Democrats For Life of America, Inc.

DFLA – The pro-life voice within the Democratic Party

June 19, 2012

SUBMITTED ELECTRONICALLY

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Advance Notice of Proposed Rulemaking on Preventive Services
File Code No. CMS-9968-ANPRM

Dear Ms. Tavenner:

On behalf of the Democrats for Life of America (DFLA), we respectfully submit the following comments on the Advance Notice of Proposed Rulemaking ("ANPRM") on preventive services. 77 Fed. Reg. 16501 (Mar. 21, 2012). The ANPRM expresses the Administration's intention to propose additional regulations, in order to establish "alternative ways" of "ensuring contraceptive coverage for plan participants and beneficiaries" enrolled in plans offered by non-exempt "religious organizations" that object to such coverage while, at the same time, "accommodating such organizations." *Id.* at 16501.

Introduction and Summary of Points

Democrats for Life of America (DFLA) is the preeminent national organization for pro-life Democrats. We believe that the protection of human life is the foundation of human rights, authentic freedom, and good government. These beliefs animate our opposition to abortion, euthanasia, capital punishment, embryonic stem cell research, poverty, genocide, and all other injustices that directly and indirectly threaten human life. As pro-life Democrats, we share the party's historic commitments to supporting women and children, strengthening families and communities, and striving to ensure the equality of opportunity, a reduction in poverty, and the existence of an effective social safety net that guarantees that all people have sufficient access to food, shelter, healthcare, and life's other basic necessities.

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DFLA has supported the Affordable Care Act (ACA or the Act), including the pro-life Democrats whose support was crucial to the Act's passage. Throughout the process that led to the ACA's passage, we offered means by which the Act could achieve the pro-life goals of ensuring comprehensive health-care coverage while directly respecting unborn life and the consciences of citizens and organizations opposed to abortion. We defended the President's Executive Order on abortion funding under the ACA, which was designed to achieve those goals, and offered mechanisms for ensuring the Order's validity and effectiveness.[1] At the time of passage, including through the Executive Order, the administration promised that conscience rights would be protected, including through avoiding any mandated funding of abortion. The administration should keep that promise.

DFLA strongly supports the inclusion of basic preventive services in the ACA and the emphasis on health care for women. Our members take varying positions on the underlying mandate that employers provide insurance coverage for contraceptive services.[2] But we are unanimously committed, as a pro-life voice, to protecting the conscience rights of individuals and organizations with objections to abortion, including religious charitable organizations that provide health care, social services, and education to the neediest in our society. The contraception-coverage mandate affects these rights both directly and indirectly. For those reasons, the government should give meaningful—not minimal or grudging—accommodation of conscience in this context.

First, the mandate affects abortion and conscience directly because so-called emergency contraceptives may operate not only by preventing ovulation, but sometimes by preventing an embryo from implanting in the uterine wall or even killing an implanted embryo. In particular, it is reasonable to believe that ulipristal acetate, often called Ella or the "five-day after" pill, may sometimes operate this way. On the premise that a distinct human life begins at the moment of fertilization—a moral view supported by genetics and other science, and a view that organizations are of course entitled to hold—prevention of implantation is an abortion. To be forced to fund an abortion is a very serious imposition on conscience, as countless federal and state laws recognize including the ACA itself. Whether or not federal law generally defines prevention of implantation as an abortion, accommodations of conscience should defer substantially to the objector's moral understanding. Therefore we urge that such medications be excluded from the employer mandate, or at least that individuals and organizations, including commercial businesses, with sincere religious objections to including them in coverage be exempted from the mandate to do so.

Second—indirectly but still importantly—even outside the context of possible abortifacient medications, the narrowness of the current exemption for religious organizations will set a harmful precedent if, as may be anticipated, government ever considers mandates to fund or facilitate abortions. Some arguments made in the contraception dispute, if applied to abortion,

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[1] Thomas C. Berg, "Abortion and Key Provisions of the Patient Protection and Affordable Care Act (PPACA)," available at http://www.wholelifeheroes.org/berg/.

[2] It is our understanding that to the extent that the medicines in question are prescribed for non-contraceptive purposes, there are no conscientious objections to covering them in employees' insurance.

could severely undercut conscience protection in that crucial context. For example, opponents of accommodating conscience have argued that the contraception mandate imposes no burden on an objecting religious organization because the employee chooses whether to use contraception. The same logic would justify a government mandate that employers cover employees' abortions. Such implications make it important that the government set a precedent now for meaningful, rather than minimal or grudging, accommodation of conscience in the healthcare context.

In particular, HHS's initial (and still operative) definition of an exempted "religious employer" could set a very negative precedent for accommodation of conscience in other contexts, including exemptions from possible mandates to fund or facilitate abortions. Therefore, HHS's recent proposal, in the March ANPRM, to retain the definition in federal law while providing some accommodation for other organizations remains inadequate. The extremely restrictive four-part requirement should not appear in federal law at all, for it puts in a second-class category not only organizations that reach out to employ persons outside their faith, but also organizations that reach out to serve others outside the faith, and indeed any religious organization that emphasizes service to others over explicit preaching or teaching. Such works of justice and mercy lie at the core of many religious faiths; they are among the features that progressives value most in religious organizations. It thus has been ironic and disturbing for a progressive administration to exclude organizations that emphasize such works from the definition of "religious employer." The narrow definition should be scrapped entirely. It should not be introduced into federal law even as part of a two-tier approach. We propose an alternative below that will protect organizations engaged in charitable work in social services, healthcare, and education as an outgrowth of their religious identity.

A. With Respect to So-Called Emergency Contraceptives, Particularly "Ella," Conscience Protection Must Be Especially Strong Because of Reasonable Concerns That They May Act as Abortifacients.

The labeling information on both of the FDA-approved "emergency contraceptives"—ulipristal acetate (Ella) and levonorgestrel (Plan B)—states that although the primary mechanism for preventing pregnancy is inhibition or delay of ovulation, "[a]lterations to the endometrium that may affect implantation may also contribute to efficacy."[3] Based on that information alone, an organization or individual convinced that a distinct human life begins at fertilization has a reasonable basis for conscientiously objecting to the requirement to cover such medications in employees' health plans. On a matter as grave as the risk of terminating, in the objector's view, a new human person by inhibiting implantation, the objector should certainly be able to take seriously the government's statement that the risk exists.

With respect to Ella in particular, there is ample reason for objectors to conclude that the medication creates sufficient risk of aborting an embryo that paying for it would violate their

[3] *Ella* Full Prescribing Information, 12.1 (Aug. 2010), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (last visited June 18, 2012). See also Plan B Prescribing Information, 12.1 (rev. July 2009) ("Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium)."), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf.

beliefs against abortion. "Ulipristal has similar biological effects to mifepristone, the antiprogestin used in medical abortion."[4] Although Ella involves lower doses of mifepristone than does RU-486, the so-called abortion pill, the record of the FDA's approval for Ella contains multiple statements that when administered after ovulation, the drug affects the endometrium, the uterine lining, in a way that could prevent implantation of a fertilized embryo. For example, the background document for the FDA advisory committee on Ella states that "[a]dministration of ulipristal in the luteal phase [of the menstrual cycle] also alters the endometrium. Based on the findings of the pharmacodynamic studies, ulipristal appears to exert an anti-progesterone contraceptive effect on both the ovary and endometrium, depending on the dose and time of drug administration during the menstrual cycle."[5] As one member of the FDA's advisory committee stated: "I'll even concede that the primary mechanism of action might be delayed ovulation, but not in this group that's five days out from unprotected intercourse. . . . I can't imagine how we can put all of these numbers together to say that delayed ovulation explains this continued efficacy [at five days after intercourse]."[6] Even further, on the question of effects beyond implantation, the FDA's own materials cite studies in pregnant rats and rabbits in which ulipristal "at drug exposures comparable to human exposure based on surface area (mg/m2)" were lethal to embryos.[7] These studies may not have conclusively determined the drug's effect on fetal development after implantation,[8] but they certainly raise significant concerns for the objector who believes that the genetically distinct human life that begins at fertilization is entitled to protection.

With respect to Plan B, it is true that recent scientific work has argued that it does no more than prevent conception and that the government's labeling statements should be changed.[9] But at least until the government makes such a change, objectors have a right to take seriously the label's statements that the medication may act by preventing implantation.

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[4] G. Bernagiano & H. von Hertzen, "Towards more effective emergency contraception?," 375 *The Lancet* 527-28 (Feb. 13, 2010), at 527.

[5] See Background Document for meeting of Advisory Committee for Reproductive Health Drugs, FDA Advisory Committee Materials, NDA 22-474 (Ella) (June 17, 2010), at 11-12, available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM215425.pdf (hereinafter "FDA Background Document"). See also Transcript of Proceedings, Advisory Committee on Reproductive Health Drugs (June 17, 2010), at 121 (Dr. Ronald Orleans, FDA Medical Officer) ("Another possible mode of action is delaying the normal endometrial maturation which occurs in the luteal phase of the cycle. This delay of maturation could possibly prevent implantation."), available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf (hereinafter "Advisory Committee Proceedings").

[6] *Id.* at 160, 164 (Dr. Scott Emerson).

[7] FDA Background Document, *supra* note 5, at 10.

[8] *Id.* at 10-11.

[9] See, e.g., Sandra E. Reznik, "Plan B": How It Works, Health Progress (Jan.-Feb. 2010), at 59, available at www.chausa.org/workarea/DownloadAsset.aspx?id=6159. These arguments concerning the mechanism of action of levonorgestrel do not apply to ulipristal, which "is a new chemical entity, has a different mechanism of action, and a more limited safety profile." Advisory Committee Proceedings, *supra* note 5, at 222-23 (statement of Dr. Carol Ben-Maimon).

It must be emphasized that the question concerning conscience protection is not whether the government concludes the objector's position is correct. As the Supreme Court stated in *Thomas v. Review Board*, 450 U.S. 707, 714 (1981), whether a law burdens a claimant's religious belief "is not to turn upon a judicial perception of the particular belief or practice in question." In that case, Thomas quit his job because he was unwilling to work in a factory that produced tank turrets. The state denied him unemployment benefits and argued that his objection was unfounded because he had been willing to work in a different factory that produced materials that might be used for tanks. The Court held that in determining whether Thomas's religious beliefs were burdened, it could not second-guess his own judgment about what connection to armament production was unacceptably close for him: "Thomas drew a line, and it is not for us to say that the line he drew was an unreasonable one." *Id.* at 715. Likewise, those who object to funding or dispensing emergency contraceptives make a judgment that the risk that it may cause termination of a new embryo is too great for them to participate given their belief that a distinct human life begins at fertilization. This is a matter of judgment stemming from the objector's underlying conscientious view, and the government may not second-guess it.

The Affordable Care Act itself confirms protection of conscience rights against what objectors reasonably regard as abortions. Section 1303(a) (1)(A) of the ACA, that "nothing in this title"—the title that includes the provision dealing with "preventive services"—"shall be construed to require a qualified health plan to provide coverage of [abortion] services . . . as part of its essential health benefits for any plan year." Section 1303 further states that it is "the issuer" of a plan, not the government, that "shall determine whether or not the plan provides coverage" of abortion services.[10] As a result, the contraception mandate may violate the ACA insofar as the mandate requires coverage of emergency contraceptives that objectors reasonably regard as abortions. At the very least, requiring such coverage is inconsistent with the ACA's policy of protecting the conscience rights of those opposed to abortion.

The ACA is just the latest confirmation that our tradition of protecting conscience is strongest for those who object to supporting abortions. The first "healthcare conscience clauses" were responses to efforts, immediately after *Roe v. Wade*, to force hospitals receiving federal funds to facilitate abortions against their beliefs.[11] Congress quickly passed the Church Amendment of 1973, which (among other things) protected federally funded entities from having to provide facilities for abortions or sterilization procedures against their "religious beliefs or moral convictions."[12] Since 2004, the Weldon Amendment to appropriations bills has denied federal funds to a federal agency or state or local government if the agency or government "subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, *provide coverage of*, or refer for abortions."[13] Protection for conscientious objections to abortion is also the central feature of the conscience clauses enacted in numerous states.[14] Indeed, our tradition protects not only individuals and organizations that

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[10] ACA § 1303(a)(1)(A)(ii).

[11] See Robin Fretwell Wilson, The Limits of Conscience: Moral Clashes Over Deeply Divisive Healthcare Procedures, 34 Am. J. L. & Med. 41, 47-48 (2008).

[12] Section 401 of the Health Programs Extension Act of 1973, Pub. L. No. 93-45, 87 Stat. 91, 95 (1973).

[13] See, e.g., Weldon Amendment, Consolidated Appropriations Act, 2009, § 508, Pub. L. No. 111-117, 123 Stat. 3034.

[14] Wilson, *supra* note 11, at 50-52.

would directly have to fund or facilitate abortions, but also taxpayers who would have to fund them through federal expenditures. The Hyde Amendment has long prohibited federal expenditures for non-medically-necessary abortions, and both the ACA and the President's order of March 24, 2010, continue that policy.[15]

Given the reasonable concerns that particular emergency contraceptives may cause abortions of new embryos, objections to covering such medications must be protected especially generously. Such medications should be removed from the mandate altogether—or at the very least, protection for objectors should extend not just to religious nonprofit organizations, but also to individuals and commercial businesses. This will keep the contraception mandate in line with our tradition of broadly accommodating objections to supporting abortion.

B. The Definition of Exempted Religious Employers Must Be Expanded.

With respect to other forms of contraception, we focus on the current cramped definition of an exempted "religious employer"—see *supra* p.2—which has been a fundamental cause for objections since the date HHS first announced the mandate. The definition, unprecedented in federal law in its narrowness, fails to give equal respect to the activities of service, mercy, and justice that lie at the core of religious practice for many faiths. President Obama has spoken eloquently of the "millions of Americans who share [this] view of their faith, who feel they have an obligation to help others. . . . [W]hile these groups are often made up of folks who've come together around a common faith, they're usually working to help people of all faiths or of no faith at all."[16] But remarkably, under the HHS "religious employer" definition, these very acts of service to non-adherents that the President commended are the basis for denying an organization exemption as a "religious employer."

In its March 2012 advance notice (the ANPRM), HHS proposed to retain this deeply objectionable definition while extending a more limited accommodation to a broader category of "religious organizations." But even assuming that a limited accommodation could be developed that protected organizations' claims of conscience, it would still be wrong and dangerous to insert the narrow definition into federal law. The adoption of this language in the Code of Federal Regulations, even as part of a two-tiered set of accommodations, would legitimate it in future situations. The March ANPRM also stated that "whatever definition of religious organization is adopted will not be applied with respect to any other provision of the PHS Act, ERISA, or the Code, nor is it intended to set a precedent for any other purpose." This assurance is inadequate, as the history of this debate teaches. When courts in California and New York upheld state "contraceptive equity" statutes with the same cramped exemption as HHS's, they emphasized that those statutes were distinctive because they allowed the objecting organization to avoid the conflict "simply by not offering coverage for prescription drugs."[17] But HHS then

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[15] See Executive Order 13535, http://www.whitehouse.gov/the-press-office/executive-order-patient-protection-and-affordable-care-acts-consistency-with-longst (Mar. 24, 2010).

[16] Text, Obama Delivers Speech on Faith in America, N.Y. Times, July 1, 2008, http://www.nytimes.com/2008/07/01/us/politics/01obama-text.html?pagewanted=all

[17] *Catholic Charities of Sacramento v. Superior Court*, 32 Cal. 4th 527, 562, 85 P.3d 67, 91-92 (2004) (rejecting religious-freedom claim under state constitution on this ground); see also *Catholic Charities of Diocese of Albany v. Serio*, 7 N.Y.3d 510, 527, 859 N.E.2d 459, 468 (2006) (objecting organizations

cited the California and New York statutes as precedent for a new federal mandate that goes much further—flatly requiring, on pain of large fines, that the organization must provide health insurance and it must cover contraceptives. Just as the mandate with minimal exemption was bootstrapped from narrower state laws to a far broader federal mandate, it likely will be bootstrapped later to other federal statutes. HHS, having legitimized the minimal exemption by introducing it into federal law, will have no way of stopping others from using it as a precedent.

The two-tier approach, with its minimal definition of "religious employer," should be scrapped and replaced with a unitary test that reflects the fact that works of service and mercy to those in need lie at the core of religious exercise. An organization should be accommodated as "religious" if it

> (1) is a non-profit religious educational or charitable organization; (2) engages in its charitable or educational activities for bona fide religious purposes or reasons; and (3) holds itself out to the public as a religious organization.[18]

Courts have applied a similar set of criteria in various employment contexts—including the Title VII exemption for religion-based hiring by religious organizations—and have found that organizations should be exempt as "religious" because their charitable or educational activities were deeply religiously motivated, even though the activities did not primarily involve explicit proselytizing or religious teaching and were not limited to members of the faith community in question. See, e.g., *Spencer v. World Vision, Inc.*, 633 F.3d 723 (9th Cir. 2011) (en banc) (evangelical Protestant humanitarian relief agency exempt as "religious organization" under Title VII;); *LeBoon v. Lancaster Jewish Community Center Assn.*, 503 F.2d 217 (3d Cir. 2007) (same Title VII exemption for Jewish-oriented community organization); *University of Great Falls v. NLRB*, 278 F.3d 1335 (D.C. Cir. 2002) (ecumenically oriented Catholic college protected from NLRB jurisdiction over faculty); *Universidad Cent. de Bayamon v. NLRB*, 793 F.2d 383 (1st Cir. 1985) (Breyer, J.) (Catholic college; NLRB jurisdiction over faculty).

As the court of appeals for the D.C. Circuit stated in the *University of Great Falls* case, confining "exemption to religious institutions with hard-nosed proselytizing, that limit their enrollment to members of their religion, . . . is an unnecessarily stunted view of the law, and perhaps even itself a violation of the most basic command of the Establishment Clause not to prefer some religions (and thereby some approaches to indoctrinating religion) to others." 278 F.3d at 1346. By contrast, our proposed language would harmonize with progressive goals by giving tangible respect to the religious mission of organizations on the front lines of serving the poor, the sick, and the needy.

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could not show "the State has interfered unreasonably with their right to practice their religion," because they "are not required by law to purchase prescription drug coverage at all" and could "compensate employees adequately without including prescription drugs in their group health care policies").

[18] HHS and some other commenters propose to accommodate or exempt organizations whose health plans would qualify for "church plan" status under 26 U.S.C. § 414(e). Although this test is far better than HHS's original "religious employer" definition, it could leave unprotected some deeply religious organizations not connected to a formal church or denomination. Accordingly, we believe our suggested test is better yet.

If the administration wishes to provide free contraception insurance (for non-abortifacients) to employees of exempted religious organizations, it should do so in a way that does not involve the religious organizations themselves. The proposition that an organization's policy should trigger a duty of its own insurer to cover contraception directly has simply proven insufficient to separate the organization from involvement in the coverage—and thus insufficient to satisfy the claims of conscience. A different approach, consistent with the general vision of the ACA, might be to provide the recipients with contraceptive insurance policies through the ACA's state exchanges. Conceivably, this could be funded by Title X monies—monies that would be freed up as many of the services now provided by Title X would be covered by the ACA. Alternatively, insurance companies participating in the exchanges could also be charged fees to pay for this coverage or required to provide this coverage as part of their participation in the exchange.

Respectfully submitted,

Bart Stupak

The Honorable Bart Stupak
Board Member
Democrats For Life of America

Kristen Day

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