IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROMAN CATHOLIC ARCHBISHOP OF WASHINGTON, *et al.*, Plaintiffs,	)	
v.	)	Case No. 12-cv-00815-ABJ
KATHLEEN SEBELIUS, *et al.*, Defendants.	)	

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs challenge regulations that defendants are not enforcing against them and that defendants are amending in order to accommodate the precise religious liberty concerns that form the basis of plaintiffs' Complaint. Yet plaintiffs ask this Court to ignore the fact that the regulations will change before defendants could ever enforce them against plaintiffs, thereby inviting the Court to waste time and effort to issue a purely advisory opinion. Because plaintiffs have not met the basic jurisdictional prerequisites of standing and ripeness, the Court should decline plaintiffs' invitation and dismiss this case.

It is plaintiffs' burden to demonstrate injury stemming from the regulatory actions they seek to challenge. But because the regulations will have changed by the earliest time defendants could enforce them against plaintiffs, any injury is wholly speculative at this time. Contrary to plaintiffs' dire predictions, the amended regulations likely will address their concerns (after all, that is the intent of the ongoing rulemaking). At the very least, the amendments will change what the Court is to review. Plaintiffs cannot transform their allegations of speculative future harm into a current concrete injury by claiming a need to prepare for that speculative future harm. Of course, if plaintiffs still believe their rights have been violated once the amended regulations are issued, they can file suit challenging them at that time and will have lost nothing in the interim. But this Court cannot now assess what, if any, injury plaintiffs might suffer as a result of a not yet promulgated rule.

It is also plaintiffs' burden to show a ripe claim – that, even though the challenged regulations will inevitably change before defendants could enforce them against plaintiffs, this Court should nonetheless intervene to review regulations that are currently being amended. But such review would impermissibly interfere with defendants' ongoing rulemaking and expend the parties' and the Court's resources unnecessarily – requiring the parties to brief the propriety of, and the Court to issue rulings on, two sets of regulations. In fact, it would result in an advisory decision on the regulations in their current form even though they do not and will not harm plaintiffs in such form (if ever).

To date, every court to have considered defendants' jurisdictional arguments has ruled in defendants' favor. Indeed, since defendants filed their opening brief in this case, another court joined the two that have already dismissed nearly identical challenges to the preventive services coverage regulations for lack of standing and lack of ripeness. *See Wheaton Coll. v. Sebelius*, No. 12-cv-1169, --- F. Supp. 2d ----, 2012 WL 3637162 (D.D.C. Aug. 24, 2012). Like the court in *Belmont Abbey College v. Sebelius*, No. 11-cv-1989, --- F.Supp.2d ----, 2012 WL 2914417 (D.D.C. July 18, 2012), the *Wheaton* court concluded that the plaintiff lacked standing in light of the temporary enforcement safe harbor and the forthcoming regulatory accommodations, and that the plaintiff's claims were not ripe because "the regulations [the plaintiff] challenges are being amended precisely in order to accommodate [the plaintiff's] concerns." 2012 WL 3637162, at *8; *see also Nebraska v. HHS*, No. 4:12-cv-3035, --- F.Supp.2d ----, 2012 WL 2913402 (D. Neb. July 17, 2012).[1] Defendants respectfully ask this Court to do the same.

ARGUMENT

I. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE PLAINTIFFS LACK STANDING

Defendants demonstrated in their opening brief that plaintiffs lack standing because they have not alleged an injury-in-fact resulting from the operation of the preventive services coverage regulations.[2] Plaintiffs have not shown otherwise in their opposition. Plaintiffs acknowledge that their health plans are eligible for the temporary enforcement safe harbor, *see* Pls.' Opp'n to Defs.' Mot. to Dismiss ("Opp'n") at 19, ECF No. 21, pursuant to which defendants will not bring any enforcement action against plaintiffs for failing to provide

[1] The plaintiffs in *Belmont Abbey*, *Wheaton*, and *Nebraska* have appealed the district courts' rulings. The D.C. Circuit has granted expedited consideration of, and consolidated, the *Wheaton* and *Belmont Abbey* appeals.

[2] Defendants no longer contend, at this stage, that plaintiffs' allegations regarding grandfathering are insufficient. Defs.' Mem. in Supp. of Mot. to Dismiss at 12 n.6 ("Defs.' Mem."), ECF No. 19-1. Plaintiffs have plausibly explained that they failed to provide the required statement of grandfathered status long before the scope of the challenged regulations was known. *See* Opp'n at 21 n.12.

contraceptive coverage until at least January 1, 2014.[3] By that time, defendants will have finalized amendments to the preventive services coverage regulations that are designed to accommodate the religious objections of religious organizations, like plaintiffs, to providing contraceptive coverage. Thus, plaintiffs have not been, and likely never will be, injured by the current regulations, and therefore lack standing. *See Wheaton*, 2012 WL 3637162; *Belmont Abbey*, 2012 WL 2914417.

Plaintiffs' standing allegations rest on two alleged types of injuries: (1) imminent injury from the supposedly "looming" enforcement of the regulations in their current form and (2) current actual injury from the "uncertainty" created by the regulations in their current form. Opp'n at 12. But both types of alleged injuries suffer from the same fatal flaw, which is why the courts in *Belmont Abbey* and *Wheaton* rejected them as a basis for standing. Plaintiffs' allegations of injury rest entirely on plaintiffs' speculation that the regulations will apply to plaintiffs in their current form come August 2013. This, however, ignores the uncontroverted reality that defendants have begun the process of amending the regulations for the very purpose of addressing the religious objections to covering contraception by religious organizations like plaintiffs. Plaintiffs' baseless conjecture that defendants will not do what they say they will do – and are currently doing – does not constitute an imminent injury for standing purposes. Nor does planning for such an imagined scenario (the continuation of the challenged regulations in their current form) – even if plaintiffs have actually incurred some cost to plan for something that will never happen – provide standing.[4]

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[3] Plaintiffs incorrectly claim that the safe harbor does not encompass failure to provide coverage of sterilization. *See* Opp'n at 19, 41. The safe harbor guidance uses the phrase "contraceptive services" as shorthand for "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," as prescribed by a health care provider. *See* HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines, *available at* http://www.hrsa.gov/womensguidelines/ (last visited Sept. 6, 2012); HHS, Guidance on the Temporary Enforcement Safe Harbor ("Guidance") (Aug. 15, 2012), *available at* http://cciio.cms.gov/resources/files/prev-services-guidance-08152012.pdf (last visited Sept. 17, 2012).

[4] Plaintiffs suggest that that the Court's standing analysis should be "lenient" because this is a pre-enforcement suit alleging First Amendment claims. Opp'n at 2, 9. But this principle only applies, if at all, where there is a "credible" threat of enforcement. *Bloedorn v. Grube*, 631 F.3d 1218, 1228 (11th Cir. 2011); *Skaggs v. Carle*, 110 F.3d 831, 836-37 (D.C. Cir. 1997). There is no such credible threat here because plaintiffs acknowledge they are eligible for

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Plaintiffs note that an injury can be imminent "even if it would not arise until years later," Opp'n at 11, 19-20, but that argument misses the point. The issue here is not just that the regulations will not be enforced against plaintiffs right away, but that these regulations almost certainly will never be enforced against plaintiffs. 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 Reorg. Act Cases*, 419 U.S. 102, 143 (1974) (emphasis added), and it "appear[s] that the [law] certainly would operate as the complainant [] apprehend[s] it would," *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923). "Because an amendment to the [regulations] that may vitiate the threatened injury is not only promised but underway, the injuries alleged by Plaintiff are not 'certainly impending.'" *Belmont Abbey*, 2012 WL 2914417, at *10 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)); *see also Wheaton*, 2012 WL 3637162, at *1.

Plaintiffs are not helped by the cases they cite in support of their imminent injury argument. *See* Opp'n at 11-12. Those cases recognize standing in run-of-the-mill pre-enforcement suits where – unlike here – there was "no reason to think the law will change," *Thomas More Law Ctr. v. Obama*, 651 F.3d 529, 538 (6th Cir. 2011), or not be enforced, *see, e.g.*, *Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383, 393 (1988) ("We are not troubled by the pre-enforcement nature of this suit. The State has not suggested that the newly enacted law will not be enforced, and we see no reason to assume otherwise."); *520 S. Mich. Ave. Assocs., Ltd. v. Devine*, 433 F.3d 961, 963-64 (7th Cir. 2006) (emphasizing that defendants had not promised non-enforcement of law against plaintiff); *Bloedorn*, 631 F.3d at 1229. In fact, *none* of the cases cited by plaintiffs in support of their claim of imminent injury arise in a context comparable to

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the enforcement safe harbor. *Cf. Bloedorn*, 631 F.3d at 1229 (finding "every indication" of enforcement). And it is hard to fathom how plaintiffs can reasonably incur costs planning for the effects of a not-yet promulgated regulation, particularly one that is intended to accommodate concerns of the very type that plaintiffs have raised.

this case – that is, where the challenged law is not being enforced by the government against the plaintiff and is virtually certain to change.[5]

Plaintiffs maintain that defendants' intent to amend the regulations cannot defeat standing because defendants could change their minds. Opp'n at 23. But the federal government is entitled to a presumption that it acts in good faith. *See, e.g.*, *Comcast Corp. v. FCC*, 526 F.3d 763, 769 n.2 (D.C. Cir. 2008) ("We must presume an agency acts in good faith."); *Sossamon v. Lone Star State of Tex.*, 560 F.3d 316, 325 (5th Cir. 2009) ("[W]e assume that formally announced changes to official governmental policy are not mere litigation posturing."). As the *Belmont Abbey* court explained in rejecting an argument identical to plaintiffs':

> [Defendants] have published their plan to amend the rule to address the exact concerns Plaintiff raises in this action and have stated clearly and repeatedly in the Federal Register that they intend to finalize the changes before the enforcement safe harbor ends. Not only that, but Defendants have already initiated the amendment process by issuing an ANPRM. The government, moreover, has done nothing to suggest that it might abandon its efforts to modify the rule – indeed, it has steadily pursued that course – and it is entitled to a presumption that it acts in good faith.

2012 WL 2914417, at *9 (internal citations omitted). Accordingly, any suggestion by plaintiffs that defendants may not abide by their commitments, *see, e.g.*, Opp'n at 23, is not only dubious, but also insufficient to establish injury in fact. *See Wheaton*, 2012 WL 3637162, at *6.

[5] *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (no indication challenged law would change or not be enforced); *Pierce v. Soc'y of the Sisters*, 268 U.S. 510, 533, 536 (1925) (same); *LaRoque v. Holder*, 650 F.3d 777 (D.C. Cir. 2011) (same); *Village of Bensenville v. FAA*, 376 F.3d 1114, 1119 (D.C. Cir. 2004) (only "action by [the court]" prevented the challenged fee collection). Those cases that plaintiffs cite for the proposition that there is standing "even if the government has suggested that it will not enforce a particular law," because "there is nothing that prevents [Defendants] from changing [their] mind," Opp'n at 12 & n.10, 18-19, are inapposite. *See Eckles v. City of Corydon*, 341 F.3d 762, 767-68 (8th Cir. 2003) (city stated it would not the enforce a notice to abate "while the suit is pending"); *Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 388-89 (4th Cir. 2001) (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); *Vt. Right to Life Comm., Inc. v. Sorrell*, 221 F.3d 376, 383 (2d Cir. 2000) (no indication that law would change, and only indication that state would not apply law to plaintiff was informal statement made in the context of litigation); *Chamber of Commerce v. FEC*, 69 F.3d 600, 603 (D.C. Cir. 1995) (enforcement was contingent on the vote of six Commissioners who split three-three with one Commissioner changing her mind at the last minute, and there was no evidence the challenged rule would change before the next vote). Indeed, courts have found similar promises not to enforce by the government sufficient to defeat jurisdiction. *See, e.g.*, *Winsness v. Yocom*, 433 F.3d 727, 732-33 (10th Cir. 2006); *Wis. Right to Life, Inc. v. Schober*, 366 F.3d 485, 490 (7th Cir. 2004); *Presbytery of N.J. v. Florio*, 40 F.3d 1454, 1470-71 (3d Cir. 1994).

The theoretical possibility of a future third-party ERISA action against The Catholic University of America ("CUA") is no exception, *see* Opp'n at 13, 14, especially where CUA does not allege that any such suit has been brought against it. The mere possibility of private-party lawsuits is insufficient to establish standing. *See Wheaton*, 2012 WL 3637162, at *4 (rejecting identical argument); *Belmont Abbey*, 2012 WL 2914417, at *15 (same), *recons. denied*, 2012 WL 3861255, at *1-2 (D.D.C. Sept. 5, 2012) (same); *see also City of Orrville v. FERC*, 147 F.3d 979, 987 (D.C. Cir. 1998); *Salvation Army v. Dep't of Cmty. Affairs of N.J.*, 919 F.2d 183, 193 (3d Cir. 1990) (rejecting "theoretical possibility of a suit against [plaintiff] by a program beneficiary" as a basis for jurisdiction).

Plaintiffs also have not established standing by alleging *current* harm from the "uncertainty" regarding whether the regulations will be amended. *See* Opp'n at 12, 14-18. Plaintiffs cannot transform their allegations of speculative (and highly unlikely) future harm (i.e., that the regulations in their current form might be enforced against plaintiffs in the future) into a current concrete injury by claiming a need to prepare for that speculative (and highly unlikely) future harm. *See Nw. Airlines, Inc. v. FAA*, 795 F.2d 195, 201 (D.C. Cir. 1986) ("The injury requirement will not be satisfied simply because a chain of events can be hypothesized in which the action challenged eventually leads to actual injury."). The plaintiffs in *Wheaton* and *Belmont Abbey* made similar allegations, and yet both courts found standing lacking. *See Wheaton*, 2012 WL 3637162 (dismissing identical suit for lack of standing where religious college alleged in its complaint that it had already spent staff resources and money planning for the possibility of eventual compliance with the preventive services coverage regulations in their current form, that legal uncertainty harmed its employee recruitment and retention, and that the challenged regulations put plaintiff at a competitive disadvantage); *Belmont Abbey*, 2012 WL 2914417 (same).

With good reason: under plaintiffs' theory, a party claiming to be currently affected by the most uncertain, remote, or ill-defined government actions would have standing to challenge those actions, thereby sapping the imminence requirement of any meaning. *See* Defs.' Mem. at

15. Every organization plans for the future, sometimes even for events that are unlikely to occur. Under plaintiffs' theory, an organization would have standing to challenge a future event that has only a one-percent chance of happening – after all, the organization might feel the need to prepare for such an event just in case. But a theory that permits standing to challenge a future event that has a one-percent chance of occurring cannot be reconciled with the Supreme Court's admonition that the threatened injury must be "certainly impending." *Whitmore*, 495 U.S. at 158. Plaintiffs' present-injury allegations are predicated upon the possibility that defendants will enforce the preventive services coverage regulations against plaintiffs in their current form after the safe harbor expires. But it is impossible to square any assertion that this scenario is "certainly impending" (or even at all likely), with the fact that defendants have publicly committed themselves to developing amended regulations – and have indeed initiated the development of such regulations – aimed at addressing concerns of the very type that plaintiffs have raised before the expiration of the safe harbor.

Tellingly, plaintiffs hang their present-harm argument on cases wholly dissimilar from this one.[6] In fact, once again, *none* of the cases plaintiffs cite, *see* Opp'n at 10-11 & n.9, 20-21, involves the present effects of a law that is undergoing amendment and not being enforced by the government during the amendment process, or finds standing based on a need to prepare for a highly speculative and unlikely future occurrence.[7] Plaintiffs seize on the Seventh Circuit's

[6] In *Clinton v. City of New York*, for example, the Supreme Court held that a city suffered actual injury when the government action at issue – the President's line-item veto – had immediately revived a multi-million dollar tax liability on the city. 524 U.S. 417, 426, 430-31 (1998). Not only was there no suggestion in *Clinton* that the veto would change, but here, unlike in *Clinton*, plaintiffs are "*not* contingently liable," *id.* at 431 n.16 (emphasis added), for any penalties thanks to the safe harbor and ongoing rulemaking. In fact, the soonest plaintiffs *could be* liable for civil monetary penalties for violating the challenged regulations is January 1, 2014; and that hypothetical future liability is itself unlikely to materialize. Furthermore, it was not an "uncertain *future* liability" that impacted the city's finances in *Clinton*, as plaintiffs say, Opp'n at 10-11 (emphasis added), but rather the *present* liability revived by the veto, *see* 524 U.S. at 431 (explaining that "the *revival* of a substantial contingent liability immediately and directly affects the borrowing power, financial strength, and fiscal planning of the potential obligor" (emphasis added)). And plaintiffs, of course, "do[] not contend that [they] lost a benefit. Thus, *Clinton* is inapposite to the case at bar." *Comsat Corp. v. FCC*, 250 F.3d 931, 936 (5th Cir. 2001).

[7] *See, e.g.*, *Fin. Planning Ass'n v. SEC*, 482 F.3d 481 (D.C. Cir. 2007) (no sign that challenged regulations, which already applied to petitioner's members, would change); *Idaho Power Co. v. FERC*, 312 F.3d 454 (D.C. Cir. 2003) (no indication that agency orders, which currently required petitioner to enter into a particular contract, would

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statement that "the present impact of a future though uncertain harm *may* establish injury in fact," *Lac Du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490, 498 (7th Cir. 2005) (emphasis added); *e.g.*, Opp'n at 10, but *Lac Du Flambeau* simply recognized that a tribe was currently harmed when the capital costs of its casino ventures rose as a result of an anti-competitive compact between the state and another tribe that was in force and unchanging. 422 F.3d at 499. *Lac Du Flambeau* was not a pre-enforcement challenge and has no bearing on plaintiffs' standing to challenge the preventive services coverage regulations here.

In sum, this case involves not only a time delay before defendants will enforce the challenged regulations against plaintiffs, but also a commitment by defendants to amend the regulations as they relate to organizations like plaintiffs, initiation of the amendment process, and opportunities for plaintiffs to participate in that process. In these circumstances, no injury to plaintiffs is "certainly impending," *Whitmore*, 495 U.S. at 158, and plaintiffs cannot transform their speculative future injuries into current concrete injury for standing purposes, *see Wheaton*, 2012 WL 3637162; *Belmont Abbey*, 2012 WL 2914417.

II. THE COURT SHOULD DISMISS THIS CASE FOR LACK OF JURISDICTION BECAUSE IT IS NOT RIPE

Even if the Court were to conclude that plaintiffs have standing, plaintiffs have not shown that this case is ripe for judicial review under the test articulated in *Abbott Laboratories*. Adjudicating the merits of plaintiffs' claims now, while defendants are actively working to accommodate the religious concerns of religious organizations like plaintiffs, would only entangle the court in an "abstract disagreement[] over administrative policies." *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 807 (2003). The preventive services coverage regulations reflect defendants' tentative (and virtually certain to change), rather than

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change); *Great Lakes Gas Transmission Ltd. v. FERC*, 984 F.2d 426, 431 (D.C. Cir. 1993) (agency had already imposed its "at-risk" condition policy upon petitioner's pipeline facility, and it was "undisputed that the at-risk condition reflect[ed] 'crystallized' agency policy"); *Thomas More*, 651 F.3d at 536 ("[T]here is no reason to think the law will change"); *Protocols, LLC v. Leavitt*, 549 F.3d 1294, 1301 (10th Cir. 2008) (agency "d[id] not dispute" that its "present view of the law" was "contrary to [plaintiff]'s prior practice, thereby exposing [plaintiff] to liability"); *520 S. Mich. Ave.*, 433 F.3d 961 (plaintiff had standing in the *absence* of a promise not to enforce the law at issue); *supra* at n.5 (distinguishing other cases).

final, position as to organizations like plaintiffs. And although plaintiffs claim that they are currently harmed by their need to plan for the possible, speculative impact of the challenged regulations, that type of harm is insufficient to make a case ripe for review. *See Cephalon, Inc. v. Sebelius*, 796 F. Supp. 2d 212, 218 (D.D.C. 2011) ("Plaintiff cannot base an argument of undue burden from postponement of a judicial decision on its having to plan for a future event, as opposed to the actual event, if that event is too speculative in the first instance.").

Plaintiffs maintain that the challenged regulations are fit for judicial review because they are "final" and published in the Code of Federal Regulations. Opp'n at 28. This formalistic argument ignores defendants' "clear[] and repeated[]" statements that they intend to amend the regulations to address the concerns raised by religious organizations with religious objections to providing contraceptive coverage, like plaintiffs. *Belmont Abbey*, 2012 WL 2914417, at *9. It also ignores the ANPRM, whereby defendants "initiated the amendment process." *Id*. And it is inconsistent with the Supreme Court's instruction that the finality requirement should be applied "in a 'flexible' and 'pragmatic' way." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 435 (D.C. Cir. 1986) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149-50 (1967)). Because defendants' position is "tentative" and "indeterminate," and because the forthcoming amendments will eliminate the need for judicial review entirely or at least narrow and refine the controversy, the regulations are not "final" in any meaningful sense. *Belmont Abbey*, 2012 WL 2914417, at *12 (citing *Ciba-Geigy*, 801 F.2d at 436); *see also Wheaton*, 2012 WL 3637162, at *8 ("Because they are in the process of being amended, the preventive services regulations are by definition a tentative agency position 'in which the agency expressly reserves the possibility that its opinion might change.'") (quoting *Birdman v. Office of the Governor*, 677 F.3d 167, 173 (3d Cir. 2012)). "The interest in postponing review is strong if the agency position whose validity is in issue is not in fact the agency's final position. If the position is likely to be abandoned or modified before it is actually put into effect, then its review wastes the court's time and interferes with the process by which the agency is attempting to reach a final decision." *Cont'l Air Lines, Inc. v. Civil Aeronautics Bd.*, 522 F.2d 107, 125 (D.C. Cir. 1975 (en banc).

Thus, this case does not involve "[t]he mere contingency that [an agency] might revise the regulations at some future time," as plaintiffs claim. Opp'n at 33 (quoting *Albertson v. Subversive Activities Control Bd.*, 382 U.S. 70, 77 (1965)). There is nothing *contingent* about defendants' intent to amend the challenged regulations. *See Am. Petroleum Inst. v. EPA*, 683 F.3d 382 (D.C. Cir. 2012) (concluding challenge to regulation was not ripe where agency had initiated a rulemaking that could significantly amend the regulation); *Tex. Indep. Producers & Royalty Owners Ass'n v. EPA*, 413 F.3d 479, 483-84 (5th Cir. 2005) (dismissing challenge to rule as unripe where agency deferred effective date of rule and announced its intent to consider issues raised by plaintiff in new rulemaking during the deferral period); *Belmont Abbey*, 2012 WL 2914417, at *13.[8] And plaintiffs' suggestion that they will be unsatisfied with whatever amendments result from the pending rulemaking, *see* Opp'n at 6, 38-39, is not grounds for this Court to issue an advisory opinion on the lawfulness of the ideas proposed in the ANPRM. *See Belmont Abbey*, 2012 WL 2914417, at *13 ("It would . . . be premature to find that the amendment will not adequately address Plaintiff's concerns."). Plaintiffs cannot maintain that nothing flowing from the ANPRM could possibly alter their challenge to the regulations when the ANPRM is a mere starting point, and plaintiffs have ample opportunity to express their concerns and help shape the forthcoming amendments.

The fact that plaintiffs' challenges may be "legal" – and therefore may be addressed without post-enactment factual development – is irrelevant to the ripeness issue here. Courts may not opine on the lawfulness of regulations that are not yet final no matter how "legal" the issues may be. *See, e.g.*, *Pub. Water Supply Dist. No. 8 v. City of Kearney*, 401 F.3d 930, 932 (8th Cir. 2005); *Motor Vehicle Mfrs. Ass'n v. N.Y. State Dep't of Envtl. Conservation*, 79 F.3d

[8] Although plaintiffs understandably hope to distinguish *American Petroleum Institute, Texas Independent Producers*, and other cases cited by defendants, *see* Opp'n at 35-38, their attempts to do so rest largely on the inaccurate refrain that the regulations challenged here are "final." Moreover, plaintiffs' attempt to distinguish *American Petroleum Institute* is unavailing for the reasons explained by Judge Boasberg in *Belmont Abbey*, including the "significant research and deliberation" of which the ANPRM is the product and the publication of the safe harbor end dates, "creating external accountability for the agency's self-imposed deadline." 2012 WL 2914417, at *13.

1298, 1306 (2d Cir. 1996). Until the pending rulemaking is completed, this Court has nothing to review. *See Pub. Serv. Comm'n v. Wycoff Co.*, 344 U.S. 237, 244 (1952) (indicating that, 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 . . . ."); *Chamber of Commerce of U.S. v. Reich*, 57 F.3d 1099, 1100 (D.C. Cir. 1995) (per curiam) ("[E]ven in cases involving pure legal issues, review is inappropriate when the challenged policy is not sufficiently fleshed out to allow the court to see the concrete effects and implications of its decision . . . or when deferring consideration might eliminate the need for review altogether." (internal quotations and citations omitted)); *Bethlehem Steel Corp. v. EPA*, 536 F.2d 156, 161 (7th Cir. 1976) ("[T]he issues here are fit for judicial review in the sense that they present concrete legal questions, but are not fit for judicial review in the sense that the actions challenged are part of a continuing agency decision-making process which has not yet resulted in an order requiring compliance by the petitioners."); *Belmont Abbey*, 2012 WL 2914417, at *14 ("[C]ourts should refrain from 'intervening into matters that may best be reviewed at another time or in another setting,' even if the issue presented is 'purely legal' and 'otherwise fit for review.'" (quoting *Full Value Advisors, LLC v. SEC*, 633 F.3d 1101, 1106 (D.C. Cir. 2011)).

Defendants, through the enforcement safe harbor and the ongoing amendment process, have consistently sought to *accommodate* religious organizations' religious objections to the regulations, working quickly to begin the rulemaking process, and have committed to finalizing their amendments in advance of the expiration of the safe harbor. There is nothing to suggest that, if the amendment process does not alleviate plaintiffs' concerns altogether, plaintiffs would not have an opportunity to present a legal challenge in a timely manner once there are regulations that are ripe for review.[9] And even if plaintiffs' worst fears were to somehow come to pass,

[9] For these reasons, the Court should reject out of hand plaintiffs' implausible suggestion that defendants will wait until "a nanosecond" before the expiration of the enforcement safe harbor to finalize regulatory amendments, leaving plaintiffs no time to litigate if they are ultimately unsatisfied with those amendments. *See* Opp'n at 39. Indeed, this suggestion is misleading. The safe harbor will be in effect until the first plan year that begins *on or after* August 1, 2013, *see* 77 Fed. Reg. 16,501, 16,504 (Mar. 21, 2012); Guidance at 3, and defendants intend to finalize amendments before this rolling expiration period begins, 77 Fed. Reg. at 16,503; *see also* 77 Fed. Reg. at

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plaintiffs could then seek preliminary injunctive relief to preserve the status quo while the Court considers the merits of plaintiffs' claims. By seeking review of the challenged regulations now, before they have taken on fixed and final shape, plaintiffs ask the Court to issue an advisory opinion on the lawfulness of regulations that may never be enforced against plaintiffs.[10]

The hardship of which plaintiffs complain – that the preventive services coverage regulations require advanced planning and impact their current decision-making – is not a hardship sufficient to overcome the lack of finality and fitness for review of the regulations that they challenge. The event for which they are planning is just too speculative. Plaintiffs "cannot base an argument of undue burden from postponement of a judicial decision on its having to plan for a future event, as opposed to the actual event, if that event is too speculative in the first instance." *Cephalon*, 796 F. Supp. 2d at 218. Plaintiffs' alleged desire to plan for future contingencies does not constitute a hardship, even if, as plaintiffs claim, they feel the effects of that planning at present. *See, e.g.*, *Tenn. Gas Pipeline Co. v. FERC*, 736 F.2d 747, 751 (D.C. Cir. 1984); *Wilmac Corp. v. Bowen*, 811 F.2d 809, 813 (3d Cir. 1987); *Bethlehem Steel Corp.*, 536 F.2d at 162; *see also Am. Petroleum Inst.*, 683 F.3d at 389 ("Considerations of hardship that might result from delaying review will rarely overcome the finality and fitness problems inherent in attempts to review tentative positions." (quotation omitted)); *Cephalon*, 796 F. Supp. 2d at 218 ("If the Court were to adopt [plaintiff's] reasoning, it would effectively create a rule where any future event, however remote or speculative, could constitute a burden when a plaintiff claims

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8725, 8728 (Feb. 15, 2012). Thus, since plaintiffs' plan years begin on January 1, defendants will have amended the regulations, at the latest, several months before plaintiffs will be subject to enforcement. Moreover, the federal government is presumed to act in good faith, *see supra*, at 5, and plaintiffs offer no reason to doubt that it will do so here. Thus, there is no indication that plaintiffs would not have an opportunity to bring a challenge once the regulations are ripe for review, assuming that the amendments do not alleviate their concerns altogether.

[10] Plaintiffs also miss the point by suggesting the Court should maintain jurisdiction because they will "'return here shortly' with the same claims." Opp'n at 40 (quoting *Neb. Pub. Power Dist. v. MidAm. Energy Co.*, 234 F.3d 1032, 1039-40 (8th Cir. 2000)). The entire purpose of amending the preventive services coverage regulations is to accommodate religious objections such as those raised by plaintiffs. But plaintiffs simply assume that no such amendment could ever alleviate the need for judicial review. That assumption is baseless, and prejudges defendants' ongoing rulemaking process. Because the challenged regulations are not sufficiently final, and will certainly take a different form before the expiration of the enforcement safe harbor, the Court should reject plaintiffs' attempt to obtain premature review of their claims.

that it must prepare for this future contingency."). Nor do plaintiffs' allegations of hardship demonstrate the sort of "direct and immediate" effect on plaintiffs' "day-to-day business" with "serious penalties attached to noncompliance," as required by *Abbott Laboratories*, 387 U.S. at 152-53. Instead, the "hardship" that plaintiffs claim is rooted entirely in a desire to plan for contingencies that likely will never arise given defendants' ongoing efforts to amend the challenged regulations. *See Nat'l Park Hospitality Ass'n*, 538 U.S. at 811-12 ("Petitioner's argument appears to be that *mere uncertainty as to the validity of a legal rule* constitutes a hardship for purposes of the ripeness analysis. We are not persuaded. If we were to follow petitioner's logic, courts would soon be overwhelmed with requests for what essentially would be advisory opinions because most business transactions could be priced more accurately if even a small portion of existing legal uncertainties were resolved. In short, petitioner has failed to demonstrate that deferring judicial review will result in real hardship." (emphasis added)). And because plaintiffs do not know what form the regulations will take once they are amended – other than they will attempt to accommodate concerns of the very type that plaintiffs have raised – it is not clear what contingencies plaintiffs could plan for.

Faced with substantially similar allegations, the courts in *Belmont Abbey*, *Wheaton*, and *Nebraska* concluded that the plaintiffs had not demonstrated hardship from delayed review. *Belmont Abbey*, 2012 WL 2914417, at *14 ("Costs stemming from [a plaintiff's] desire to prepare for contingencies are not sufficient . . . to constitute a hardship for purposes of the ripeness inquiry – particularly when the agency's promises and actions suggest the situation [the plaintiff] fears may not occur."); *Wheaton*, 2012 WL 3637162, at *8 ("'The planning insecurity [plaintiff] advances' with regard to what the preventive services regulations may (or may not) require of it does not suffice to show hardship." (quoting *Tenn. Gas Pipeline*, 736 F.2d at 751)); *Nebraska*, 2012 WL 2913402, at *23 ("[T]he plaintiffs' desire to plan for future contingencies

that may never arise does not constitute the sort of hardship that can establish the ripeness of their claims[.]"). Plaintiffs make no serious effort to distinguish those cases.[11]

The cases plaintiffs do cite do not suggest that planning for hypothetical future contingencies is a sufficient hardship to make this case ripe for review. For instance, in *Pacific Gas & Electric Co. v. State Energy Resource Conservation & Development Comm'n*, 461 U.S. 190 (1983), the plaintiff challenged a state law that *currently* imposed a moratorium on construction of nuclear plants until the State Energy Commission determined that there has been developed "demonstrated technology or means for the disposal of high-level nuclear waste." *Id.* at 198. Thus, unlike the challenged regulations in this case, the challenged law in *Pacific Gas* immediately affected the day-to-day operations of the plaintiffs, as they could not engage in the construction of new facilities. Nor was there an expectation that the law itself was subject to change. *Id.* at 201. Indeed, in *none* of the cases plaintiffs cite with respect to hardship was there any indication that the defendants intended to amend the challenged law, much less that they were actively engaged in doing so.[12]

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[11] Although plaintiffs cite the court's decision in *Newland v. Sebelius*, No. 1:12-cv-1123, 2012 WL 3069154 (D. Colo. July 27, 2012), for the point that changes to an employee health plan require advance planning, *see* Opp'n at 31, plaintiffs ignore that the employer in that case, unlike plaintiffs here, did not have the benefit of the enforcement safe harbor, *see* 2012 WL 3069154, at *2. The plaintiff in *Newland*, therefore, had to comply with the contraceptive coverage requirement by November 1, 2012. And there was no indication that the requirement would change as to the *Newland* plaintiffs; so, unlike plaintiffs here, they were planning for a certainty, not an improbability.

[12] *See, e.g.*, *Wis. Pub. Power Inc. v. FERC*, 493 F.3d 239 (D.C. Cir. 2007) (per curiam) (challenged agency decision was already being enforced, with no suggestion that agency would change it); *Cont'l Air Lines*, 522 F.2d at 125 (challenged regulation was already being enforced and "there [was] every indication that the Board consider[ed] its position on seating configuration to be final"); *Retail Indus. Leaders Ass'n v. Fielder*, 475 F.3d 180, 186-87 (4th Cir. 2007) (challenged law required plaintiff to alter its accounting practices *immediately* because existing accounting practices did not permit plaintiff to collect information that had to be reported under the challenged law); *Miller v. Brown*, 462 F.3d 312, 321 (4th Cir. 2006) (state's open primary law required plaintiffs to alter their political campaign decisions *immediately*, and delay would have diminished the effectiveness of those decisions); *Skull Valley Band v. Nielson*, 376 F.3d 1223, 1239 (10th Cir. 2004) (holding that plaintiffs should not be required to obtain a costly license from the federal Nuclear Regulatory Commission before challenging a currently applicable state nuclear regulatory scheme); *Metro. Milwaukee Ass'n of Commerce v. Milwaukee Cnty.*, 325 F.3d 879, 882-83 (7th Cir. 2003) (challenged state law was in place and was already impacting contracts between plaintiffs and defendant); *Neb. Pub. Power Dist.*, 234 F.3d at 1036-37 (private contract had been entered into nearly forty years prior to suit); *Gary D. Peake Excavating, Inc. v. Town Bd. of Hancock*, 93 F.3d 68, 71-72 (2d Cir. 1996) (holding that plaintiff should not be required to continue with a costly state licensing process before challenging a city ordinance currently prohibiting the conduct for which he sought a license); *Riva v. Massachusetts*, 61 F.3d 1003, 1011 (1st Cir. 1995) (holding that plaintiffs' challenge to the state's seniority-based system for determining

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Plaintiffs also reiterate the contention – rejected in both *Belmont Abbey* and *Wheaton* – that the possibility of a future third-party ERISA action against CUA creates a hardship. Opp'n at 32. But as explained already, *supra*, at 6, plaintiffs do not allege that any such suit has been brought against CUA, and, thus, this alleged hardship is purely theoretical. Hypothetical future hardship does not render a case ripe for review. *See Belmont Abbey*, 2012 WL 2914417, at *15; *Wheaton*, 2012 WL 3637162, at *8-9; *see also Salvation Army*, 919 F.2d at 193.

Finally, although plaintiffs suggest that the First Amendment implications of this case weigh in favor of review now, *see* Opp'n at 32, exactly the opposite is true. As explained by Judge Boasberg, "[j]udicial restraint is particularly warranted where, as here, 'the issue is one of constitutional import' and its 'uncertain nature . . . might affect a court's ability to decide intelligently.'" *Belmont Abbey*, 2012 WL 2914417, at *14 (quoting *Full Value Advisors*, 633 F.3d at 1107). Because defendants are amending the challenged regulations to address the precise concerns raised by organizations like plaintiffs, and plaintiffs have not shown that they will suffer cognizable hardship during this amendment process, plaintiffs' challenge is not ripe.

III. STANDING AND RIPENESS, NOT MOOTNESS, ARE THE PROPER STANDARDS TO APPLY

The Court should reject plaintiffs' attempts to recast defendants' jurisdictional arguments as questions of mootness. *See* Opp'n at 23, 34-35. This case would be about mootness if plaintiffs had already established injury, the case was proceeding, and then the cause of the injury disappeared. But here, any injury is speculative and in the future, which raises quintessential standing and ripeness questions. Indeed, the plaintiffs in *Belmont Abbey* and *Wheaton* raised precisely the same mootness arguments to no avail. *See, e.g.*, Pl.'s Opp'n to Defs.' Mot. to Dismiss at 17-19, *Wheaton*, No. 1:12-cv-01169, ECF No. 18; *Wheaton*, 2012 WL 3637162, at *4 n.6. The standing and ripeness doctrines serve different interests than the mootness doctrine. "Standing doctrine functions to ensure . . . that the scarce resources of the

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disability benefits was ripe "[g]iven the relative certainty of the statute's application"); *Triple G Landfills, Inc. v. Bd. of Comm'rs of Fountain Cnty.*, 977 F.2d 287 (7th Cir. 1992) (local ordinance being challenged was already in place and directly applied to the plaintiff, with no suggestion that it would change in the future).

federal courts are devoted to those disputes in which the parties have a concrete stake." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs., Inc.*, 528 U.S. 167, 191 (2000). And the ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" and "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way." *Nat'l Park Hospitality Ass'n*, 538 U.S. at 807-08 (quotation omitted). "In contrast, by the time mootness is an issue, the case has been brought and litigated, often . . . for years." *Laidlaw*, 528 U.S. at 191. The mootness doctrine serves the distinct interest of avoiding "abandon[ing] [a] case at an advanced stage" where doing so "may prove more wasteful than frugal." *Id*. at 191-92. Because this case has not been litigated "for years" and is not at "an advanced stage," the interests served by the mootness doctrine simply are not implicated here.[13]

Accordingly, the Court should reject plaintiffs' attempt to shift their burden to establish standing and ripeness by requiring defendants to show that under no set of circumstances would plaintiffs be adversely affected by the challenged regulations. Plaintiffs have it backwards. It is plaintiffs' burden – not defendants' – to demonstrate current or imminent injury stemming from the regulatory actions it seeks to challenge. "[A]lthough the burden lies with the party *asserting* mootness . . . the fact that a case *becomes* moot when plaintiff loses standing . . . does not mean that it is somehow defendant's burden to show that plaintiff no longer faces imminent injury. To the contrary, the party asserting federal jurisdiction bears the burden of establishing that it has standing at every stage of the litigation." *Wheaton*, 2012 WL 3637162, at *4 n.6 (internal citations, quotation marks, and alterations omitted).[14]

[13] Plaintiffs rely on *CSI Aviation Services, Inc. v. DOT*, 637 F.3d 408 (D.C. Cir. 2011), to suggest that mootness is the proper analysis, *see* Opp'n at 34-35, but their discussion of that case is misleading. The court did not, as plaintiffs suggest, recast the defendant's ripeness argument as a mootness argument. Rather, it rejected the defendant's alternative mootness argument after determining that the plaintiff's claims were ripe. *See id.* at 412-14. In any event, with respect to ripeness, *CSI Aviation Services* does not support plaintiffs' position because, unlike here, the agency had taken a "definitive" legal position; the policy at issue "'gave no indication that it was subject to further agency consideration or possible modification.'" *Id.* at 412 (quoting *Ciba-Geigy*, 801 F.2d at 436-37).

[14] In attempting to re-write defendants' standing argument as a mootness argument, plaintiffs assert that "a potential change in the law is 'not the kind[] of future development[] that enter[s] into the imminence inquiry.'" Opp'n at 23

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IV. PLAINTIFFS LACK BOTH STANDING AND RIPENESS TO ASSERT EACH OF THEIR CLAIMS

Finally, plaintiffs wholly miss the mark by arguing that the enforcement safe harbor and the ongoing rulemaking do not affect a subset of their claims, i.e., their challenge to the religious employer exemption and their Administrative Procedure Act claims. *See* Opp'n at 43-45. Because plaintiffs cannot know what form the final regulations will take, it is pure speculation to suggest that the amended regulations will not address these concerns as well. For instance, defendants have not foreclosed the possibility that the amendment process will alter the religious employer exemption as it currently exists. *See Wheaton*, 2012 WL 3637162, at *8 & n.11. And defendants have made clear that an employer can avail itself of the safe harbor without prejudicing its ability to later avail itself of the religious employer exemption. *See* Guidance at 4. Moreover, although plaintiffs contend that the preventive services regulations are contrary to certain other provisions in federal law, such as the Weldon Amendment, *see* Opp'n at 44 (citing Compl. ¶¶ 291-305, ECF No. 1), that contention – in addition to lacking merit – assumes that the regulations will remain in their current form. Indeed, it is difficult to imagine how the Court could meaningfully review regulations that are still in flux, as any ruling would be irrelevant once the ongoing rulemaking process is complete. Because there is a substantial likelihood that plaintiffs' claims will be materially affected, if not made entirely irrelevant, by changes to the regulations, this Court should dismiss all of plaintiffs' claims for lack of standing and ripeness.

CONCLUSION

For these reasons and those set forth in defendants' opening brief, plaintiffs lack standing to challenge the preventive services coverage regulations and their claims are not ripe for review. This Court, accordingly, should grant defendants' motion to dismiss.[15]

(quoting *Thomas More*, 651 F.3d at 537). But *Thomas More* noted only "that a time delay, without more, will not render a claim of statutory invalidity unripe if the application of the statute is otherwise sufficiently probable." 651 F.3d at 537 (quotation omitted). The court's conclusion that "no function of standing law is advanced by requiring plaintiff to wait" to sue where "there is no reason to think the law will change," *id.* at 538, plainly does not support plaintiffs' argument here, in light of the ongoing amendment process.

[15] In their opposition, plaintiffs request oral argument on defendants' motion to dismiss. Defendants do not believe oral argument is necessary but do not oppose it if the Court believes it would be helpful.

Respectfully submitted this 24th day of September, 2012,

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