Id.* at 2759. That argument lacks support in precedent flies in the face of the reasoning of *Hobby Lobby*.

Plaintiffs' Establishment Clause and Administrative Procedure Act claims are likewise meritless. And plaintiffs cannot satisfy the remaining requirements for obtaining emergency relief. For these reasons, and those explained below, defendants respectfully request that the Court deny plaintiffs' motion for preliminary injunction.

BACKGROUND

The preexisting regulatory accommodations were discussed in detail in defendants' opposition to the plaintiffs' motion for a preliminary injunction in *CBA I*, and defendants respectfully refer the Court to that filing for the relevant background prior to August 22, 2014. *See* Defs.' Opp'n to Pls.' Mot. for Prelim. Inj. at 4-8, *CBA I*, ECF No. 29 ("*CBA I* PI

Opp'n"). On that date, the Departments augmented the regulatory accommodation process in light of the Supreme Court's interim order in connection with an application for an injunction in *Wheaton College*. The interim order provided that, "[i]f [Wheaton College] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments] are enjoined from enforcing against" Wheaton College provisions of the ACA and related regulations "pending final disposition of appellate review." *Wheaton Coll.*, 134 S. Ct. at 2807. The order also stated that this relief neither affected "the ability of [Wheaton College's] employees and students to obtain, without cost, the full range of FDA approved contraceptives," nor precluded the government from relying on the notice it receives from Wheaton College "to facilitate the provision of full contraceptive coverage under the Act." *Id.*

The *Wheaton College* order does not reflect a final Supreme Court determination that RFRA requires the government to apply the accommodations in this manner. Nevertheless, the Departments issued regulations that augment the accommodation process in light of the *Wheaton College* order by "provid[ing] an alternative process for the sponsor of a group health plan or an institution of higher education to provide notice of its religious objection to coverage of all or a subset of contraceptive services." 79 Fed. Reg. at 51,094. Under the interim final regulations, an organization may opt out of the contraceptive coverage requirement by notifying HHS of its decision directly rather than by notifying its insurance issuer or TPA. An organization need not use any particular form and need only indicate the basis on which it qualifies for an accommodation and its objection to providing some or all contraceptive services, as well as the type of plan and contact information for the plan's issuer. 45 C.F.R. § 147.131(c)(1)(ii).

If a group health plan sponsor notifies HHS that it is opting out, the Departments will then make the necessary communications to ensure that health insurance issuers or TPAs make or arrange separate payments for contraception. In the case of an "insured" group health plan, HHS "will send a separate notification to each of the plan's health insurance issuers informing the issuer" that HHS "has received a notice" that the group health plan is opting out of providing contraceptive coverage on religious grounds "and describing the obligations of the issuer" under the regulations. *Id.* An issuer that receives such a notice from HHS will "remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services to participants and beneficiaries," but the objecting organization "will not have to contract, arrange, pay, or refer for such coverage." 79 Fed. Reg. at 51,095.

In the case of a "self-insured" group health plan, the Department of Labor will "send a separate notification to each third party administrator of the ERISA plan." *Id*. The notification will state that HHS has received a notice from the employer opting out of the contraceptive coverage requirement and will "describe[] the obligations of the third party administrator under" the applicable regulations. 29 C.F.R. § 2590.715-2713A(b)(1)(ii)(B). These include the obligation to make or arrange separate payments for contraceptive services. *Id*. § 2590.715-2713A(b)(2). The Department of Labor's communication to the third party administrator(s) will also "designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage." 79 Fed. Reg. at 51,095.

In all cases, the eligible organization that opts out of providing contraceptive coverage has no obligation to inform plan participants or enrollees of the availability of these separate payments made by third parties. Instead, the health insurance issuer or TPA provides this notice, and does so "separate from" materials that are distributed in connection

with the eligible organization's group health coverage. 45 C.F.R. § 147.131(d). That notice must make clear that the eligible organization is neither administering nor funding the contraceptive benefits. *Id*.

STANDARD OF REVIEW

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 20 (2008).

ARGUMENT

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS

A. Plaintiffs' Religious Freedom Restoration Act Claim Fails

Under the regulations that plaintiffs challenge, nonprofit religious organizations—like CBA's Group II members—can opt out of the contraceptive coverage requirement. CBA thus does not challenge any obligation to provide contraceptive coverage because it has none. If CBA's Group II members opt out, their insurers or third-party administrators will be independently required under federal law to make or arrange separate payments for contraceptive coverage.

Plaintiffs argue, however, that by declining to provide coverage CBA's Group II members will "trigger" the independent provision of contraceptive coverage, and that is what violates RFRA in their view. As the Sixth and Seventh circuits have explained in rejecting this contention, "[s]ubmitting the self-certification form to the insurance issuer . . . does not 'trigger' contraceptive coverage; it is federal law that requires the insurance issuer . . . to provide this coverage." *Mich. Catholic Conf. v. Burwell*, 755 F.3d 372, 387 (6th Cir. 2014) ("*Mich. Catholic Conf. II*"); *accord Univ. of Notre Dame v. Sebelius*, 743 F.3d 547, 554 (7th Cir. 2014) ("*Notre Dame II*"). The Supreme Court has also suggested that the

government may "rely[] on" a notice from objecting parties to "facilitate the provision of full contraceptive coverage under the Act." *Wheaton Coll.*, 134 S. Ct. at 2807, and the interim final regulations do precisely that; they provide alternative accommodations that allow eligible organizations to opt out by notifying HHS rather than their insurers or third party administrators. As with the preexisting regulations, after an organization informs HHS that it is opting out, federal law independently obligates the insurer to provide coverage.

Plaintiffs would transform RFRA from a shield into a sword by invoking CBA II's Group II members' religious beliefs to preclude women from receiving health coverage for recommended preventive health care services from third parties. That position finds no support in precedent and is sharply at odds with the Supreme Court's analysis in *Hobby Lobby*. There, the Supreme Court addressed for-profit employers not eligible for the accommodations and contrasted their obligations to those of non-profit religious organizations such as CBA's Group II members. The Court explained that the opt-out regulations "effectively exempt[]" eligible non-profit religious organizations like CBA's Group II members, *id.* at 2763, and do so by "seek[ing] to respect the religious liberty of religious nonprofit corporations while ensuring that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage, *id*. at 2759.

The regulations provide opt-out mechanisms that respect religious liberty while allowing the government to achieve its "compelling interest in providing insurance coverage that is necessary to protect the health of female employees, coverage that is significantly more costly than for a male employee." *Id.* at 2785-86 (Kennedy, J., concurring); *accord id.* at 2800 & n.23 (Ginsburg, J., dissenting). They offer an administrable way for organizations to state that they object and opt out—including without contacting their insurers directly—while ensuring that the government has the information needed to implement the

independent obligation that third parties provide contraceptive coverage so that participants and beneficiaries can "obtain, without cost, the full range of FDA approved contraceptives." *Wheaton Coll.*, 134 S. Ct. at 2807.

Plaintiffs' position ignores the Supreme Court's repeated admonition that, under RFRA, the interests of third parties count. *See Hobby Lobby*, 134 S. Ct. at 2781 n.37. Simply put, the free exercise of religion protected by RFRA cannot "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *Id.* at 2787 (Kennedy, J., concurring). CBA's claim is incompatible with fundamental principles that inform the proper interpretation of RFRA.

1. The Supreme Court's decision in *Hobby Lobby* and interim order in *Wheaton College* confirm the validity of the accommodations

The Supreme Court's decision in *Hobby Lobby* confirms the validity of the regulatory accommodations, and its reasoning cannot be reconciled with plaintiffs' position. The Supreme Court held that application of the contraceptive coverage requirement to the plaintiffs in that case—closely held companies that were not eligible for the regulatory opt-out—violated their rights under RFRA. Central to the Court's reasoning was the existence of the opt-out alternative that the Departments afford to organizations such as CBA's Group II members. The Court explained that the opt-out regulations "effectively exempt[]" organizations that are eligible for an accommodation. *Id.* at 2763. This accommodation, the Supreme Court elaborated, "seeks to respect the religious liberty of religious nonprofit corporations while ensuring that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage." *Id.* at 2759. Without specifically deciding whether the accommodations at issue in *Hobby Lobby* "compl[y] with RFRA for purposes of all religious claims," *id.* at 2782, the Court declared that the accommodations

are "an alternative" that "achieves" the aim of seamlessly providing coverage of recommended health services to women "while providing greater respect for religious liberty," *id.* at 2759.

The Supreme Court did not suggest that employers could (or should be allowed to) prevent their employees from obtaining contraceptive coverage from third parties through the accommodations. Rather, the Court reiterated that "in applying RFRA courts must take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries." *Id.* at 2781 n.37. The free exercise of religion protected by RFRA cannot "unduly restrict other persons, such as employees, in protecting their own interests, interests the law deems compelling." *Id.* at 2787 (Kennedy, J., concurring).

The Supreme Court thus stressed that "[t]he effect of the HHS-created accommodation on the women employed by Hobby Lobby and the other companies involved in these cases would be precisely zero." *Id.* at 2760; *see id.* at 2782-83. After employers opt out, employees "would continue to receive contraceptive coverage without cost sharing for all FDA-approved contraceptives, and they would continue to face minimal logistical and administrative obstacles because their employers' insurers would be responsible for providing information and coverage." *Id.* at 2782 (quotation omitted); *see id.* at 2786 (Kennedy, J., concurring) (explaining that the accommodation "works by requiring insurance companies" to provide contraceptive coverage and "equally furthers the [g]overnment's interest"). In responding to the dissent, the Court emphasized that the accommodations would not "impede women's receipt of benefits by requiring them to take steps to learn about, and to sign up for, a new government funded and administered health benefit." *Id.* at 2783 (quotation and brackets omitted); *see* 78 Fed. Reg. at 39,888.

The Supreme Court's interim order in connection with an application for an injunction in *Wheaton College* underscores the validity of the alternative method of opting

out promulgated in the interim final regulations. The Court's interim order provided that, "[i]f [Wheaton College] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments] are enjoined from enforcing against" Wheaton College provisions of the ACA and related regulations requiring coverage without cost-sharing of certain contraceptive services "pending final disposition of appellate review." *Wheaton Coll.*, 134 S. Ct. at 2807. The order stated that Wheaton College need not use the self-certification form prescribed by the government or send a copy of the executed form to its health insurance issuers or TPAs to meet the condition for this injunctive relief. The order also stated that this relief neither affected "the ability of [Wheaton College's] employees and students to obtain, without cost, the full range of FDA approved contraceptives," nor precluded the government from relying on the notice it receives from Wheaton College "to facilitate the provision of full contraceptive coverage under the Act." *Id.* The same is true of the augmented accommodations.

The *Wheaton College* injunction does not reflect a final Supreme Court determination that RFRA requires the government to apply the accommodations in this manner. Nevertheless, the Departments have augmented the existing accommodations. 79 Fed. Reg. at 51,094-95. CBA's Group II members now have an alternative means by which they may opt out of providing contraceptive coverage, and one that, like the Supreme Court's *Wheaton College* interim order, provides for notice to the government, rather than to CBA's Group II members' insurers or third-party administrators.

2. The regulations do not substantially burden CBA's Group II members' exercise of religion

Whether a burden is "substantial" under RFRA is a question of law, not a "question[] of fact, proven by the credibility of the claimant." *Mich. Catholic Conf. II*, 755 F.3d at 385 (quoting *Mahoney* v. *Doe*, 642 F.3d 1112, 1121 (D.C. Cir. 2011)); *accord Notre Dame II*,

743 F.3d at 558; *Kaemmerling v. Lappin*, 553 F.3d 669, 673-74, 678-79 (D.C. Cir. 2008). Thus, it is for this Court, not the plaintiffs, to determine whether a substantial burden exists. And in light of the accommodations that enable Group II members to opt out of providing contraceptive coverage, as a matter of law, no such burden can be said to exist here.

CBA's Group II members do not object to informing insurance issuers, third party administrators, or the government, that they believe they are legally permitted not to provide contraceptive coverage and choose not to do so. Indeed, they have presumably informed such third parties of their objection to providing contraceptive coverage in the past, and would presumably need to do so even if they obtained an injunction. And if the Group II members were to opt out, they cannot be made to subsidize the cost of providing the contraceptives to which they object because the regulations bar an insurance issuer or third party administrator from charging the eligible organization, directly or indirectly, with respect to payments for contraceptive services. *See* 45 C.F.R. § 147.131(c)(2)(ii); C.F.R. § 2590.715-2713A(b)(2)(i), (ii). The insurance issuer or third party administrator must also notify plan participants and beneficiaries of the availability of separate payments for contraceptive services, and "[t]he notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides separate payments for contraceptive services." 45 C.F.R. § 147.131(d); 29 C.F.R. § 2590.715-2713A(d).[3]

[3] CBA wrongly insists that, were its members to avail themselves of the accommodations, they would effectively still be paying for contraceptives because their insurance issuers may adjust their claims costs to account for any separate payments for covered contraceptives, thereby reducing any rebate the issuer would otherwise owe to the insured members under the ACA's "medical loss ratio" rule. Pls.' Mot. at 11-12. CBA misunderstands the medical loss ratio rule requirements. Most significantly, the medical loss ratio is calculated by an issuer on a collective basis across *all* of its customers in the relevant market (*e.g.*, individual, small group, or large group) in the state for a given year. *See* 75 Fed. Reg. 74,864, 74,869 (Dec. 1, 2010). Therefore, in the large group market (as relevant here), an issuer's medical loss ratio is calculated on an aggregate basis for all of its large group

Plaintiffs object to the fact that after their Group II members opt out of providing contraceptive coverage, the government requires their insurance issuer or third-party administrator to make or arrange separate payments for contraceptive services for the plan participants and beneficiaries. The crux of plaintiffs' theory is that opting out of the coverage requirement "trigger[s]" the provision of contraceptive coverage by third parties, because only if employers opt out does the government require third parties to make or arrange separate payments for contraception.

The Sixth and Seventh Circuits have specifically rejected the trigger theory that plaintiffs put forth here. "The purpose of the [self-certification] is to enable the provision of the very contraceptive services to the organization's employees that the organization finds abhorrent.'" *Notre Dame II*, 743 F.3d at 554; *accord Mich. Catholic Conf. II*, 755 F.3d at 387. "Submitting the self-certification form to the insurance issuer . . . does not 'trigger' contraceptive coverage; it is federal law that requires the insurance issuer . . . to provide this coverage." *Id.*; *accord Notre Dame II*, 743 F.3d at 554.

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market employers in the state. Specifically, the medical loss ratio is generally calculated by the issuer using a fraction that divides all incurred claim costs—including separate contraceptive coverage payments—for all of the issuer's large group employers in the state plus the issuer's expenditures for activities that improve health care quality (the numerator) divided by all premium revenues for those employers, excluding the issuer's federal and state taxes and licensing and regulatory fees and after certain other adjustments to account for payments or receipts related to the ACA's risk adjustment, risk corridors, and reinsurance programs (the denominator). *See* 45 C.F.R. § 158.221. If the issuer's incurred claims costs (plus quality improvement activities) are not at least 85 percent of the premium revenues for all of the issuer's large employer business in the state, the issuer will owe a rebate back to all of its large employer policyholders. *See id.* Part 158. The portion of the total rebate allocated to a given employer reflects the relative portion of premium revenue paid by that employer. *See id*. § 158.220. The medical loss ratio does not evaluate what claim costs (relating to contraceptive coverage or otherwise) are paid on behalf of an individual employer relative to premium revenue generated on behalf of that employer. Thus, a given employer's entitlement to a rebate does not stem from the claims and premiums paid on behalf of that employer; rather, the entitlement stems from the collective claims paid relative to collective premiums collected from all employers in the state market. In any event, plaintiffs have not alleged that its issuer will owe rebates to its employer policyholders.

Plaintiffs' view—that the Group II members' opt out can constitute a "substantial burden" under RFRA—is at odds with our nation's long history of allowing religious objectors to opt out and the government then requiring others to fill the objectors' shoes. *See, e.g.*, *Thomas*, 450 U.S. at 716-18; *cf.* EEOC Compliance Manual § 12-IV.C. (Example 43) (July 22, 2008) (explaining that reasonable accommodations of workplace religious objections can include requiring the objecting employee to transfer objectionable tasks to co-workers), *available at* http://goo.gl/4IrfUh. On CBA's reasoning, a conscientious objector could object not only to his own military service, but also to opting out, on the theory that his opt-out would "'trigger' the drafting of a replacement who was not a conscientious objector." *Notre Dame II*, 743 F.3d at 556 ("That seems a fantastic suggestion."). Similarly, the claimant in *Thomas* could have demanded not only that he not make weapons but also that he not be required to *opt out* of doing so, because his opt out would cause someone else to take his place on the assembly line. Thus, as the Seventh Circuit explained, plaintiffs "can derive no support from" decisions like *Hobby Lobby* because the accommodations authorize non-profit religious employers to refuse to comply with the contraceptive regulation. *Notre Dame II*, 743 F.3d at 558.[4]

In sum, CBA's Group II members are "effectively exempt[]," *Hobby Lobby*, 134 S. Ct. at 2763, and its attempt to collapse the provision of contraceptive coverage by a third party with its own decision not to provide such coverage fails. If the employees of organizations that have opted out of providing contraceptive coverage nonetheless receive

[4] The Sixth Circuit indicated its agreement with this principle when it denied the plaintiffs' petition for rehearing en banc in *Michigan Catholic Conference II*, Nos. 13-2723, 13-6640, ECF No. 63 (Sept. 16, 2014), which argued primarily that the panel's decision conflicted with the Supreme Court's decision in *Hobby Lobby*, *see* Pls.-Appellants' Pet. for Reh'g/Reh'g En Banc at 3-13, *Mich. Catholic Conf. II*, 755 F.3d 372 (2014) (Nos. 13-2723, 13-6640), ECF No. 59.

such coverage, they will do so "*despite* [the Group II members'] religious objections, not *because* of them." *Mich. Catholic Conf. II*, 755 F.3d at 389 (emphasis added). Plaintiffs have "failed to demonstrate a substantial burden." *Notre Dame II*, 743 F.3d at 559.

3. The regulations advance defendants' compelling interests in seamlessly providing contraceptive coverage

Plaintiffs' claims would fail even if the accommodations were subject to RFRA's compelling interest test. As the Supreme Court acknowledged in *Hobby Lobby*, the challenged accommodations serve interrelated and compelling interests. Five members of the Court endorsed the position that providing contraceptive coverage to employees "serves the [g]overnment's compelling interest in providing insurance coverage that is necessary to protect the health of female employees, coverage that is significantly more costly than for a male employee." *Hobby Lobby*, 134 S. Ct. at 2785-86 (Kennedy, J., concurring); *accord id.* at 2799-800 & n.23 (Ginsburg, J., dissenting).[5] The remaining Justices assumed without deciding that the contraceptive coverage requirement furthers compelling interests, *id.* at 2780, and emphasized that, under the accommodations for eligible non-profit organizations, employees "would continue to receive contraceptive coverage without cost sharing for all FDA-approved contraceptives, and they would continue to face minimal logistical and administrative obstacles because their employers' insurers would be responsible for providing information and coverage," *id.* at 2782 (quotation omitted).

As an initial matter, the government's interest is compelling because its ability to accommodate religious concerns in this and other areas depend on its ability to ask that religious objections who do not belong to a pre-defined class (such as the "religious employer" exemption defined by reference to the Internal Revenue Code) certify that they

[5] Accordingly, plaintiffs are incorrect to say that the Tenth Circuit's strict scrutiny analysis remains controlling. *See* Pls.' Mot. at 1-2, 13-14. To the contrary, the Supreme Court has now made clear that that the government' interest is compelling.

are entitled to the religious exception. *See Notre Dame*, 743 F.3d at 557. It also depends on the government's ability to accommodate religious concerns in this and other areas and on the government's ability to fill the gaps created by the accommodations. CBA, by contrast, asserts that it is insufficient to permit an objector to opt out of an objectionable requirement; in CBA's view, the government's filling each gap must itself be subject to compelling-interest analysis and thus the government often may not shift its members' obligations to a third party but must instead fundamentally restructure its operations.

Hobby Lobby confirms, however, that, when religious objectors opt out of their legal obligations, the government may fill those gaps and do so as seamlessly as possible. *See* 134 S. Ct. at 2782-83. In our diverse nation, many requirements may give rise to religious objections. But government programs, and particularly national systems promoting health and welfare, need not vary from point to point or, for example, be based around what, if any, method of provision of medical coverage can be agreed upon by all parties, including those who object. The challenged accommodations provide an administrable way for organizations to state that they object and opt out, and for the government to require third parties to provide contraceptive coverage. The Supreme Court admonished in its pre-*Smith* decisions that "[t]he 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." *Bowen*, 476 U.S. at 699.

The government's requirement that insurance issuers and third party administrators provide contraceptive coverage after employers decline to do so furthers compelling interests by directly and substantially reducing the incidence of unintended pregnancies, improving birth spacing, protecting women with certain health conditions for whom pregnancy is contraindicated, and otherwise preventing adverse health conditions. *See* 78 Fed. Reg. at 39,872; IOM REP. at 103-07; *see also Hobby Lobby*, 134 S. Ct. at 2786

(Kennedy, J., concurring) ("There are many medical conditions for which pregnancy is contraindicated," and "[i]t is important to confirm that a premise of the Court's opinion is its assumption that the HHS regulation here at issue furthers a legitimate and compelling interest in the health of female employees.").

Physician and public health organizations, such as the American Medical Association, the American Academy of Pediatrics, and the March of Dimes accordingly "recommend the use of family planning services as part of preventive care for women." IOM REP. at 104. This is not a "broadly formulated interest[] justifying the general applicability of government mandates," *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006), but rather a concrete and specific one, supported by a wealth of empirical evidence.[6]

[6] Plaintiffs also question whether the regulations will actually further the government's public health goals, and it flyspecks the IOM Report to suggest that the regulations will not do so. Pl.'s Mot. at 15-16. But the IOM Report is the work of independent experts in the field of public health. After undertaking an extensive science-based review of the available evidence, IOM determined that access to the full range of FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity is necessary for women's health and well-being. The HRSA Guidelines, which were based on the IOM's expert, scientific recommendations, are entitled to deference. *See Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984); *see also Marsh v. Ore. Natural Res. Council*, 490 U.S. 360, 376-77 (1989) (emphasizing that deference is particularly appropriate when an interpretation implicates scientific and technical judgments within the scope of agency expertise).

Further, CBA's reliance on law review articles to suggest that there is "no direct causal link," *see* Pl.'s Mot. at 15-16 (citing, *inter alia*, Helen M. Alvare, *No Compelling Interest: The 'Birth Control' Mandate & Religious Freedom*, 58 VILL. L. REV. 379 (2013)), is inappropriate. A law review article is a poor substitute for the scientific studies relied on by the IOM. Furthermore, the materials CBA cites are not part of the administrative record, and therefore should not be considered by the Court. *See, e.g., United States v. Carlo Bianchi & Co.*, 373 U.S. 709, 715 (1963). Were the Court to review extra-record materials, however, and specifically in response to CBA's suggestion that there is no evidence that requiring coverage for contraceptives without cost sharing will further the government's compelling interests, *see* Pl.'s Mot. at 15-16, it is relevant to note that in Colorado, for example, a state program to provide certain contraceptive services to low-income women without cost-sharing was found to have been responsible for three-quarters of the 40 percent drop in the state's teen birth rate over four years. *See* Sue Ricketts, Greta Klingler, & Renee

Use of contraceptives reduces the incidence of unintended pregnancies. IOM REP. 102-104. Unintended pregnancies pose special health risks because a woman with an unintended pregnancy "may not immediately be aware that [she is] pregnant, and thus delay prenatal care" and engage in behaviors that "pose-pregnancy-related risks." 78 Fed Reg. at 39,872, *see* IOM REP. 103. As a result, "[s]tudies show a greater risk of preterm birth and low birth weight among unintended pregnancies." 78 Fed. Reg. at 39,872. And, because contraceptives reduce the number of unintended pregnancies, they "reduce the number of women seeking abortions." *Id.*

The contraceptive coverage regulations, including the religious accommodations, also advance the government's related compelling interest in assuring that women have equal access to recommended health care services. 78 Fed. Reg. at 39,872, 39,887. Congress enacted the women's preventive-services coverage provision because "women have different health needs than men, and these needs often generate additional costs." 155 Cong. Rec. 29,070 (2009) (statement of Sen. Feinstein); *see* IOM REP. 18. Prior to the Affordable Care Act, "[w]omen of childbearing age spen[t] 68 percent more in out-of-pocket health care costs than men." 155 Cong. Rec. at 29,070 (statement of Sen. Feinstein). These disproportionately high costs had a tangible impact: Women often found that copayments and other cost sharing for important preventive services "[were] so high that they avoid[ed] getting [the services] in the first place." 155 Cong. Rec. at 29,302 (statement of Sen. Mikulski). Studies have demonstrated that "even moderate copayments for preventive

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Schwalberg, *Game Change in Colorado: Widespread Use of Long-Acting Reversible Contraceptives and Rapid Decline in Births Among Young, Low-Income Women*, 46 PERSP. ON SEXUAL & REPROD. HEALTH, no. 3 (Sept. 2014); *see also* Press Release, State of Colorado (July 3, 2014), *available at* http://goo.gl/scSLrH.

services" can "deter patients from receiving those services." IOM REP. at 19. The challenged regulations thus clearly survive the first step of RFRA scrutiny.[7]

Plaintiffs have identified no sound reason to doubt that these interests are compelling. Contrary to plaintiffs' claim, *see* Pls.' Mot. at 14, plaintiffs' alleged "exemptions" do not undercut the government's position. Plaintiffs point to the grandfathering of certain health plans with respect to certain provisions of the ACA, but grandfathering is not specifically limited to the preventive services coverage regulations, *see* 42 U.S.C. § 18011; 45 C.F.R. § 147.140, and the effect of grandfathering is not a permanent "exemption" but rather, over the long term, a transition in the marketplace with respect to several provisions of the ACA. Fewer and fewer group health plans will be grandfathered over time. *See* 78 Fed. Reg. at 39,887 n.49; 75 Fed. Reg. at 34,552; Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2013 Annual Survey at 7, 196, *available at* http://goo.gl/9FKG5o (percentage of employees in grandfathered plans is steadily declining). This incremental transition does not call into question the compelling interests furthered by the preventive services coverage regulations. Plaintiffs cite no authority to suggest that, in order for an interest to be compelling, the government must achieve its goals immediately. To the contrary, such a holding would undermine any attempt to phase in important and large-scale government programs over time, perversely encouraging Congress to require immediate and draconian enforcement of

[7] Although plaintiffs attempt to portray these interests as too "broadly formulated" to be characterized as compelling, Pls.' Mot. at 14, plaintiffs ignore that the regulations promote these interests specifically with respect the many employees of CBA's Group II members who have elected to be covered by their insurance plans by ensuring that those employees (and their covered dependents) have access to the clinically recommended contraceptive services to which CBA's Group II members—but not necessarily their employees—object. The government has shown with "particularity," therefore, that these interests "would be adversely affected by granting an exemption," *Wisconsin v. Yoder*, 406 U.S. 205, 236 (1972), as those employees would not enjoy the full range of recommended preventive services coverage if not for the challenged regulations.

all provisions of major laws, without regard to pragmatic considerations, in order to preserve compelling interest status. *Cf. Heckler v. Mathews*, 465 U.S. 728, 746-48 (1984).

Moreover, employers with fewer than fifty employees are *not*, as plaintiffs claim, exempt from the preventive services coverage regulations. *See* 42 U.S.C. § 300gg-13(a); 78 Fed. Reg. at 39,887 n.49. Instead, employers with fewer than fifty full-time equivalent employees are excluded 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.

4. The regulations are the least restrictive means of advancing the government's compelling interests

As the Supreme Court emphasized in *Hobby Lobby*, the accommodations ensure that women "would continue to receive contraceptive coverage without cost sharing for all FDA-approved contraceptives, *and* they would continue to face minimal logistical and administrative obstacles because their employers' insurers would be responsible for

providing information and coverage," 134 S. Ct. at 2782 (emphasis added); *see also id.* at 2760 (stressing that "[t]he effect of the HHS-created accommodation on the women employed by Hobby Lobby and other companies involved in these cases would be precisely zero"); *id.* at 2783 (emphasizing that the accommodations would not "'imped[e] women's receipt of benefits by "requiring them to take steps to learn about, and to sign up for, a new government funded and administered health benefit"'") (alterations in original, quoting dissent (in turn quoting 78 Fed. Reg. at 39,888 (with alterations))); *id.* at 2786 (Kennedy, J., concurring) (explaining that the accommodation "works by requiring insurance companies" to provide contraceptive coverage and "equally furthers the Government's interest").

Plaintiffs suggest that the government should "directly provid[e] coverage" of contraceptive services, or "reimburse[e] those who pay out of pocket" for contraceptive services" through a combination of direct subsidies, tax deductions, and tax credits. Pls.' Mot. at 19 But RFRA does not require the government to create entirely new programs to accommodate religious objections. *See, e.g.*, *Hobby Lobby*, 134 S. Ct. at 2786 (Kennedy, J., concurring) ("[I]t is the Court's understanding that an accommodation may be made to the employers without imposition of a whole new program or burden on the Government."). An employer with a sincere religious objection to paying the minimum wage to female employees, for example, cannot simply demand that the government make up the difference with tax credits or direct provision of financial aid.

Moreover, whereas "[t]he effect of the HHS-created accommodation on the women employed by Hobby Lobby and the other companies involved in these cases would be precisely zero," *id.* at 2760, plaintiffs' schemes would not "equally further[] the Government interest," *id.* at 2760 (Kennedy, J., concurring), by ensuring that women can seamlessly obtain contraceptive coverage without additional burden—the very point of requiring that health coverage include coverage of contraceptives without cost sharing. *See*

78 Fed. Reg. at 39,888; IOM REP. 18-19; *see also Hobby Lobby*, 134 S. Ct. at 2782-83; *see generally Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997) (question under free speech strict scrutiny is whether "less restrictive alternatives would be *at least as effective* in achieving the legitimate purpose that the statue was enacted to serve") (emphasis added). The Supreme Court repeatedly explained in *Hobby Lobby* that the regulatory accommodations challenged by plaintiffs here "ensur[e] that the employees of these entities have precisely the same access to all FDA-approved contraceptives as employees of companies whose owners have no religious objections to providing such coverage." 134 S. Ct. at 2759. Plaintiffs proposed alternatives, by contrast, could impose burdens on women—such as up-front costs and administrative obstacles—that they would not face otherwise.

The initial accommodations offer CBA's Group II members a way to opt out by notifying their insurers or third party administrators that they do not wish to provide contraceptive coverage, while requiring or encouraging third parties to make or arrange separate payments for contraception where employers have opted out. Importantly, the augmented accommodation process offers CBA's Group II members an alternative but still administrable way to state that they object and opt out—without contacting their insurer or third party administrator—while providing the government with the information needed to implement the requirement that third parties provide contraceptive coverage so that participants and beneficiaries can "obtain, without cost, the full range of FDA approved contraceptives." *Wheaton Coll.*, 134 S. Ct. at 2807.[8] Under both methods of opting out, the effect on participants and beneficiaries is "precisely zero." *Hobby Lobby*, 134 S. Ct. at 2760.

[8] Under the augmented accommodation whereby CBA's Group II members may notify HHS, "[t]he content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations." 79 Fed. Reg. at 51,095.

The regulatory accommodation process is the least restrictive means of ensuring that women seamlessly obtain coverage for contraception alongside their remaining health coverage.

B. The Regulations Do Not Violate the Establishment Clause

Every court to consider an Establishment Clause challenge to the regulations on the merits, including the only two courts of appeal to have done so, has rejected it. Given that CBA presents no new arguments in its motion with respect to the Establishment Clause, defendants respectfully refer the Court to its response in opposition to the plaintiffs' motion for a preliminary injunction in *CBA I*. *See CBA I* PI Opp'n at 21-23.[9]

C. Plaintiff's Administrative Procedure Act Claims Fail

Plaintiffs assert various arguments under the Administrative Procedure Act, none of which has any merit. First, plaintiffs make the bare assertion for the first time that both the preexisting and the augmented accommodation violate ERISA. Pls.' Mot. at 22-23. The Departments, however, explained at length in the preambles to both the July 2013 final rules and August 2014 interim final rules that Congress has given the Department of Labor the broad authority under Title I of ERISA, "which includes the ability to interpret and apply the definition of a plan administrator" under 29 U.S.C. § 1002(16)(A). 79 Fed. Reg. at 51,095; *see also* 78 Fed. Reg. at 39,880. The Department of Labor's interpretation of ERISA in a formal rulemaking is clearly entitled to deference and plaintiffs have not shown, as is their burden here, that this interpretation is barred by the clear language of the statute. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984); *see also United States v. Mead Corp.*, 533 U.S. 218, 230 (2001). Plaintiffs' conclusory statutory analysis is unconvincing. The phrase "instrument under which a plan is operated" means

[9] Defendants additionally note that, even if the challenged regulations, in fact, discriminated among religions (which they do not), they are valid under the Establishment Clause because they satisfy strict scrutiny. *See supra* Part I.A.3.

"the formal legal documents that govern or confine a plan's operations." *Board of Trustees v. Weinstein*, 107 F.3d 139, 142 (2d Cir. 1997). Nothing in the language or structure of § 1002(16)(A), which merely defines the term "administrator," prevents defendants from treating the self-certification as an "instrument under which the plan is operated," *id.* at 1002(16)(A), which in turn, designates the third-party administrator of a self-insured eligible organization as the plan administrator for the limited purpose of providing contraceptive services. Nor does ERISA prohibit a government notification from being an "instrument under which the plan is operated." *See* 63 Fed. Reg. 48,876, 48,378 n.8 (1998) (indicating that this phrase, as relevant to ERISA disclosure requirements, includes procedures governing qualified domestic relations order determinations and qualified medical child support order determinations).

Plaintiffs also claim that defendants violated the APA by "rubber-stamping" the findings of the IOM. Plaintiffs ignore, however, that the substantive obligations that are imposed on group health plans and health insurance issuers were established by Congress, in 42 U.S.C. § 300gg-13(a), and in corresponding provisions of ERISA and the Internal Revenue Code, which expressly and automatically imported the content of various guidelines (including the HRSA Guidelines, which were informed by IOM's science-based recommendations), as well as new content after a specified period of time. Indeed, in the same provision, Congress also imported by reference clinical recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. *Id.* The clinical recommendations of these entities are not generally required to be subject to notice and comment, and there is no suggestion that Congress intended otherwise here for any of the referenced recommendations. Nothing in the APA, or any other statute, requires defendants to have subjected IOM's recommendations to notice and comment procedures—or to make

any sort of "factual determination," as plaintiffs suggest, Pls.' Mot. at 23—before HRSA adopted them in the guidelines.[10] While the APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose, *see* 5 U.S.C. § 553(b), (c), a "rule" is defined in the APA, in relevant part, as being "designed to implement, interpret, or prescribe law or policy," *id.* § 551(4). The guidelines neither do nor are designed to do any such thing, and as such they do not constitute a "rule" within the meaning of the APA; they are simply clinical recommendations of a scientific body.[11]

[10] In support of their argument, plaintiffs rely on wholly inapposite principles of administrative law. Specifically, *New Mexico ex rel. Richardson v. BLM*, 565 F.3d 683 (10th Cir. 2009), analyzed the agency's factual determinations under a standard specific to the National Environmental Policy Act, *id.* at 704, as did *League of Wilderness Defenders v. Connaughton*, 752 F.3d 755, 759-60 (9th Cir. 2014). The passage cited by plaintiffs from *Electric Power Supply Association v. FERC*, 753 F.3d 216 (D.C. Cir. 2014), addressed the Federal Energy Regulatory Commission's failure to address the reasoned arguments of a dissenting Commissioner. And *Christ the King Manor, Inc. v. Secretary of Health and Human Services*, 730 F.3d 291 (3d Cir. 2013), dealt with whether data provided by the State of Pennsylvania was sufficient for the Secretary to conclude that a proposed amendment to the State's Medicaid plain did not undermine quality of care. None of these cases even remotely supports the claim that the challenged regulations are arbitrary or capricious.

[11] Nor was it arbitrary and capricious for defendants to define a religious employer as a non-profit organization described in the Internal Revenue Code provision that refers to churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. *See* 45 C.F.R. § 147.131(a) (cross referencing 26 U.S.C. § 6033(a)(3)(A)(i) and (iii)). Plaintiffs' claim to the contrary is belied by the explicit consideration of the exemption's scope in the preamble to the July 2013 final rules. *See* 78 Fed. Reg. 39,870, 39,873-74; *see also Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency action must be upheld so long as "the agency's path may reasonably be discerned"). That plaintiffs may disagree with defendants' decision does not render it arbitrary and capricious.

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

Plaintiffs have not established that they are likely to suffer irreparable harm in the absence of preliminary relief because they have not shown a likelihood of success on the merits of its claims. As to 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). Moreover, it would be contrary to the public interest to deny the Group II members' employees (and their families) the benefits of the preventive services coverage regulations. 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; 77 Fed. Reg. at 8,727; 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 8,728. 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); IOM REP. at 20. 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; 77 Fed. Reg. at 8,728—would thus inflict a very real harm on the public and on a readily identifiable group of individuals, CBA's Group II members' employees.

CONCLUSION

The Court should deny plaintiffs' motion for preliminary injunction.

Respectfully submitted this 31st day of October, 2014,

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CERTIFICATE OF SERVICE

I hereby certify that on October 31, 2014, I electronically filed the foregoing using the Court's CM/ECF system, which sent notice of such filing to all parties.

/s/ Bradley P. Humphreys
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