UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

AVE MARIA UNIVERSITY, *Plaintiff,* v. KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, HILDA SOLIS, Secretary of the United States Department of Labor, UNITED STATES DEPARTMENT OF LABOR, TIMOTHY GEITHNER, Secretary of the United States Department of the Treasury, and UNITED STATES DEPARTMENT OF THE TREASURY, *Defendants*.	CIVIL NO. 2:12-CV-88-FtM-29SPC

PLAINTIFF'S OPPOSITION TO MOTION TO DISMISS AND MEMORANDUM IN SUPPORT

Plaintiff Ave Maria University ("Ave Maria") hereby opposes defendants' motion to dismiss. As explained below, defendants' standing and ripeness arguments depend on a speculative proposed rulemaking that, by its own terms, could not affect Ave Maria's challenge to defendants' contraception, sterilization, and abortion-drug mandate.

INTRODUCTION

This case concerns a Catholic university that wants to follow its faith and a government mandate that will fine it for doing so. The mandate in question is composed of two parts. Part one is a statute—found in the Patient Protection and Affordable Care Act—that requires most employers to provide free insurance coverage for "preventive care." Part two is a regulation that defines "preventive care" to include contraceptives

and sterilization. Both parts of the mandate—the statute and the implementing regulation—are definitive, final and enforceable on a specific date.

Ave Maria cannot comply with the mandate without violating its faith. In advance of the mandate's enforcement, Ave Maria will have to drop insurance for its 200 employees and prepare to pay annual fines of over $300,000. Its only way out would be to publicly abandon the faith that forms its mission and identity. Ave Maria's final deadline for making that choice is twenty months from the date of this pleading—January 1, 2014—when the mandate will be enforceable against it.

Ave Maria therefore filed this lawsuit, claiming the mandate violates its religious liberties. Its straightforward legal claims can be resolved with no factual development. Yet defendants say the suit should be dismissed because Ave Maria has no standing and its claims are not ripe. Why? Defendants have given advance notice of a proposed new rulemaking which, they say, will solve Ave Maria's problems before January 1, 2014.

This argument is puzzling. By its own terms, the rulemaking proposed in the advance notice would not change anything about the mandate that now inflicts constitutional injury on Ave Maria. Instead, the advance notice merely brainstorms ways of transferring the financial and administrative burdens of providing contraceptive coverage from an employer to its insurer. But accounting arrangements are irrelevant to Ave Maria's claims. Whatever might emerge from the future rulemaking—and that is anybody's guess—two things will remain unchanged: the mandate will *still* make Ave Maria provide "preventive care" coverage, and the mandate will *still* define "preventive care" to include contraceptives and sterilization. The new rulemaking process promises

to change neither of those two pillars of the mandate, and therefore cannot influence Ave Maria's current challenge one iota. The Court should deny the motion to dismiss and allow the parties to proceed expeditiously to the merits of that challenge.

STATEMENT OF FACTS

1. Ave Maria University ("Ave Maria") was founded in 2003 as an institution of higher education faithful to the Catholic Church. Compl. ¶¶ 2, 26. Ave Maria believes that Catholic teachings on human sexuality and human life forbid it from providing insurance coverage for contraception, sterilization, or abortifacient drugs. Compl. ¶ 34.

2. In March 2010, Congress passed the Patient Protection and Affordable Care Act ("Affordable Care Act" or "Act").[1] Among other things, the Act requires that "[a] group health plan … shall … provide coverage for" women's "preventive care and screenings," without cost sharing. 42 U.S.C § 300gg–13(a)(4). "Preventive care and screenings" are defined in guidelines issued by a division of Defendant Department of Health and Human Services (HHS). *Id.* In August 2011, HHS issued an "amended interim final rule" defining preventive care to include "[a]ll Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." Health Resources and Services Administration, *Women's Preventive Services: Required Health Plan Coverage Guidelines* (Aug. 1, 2011), http://www.hrsa.gov/womensguidelines/ (last visited May 18, 2012). FDA-approved contraceptive methods include birth-control pills; prescription IUDs; Plan B (the "morning-after pill"); and ulipristal ("ella" or the "week-after pill"). *See*

[1] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (Mar. 23, 2010); Health Care and Education Reconciliation Act, Pub. L. No. 111-152 (Mar. 30, 2010).

http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118465.htm (last visited May 18, 2012). These requirements would go into effect one year after their issuance, on August 1, 2012. 42 U.S.C. § 300gg-13(b)(1), (2); 76 Fed. Reg. at 46624.

3. The rule added an exemption for those "religious employer[s]" who meet all of the following criteria:

> (1). The inculcation of religious values is the purpose of the organization.
>
> (2). The organization primarily employs persons who share the religious tenets of the organization.
>
> (3). The organization serves primarily persons who share the religious tenets of the organization.
>
> (4). The organization is a nonprofit organization as described in section 6033(a)(1) and 6033(a)(3)(A)(i) or (iii)[2] of the Internal Revenue Code of 1986, as amended.

45 C.F.R. § 147.130(a)(1)(B)(1)-(4). Ave Maria meets none of them. Compl. ¶¶ 102-09.

4. The mandate and the exemption provoked public outcry, including some 200,000 comments. Compl. ¶ 75. This lawsuit and several others followed. On February 10, 2012, following a press conference by President Obama, HHS issued a bulletin describing a "Temporary Enforcement Safe Harbor." Under that Safe Harbor, defendants would wait an additional year before enforcing the mandate against certain non-exempt, religious organizations.[3] That same day, defendants adopted the religious employer exemption "as a final rule without change." 77 Fed. Reg. 8725, 8730.

5. About a month later, defendants announced an "Advance Notice of Proposed Rulemaking" (ANPRM). 77 Fed. Reg. 16501 (Mar. 21, 2012) (to be codified at 45

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[2] These IRC sections "refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order." 76 Fed. Reg. at 46623.

[3] HHS Bulletin at 3, 6, at http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf (last visited May 18, 2012).

C.F.R. pt. 147). The ANPRM does not propose to amend the mandate or the religious employer exemption in any way. Rather, it solicits comments on how to craft another mandate that would force a non-exempt religious organization's insurer to provide the mandated contraceptive services separately to employees with "no premium charge." *See* ANPRM at 16503. The ANPRM states that the original mandate will remain in effect. *Id*. at 16502.

6. Ave Maria's insurance plan year for its 200 employees begins on January 1 of each year. Compl. ¶ 36. The mandate takes effect for the first plan year after August 1, 2012. *See* 42 U.S.C. § 300gg-13(b); 76 Fed. Reg. at 46623. Ave Maria's religious beliefs forbid it from complying with the mandate, however. Compl ¶ 33-34, 83. Consequently, Ave Maria will violate the mandate about eight months from now, on January 1, 2013. One year later, on January 1, 2014, the government will begin enforcing the mandate, and Ave Maria will begin paying annual fines of about $2,000 per employee. HHS Bulletin at 3; 26 U.S.C.A. § 4980H(a), (c)(1). It will face fines of $340,000 in the first year alone,[4] and will have to drop employee health insurance. Compl. ¶ 31. Ave Maria has already begun planning for this approaching reality. Compl. ¶ 99.

STANDARD OF REVIEW

In evaluating a motion to dismiss, the Court "must accept all well-pleaded factual allegations in a complaint as true and take them in the light most favorable to plaintiff." *Smith* v. *Williams*, 819 F. Supp. 2d 1264, 1268 (M.D. Fla. 2011). Ave Maria must show

[4] *See* Compl. ¶ 31 (200 employees). Fines are assessed on every employee over 30. *See* 26 U.S.C.A. § 4980H(c)(2)(D)(i) ((200 - 30) x $2000 = $340,000).

subject matter jurisdiction. *Lamb* v. *Charlotte County*, 429 F. Supp. 2d 1302, 1305 (M.D. Fla. 2006). Standing and ripeness are relaxed in First Amendment cases. *See, e.g.*, *Digital Properties Inc.* v. *City of Plantation*, 121 F.3d 586, 590 (11th Cir. 1997) ("[T]he injury requirement is most loosely applied when a plaintiff asserts a violation of First Amendment rights based on the enforcement of a law, regulation or policy."); *see also Bloedorn* v. *Grube*, 631 F. 3d 1218, 1228 (11th Cir. 2011). Courts weighing ripeness "are appropriately guided by the presumption of reviewability, especially when the affected person is confronted with the dilemma of choosing between disadvantageous compliance or risking imposition of serious penalties." *Ciba-Geigy Corp.* v. *EPA*, 801 F.2d 430, 434 (D.C. Cir. 1986).

ARGUMENT

I. AVE MARIA HAS STANDING TO CHALLENGE THE MANDATE.

To demonstrate standing, Ave Maria must allege (1) it suffers an actual or imminent injury (2) fairly traceable to defendants' actions and (3) likely to be "redressed by a favorable decision." *Sierra Club* v. *Johnson*, 436 F.3d 1269, 1276 (11th Cir. 2006). Defendants argue only that Ave Maria has not alleged an actual or imminent injury. Mot. to Dismiss (MTD) at 13. They are mistaken.

A. Ave Maria alleges both actual and imminent injuries.

Ave Maria's complaint details how the mandate coerces it to violate its faith under threat of severe penalties. Specifically, Ave Maria alleges that (1) it now offers coverage to its 200 employees that excludes the mandated contraceptive services; (2) it will be subject to the mandate and is not exempt; (3) it cannot provide the mandated coverage

without violating its faith; and (4) it will therefore face, on a date certain, heavy fines and the inability to offer employee insurance. Compl. ¶¶ 32-34, 80, 102, 105-09. (Indeed, defendants do not dispute that Ave Maria will be subject to enforcement under the mandate by January 1, 2014. MTD at 15, 23.) Further, Ave Maria also alleges that it has already devoted considerable resources to determine how to respond to the mandate, and must continue doing so in anticipation of violating the mandate in less than one year. Compl. ¶ 99. These allegations easily establish actual and imminent injuries. *See, e.g.*, *ACLU of Fla.* v. *Miami Dade Cnty Sch. Bd.*, 557 F.3d 1177, 1194 (11th Cir. 2009) (imminent injury "requires only that the anticipated injury occur with[in] some fixed period of time in the future").

B. Ave Maria's plan is not eligible for grandfather status.

Defendants claim Ave Maria fails to allege injury, because its complaint does not rule out that its plan may be "grandfathered." MTD at 13-15. Under the Affordable Care Act, group health plans in effect on March 23, 2010 may be grandfathered and therefore exempt from the mandate. *See* 42 U.S.C. § 18011. To remain grandfathered, however, a plan must provide annual notices and must avoid certain changes to coverage, annual limits, and cost-sharing. *See* 45 C.F.R. § 147.140(a), (g); 26 C.F.R. § 54.9815–1251T(a), (g); 29 C.F.R. § 2590.715–1251(a), (g). Defendants argue that Ave Maria's complaint does not establish that its plan is ineligible for grandfather status. MTD at 13-15.

Defendants are mistaken. Ave Maria's complaint states that, "[g]iven plan changes since March 23, 2010, the University's health insurance plan does not qualify as a grandfathered health plan." Compl. ¶ 100. No more specificity is required since "[a]t the

pleading stage . . . the court 'presume[s] that general allegations embrace those specific facts that are necessary to support the claim.'" *31 Foster Children* v. *Bush*, 329 F.3d 1255, 1263 (11th Cir. 2003) (quoting *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 561 (1992)). In any event, Ave Maria has attached a summary of its plans from 2009 to 2012. *See* Towey Decl., Exh. 1.[5] As shown, since March 2010, Ave Maria made plan changes that would forfeit grandfather status, *see* MTD at 13-14, and has also not included any required grandfather notices in plan materials, *see* MTD at 15 n.6. Grandfather status is simply not an issue.

C. The Safe Harbor does not make Ave Maria's injury non-imminent.

Defendants also try to defeat standing on the ground that "defendants will not take any enforcement action against [Ave Maria] until [January 1, 2014]." MTD at 15. They say this makes Ave Maria's asserted injury "too remote temporally" and thus lacking "imminence." *Id*. at 15-16. Not so. A plaintiff "does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979) (citation omitted); *see also Miami Dade Cnty Sch. Bd.*, 557 F.3d at 1194 ("[i]mmediacy requires only that the anticipated injury occur with[in] some fixed period of time in the future, not that it happen in the colloquial sense of soon or precisely within a certain number of days, weeks, or months.") (citing *NAACP* v. *Browning*, 522 F.3d 1153, 1161 (11th Cir. 2008)).

[5] The district court may consider extra-pleading material when reviewing a motion to dismiss for lack of jurisdiction. *Mulhall* v. *UNITE HERE Local 355*, 618 F.3d 1279, 1286 n.8 (11th Cir. 2010); *Kuhlman* v. *United States*, 822 F. Supp. 2d 1255, 1258 (M.D. Fla. 2011).

The Safe Harbor merely delays enforcement by one year. It is settled that, "[w]here the inevitability of the operation of a statute against certain individuals is patent, it is *irrelevant* . . . that there will be a time delay before the disputed provisions will come into effect." *Regional Rail Reorg. Act Cases*, 419 U.S. 102, 143 (1974). The Supreme Court has found delays of three and six years insufficient to defeat standing. *See Thomas More Law Ctr.* v. *Obama*, 651 F.3d 529, 536-37 (6th Cir. 2011) (citing *New York* v. *United States*, 505 U.S. 144 (1992); *Pierce* v. *Soc'y of Sisters*, 268 U.S. 510 (1925)). The D.C. Circuit was not fazed by a *thirteen-year* gap. *Vill. of Bensenville* v. *FAA*, 376 F.3d 1114, 1119 (D.C. Cir. 2004). The mandate will take effect no later than January 1, 2014—a comparatively short twenty months from today—and thus is imminent.[6]

In a nearly identical legal setting in this Circuit, defendants recently conceded that a *forty* month gap does not defeat standing. In their defense of the Affordable Care Act's "individual mandate"—which also does not take effect until 2014—defendants argued that the individual plaintiffs' alleged injuries were not imminent. *See Fla. ex rel. McCollum* v. *HHS*, 716 F. Supp. 2d 1120, 1145-46 (N.D. Fla. 2010). The argument failed, however, *id.* at 1146-47, and on appeal, defendants conceded individual standing. *See Fla. ex rel. Att'y Gen.* v. *HHS*, 648 F.3d 1235, 1243 (11th Cir. 2011); *see also Seven-*

[6] Defendants' cited authorities are inapposite. *See* MTD at 15-16. In *McConnell* v. *FEC*, the plaintiff politicians challenged a statute setting broadcasting rates that would not impact them unless and until they ran for re-election in five years. 540 U.S. 93 (2003). In *Whitmore* v. *Arkansas*, a death row inmate was denied standing to challenge the validity of a death sentence imposed on another inmate. 495 U.S. 149 (1990). In *Koziara* v. *City of Casselberry*, an exotic dancer did not have standing to contest the future revocation of her employer's license when she did not allege that a future revocation was imminent. 392 F.3d 1302 (11th Cir. 2004).

Sky v. *Holder*, 661 F.3d 1, 4 (D.C. Cir. 2011) (addressing constitutionality of same mandate).[7]

D. The speculative promise of an additional future mandate does not make the current mandate's impending harm speculative.

Defendants also attempt to rely on the future rulemaking promised in the ANPRM to defeat standing. The ANPRM reports that, during the safe-harbor period, defendants "intend to propose" a new mandate that will force insurers to provide free contraceptive coverage to employees of certain non-exempt religious organizations. 77 Fed. Reg. at 8728-29; *see* MTD at 16-17. The ANPRM "suggest[s] multiple options" for how this might be accomplished and invites comment. ANPRM at 16503. In light of that, defendants say there is "no basis to conclude" that Ave Maria will ever be subject to the mandate and insist that "any suggestion to the contrary is entirely speculative at this point." MTD at 17. This self-serving argument fails.

First, standing "must be determined as of the time at which the plaintiff's complaint is filed," not later in the litigation after the defendant seeks to cure its wrongful conduct. *Focus on the Family* v. *Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1275 (11th Cir. 2003); *see also Lujan*, 504 U.S. at 571 ("The existence of federal jurisdiction ordinarily depends on the facts *as they exist when the complaint is filed.*") (emphasis in original) (internal citations omitted). The ANPRM did not exist when this case was filed and hence is irrelevant to standing.

[7] Moreover, the "safe harbor" is non-binding and cannot destroy standing. *See, e.g., Va. Soc'y for Human Life, Inc.* v. *FEC*, 263 F.3d 379, 388 (4th Cir. 2001) (holding that "policy of nonenforcement," "not contained in a final rule that underwent the rigors of notice and comment rulemaking," did "not carry the binding force of law," and thus could not defeat standing).

Second, defendants' argument is really about mootness. *See Arizonans for Official English* v. *Arizona*, 520 U.S. 43, 68 n.22 (1997) (standing addresses "personal interest that must exist at the commencement" of a suit, whereas mootness requires that interest continue "throughout [the suit's] existence"). A case is moot when "the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Los Angeles Cnty.* v. *Davis*, 440 U.S. 625, 631 (1979). Under the "stringent" mootness standards, it must be "*absolutely clear* that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc.* v. *Laidlaw Envtl. Servs.*, 528 U.S. 167, 189 (2000). This "heavy burden" lies with the party claiming mootness. *Id; see also, e.g., Sheely* v. *MRI Radiology Network, PA*, 505 F.3d 1173, 1184 (11th Cir. 2007) (noting *Laidlaw*'s "formidable … burden" on "party asserting mootness").

Mootness is simply out of the question at this point, because there has been no change to the mandate or the exemption. *See, e.g.,* Wright & Miller, 13C Fed. Prac. & Proc. Juris. § 3533.7 (3d ed.) ("It hardly need be added that mootness does not occur when there has been no change in the challenged activity."). Defendants must do far more than offer prospects for future corrective action to moot ongoing litigation. *See, e.g., Harrell* v. *The Fla. Bar*, 608 F.3d 1241, 1265 (11th Cir. 2010) (case mooted if "interim relief or events have *completely and irrevocably eradicated* the effects of the alleged violation") (quoting *Davis*, 440 U.S. at 631) (emphasis added). But "an agency *always* retains the power to revise a final rule through additional rulemaking. If the possibility of unforeseen amendments were sufficient to render an otherwise fit challenge unripe, review could be deferred indefinitely." *Am. Petroleum Inst.* v. *EPA*, 906 F.2d 729, 739-

40 (D.C. Cir. 1990). Similarly, "agencies cannot avoid judicial review of their final actions merely because they have opened another docket that may address some related matters." *Am. Bird Conservancy, Inc.* v. *FCC*, 516 F.3d 1027, 1031 (D.C. Cir. 2008) (citations omitted).

Here, defendants concede they have presented only "questions and ideas" to shape future discussions about an hypothesized insurer mandate. MTD at 10; 77 Fed. Reg. at 16503. They have not amended the original mandate; they have confirmed it. *Id.* at 16502. Thus, statements of future good intentions are irrelevant. *See Sackett* v. *EPA*, 132 S. Ct. 1367, 1372 (2012) ("The mere possibility that an agency might reconsider in light of 'informal discussion' … does not suffice to make an otherwise final agency action nonfinal."); Wright & Miller § 3533.7 ("Nor does mootness follow announcement of an intention to change or adoption of a plan to work toward lawful behavior.").

Third, even the accommodations sketched out in the ANPRM would not assuage Ave Maria's religious conflict. Ave Maria would still be required to "provide coverage for" objectionable drugs and services. 42 U.S.C. § 300gg-13(a)(4). Although its insurer ostensibly would administer them, Ave Maria would still have to provide "access to information necessary to communicate with the plan's participants." 77 Fed. Reg. at 16505. This would not budge the status quo, since Ave Maria *already* does not directly provide health care to employees. Ave Maria selects and pays for the plan, but the medical care, payment, and administration are handled directly between the insurer and employees' medical providers. Thus, even under the hypothesized new rule, Ave Maria

would be forced to serve as a gatekeeper, making objectionable drugs and services available to employees through a plan it sponsors, just as under the current final rule.[8]

Defendants' standing argument ultimately amounts to a prediction that the unforeseeable results of a speculative proposed rulemaking might, sometime in the future, remove Ave Maria's injury. Prophecies like this, however, cannot change the fact that Ave Maria faces the real prospect of harm from a concrete regulatory mandate on January 1, 2014—harm for which it must plan well in advance. This is more than enough to show imminent harm. *See, e.g., Johnson* v. *Bd. of Regents*, 263 F.3d 1262, 1265 (11th Cir. 2001) ("[T]o have standing to obtain forward-looking injunctive relief, a plaintiff must show a sufficient likelihood that he will be affected by the allegedly unlawful conduct in the future."); *see also, e.g., Mulhall* v. *UNITE HERE Local 355*, 618 F.3d 1279, 1288 (11th Cir. 2010) (explaining that "under our law, probabilistic harm is enough injury in fact to confer standing in the undemanding Article III sense"); *Thomas More Law Ctr.* v. *Obama*, 651 F.3d 529, 536-37 (6th Cir. 2010) (noting that "[i]mminence is a function of probability" and finding imminent injury over two years in the future where "[t]he only developments that could prevent this injury from occurring are not probable and indeed themselves highly speculative").

[8] Defendants' assumption that religious institutions would not have to pay under the theorized new rule is fanciful. Nothing guarantees that covering contraception (let alone more expensive sterilization, counseling and education) will reduce costs, or that savings would be passed on to Ave Maria. Indeed, the ANPRM assumes costs and discusses how they can be recovered by insurers, including through "rebates, service fees, disease management program fees, or other sources," even though these programs would otherwise ultimately benefit the religious institution. 77 Fed. Reg. at 16507 ("These funds may inure to the third-party administrator *rather than* the plan or its sponsor ….") (emphasis added).

II. AVE MARIA'S CLAIMS ARE RIPE.

Defendants also claim Ave Maria's claims are unripe. Specifically, they say that the future rulemaking projected by the ANPRM raises a "significant chance" that amendments to the mandate will either moot or alter the litigation. MTD at 20. Defendants are mistaken.

The ripeness doctrine addresses the timing of a lawsuit and prevents courts from umpiring "potential or abstract disputes." *Digital Props., Inc.* v. *City of Plantation*, 121 F.3d 586, 589 (11th Cir. 1997); *see also Wilderness Soc'y* v. *Alcock*, 83 F.3d 386, 390 (11th Cir. 1996) (unlike standing, ripeness asks "whether this is the correct *time* … to bring the action") (emphasis in original). "To determine whether a claim is ripe, [courts] assess both the fitness of the issues for judicial decision and the hardship to the parties of withholding judicial review." *Harrell*, 608 F.3d at 1258 (11th Cir. 2010) (citing *Coal. for the Abolition of Marijuana Prohibition* v. *City of Atlanta*, 219 F.3d 1301, 1315 (11th Cir. 2000)). If a dispute is fit, then "[lack of] 'hardship' cannot tip the balance against judicial review," and, indeed, need not even be considered. *Harrell*, 608 F.3d at 1259 (citing *Consol. Rail Corp.* v. *United States*, 896 F.2d 574, 577 (D.C. Cir. 1990)) (brackets in original). Finally, ripeness analysis applies "most permissively in the First Amendment context." *Harrell*, 608 F.3d at 1258 (citing *Beaulieu* v. *City of Alabaster*, 454 F.3d 1219, 1227–28 (11th Cir. 2006).

A. Ave Maria's claims are fit for review.

Ave Maria's claims are presumptively ripe because they involve facial challenges to the mandate's constitutionality that require no factual development. *See, e.g.*, *Harris* v.

Mexican Specialty Foods, Inc., 564 F.3d 1301, 1308 (11th Cir. 2009) ("In the context of a facial challenge, a purely legal claim is presumptively ripe for judicial review because it does not require a developed factual record."); *Pittman* v. *Cole*, 267 F.3d 1269, 1278 (11th Cir. 2001) (ripeness favors disputes involving "pure question[s] of law"). For instance, Ave Maria's Free Exercise and Establishment Clause claims present purely legal challenges to the various exemption schemes found on the face of the regulations.[9] Its APA and RFRA claims likewise turn on questions of law. *See, e.g., Eagle-Picher Indus., Inc.* v. *EPA*, 759 F.2d 905, 916 (D.C. Cir. 1985) (APA review presents "a purely legal question"); *Hamilton* v. *Schriro*, 74 F.3d 1545, 1552 (8th Cir. 1996) ("[T]he ultimate conclusion as to whether [a] regulation deprives [plaintiff] of his free exercise right [under RFRA] is a question of law."). Defendants themselves agree. *See* MTD at 21 (noting that "plaintiff's complaint raises largely legal claims").

Moreover, Ave Maria challenges a regulation that is definite and concrete, and that emerged at the conclusion of a lengthy administrative process. *See, e.g., Abbott Labs.* v. *Gardner*, 387 U.S. 136, 149-51 (1967) (assessing ripeness by reference to finality of agency action); *Atlanta Gas Light Co.* v. *FERC*, 140 F.3d 1392, 1404 (11th Cir. 1998) (assessing ripeness by asking, *inter alia*, whether "challenged agency action constitutes 'final agency action'"). Defendants included contraception and sterilization within the Affordable Care Act's mandated "preventive services" after lengthy deliberation that

[9] *See, e.g.*, Compl. ¶ 50 (alleging implementing regulations non-neutral under Free Exercise Clause because they expressly exempt a favored class of religious objectors in 45 C.F.R. § 147.130(a)(1)(iv)(A)-(B)); Compl. ¶¶ 51, 60 (alleging same regulations not generally applicable under Free Exercise Clause because they expressly create a system of individualized exemptions); Compl. ¶¶ 55-59 (alleging same regulations violate Establishment Clause by expressly preferring one religious denomination over another).

included an "extensive science-based review" by the Institute of Medicine. MTD at 7. And they finalized the religious employer exemption after "carefully considering"—over an additional six months—"more than 200,000 comments." *Id.* at 9. Consequently, the challenged regulation is "quite clearly definitive" because it was "promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties." *Abbott Labs.*, 387 U.S. at 151. It is not "informal," nor is it "only the ruling of a subordinate official," nor is it "tentative." *Id.* (citations omitted). To the contrary, the mandate "mark[ed] the 'consummation' of the agency's decisionmaking process." *In re MDL-1824 Tri-State Water Rights Litig.*, 644 F.3d 1160, 1181 (11th Cir. 2011) (quoting *Bennett* v. *Spear*, 520 U.S. 154, 177-78 (1997)). These indicia of finality mark Ave Maria's claims as ripe—especially since they involve First Amendment rights.

Nonetheless, defendants insist that the ANPRM's proposed rulemaking renders Ave Maria's lawsuit unripe by raising a "significant chance" that future amendments to the mandate will either moot or alter Ave Maria's claims before the mandate's effective date. MTD at 20. Defendants' argument is perplexing and misguided.

First, defendants misunderstand the nature of Ave Maria's claims. Ave Maria challenges the Act's preventive services mandate because—and only because—defendants have defined "preventive services" to include contraception and sterilization.[10] The ANPRM promises *no* change to that status quo—that is, it promises

[10] *See* 42 U.S.C. § 300gg-13(a)(4) (requiring group health plans to "provide coverage" without cost-sharing for "preventive care … as provided for in [HRSA] guidelines"); HRSA Guidelines, http://www.hrsa.gov/womensguidelines/ (last visited May 18, 2012) (defining "women's preventive

neither to alter the preventive services mandate itself, nor to subtract contraception from the ambit of "preventive services." Nor does it propose to expand the previously finalized religious employer exemption. Instead, the ANPRM merely proposes rulemaking to consider how to route free contraception coverage to employees of objectors like Ave Maria.[11]

Nothing the ANPRM proposes to do, then, could possibly alter Ave Maria's challenge. Following the proposed rulemaking, "preventive services" *will still* include FDA-approved contraception and sterilization. And, following the proposed rulemaking, the ACA *will still* demand that group health plans like Ave Maria's "shall … provide coverage for and shall not impose any cost sharing requirements for" those same services. 42 U.S.C. § 300gg-13(a)(4). And the ANPRM—by defendants' own statements—does not anticipate expanding the religious employer exemption. 77 Fed. Reg. 8725, 8729.

Consequently, defendants are wrong that the parameters of the rulemaking sketched out by the ANPRM could do anything to undermine the ripeness of Ave Maria's claims. "[A]gencies cannot avoid judicial review of their final actions merely because they have opened another docket that may address some related matters." *Am. Bird Conservancy*, 516 F.3d at 1031 n.1 (and collecting authorities). Here, defendants' proposed future rulemaking will, by its own terms, address matters that cannot impact Ave Maria's constitutional claims.

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services" to include "[a]ll [FDA] approved contraceptive methods, sterilization procedures, and patient education and counseling").

[11] *See* 77 Fed. Reg. at 16503 (announcing defendants' "plans for a rulemaking to require issuers to offer group health insurance coverage without contraceptive coverage to such an organization … and *simultaneously to provide contraceptive coverage directly to the participants and beneficiaries covered under the organization's plan with no cost sharing*") (emphasis added).

Defendants cite no case to support their novel argument that a speculative and irrelevant future rulemaking derails a challenge to a final and concrete regulation. The cases defendants cite, *see* MTD at 21, stand for the ordinary proposition that challenges to open-ended, non-binding, or rescinded laws and regulations are unripe.[12] In such cases, additional rulemaking undermined ripeness—not because it automatically renders challenges to definite rules unripe—but because, there, new rulemaking was necessary to flesh out open-ended rules that courts could not apply in their present form. Those cases might have affected Ave Maria had it sued *before* "preventive care" was defined to include FDA-approved contraceptives and sterilization methods. But nothing like that situation is presented here. To the contrary, Ave Maria has brought facial legal challenges to a concrete and carefully-defined regulatory scheme whose application to religious objectors like Ave Maria is as clear as it is unconstitutional.

Like their standing argument, *supra*, defendants' ripeness argument really concerns mootness. Indeed, in arguing why the challenged regulations "have not 'taken on fixed and final shape,'" MTD at 21, defendants promise that—following the proposed rulemaking—Ave Maria's challenge "*likely will be moot*." *Id.* (emphasis added). But

[12] *See, e.g.*, *Texas* v. *United States*, 523 U.S. 296, 300-01 (1998) (declaratory judgment that school district law would never trigger Voting Rights Act preclearance was unripe because, absent application, impossible to determine how the law implicated elections); *Ohio Forestry Ass'n* v. *Sierra Club*, 523 U.S. 726, 733 (1998) (suit against forestry plan unripe because plan "d[id] not command anyone to do anything," "create[d] no legal rights or obligations," and required further agency action to flesh out application to specific land); *Alcock*, 83 F.3d at 390-91 (challenge to forestry plan unripe because plan did not injure plaintiff but foresaw more decisionmaking before any dispute could materialize); *Tex. Indep. Producers and Royalty Ass'n* v. *EPA*, 413 F.3d 479, 483-84 (5th Cir. 2005) (challenge to EPA permitting rule unripe where, *inter alia*, rule's scope impossible to determine on its face; EPA had officially deferred rule and initiated rulemaking to clarify rule); *Lake Pilots Ass'n, Inc.* v. *U.S. Coast Guard*, 257 F. Supp. 2d 148, 161 (D.D.C. 2003) (challenge unripe because agency had admitted its error respecting challenged rule, had reinstated prior rule, and undertaken new rulemaking).

defendants misunderstand which regulations Ave Maria challenges. Ave Maria challenges the mandate and exemption—regulations that were finalized after an extensive process on August 1, 2011 and February 10, 2012, respectively. Ave Maria is not challenging whatever might come out of the proposed rulemaking. Such a challenge would be incoherent because, as defendants point out, the ANPRM "does not preordain what amendments to the preventive services coverage regulations defendants will ultimately promulgate." MTD at 22. More importantly, any such future amendments would not, *by the very terms of the ANPRM*, change Ave Maria's current challenge.

B. Ave Maria faces imminent hardship absent immediate review.

Because Ave Maria's claims are fit, it is not necessary to consider hardship. *See, e.g.*, *Harrell*, 608 F.3d at 1259 (where claim was fit, "we need not consider whether [plaintiff] would suffer any hardship"). Regardless, the hardships Ave Maria faces from delay weigh decisively in favor of judicial review.

First, since the ANPRM will not alter Ave Maria's claims, *see supra*, Ave Maria will still be compelled to drop employee insurance and pay heavy fines. And, even under the Safe Harbor, Ave Maria must plan *now* to address that negative consequence (which will be consummated in only twenty months). Inability to offer insurance will severely impact Ave Maria's ability to retain and recruit employees. These and other potential implications demand immediate review. Compl. ¶¶ 81-82, 99; *see also Retail Indus. Leaders Ass'n* v. *Fielder*, 475 F.3d 180, 188 (4th Cir. 2007) (finding ripeness where plaintiff had to alter "accounting procedures and healthcare spending *now*" to plan for new law).

Moreover, the Safe Harbor protects Ave Maria only from enforcement by *defendants*, not third parties. The Affordable Care Act empowers private parties to enforce the mandate, through its incorporation into Part 7 of ERISA. 29 U.S.C. § 1185d(a)(1). Under that part, a plan participant or beneficiary may bring a civil action to recover plan benefits or enforce or clarify plan rights. 28 U.S.C. § 1132(a)(1)(B). Thus even without enforcement by defendants, Ave Maria would still be subject to actions by plan participants or beneficiaries. *Chamber of Commerce* v. *FEC*, 69 F.3d 600, 603 (D.C. Cir. 1995) (retaining jurisdiction in part because "even without a Commission enforcement," plaintiffs would be "subject to [private] litigation challenging the legality of their actions").

Both of these "direct and immediate" consequences of the mandate warrant immediate review. *See Abbott Labs.*, 387 U.S. at 152-53.

CONCLUSION

For the foregoing reasons, the Court should deny the motion to dismiss.

Respectfully submitted,

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Dated: May 18, 2012

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2012, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system and that the following parties were served via that system:

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