

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

ETERNAL WORD TELEVISION)
NETWORK, INC.,)
)
Plaintiff,)
)
v.)
)
KATHLEEN SEBELIUS,)
et al.,)
)
Defendants.)
_____)

Case No. 2:12-cv-00501-SLB

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT**

INTRODUCTION

Plaintiff's opposition to defendants' motion to dismiss makes clear that plaintiff seeks to challenge regulations – that neither defendants, nor anyone else, is enforcing against plaintiff – as well as forthcoming amendments to those regulations – that do not even exist yet. This Court should reject plaintiff's request for premature adjudication of its claims because the Court lacks jurisdiction.

Plaintiff's basic premise seems to be that it has standing and its claims are ripe for review unless defendants can show that there is no set of circumstances under which plaintiff could ever be adversely affected by the challenged regulations and prove that plaintiff will be wholly satisfied with forthcoming amendments to those regulations that are designed to accommodate religious organizations' religious liberty interests. Plaintiff has it backwards. It is plaintiff's burden – not defendants' – to demonstrate current or imminent injury from the regulatory actions it seeks to challenge. And it is plaintiff's burden to show that, even though the challenged regulations will inevitably change before they could have any effect on plaintiff, this Court should nonetheless intervene to review amendments that are still being formulated and whose content is thus unknowable. Because plaintiff has not met its burden, the Court should dismiss this case.

ARGUMENT

I. PLAINTIFF LACKS STANDING

Defendants' opening brief demonstrated that plaintiff lacks standing because it has not alleged a concrete and imminent injury resulting from the operation of the preventive services coverage regulations. Plaintiff's opposition does not show

otherwise.¹ Plaintiff admits it is eligible for the temporary enforcement safe harbor, *see* Opp'n at 13, ECF No. 33, pursuant to which defendants will not bring any enforcement action against plaintiff for failing to provide contraceptive coverage until at least July 1, 2014.² By then, defendants will have finalized amendments to the challenged regulations to accommodate the religious objections of religious organizations, like plaintiff, to providing contraceptive coverage. Thus, plaintiff has not been, and never will be, injured by the regulations in their current form.

Plaintiff nevertheless argues that, even though it is eligible for the enforcement safe harbor, the existence of “a time delay before the disputed provision[] will come into effect” is “irrelevant” to plaintiff’s standing. *Id.* at 16 (quoting *Reg'l Rail Reorganization Act Cases*, 419 U.S. 102, 143 (1974)). Plaintiff believes it need not await the consummation of a threatened injury to obtain preventive relief. *Id.* But this case involves more than mere delay. Defendants also

¹ Defendants no longer contend, at this stage, that plaintiff has not sufficiently alleged that its group health plan is not grandfathered. Defs.’ Mot. at 15-17, ECF No. 29-1. The declaration submitted with plaintiff’s opposition plausibly suggests that its health plan has not satisfied certain requirements for maintaining grandfathered status. *See* 45 C.F.R. § 147.140(a)(2); 26 C.F.R. § 54.9815-1251T(a)(2); 29 C.F.R. § 2590.715-1251(a)(2).

² Plaintiff errs by suggesting that a somewhat relaxed standing or ripeness analysis applies here. *See* Opp'n at 13, 25. As the Eleventh Circuit cases cited by plaintiff make clear, the principle on which plaintiff relies applies only where, unlike here, there is a “credible threat” of enforcement. *Bloedorn v. Grube*, 631 F.3d 1218, 1228 (11th Cir. 2011); *Harrell v. The Fla. Bar*, 608 F.3d 1241, 1258, 1261 (11th Cir. 2010); *see also Dermer v. Miami-Dade Cnty.*, 599 F.3d 1217, 1220 (11th Cir. 2010) (“[A]n injury must be imminent.”). There is no such threat here because of the existence of the temporary enforcement safe harbor. Indeed, unlike in *Bloedorn*, there is no “indication that [defendants] would [bring an enforcement action against]” organizations that qualify for the safe harbor. 631 F.3d at 1229; *see also Presbytery of N.J. v. Florio*, 40 F.3d 1454, 1470-71 (3d Cir. 1994) (dismissing churches’ challenge to discrimination law as unripe where affidavit from State official indicated that State would not prosecute churches for violating law).

intend to amend the challenged regulations during the safe harbor period to accommodate religious organizations' religious objections to covering contraceptive services. These forthcoming amendments are not irrelevant to plaintiff's standing. In fact, the Supreme Court has made clear that a time delay is only "irrelevant" to justiciability when "the inevitability of the operation of a statute against certain individuals is *patent*." *Reg'l Rail Reorganization Act Cases*, 419 U.S. at 143 (emphasis added). Here, there is nothing patently inevitable about the operation of the regulations in their current form against plaintiff. Moreover, this is not a case where defendants are relying on the general authority of an agency to change regulations it promulgated whenever it desires. *See* Opp'n at 20. The advance notice of proposed rulemaking (ANPRM) goes much further than that by promising imminent regulatory amendments intended to address the concerns raised by organizations like plaintiff.³

Plaintiff's reliance on defendants' position in an unrelated appeal, *id.* at 17 (citing *Fla. ex. rel. Attorney Gen. v. HHS*, 648 F.3d 1235 (11th Cir. 2011)), fares no better.⁴ As an initial matter, courts in several other cases – none of which plaintiff cites – dismissed challenges to the minimum coverage provision for lack

³ Contrary to plaintiff's assertions, *see* Opp'n at 18-24, 27-30, defendants have done more than merely promise a future rulemaking. They have actually initiated the rulemaking by issuing the ANPRM, made clear that the rulemaking will amend the regulations, and stated they will finalize the amendments before the safe harbor expires. 77 Fed. Reg. 16,501, 16,503 (Mar. 21, 2012).

⁴ The government's failure to appeal a decision in one case has no bearing on even the same issue in a related case, much less – as plaintiff urges here – a different issue in an unrelated case. *United States v. Mendoza*, 464 U.S. 154, 162 (1984) (holding that nonmutual offensive collateral estoppel does not apply against the government); *id.* at 160-62 (noting that the Solicitor General considers many factors in deciding whether to appeal an issue).

of standing where the plaintiffs could not show that the provision was certain to injure them when it takes effect in 2014. *See, e.g., Baldwin v. Sebelius*, 654 F.3d 877, 879 (9th Cir. 2011); *New Jersey Physicians, Inc. v. Obama*, 653 F.3d 234, 239-40 (3d Cir. 2011). More importantly, this case differs sharply from those challenging the minimum coverage provision. There was no hint that Congress would amend the minimum coverage provision; the lone question in those cases was whether the particular plaintiff would be subject to the provision. *See, e.g., Baldwin*, 654 F.3d at 879. Indeed, in concluding that the plaintiff in *Thomas More Law Center v. Obama*, 651 F.3d 529, 538 (6th Cir. 2011), had standing, the court specifically noted that there was “no reason to think the law will change.”⁵ Here, in contrast, there is every reason to think the challenged regulations will change materially; defendants have publicly announced their intent to amend the regulations to accommodate concerns of the sort at issue here and have in fact begun that process. Because the forthcoming amendments may foreclose any injury to plaintiff, or at least alter the nature of any injury (and the substance of plaintiff’s legal claims), plaintiff has not established standing.⁶

⁵ Similarly, in *Village of Bensenville v. FAA*, 376 F.3d 1114, 1119 (D.C. Cir. 2004), another case on which Plaintiff relies, only “action by [the court]” prevented the challenged fee collection. *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 533, 536 (1925), also is inapposite, as there the Court concluded that “injury to [the plaintiff school] was present . . . , not a mere possibility in the remote future” where, among other things, the challenged compulsory education law caused parents to withdraw their children from the plaintiff school or refuse to make contracts for future instruction at the school.

⁶ Plaintiff suggests it is injured notwithstanding the enforcement safe harbor because the safe harbor is “non-binding.” Opp’n at 18. But plaintiff is dealing with the federal government, which is presumed to act in good faith. *See, e.g., Schism v. United States*, 316 F.3d 1259, 1302 (11th Cir. 2002) (explaining that government officials presumed to act in good faith). Indeed, courts
(continued on next page...)

Contrary to plaintiff's argument, *see* Opp'n at 18-20, the forthcoming changes to the regulations *do* make any alleged harm to plaintiff too speculative to support standing. And the Court should reject plaintiff's attempts to recast defendants' standing argument as a question of mootness, *see id.* at 19-20, thereby shifting plaintiff's burden of proof onto defendants.⁷ First, this case has not been litigated "for years" and is not at "an advanced stage," and thus, the interest served by the mootness doctrine, i.e. avoiding waste, is simply not implicated here. *See Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs., Inc.*, 528 U.S. 167, 191-92 (2000). Second, plaintiff's First Amended Complaint adds new claims and makes

have found similar promises of non-enforcement by the government sufficient to defeat jurisdiction. *See, e.g., Winsness v. Yocom*, 433 F.3d 727, 732-33 (10th Cir. 2006) (plaintiff's prosecution for violation of state flag-abuse law was too speculative to support standing where district attorney filed affidavit promising non-prosecution); *Presbytery of N.J.*, 40 F.3d at 1470-71 (churches' challenge to discrimination law was unripe where affidavit from state official indicated that state would not prosecute churches for violating law). The cases cited by plaintiff, Opp'n at 18, do not show otherwise. *See Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 388-89 (4th Cir. 2001) (basing decision on fact that agency's non-enforcement policy was expressly limited to a defined geographic region, and plaintiff alleged a specific intent to engage in advocacy outside of that region); *U.S. Dep't of Labor v. N.C. Growers Ass'n*, 377 F.3d 345, 353-54 (4th Cir. 2004) (addressing deference to agency interpretation of statute). Any implication that defendants may take back the safe harbor is not only dubious, but insufficient to establish injury in fact. *See Schutz v. Thorne*, 415 F.3d 1128, 1134-35 (10th Cir. 2005) ("Standing is not conferred by 'conjecture' or 'speculation' about future [events].").

⁷ In attempting to re-write defendants' standing argument as a mootness argument, plaintiff relies on cases about standing and/or ripeness, not mootness. *See* Opp'n at 20. Because defendants have initiated a rulemaking specifically intended to amend the challenged regulations to address the concerns raised by organizations like plaintiff, none of the cases cited by plaintiff establish its standing or that its claims are ripe. *See Am. Petroleum Inst. v. EPA*, 906 F.2d 729, 739 (D.C. Cir. 1990) (pending rulemaking was "entirely separate from" challenged rule and agency would not have any "occasion to refine" or change challenged rule during pending rulemaking); *Am. Bird Conservancy, Inc. v. FCC*, 516 F.3d 1027, 1030 & n.1 (D.C. Cir. 2008) ("new docket" opened by agency was not designed to address problems identified by plaintiff); *Sackett v. EPA*, 132 S. Ct. 1367, 1372 (2012) (only possibility of future "informal discussion[s]").

new allegations with respect to standing. *See* First Am. Compl. ¶¶ 86-93, 115-117, ECF No. 13 (alleging that final version of amended final rule is unlawful, that plaintiff’s employee health plan is not grandfathered, and that challenged regulations will apply to plaintiff on July 1, 2014). Thus, the First Amended Complaint, which was filed after – and addresses – defendants’ issuance of the safe harbor and the ANPRM, is the operative complaint for assessing standing. *See Cnty. of Riverside v. McLaughlin*, 500 U.S. 44, 51 (1991); *cf. Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 473-74 (2007) (“[W]hen a plaintiff files a complaint in federal court and then voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction.”).⁸

Finally, plaintiff’s assertion that “the accommodations forecast in the ANPRM . . . would not remedy the religious conflict,” Opp’n at 21, only underscores the prematurity of this suit and further illuminates why the Court lacks jurisdiction here. Plaintiff makes clear that it is asking the Court to assess the lawfulness of regulations that do not yet exist. Plaintiff’s theory appears to be that, no matter what accommodations defendants ultimately adopt, they will not satisfy plaintiff. But plaintiff has had and will have opportunities – throughout the pending rulemaking – to express its concerns (such as those set forth in pages 21 through 23 of plaintiff’s opposition) and help shape the forthcoming amendments. Defendants

⁸ Even if the Court determines that standing should be assessed at the time plaintiff filed its original complaint, plaintiff also lacked standing at that time. The contraception coverage requirement is not effective until August 1, 2012. *See, e.g.*, 45 C.F.R. § 147.130(b)(1). Thus, when plaintiff filed its original complaint on February 9, 2012, it was not under any obligation to provide contraception coverage. And plaintiff is under no such obligation today.

have stressed that the ideas suggested in the ANPRM are not all that they will consider adopting and have expressly invited alternative ideas. 77 Fed. Reg. at 16,501, 16,503.

In sum, this case involves not only a twenty-five month delay before defendants will enforce the challenged regulations against plaintiff, but also a commitment by defendants to amend the regulations as to organizations like plaintiff, initiation of the amendment process, and opportunities for plaintiff to participate in that process. In these circumstances, no injury to plaintiff is “certainly impending.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990).

II. THIS CASE IS NOT RIPE

Defendants also demonstrated in their opening brief that plaintiff’s challenge to the preventive services coverage regulations is not ripe. Defendants explained that the challenged regulations are not fit for judicial review because of the ongoing rulemaking, which is intended to amend the regulations to accommodate the religious objections of religious organizations, like plaintiff, to providing contraceptive coverage. Moreover, the temporary enforcement safe harbor will be in effect until defendants finalize the amendments such that plaintiff will not suffer any hardship prior to the regulatory changes.⁹

Plaintiff contends its claims are fit for judicial review because they “involve facial challenges” to the regulations “that require no factual development.” Opp’n

⁹ As stated already, *supra* n. 2, the principle that ripeness doctrine is relaxed in certain First Amendment contexts does not help plaintiff here.

at 25. Plaintiff's claims may be largely legal,¹⁰ but it does not follow that further factual development is unwarranted. One relevant – indeed, essential – fact that has yet to be developed is what the preventive services coverage regulations will actually require *of plaintiff*, if anything. Until that is known – and it will not be known until the pending rulemaking is completed – the Court cannot know what it is reviewing. *See Pub. Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952) (to be ripe for review, a case “must have taken on fixed and final shape so that a court can see what legal issues it is deciding”); *Eagle-Picher Indus., Inc. v. EPA*, 759 F.2d 905, 915 (D.C. Cir. 1985) (court must consider whether it “will benefit from deferring review until the agency’s policies have crystallized and the question arises in some more concrete and final form” (quotation omitted)).¹¹

Plaintiff further asserts that the preventive services coverage regulations are fit for judicial review because they are final. Opp'n at 26. As evidence of this finality, plaintiff refers to defendants' issuance of final rules on February 15, 2012. *Id.* Plaintiff, however, misunderstands the nature of those rules: They did not serve to finalize the preventive services coverage regulations in their entirety as plaintiff claims. *See id.* Rather, they finalized an amendment to the interim final rules – i.e., the amendment that authorized an exemption from the contraceptive coverage

¹⁰ Defendants note, however, that the substantial burden analysis under the Religious Freedom Restoration Act is fact-specific. *See, e.g., Mintz v. Roman Catholic Bishop of Springfield*, 424 F. Supp. 2d 309, 312 (D. Mass. 2006).

¹¹ The Eleventh Circuit cases cited by plaintiff, Opp'n at 25, are inapposite because neither involved a law that was subject to a forthcoming change. *See Harris v. Mexican Specialty Foods, Inc.*, 564 F.3d 1301, 1308 (11th Cir. 2009); *Pittman v. Cole*, 267 F.3d 1269 (11th Cir. 2001).

requirement for certain religious employers. 77 Fed. Reg. 8725, 8730 (Feb. 15, 2012) (“[T]he amendment to the interim final rule . . . is adopted as a final rule without change.”). Indeed, the February 15, 2012 final rules explicitly announced that defendants would engage in a “future rulemaking” to “develop alternative ways of providing contraceptive coverage without cost sharing with respect to non-exempted, non-profit religious organizations with religious objections to such coverage.” *Id.* at 8728. And defendants then initiated that announced rulemaking by issuing the ANPRM on March 21, 2012. *See* 77 Fed. Reg. at 16,501. Thus, as applied to non-exempted, non-grandfathered religious organizations with religious objections to providing contraceptive coverage, like plaintiff, the preventive services coverage regulations are not final or definitive. Rather, further administrative proceedings – which may eliminate the need for judicial review or at least narrow and refine the controversy – are contemplated and, indeed, underway. *See Am. Petroleum Inst. v. EPA*, No. 09-1038, 2012 WL 2053572 (D.C. Cir. June 8, 2012) (concluding challenge to regulation was unripe where agency had initiated a rulemaking that could significantly amend the regulation). The Court lacks jurisdiction to reach out to preview a potential controversy that may well evaporate.

While the “possibility of unforeseen amendments” does not render an otherwise fit challenge unripe, *Am. Petroleum Inst.*, 906 F.2d at 739-40, there is nothing *unforeseen* about defendants’ intent to amend the regulations challenged here. *See Tex. Indep. Producers & Royalty Owners Ass’n v. EPA*, 413 F.3d 479, 483 (5th Cir. 2005) (challenge to rule not ripe where agency announced intent to

consider issues raised by plaintiff in new rulemaking); *AT&T Corp. v. FCC*, 369 F.3d 554, 563 (D.C. Cir. 2004) (claim unripe where issues raised by plaintiff were “still under consideration in ongoing rulemaking proceedings”); *Util. Air Regulatory Grp. v. EPA*, 320 F.3d 272, 279 (D.C. Cir. 2003) (case not ripe where agency was “currently undertaking a rulemaking to amend [the regulations]”); *Lake Pilots Ass’n v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 161-62 (D.D.C. 2003) (challenge to rule not ripe where agency undertook new rulemaking to address issue raised by plaintiff in lawsuit).

Nor is plaintiff’s insistence that it will not be satisfied with whatever amendments result from the pending rulemaking, *see* Opp’n at 27-28, grounds for this Court to issue an advisory opinion on the lawfulness of the ideas proposed in the ANPRM. Courts may not opine on the lawfulness of regulations that are not yet final no matter how “legal” the issues may be. *See Columbian Fin. Corp. v. BancInsure, Inc.*, 650 F.3d 1372, 1376 (10th Cir. 2011) (“It is not the role of federal courts to resolve abstract issues of law.”); *Motor Vehicle Mfrs. Ass’n v. New York State Dep’t of Env’t Conservation*, 79 F.3d 1298, 1306 (2d Cir. 1996) (holding claims were not ripe where “plaintiffs’ arguments depend upon the effects of regulatory choices to be made by [the State] in the future”); *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986) (“The interest in postponing review is powerful when the agency position is tentative. Judicial review at that stage improperly intrudes into the agency’s decisionmaking process” and “squanders judicial resources since the challenging party still enjoys an opportunity to convince the agency to change its mind.”). And, as previously stated, plaintiff

cannot credibly argue that the ANPRM could not possibly alter its challenge to the regulations, *see* Opp'n at 28, when plaintiff has ample opportunity to express its concerns and help shape the forthcoming amendments.¹²

Finally, plaintiff suggests it will suffer hardship if judicial review is delayed. Plaintiff contends that it must begin planning now for the possibility that it will drop its health insurance coverage in twenty-five months and begin paying a penalty for failure to provide such coverage. *Id.* at 30. Plaintiff further notes that its inability to offer insurance may affect its retention and recruitment efforts. *Id.* These allegations, however, do not demonstrate a “direct and immediate” effect on plaintiff’s “day-to-day business” with “serious penalties attached to noncompliance,” as required to establish hardship. *Abbott Labs. v. Gardner*, 387 U.S. 136, 152-53 (1967), *overruled on other grounds in Califano v. Sanders*, 430 U.S. 99 (1977). Instead, they are contingencies that may arise in the future. And plaintiff’s alleged desire to plan for these contingencies twenty-five months in advance does not constitute a hardship; if it did, the hardship prong would become meaningless because organizations are always planning for the future. *See Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987) (“Mere economic uncertainty

¹² Plaintiff misses the point when it claims to challenge the “finalized” regulations and not “whatever might come out of the proposed rulemaking.” Opp'n at 29. As previously explained, this lawsuit is premature not because it seeks to challenge the ANPRM, but because the ANPRM makes clear that the existing regulations are not, in fact, final as to organizations like plaintiff. Plaintiff’s characterization of its claim as challenging “the Act’s preventive services mandate because – and only because – defendants have defined ‘preventive services’ to including contraception and sterilization” is also not credible. *Id.* at 27. The First Amended Complaint makes clear that plaintiff takes issue not with defendants’ interpretation of the statute’s preventive services provision, but with the application of that provision to plaintiff.

affecting the plaintiff's planning is not sufficient to support premature review."); *Tenn. Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984) (plaintiff's "planning insecurity" insufficient to show hardship); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 162 (7th Cir. 1976) ("[C]laims of uncertainty in [plaintiff's] business and capital planning are not sufficient to warrant [] review of an ongoing administrative process.").¹³ Nor is plaintiff's alleged hardship caused by the regulations. *See Abbott Labs.*, 387 U.S. at 152. It arises, rather, from plaintiff's desire to prepare for a hypothetical situation in which the forthcoming amendments do not sufficiently address its religious concerns.¹⁴

Plaintiff also claims hardship from the chance that third parties may sue it to enforce the challenged regulations. Opp'n at 30-31. But plaintiff does not allege

¹³ *Retail Industry Leaders Ass'n v. Fielder*, 475 F.3d 180 (4th Cir. 2007) is not to the contrary. There, the challenged law required the plaintiff to alter its accounting practices immediately because the plaintiff's existing accounting practices did not permit it to collect the type of information that the challenged law required the plaintiff to report. *Id.* at 186-87.

¹⁴ Plaintiff, moreover, cannot transmute the speculative possibility of future injury into a current concrete injury for standing purposes by asserting that it has "already devoted considerable resources to determine how to respond to" the preventive services coverage regulations. Opp'n at 14. Such reasoning would gut standing doctrine, as a plaintiff could manufacture standing by asserting a current need to prepare for the most remote and ill-defined harms. Even if such manipulation were not so transparent, plaintiff still would bear the burden of pleading standing with specificity. *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009); *R.W. v. Ga. Dep't of Educ.*, 353 Fed. App'x 422, 423 (11th Cir. 2009) (per curiam); *Brown v. FBI*, 793 F. Supp. 2d 368, 374 (D.D.C. 2011). Plaintiff does not meet that burden here because it does not explain what it is devoting resources to, much less why it is doing so in light of the forthcoming amendments to the regulations and the enforcement safe harbor. Further, any planning plaintiff is engaged in now "stems not from the operation of [the challenged regulations], but from [plaintiff's] own . . . personal choice" to prepare for contingencies that may never occur. *McConnell v. FEC*, 540 U.S. 93, 228 (2003), *overruled in part on other grounds*, *Citizens United v. FEC*, 130 S. Ct. 876 (2010). Thus, even if this preparation were an injury, it would not be fairly traceable to the challenged regulations. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

that any such suit has been filed against it; this alleged hardship is thus purely theoretical and insufficient to make this case ripe. *See Salvation Army v. Dep't of Cmty. Affairs of N.J.*, 919 F.2d 183, 193 (3d Cir. 1990) (“theoretical possibility of a suit against [plaintiff] by a program beneficiary” insufficient for jurisdiction).¹⁵ And if such a suit were filed in the future, plaintiff would be able to raise all the claims it asserts here as a defense in that action. *See, e.g.*, 42 U.S.C. § 2000bb-1(c).

Because defendants are amending the challenged regulations to address concerns raised by plaintiff, and plaintiff has not shown that it will suffer hardship during this amendment process, plaintiff’s challenge is not ripe.

CONCLUSION

For these reasons and those set forth in defendants’ opening brief, plaintiff lacks standing to challenge the preventive services coverage regulations and its claims are not ripe. This Court accordingly should grant defendants’ motion to dismiss plaintiff’s First Amended Complaint.

Respectfully submitted,

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¹⁵ *Chamber of Commerce v. FEC*, 69 F.3d 600, 602-03 (D.C. Cir. 1995), is distinguishable because the plaintiffs in that case had already changed their behavior as a result of the challenged rule and there was no evidence the agency was in the process of amending the rule.

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CERTIFICATE OF SERVICE

I hereby certify that on June 25, 2012, I caused a true and correct copy of this Reply Brief to be served on counsel by means of the Court's ECF system.

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