SUBMITTED VIA EMAIL

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: file code CMS-9968-P

To whom it may concern:

Americans United for Life (AUL) remains deeply concerned with the guidelines and regulation regarding preventive services for women that were issued by the Health Resources and Services Administration (HRSA) and the Department of Health and Human Services (HHS) on August 1, 2011 and finalized, without change, February 15, 2012.[1] The Notice of Proposed Rulemaking (NPRM) published by HHS on February 6, 2013[2] does not alleviate these concerns.

This comment addresses the failure of the proposed "accommodation" in the NPRM to adequately protect freedom of conscience, a core American principle. The NPRM makes clear that its definition of "accommodation" requires those with religious, moral, and ethical

[1] 45 CFR § 147.130 (a)(1)(iv), as confirmed at 77 Fed. Reg. 8725 (Feb. 15, 2012) (hereinafter referred to as the "HHS mandate" or "mandate.").
[2] Coverage of Certain Preventive Services under the Affordable Care Act, 78 Fed. Reg. 8456 (Feb. 6, 2013).

objections to comply with the HHS mandate. The NPRM does not adequately cover "interested stakeholders" and suggests impractical, unwise, and possibly impermissible options to accomplish an economic impossibility. The NPRM also fails to correct the fact that the HHS mandate will disrupt duly enacted state laws protecting the consciences of healthcare payers and violate the principles of long-standing federal laws protecting conscience.

In addition, this comment will address the NPRM's failure to redress the inappropriate over-reach of the HRSA guidelines. The mandate's inclusion of life-ending drugs and devices is contrary to the stated intent of the preventive services provision of the Affordable Care Act and was based on an ideologically driven recommendation from the Institute of Medicine. Further, HHS improperly bypassed of the Administrative Procedures Act's (APA) notice-and-comment period requirements when it issued the guidelines and regulation.

AUL urges HHS to act swiftly to comprehensively protect freedom of conscience, a bedrock American principle, and to rescind the mandate's required coverage for drugs and devices with known life-ending mechanisms of action, including the abortion-inducing drug *ella*.

1. The Narrow Exemption and Proposed "Accommodation" Fail to Adequately Protect Freedom of Conscience.

As AUL detailed in both our September 2011 and June 2012 comments to HHS,[3] the regulation's exemption (which was finalized without change in February 2012) fails to address the serious and legitimate conscience concerns of many Americans.

The modification proposed in the NPRM to drop the current rule's requirement that churches and their auxiliaries be insular, only serving and hiring primarily persons of their own faith, in order to qualify for the exemption, is a small step in the right direction. However, the NPRM simultaneously narrows the exemption, by definitively excluding the option that it had previously considered exempting (or even "accommodating") an entire single group health plan of a church or religious organization, if each affiliated employer on the single group health plan does not independently meet the narrow requirements of the NPRM's definitions.

However, even with the proposed modification, allowing churches to engage in ministries to persons of all faiths or no faith without losing their constitutionally guaranteed freedom of conscience, the exemption's limited application to *only* churches and their auxiliaries is still unconstitutionally narrow. Further, it disrupts the conscience protections enshrined in the laws of

[3] *See* AUL June 2012 comment, *available at* http://www.aul.org/wp-content/uploads/2012/06/AUL-comment-HHS-ANPRM-June-2012.pdf (*last visited* Mar. 27, 2013); *see also* AUL September 2011 comment, *available at* http://www.aul.org/aul-comment-to-hhs-on-preventive-services/ (*last visited* Mar. 27, 2013).

many states, and a mandate including abortion-inducing drugs and sterilization violates the animating principles of long-standing federal laws protecting conscience rights.

As will be discussed below, the "accommodation" outlined in the NPRM fails to provide sufficient conscience protection. The freedom of conscience guaranteed in the First Amendment is neither confined to houses of worship nor only to those that run them. All Americans with religious, moral, or ethical objections should be *exempted* from the mandate.

When HHS Secretary Kathleen Sebelius announced a one-year "temporary enforcement safe harbor" she stated the "extension" for certain nonprofit groups with religious-based objections to providing coverage for "contraception," was "the appropriate balance" for "respecting religious freedom." [4] However, putting an expiration date on the freedom of conscience—now mere months away—is not a "balance"; it is a denial of rights guaranteed by the First Amendment.

Moreover, any "balance" should clearly be weighted in favor of freedom of conscience since there is no constitutional right to subsidized life-ending drugs and devices. Even the ACLU's "Reproductive Freedom Project," dedicated to promoting abortion and "contraception," acknowledges that "access" to contraception is not a constitutional right.[5]

Importantly, however, the allowance of a "safe harbor" illustrates that HHS is capable of both broadening the category of those for whom it permits an exemption and that HHS is not bound by its self-created timeline in imposing a coercive, anti-life coverage mandate.

a. ***The proposed "accommodation" is not a conscience protection; rather, it makes clear that the "accommodation" requires compliance with the mandate.***

The definition that HHS applies to the term "accommodation" makes clear that it is not a conscience protection, but rather the forced compliance of these insurance plans.

[4] It is unsettling that when testifying before the House Education and Workforce Committee, Secretary Sebelius (who noted "I am not a lawyer and I do not pretend to understand the nuances of the constitutional balancing tests") stated that she relied on "discussions" with attorneys, but seemed to indicate that no legal memorandum was ever created addressing the fact that the fundamental constitutional guarantee of "religious freedom," that HHS appears to at least understand, hangs in the balance. *See* http://www.youtube.com/watch?v=NnO7qa7fMRc&feature=plcp (*last visited* Mar. 27, 2013).

[5] *See* Religious Refusals and Reproductive Rights, American Civil Liberties Union (ACLU) Reproductive Freedom Project (2007) http://www.aclu.org/pdfs/reproductiverights/finalreport.pdf (*last visited* Mar. 27, 2013). Addressing a pharmacist or pharmacy's decision not to participate in contraception, ACLU literature states it "does not violate a woman's federal constitutional rights. The U.S. Constitution imposes no limitations on nongovernmental institutions like privately owned pharmacies. Even if the refusal takes place in a state-owned pharmacy, a woman has no federal constitutional right to receive contraception."

> *All references to 'accommodation' are references to an arrangement under which contraceptive coverage is provided without cost sharing to the participants and beneficiaries (or, in the case of student health insurance coverage, student enrollees and their covered dependents)…*

While claiming that the organization eligible for the "accommodation" will have "no role in contracting, arranging, paying, or referring for this separate contraceptive coverage" – that, in essence, the contraceptive coverage will involve a separate and distinct plan – the "accommodation" clearly requires that employers facilitate objectionable insurance coverage or be subject to a penalty.[6] The objecting employer must arrange for health insurance and, according to the NPRM, the plan participants and beneficiaries will be automatically enrolled (without an application or enrollment process) in contraceptive coverage without cost-sharing.

Under the "accommodation," the "eligible organization's" contracting with the insurer for health insurance is the "trigger" for its plan participants and beneficiaries being enrolled in the contraceptive coverage. Rather than having "no role," the "accommodated" employer is, in fact, forced to facilitate the coverage it objects to.

Additionally, the suggestion that the health insurance plan the "accommodated" employer facilitates and pays for and the contraceptive plan that its same plan participants and beneficiaries are automatically enrolled in are somehow distinct is exposed as false by the NPRM's explanation of how this "separate" contraceptive coverage is "cost-neutral":

> *The Departments believe that issuers generally would find that providing such contraceptive coverage* ***is cost neutral because they would be insuring the same set of individuals under both policies and would experience lower costs from improvements in women's health and fewer childbirths.***

Thus, only if considered in conjunction with the supposedly separate health plan is this contraceptive coverage "cost-neutral" for the insurer. Therefore, it is a clear and intentional fiction to claim that the two plans are separate and distinct and that the "accommodated" employer plays "no role" in the facilitation of and payment for the coverage it objects to.

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[6] *See* 26 U.S.C. § 4980H(a), (c)(1). Employers who fail to provide all coverage required by the mandate face onerous annual fines of $2,000 per full-time employee. *See also* 26 U.S.C. § 4980D(b). Failing to provide certain required coverage may subject group health plans to a fine of $100 a day per individual. *See also* 42 U.S.C. § 300gg-22(b)(2)(C)(i) and Cong. Research Serv., RL 7-5700 (asserting that the Secretary of HHS' authority to impose a $100 per day per individual penalty for failure to provide coverage applies to insurers who violate the "preventive care" provision). *See also* 29 U.S.C. § 1132(a)(1)(B) and Cong. Research Serv., RL 7-5700 (asserting that the Secretary of Labor's authority to fine group health plans extends to violations of the "preventive care" provision).

Even for self-insured plans, HHS makes clear that there is no way to avoid participating in the coercive, morally offensive mandate. Those enrolled in self-insured plans *must have* contraceptive coverage. In fact, HHS requires self-insured employers to notify a third-party administrator and thus trigger the inclusion of the coverage that violates their consciences.

b. The proposed "accommodation" does not adequately cover "interested stakeholders."

There are more true "interested stakeholders" than the "eligible organizations" narrowly defined in the NPRM. For example, the interests of for-profit businesses are prominently and inexplicably ignored by HHS and the NPRM.

While an exemption to the mandate – not an insufficient "accommodation" – should be extended to all those with religious objections, the exemption should also include non-religiously affiliated conscientious objectors. Freedom of conscience is a core American principle, but it is important that the concept of conscience not be narrowly defined as solely a religiously derived right or concept. Non-religiously affiliated persons and institutions have consciences that can likewise be violated by mandates and coercive participation in healthcare services to which they have ethical or moral objections.

The Advance Notice of Proposed Rulemaking (ANPRM) (published on March 21, 2012)[7] sought input on whether the "accommodation" should be extended to for-profit employers. Since that time, in 15 of the 20 challenges to the HHS mandate brought by for-profit employers, federal courts have issued injunctions or restraining orders against enforcement of the mandate.[8] It is curious that after the vast majority of the courts examining the issue have determined that for-profit employers indeed have a religious liberty interest that is unlawfully violated by the mandate, HHS has chosen to ignore these rulings and affirmatively choose not to protect the freedom of conscience of for-profit employers.

Notably, the NPRM refers repeatedly to (seemingly) all for-profit employers as "secular." If being "secular" is a necessary attribute of a for-profit business or organization, it is superfluous for the NPRM to also cite to "for-profit secular organizations."

In fact, there are many for-profit employers that are religious, religiously affiliated, and religiously motivated. An obvious example is Tyndale, a Bible publisher, that is one of the over 150 plaintiffs challenging the mandate.[9] If the NPRM did not employ "secular" superfluously, it

[7] 77 Fed. Reg. 16501

[8] *See* HHS Mandate Information Central, THE BECKET FUND, http://www.becketfund.org/hhsinformationcentral/ (*last visited* Mar. 28, 2013).

[9] Another example is Hobby Lobby, a nation-wide arts and crafts retailer, founded and run by the Green family, who has modeled Hobby Lobby's business principles according to its religious principles. The company's statement of purpose announces its commitment to "[h]onoring the Lord in all we do by operating the company in a manner

fails to explain how religious, religiously affiliated, or religiously motivated for-profits are exempt or "accommodated."

In addition, "secular" and "moral" are not mutually exclusive. A mandate to facilitate and pay for coverage of drugs and devices with known life-ending mechanisms of action may violate the conscience of a non-religiously affiliated employer. Americans United for Life, for example, is not a religiously affiliated organization; however, our conscience as a pro-life organization would be violated by the forced facilitation and payment for coverage of life-ending drugs and devices, such as the abortion-inducing drug *ella*. While AUL does not currently meet the 50 full-time employee minimum threshold for the mandate to be enforced against us, should our organization expand, HHS offers us no conscience protection.

It must again be emphasized that the exemption afforded to a narrowly defined set of "religious employers" must be expanded. The freedom of conscience guaranteed in the First Amendment is neither confined to houses of worship nor only to those that run them. All Americans with religious, moral, or ethical objections should be *exempted* from the mandate.

c. The NPRM suggests impractical, unwise, and possibly impermissible options to accomplish an economic impossibility.

Requiring insurance providers and third-party administrators to pay for the costs of these drugs and devices, from sources other than the plan sponsor's or beneficiaries' premiums, is constitutionally suspect under Y*oungstown Sheet & Tube Co.* v. *Sawyer*.[10]

In *Youngstown*, a landmark case concerning executive encroachment on legislative powers, the U.S. Supreme Court noted that the power of the executive "must stem either from an act of Congress or from the Constitution itself."[11] The Court held President Truman's order, directing the Secretary of Commerce to take possession of and operate private industry steel mills, was impermissible since no law "expressly authorize[d]" the President's order.[12] Despite the President's stated national security interest, the Court also found the order was not justified under the President's powers as Commander-in-Chief, but was clearly an impermissible act of lawmaking.

The NPRM's "accommodation" similarly proposes the conscription of private industry, without express statutory authorization or separate constitutional authority. While the Affordable Care

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consistent with Biblical principles." For a comprehensive analysis of the relationship between profit-making and religious exercise. *See* Mark Rienzi, *God and the Profits: Is There Religious Liberty for Money Makers?* (Mar. 7, 2013), *available at* SSRN: http://ssrn.com/abstract=2229632 (*last visited* Mar. 28, 2013).

[10] 343 U.S. 579 (1952).

[11] *Id.* at 585.

[12] *Id.*

Act does mandate (without defining) that "preventive services" be provided without cost-sharing (*i.e.* no co-pay), Congress has not conferred on HHS or any other governmental body the authority to make the funding dictates on insurance providers and third-party administrators the NPRM intimates.

The Self-Insurance Institute of America, Inc. (SIIA) has noted in its comment to HHS, that the suggestion that the third-party administrator is responsible for payment, essentially transforms them into an insurance carrier, creating an additional problem: "Insurance carriers are fiduciaries and fiduciaries are regulated by state law. This directly conflicts with the federal regulatory regime under which [third-party administrators] currently operate." In addition to the legal defects of the suggestion, the SIIA comment details how "[m]arketplace realities also preclude this approach."

Polls have demonstrated that more Americans oppose the HHS mandate than support it. According to a May 24, 2012 Rasmussen poll, 48 percent oppose forcing "contraceptive" coverage, while only 39 percent approve.[13] Nor is this an issue of women versus men. Women's opinion, according to an earlier Rasmussen poll, is nearly evenly split. Only 40 percent of women approve, while 42 percent of women oppose the mandate.[14] Even these numbers fail to tell the entire story, considering that the Rasmussen polls did not mention that abortion-inducing drugs and devices such as *ella* are included in mandate.[15]

Similarly, in March 2012, polling conducted by The New York Times and CBS News found that when asked,

> Should health insurance plans for all employees have to cover the full cost of birth control for female employees or should employers be able to opt out for moral or religious reasons?

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[13] *See 51% Oppose Forcing Religious Organizations to Provide Birth Control*, RASSMUSSEN REPORTS, May 24, 2012, *available at* http://www.rasmussenreports.com/public_content/politics/current_events/healthcare/may_2012/51_oppose_forcing_religious_organizations_to_provide_birth_control (*last visited* Mar. 27, 2013). This is consistent with Rasmussen polling from August 2011 which also showed greater opposition than support for the mandate. *See 39% Say Health Insurance Companies Should Be Required to Cover Contraceptives*, RASSMUSSEN REPORTS, Aug. 4, 2011, *available at* http://www.rasmussenreports.com/public_content/politics/current_events/healthcare/august_2011/39_say_health_insurance_companies_should_be_required_to_cover_contraceptives (*last visited* Mar. 27, 2013).

[14] RASSMUSSEN REPORTS, Aug. 4, 2011, *available at* http://www.rasmussenreports.com/public_content/politics/current_events/healthcare/august_2011/39_say_health_insurance_companies_should_be_required_to_cover_contraceptives (*last visited* Mar. 27, 2013).

[15] Rather, the question posed in both surveys was general, "Should health insurance companies be required by law to cover all government-approved contraceptives for women, without co-payments or other charges to the patient?"

Fifty-one (51) percent opposed a strict mandate.[16] Majorities of both men and women also responded that an exemption should be permitted for "religiously affiliated employers, such as a hospital or university."

d. The HHS mandate and proposed "accommodation" disrupt duly enacted state laws protecting the consciences of healthcare payers.

Acknowledging that state laws that mandate contraceptive coverage in certain insurance plans offer greater protection for conscientious objectors than the HHS proposals, the ANPRM stated that HHS sought

> *[C]omment on the interaction between these State laws and the intended regulations on which we are seeking comment in this notice and on the extent to which there is a need for consistency between any Federal regulations and these State laws.*

The answer remains simple and straightforward: the HHS-termed "accommodation" that demands compliance with the HHS mandate, rather than offering an actual *exemption*, fails to respect well-reasoned, duly enacted state laws that protect against coercive involvement.

As AUL has detailed in a previous comment to HHS,[17] the guidelines and regulation issued by the HRSA and HHS far surpass any coercive measure enacted by the states and compromise duly enacted state laws protecting the conscience of healthcare payers:

- Mandated coverage for "contraceptives" is unprecedented in nearly half the states.
- Even those states that have adopted so-called "contraceptive equity" laws generally only apply their requirements to insurance plans that offer prescription coverage (thereby, allowing an employer the option, albeit a difficult choice, to drop prescription coverage altogether).
- None of the state mandates apply to self-insured or ERISA plans, thereby providing an employer with additional means to offer insurance in accord with its conscience.
- Multiple states explicitly exclude certain specific FDA-labeled "contraceptives" from their mandates.[18]

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[16] *See President Obama's Approval Rating Drops*, THE NEW YORK TIMES, March 12, 2012 *available at* http://www.nytimes.com/interactive/2012/03/13/us/politics/president-obamas-approval-rating-drops.html?ref=politics (*last visited* Mar. 27, 2013).

[17] *Available at* http://www.aul.org/aul-comment-to-hhs-on-preventive-services/ (*last visited* Mar. 27, 2013).

[18] Many states do not require coverage for *all* FDA approved contraceptives and multiple states have explicitly chosen to reject certain so-called "contraceptives" from their mandates. For example, Ark. Stat. Ann. §23-79-1103-1104 (2005) provides that "Nothing contained in this subchapter shall be construed to require any insurance company to provide coverage for an abortion, an abortifacient, or any United States Food and Drug Administration-approved emergency contraception."; N.C. Gen. Stat. § 58-3-178 (1999) excludes "[t]he prescription drug marketed

- Moreover, many states with religious employer exemptions adopt a more expansive definition than that provided for by the HHS regulation.[19]
- Further, the mandate stands in direct opposition to the duly enacted law of Mississippi which protects the conscience rights of healthcare payers.[20]

Thus, the HRSA guidelines, narrow exemption, and proposed "accommodation," supplant the reasoned judgment of the states with an ideologically driven, coercive measure.

The interim final rule wrongly insinuated that its exemption for a narrowly defined set of "religious employers" brought it in line with a majority of states. However, while HHS may have mischaracterized the scope of the exemptions, it was correct that the "majority" of states with contraceptive coverage mandates also "simultaneously provide for a religious accommodation." Bearing in mind that HHS was using the term "accommodation" to mean "exemption" in the interim final rule, HHS must be well aware that the majority of states exempt, rather than play semantics with, the insurance plans that qualify for "accommodations."

In addition, the ANPRM announced that

> *[S]tate exemptions will be narrowed to align with the final regulations because this will help more consumers*.

Thus, it is clear that any state protection broader than that proffered by HHS will not stand. To say that the state exemptions will be "narrowed" is euphemistic. The duly enacted state laws designed to protect the conscience rights of their citizens will be superseded by HHS' unprecedented, sweeping, and coercive rule.

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under the name "Preven" or any "equivalent drug product" as defined in G.S. 90-85.27(1)."; and Tex. Insurance Code Ann. § 1369.104 et seq. (2001)excludes "abortifacients or any other drug or device that terminates a pregnancy."

Other state laws clarify that their mandates are not to include abortion-inducing drugs. Ga. Code § 33-24-59.6 (1999) ("Likewise, nothing contained in this Code section shall be construed to require any insurance company to provide coverage for abortion."); Me. Rev. Stat. Ann. Tit. 24 §2332-J (1999) ("may not apply to prescriptions designed to terminate a pregnancy"); R.I. Gen. Laws § 27-18-57 (2000) ("Provided, that nothing in this subsection shall be deemed to mandate or require coverage for the prescription drug RU 486.") Keeping in mind that these laws, explicitly excluding the abortion drug RU-486, pre-date the approval of *ella*, a substantially similar drug to RU-486, the HRSA/HHS mandated coverage preempts the principles, if not the letter, of these laws.

[19] For example, Nevada law exempts insurers "affiliated with a religious organization," Nev. Rev. Stat. § 689A.047 (1999), while Missouri exempts *anyone* (not limited to religious employers) with a "moral, ethical, or religious" objection and *any* health carrier "owned, operated, or controlled … by an entity that is operated pursuant to moral, ethical or religious tenets…" Mo. Rev. Stat. § 376.1199 (2001).

[20] Miss. Code Ann. § 41-107-9 (2004).

Further, the HHS mandate, limited exemption, and proposed "accommodation," conflict with statutory and constitutional protections in states that have heretofore chosen not to impose contraceptive mandates on their citizens. For example, the State of Alabama has sought to intervene in the case *Eternal Word Television Network v. Sebelius*[21] to protect its important state interests including that,

> [T]he State seeks to preserve its ability to provide insurance coverage to its citizens in a manner that is consistent with Alabama law and the right of conscience.[22]

Alabama asserts that the HHS mandate "contravenes Article I, Section 3 to the Alabama Constitution of 1901"[23] and "contravenes the Alabama Religious Freedom Amendment ("ARFA") to the Alabama Constitution of 1901."[24]

> Indeed, Alabama's government and people have a long tradition of respect for religious freedom and the right to conscience. Alabama's Constitution has always declared 'that the civil rights, privileges, and capacities of any citizen shall not be in any manner affected by his religious principles.' And, in the 1998 election, Alabama voters ratified the Alabama Religious Freedom Amendment ("ARFA") to the Constitution, which tracks the language and intent of the federal RFRA.[25]

The HHS mandate not only disrespects Alabama's long tradition of respecting religious freedom and the freedom of conscience, it prohibits Alabama from continuing to provide such protection to its citizens. The guarantees of the Alabama constitution and law would, thus, be unenforceable under the mandate.

Thirteen state Attorneys General submitted a comment to HHS on March 26, 2013 regarding the NPRM. The chief legal officers of Alabama, Colorado, Georgia, Florida, Idaho, Kansas, Montana, Nebraska, Ohio, Oklahoma, South Carolina, Texas and West Virginia state that, "the proposed regulations do not remedy the legal infirmities in the original HHS mandate."[26]

In effect, the HHS mandate is a nation-wide evisceration of state protections for the freedom of conscience.

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[21] N.D. Ala. 12-00501. The State of Alabama and Attorney General Luther Strange's motion to intervene and full complaint, *available at* http://www.ago.state.al.us/Update-193 (*last visited* Mar. 27, 2013).
[22] Motion to Intervene at 12.
[23] *Id.* at 8.
[24] *Id.*
[25] Exhibit 1 to Motion to Intervene, Intervenors' Complaint at 18.
[26] Comment, *available at* http://www.ago.state.al.us/news/304.pdf

e. A mandate including sterilization and abortion-inducing drugs violates the principles of long-standing federal laws protecting conscience.

The Affordable Care Act, states explicitly that "[n]othing in this Act shall be construed to have any effect on Federal laws regarding – (i) conscience protection…"[27] However, the mandate and regulation issued through HRSA and HHS violate the principles of long-standing federal laws that provide broad conscience protections.

Congress first addressed the issue of conscience protections just weeks after the U.S. Supreme Court decision in *Roe v. Wade*.[28] In 1973, Congress passed the first of the Church Amendments (named for its sponsor, Senator Frank Church).[29] The Amendment provides that the receipt of funding through three federal programs cannot be used as a basis to compel a hospital or individual to participate in an abortion or sterilization procedure to which the hospital or individual has a moral or religious objection.

In addition, §§ c(2) and (d) of the Church Amendment provide broad protection ensuring that no "individual shall be required to perform or assist in the performance of any part of a health service program or research activity," funded in whole or in part by the federal government if doing so "would be contrary to his religious beliefs or moral convictions." Thus, the protections of the Church Amendment are broad and are not limited to abortion and sterilization.

Taken together, the original and subsequent Church Amendments protect healthcare providers from discrimination by recipients of HHS funds on the basis of their objections, stemming from their religious beliefs or moral convictions, to performing or participating in *any* lawful health service or research activity.

In addition, the Hyde-Weldon Amendment, first enacted in 2005, provides that no federal, state, or local government agency or program that receives funds in the Labor/Health and Human Services appropriations bill may discriminate against a healthcare provider because the provider refuses to provide, pay for, provide coverage of, or refer for abortion.[30]

Additionally, the HHS mandate's application to persons and institutions with religious objections violates the Religious Freedom Restoration Act (RFRA).[31] To abide by RFRA, the mandate

[27] Pub. L. 111-148 (2010) §1303(c)(2)(A)(i).
[28] 410 U.S. 113 (1973).
[29] 42 U.S.C. 3001-7.
[30] Consolidated Appropriations Act 2008, Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).
[31] 42 U.S.C. §§ 2000bb et seq. In 1992, the Religious Freedom Restoration Act (RFRA) was passed by a bipartisan Congress and signed into law by President Bill Clinton. Nadine Strassen, then president of the American Civil Liberties Union (ACLU), testified in favor of RFRA. Ms. Strassen told the Committee on the Judiciary that RFRA's enactment would, among other things, safeguard "such familiar practices as...permitting religiously sponsored

(which burdens the exercise of religion) would have to be both "in furtherance of a compelling governmental interest" and "the least restrictive means of furthering that compelling governmental interest."

HHS has utterly failed to offer a "compelling" interest for its mandate. As Americans United for Life and the Alliance Defending Freedom detail in our *amicus curiae* brief before the Fourth Circuit in the case *Liberty University v. Geithner*[32] (a broad challenge to the constitutionality of the Affordable Care Act) the federal government's actions with regard to the HHS mandate demonstrate exactly the opposite – there is no compelling interest supporting the coercive mandate.[33] Specifically, the government's choice to exclude of tens of millions of women from the mandate's coverage (for reasons other than conscientious objection) shows that the government's interest is not compelling. In addition, Congress chose to impose *other* requirements on "grandfathered" plans, and Congress' choice not to similarly impose the HHS Mandate on these "grandfathered" plans further demonstrates that its interest in the HHS mandate is not compelling.

Moreover, the HHS mandate and the proposals in the NPRM clearly are not the "least restrictive" means to accomplish the government's stated interest of increasing "access" to contraception. Furthering that goal does not require forcing individuals and institutions to facilitate, pay for, and participate in health insurance plans covering drugs and devices to which they have religious objections. One option would be for Congress to create new programs or expand eligibility for existing federal programs providing "contraceptives" (although public opinion strongly opposes taxpayer funding of life-ending drugs and devices[34]).

In contrast to the animating principles of federal laws which recognize a right not to be coerced into participating in abortion, sterilization, and other services "contrary to [] religious or moral convictions," the HHS mandate leaves most Americans no option but to be enrolled in insurance plans that cover abortion-inducing drugs, sterilization, and other "contraceptive" items and services to which they may have sincerely held ethical, moral, or religious objections.

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hospitals to decline to provide abortion or contraception services." *The Religious Freedom Restoration Act: Hearing on S. 2969 Before the S. Comm. on the Judiciary*, 102d Cong., 74, 192 (1992) (Statement of Nadine Strossen, President, Am. Civ. Liberties Union).

[32] 133 S. Ct. 679 (U.S. 2012). (Petition for rehearing granted.)

[33] The brief filed by AUL and ADF is available at http://www.aul.org/wp-content/uploads/2013/03/10-2347-BRIEF-OF-AMICI.pdf (*last visited* Mar. 28, 2013).

[34] Taxpayer funding for an abortion-inducing drug such as *ella*, stands in opposition to the position of the overwhelming majority of Americans who do not want their tax-dollars paying for abortions. *See U.S. Voters Oppose Health Care Plan by Wide Margin, Quinnipiac National University Poll Finds; Voters Say 3-1, Plan Should Not Pay for Abortions*, QUINNIPIAC UNIVERSITY, (Dec. 22, 2009), http://www.quinnipiac.edu/x1295.xml?ReleaseID=1408 (*last visited* Mar. 27, 2013Mar. 27, 2013). *See also Poll: Majority favor abortion funding ban*, CNN POLITICS (Nov. 18, 2009), http://articles.cnn.com/2009-11-18/politics/abortion.poll_1_public-option-abortion-issue-health-insurance?_s=PM:POLITICS (*last visited* Mar. 27, 2013).

2. HRSA Exceeded Its Discretion Under the Affordable Care Act.

The ANPRM implicitly acknowledged[35] what AUL detailed in its previous comment to HHS: HRSA exceeded the discretion it was granted under the Affordable Care Act by mandating that insurance plans fully cover "all Food and Drug Administration approved contraceptives, sterilization procedures…" Contrary to the stated intent of the preventive services provision of the Affordable Care Act, the HRSA mandate includes drugs and devices with known life-ending mechanisms of action, including the abortion-inducing drug *ella*. Moreover, the HRSA mandate, which will violate the consciences of many Americans by requiring they pay for drugs and devices to which they have ethical, moral, or religious objections, was based on an ideologically driven recommendation from the Institute of Medicine.

a. *The HRSA guidelines violate the intent of Section 2713(a)(4) of the Affordable Care Act by including mandated coverage for drugs and devices with life-ending mechanisms of action, such as the abortion-inducing drug ella.*

As AUL detailed in previous comments to HHS,[36] the statutory language of Section 2713(a)(4) of the Affordable Care Act, which requires private insurance plans to cover certain preventive services, does not require the inclusion of any "contraception" as a covered service.

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[35] The ANPRM states that HHS, "*Seek[s] comment on whether the definition of religious organization should include religious organizations that provide coverage for some, but not all, FDA-approved contraceptives consistent with their religious beliefs*." The question implicitly acknowledges that not all FDA-approved "contraceptives" work solely by preventing conception. Some organizations that do not have a conscientious objection to contraception *per se* do have a religious, moral, or ethical objection to the life-destroying capacity of certain FDA-approved "contraceptives." Multiple lawsuits have already been filed by plaintiffs whose religious beliefs are violated by mandated coverage for these particular drugs and devices. *See e.g., Louisiana College v. Sebelius* W.D. La. 12-00463. Plaintiff Louisiana College, affiliated with the Southern Baptist Convention, "believes and teaches that abortion, or methods that harm an embryo from the moment of conception/fertilization, ends a human life and is a sin" and has thus "ensured that its insurance policies do not cover drugs, devices, services or procedures that it believes may cause the death of an early human embryo, such as Plan B or 'ella.'" *See also Geneva College v. Sebelius* W.D. Pa. 12-00207. Plaintiff Geneva College, established by the Reformed Presbyterian Church of North America, argues that the mandate violates its religious beliefs prohibiting the destruction and requiring the protection of "the lives of human beings from the moment of fertilization." *See also Hobby Lobby v. Sebelius* W.D. Okla. 12-6294. The Green family, founder and owner of Hobby Lobby, "believe that human life begins at conception and that it is wrong to harm a human being from that moment." Their health insurance plan therefore excludes drugs and devices "that can terminate a pregnancy" and so-called "emergency contraceptives" that "can prevent a fertilized egg from implanting the womb." Their complaint explicitly states that "Other than this subset of drugs and devices, the Greens have no objection to other contraceptives, which Hobby Lobby's health insurance plan has always covered."

[36] *See* http://www.aul.org/aul-comment-to-hhs-on-preventive-services/ (*last visited* Mar. 27, 2013). *See also* http://www.aul.org/wp-content/uploads/2010/09/Americans-United-for-Life-Comment-on-OCIIO.9992.pdf (*last visited* Mar. 27, 2013), http://www.aul.org/wp-content/uploads/2012/06/AUL-comment-HHS-ANPRM-June-2012.pdf (*last visited* Mar. 27, 2013).

Further, during a debate over the amendment on the Senate Floor on December 3, 2009, Senator Mikulski clarified that abortion was not intended to be covered "in any way" and, in fact, her amendment was "strictly concerned with ensuring that women get the kind of preventive screenings and treatments they need to **prevent diseases** particular to women…" (Emphasis added).[37]

Thus, by mandating coverage for "all Food and Drug Administration (FDA) approved contraceptives," which includes the abortion-inducing drug *ella*, HRSA exceeded its discretion.

1. Mandated coverage for the abortion-inducing drugs including ella and other "emergency contraceptives" is directly contrary to the assurance that abortion would not be covered "in any way."

By including the abortion-inducing drug *ella* in the mandate, HRSA and HHS have required coverage for a drug that can kill a human embryo even after implantation.

Like the abortion drug RU-486, Ulipristal Acetate (*ella*), approved by the U.S. Food and Drug Administration (FDA) in August 2010 (after the enactment of the Affordable Care Act), is a selective progesterone receptor modulator (SPRM). Despite its "indication" for use as "emergency contraception," *ella* – like RU-486 – can induce an abortion.[38] This is because an SPRM "works" by blocking progesterone, a hormone that is necessary for pregnancy.[39] By blocking progesterone, *ella* can kill a human embryo even after implantation.

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[37] Cong. Rec. S12274 (daily ed. Dec. 3, 2009) (colloquy between Sen. Mikulski and Sen. Casey), *available at* http://thomas.loc.gov. "This amendment does not cover abortion. Abortion has never been defined as a preventive service. This amendment is strictly concerned with ensuring that women get the kind of preventive screenings and treatments they need to prevent diseases particular to women such as breast cancer and cervical cancer. There is neither legislative intent nor legislative language that would cover abortion under this amendment, nor would abortion coverage be mandated in any way by the Secretary of Health and Human Services."

[38] "The mechanism of action of ulipristal in human ovarian and endometrial tissue is identical to that of its parent compound mifepristone." D. Harrison & J.Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 Annals Pharmacotherapy 115 (Jan. 2011).

[39] Planned Parenthood materials acknowledge that chemical abortions are accomplished by blocking progesterone. *See e.g.* Planned Parenthood of Arizona, Client Information for Informed Consent: using the abortion pill, *available at* http://www.plannedparenthood.org/ppaz/images/Arizona/web-AB_by_Pill_E(1).pdf (*last visited* Mar. 27, 2013). ("Abortion pill" is a popular name for a medicine called mifepristone….It ends the pregnancy. It does this by keeping your body from making a certain hormone called progesterone. The pregnancy cannot go on without progesterone.")

Studies confirm that *ella* is harmful to a human embryo.[40] The FDA's own labeling notes that *ella* may "affect implantation,"[41] and contraindicates (or advices against) use of *ella* in the case of known or suspected pregnancy. Notably, at the FDA advisory panel meeting for *ella*, Dr. Scott Emerson, a professor of Biostatistics at the University of Washington and a panelist, raised the point that the low pregnancy rate for women taking *ella* four or five days after intercourse suggests that the drug *must* have an "abortifacient" quality.[42]

ella's deadliness goes beyond that of any other "contraceptive" approved by the FDA at the time of the Affordable Care Act's enactment. Without diminishing the legitimate and serious objections to the deceptive approval of other life-ending drugs and devices, it should be acknowledged that by approving *ella* as "contraception" the FDA has removed, not simply blurred, the line between "contraception" and "abortion" drugs. No longer is the FDA hiding behind a changed definition of pregnancy[43]; the FDA-approved "contraceptive" *ella* can work by ending an "established" pregnancy.

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[40] *See* European Medicines Agency, Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone 16 (2009), *available at* http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf (*last visited* Mar. 27, 2013). *See also ella* Labeling Information (Aug. 13, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (*last visited* Mar. 27, 2013).

[41] *ella* Labeling Information (Aug. 13, 2010), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf (*last visited* Mar. 27, 2013).

[42] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs, June 17, 2010, *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf (*last visited* Mar. 27, 2013). Dr. Emerson specifically stated, "What's very, very bothersome here, again, to me, is that we shouldn't be seeing this much of an effect according to your presumed mechanisms of action; that if there is no abortifacient aspect of this treatment, no effect on implantation, I just can't make these numbers jive, unless there is a substantial difference in the demographics according to the women who are presenting with this sort of data. …" He also noted, "So this still comes back to this mechanism of action then. Why would we expect that if -- and 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."

The response to Dr. Emerson's questions given by Dr. Erin Gainer, representing HRA Pharma, *ella*'s sponsor, acknowledged that HRA Pharma lacked sufficient data to make an assurance that *ella* did not have an abortifacient aspect, "Again, given the variability that we know when ovulation actually occurs in a given cycle, it's very hard to comment on how many of the women treated days 4 and 5 may have been post-ovulation. We don't have biochemical data on the individual women included. So it is very hard to comment on where those women actually were."

[43] The term "contraception" connotes that a drug or device works by preventing "conception." However, by redefining "pregnancy" to begin at implantation, as opposed to conception (or fertilization), advocates of implantation-blocking drugs and devices have successfully included post-conception mechanisms of action in the FDA's definition of "contraception." Despite the fact that a drug or device may end an already developing, distinct human being's life by preventing implantation, they are labeled by the FDA as "contraception" on the claim that they do not terminate an "established pregnancy." For an overview of how the definition of pregnancy has "changed," *see* Christopher Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of*

Though "indicated" for contraceptive use, mandated coverage for *ella* opens the door to off-label and intended-abortion usage of the drug being funded by all health insurance plans. This runs directly contrary to Senator Mikulski's assurance that "nor would abortion coverage be mandated in any way…"

Significantly, *ella* was approved by the FDA several months after the Affordable Care Act was enacted and, therefore, its inclusion in the preventive services mandate was not contemplated by Congress, even if other methods of "contraception" were. While forced coverage of contraceptives in private plans is an entirely new and unprecedented concept, in the case of *ella*, a new type of "contraceptive" drug, there is no precedent for its inclusion even in government healthcare programs. Further, there can be no reliance argument made alleging that there is a history of taxpayer-funding for the abortion-inducing drug *ella* through government programs that cover other contraceptives since it was approved in August 2010 (after the Affordable Care Act was signed into law in March 2010).

2. Similarly, mandated coverage for other "emergency contraceptives" with known life-ending mechanisms of action violates the intent of the Affordable Care Act.

Other FDA-labeled "contraceptives" also have known life-ending mechanisms of action. Plan B, commonly referred to as "the morning after pill," can kill a human embryo by preventing implantation.[44] Intrauterine Devices (IUDs), which are being heavily pushed for use as "emergency contraceptives," are also acknowledged to work not only by preventing conception, but by blocking implantation.[45] A recent study on so-called "emergency contraceptives" concludes that, "[i]ts very high effectiveness implies that emergency insertion of a copper IUD **must** be able to prevent pregnancy **after fertilization**."[46] (Emphasis added.)

Promoting the HRSA guidelines, HHS Secretary Kathleen Sebelius has admitted that the FDA's definition of "contraception" is not limited to a drug's ability to prevent conception, but extends to blocking the implantation of an already developing human embryo. "The Food and Drug

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Conception and Pregnancy, FRC INSIGHT PAPER (April 2009), *available at* http://www.frc.org/life--bioethics (*last visited* Mar. 27, 2013).

[44] Plan B Approved Labeling, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf (*last visited* Mar. 27, 2013). The FDA's labeling acknowledges that Plan B can prevent implantation of a human embryo.

[45] *See* http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf (*last visited* Mar. 27, 2013). The Department of Health and Human Services guide to "Birth Control Methods" describes among the mechanisms of action for copper IUDs, "If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus." For hormonal IUDs the guide states, "It also affects the ability of a fertilized egg to successfully implant in the uterus."

[46] J. Trussell et al., *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy*, Office of Population Research at Princeton University (June 2010).

Administration has a category [of drugs] that prevent fertilization **and implantation**. That's really the scientific definition." [47] (Emphasis added) Secretary Sebelius stated that under the HHS mandate, "These covered prescription drugs are specifically those that are designed to prevent implantation." [48]

b. ***The HRSA guidelines came from the advice of an ideologically driven Institute of Medicine panel.***

The NPRM notes that the HRSA guidelines were

> *[B]ased on recommendations of the independent Institute of Medicine, which had undertaken a review of the scientific and medical evidence on women's preventive services*.

However, the Institute of Medicine (IOM) panel tasked with advising HRSA on what should be included in the preventive services mandate had an abortion-advocacy bias in its panel membership as well as its invited presenters.

Dissenting from the IOM recommendation, committee member Dr. Anthony Lo Sasso criticized the committee's lack of transparency and creation of an advocacy-based recommendation,

> The committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy.[49]

Several members of the IOM panel had direct ties to Planned Parenthood, the nation's largest abortion provider,[50] which stands to gain financially from the IOM recommendation, as well as other openly pro-abortion organizations.[51]

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[47] Kelly Wallace, *Health and Human Services Secretary Kathleen Sebelius Tells iVillage "Historic"New Guidelines Cover Contraception, Not Abortion*, IVILLAGE, Aug. 2, 2011, *available at* http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771 (*last visited* June 12, 2012).

[48] *Id.*

[49] COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN; INSTITUTE OF MEDICINE, CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 207 (2011) *available at* http://www.nap.edu/catalog.php?record_id=13181 (*last visited* Mar. 27, 2013).

[50] According to her biography, Dr. Paula Johnson "served for many years on the board of Planned Parenthood League of Massachusetts and chaired the board from 1997-1998." *See* http://www.bphc.org/boardofhealth/boardmembers/Pages/Home.aspx (*last visited* Mar. 27, 2013); Dr. Magda Peck served as chair and vice-chair of the Board of Directors Planned Parenthood of Nebraska Council Bluffs (now Planned Parenthood of the Heartland) from 2006-2009. *See* http://www4.uwm.edu/secu/news_events/sph-dean/Peck-cv.pdf (*last visited* Mar. 27, 2013). Dr. Carol Weisman served as a member of the Affiliate Medical

A look at the organizations invited to present at the IOM's three public meetings on the preventive services mandate underscore its advocacy-based, pro-abortion bias.[52]

Notably, at the first meeting, groups invited to speak on "women's issues" included the nation's largest abortion provider, Planned Parenthood. Planned Parenthood, as a distributor of "contraceptives," stands to gain tremendously if insurance plans are required to cover contraceptives without co-pay, a financial stake which was never disclosed as a conflict of interest.

Other invited presenters included the National Women's Law Center which states on its website, "We're working to ensure that women have access to abortion care by protecting and advancing this fundamental right."[53] The second meeting included a presentation by a former official affiliate of Planned Parenthood, the Guttmacher Institute, whose "Guiding Principles" include working to "protect, expand and equalize access to information, services and rights that will enable women and men to … exercise the right to choose abortion."[54]

Never formally invited by the IOM to present, pro-life organizations–including AUL—attended and, during the public comments portion of every open IOM committee meeting, urged the panel against including life-ending drugs and devices in a mandate that would apply to nearly all health

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Committee of Planned Parenthood of Maryland from 1993-1997 and was a member of the Board of Directors of Planned Parenthood of Maryland from 1978-1984. *See* http://www.pennstatehershey.org/c/document_library/get_file?folderId=229089&name=DLFE-25907.pdf (*last visited* Mar. 27, 2013).

[51] Dr. Francisco Garcia has worked with the International Planned Parenthood Federation. *See* http://orwh.od.nih.gov/about/Garcia%20(updated%202-18-10)--edited%20clean%20copy.pdf (*last visited* June1, 2012). Dr. Paula Johnson serves on the board of the Center for Reproductive Rights, an organization which seeks to expand abortion access. *See* http://www.bphc.org/boardofhealth/boardmembers/Pages/Home.aspx (*last visited* Mar. 27, 2013). Dr. Claire Brindis is a co-founder of the Bixby Center for Global and Reproductive Health. The Bixby Center provides abortion training and runs initiatives designed to increase and expand abortion services. *See* http://bixbycenter.ucsf.edu/research/abortion.html (*last visited* Mar. 27, 2013). Dr. Brindis also chaired the Population, Family Planning and Reproductive Health Section (PRSH) of the American Public Health Association. The PRSH has a "task force" dedicated to abortion. *See* http://www.apha.org/membergroups/sections/aphasections/population/benefits/taskforces.htm (*last visited* Mar. 27, 2013). Dr. Angela Diaz has served as a Board Member for the Physicians for Reproductive Choice and Health. *See* http://www.prch.org/about-board-directors (*last visited* Mar. 27, 2013). Dr. Alina Salganicoff has worked as a trainer and counselor for CHOICE, "a Philadelphia-based reproductive health care advocacy organization." *See* http://www.kff.org/womenshealth/upload/Speaker-Biographies-Women-and-Health-Care-A-National-Profile.pdf (*last visited* Mar. 27, 2013).

[52] The IOM meeting information and agendas are *available at* http://iom.edu/Activities/Women/PreventiveServicesWomen.aspx (*last visited* Mar. 27, 2013).

[53] National Women's Law Center, *Our Issues, Abortion, available at* http://www.nwlc.org/our-issues/health-care-%2526-reproductive-rights/abortion (*last visited* Mar. 27, 2013).

[54] Guttmacher Institute, "Mission," *available at* http://www.guttmacher.org/about/mission.html (*last visited* Mar. 27, 2013).

insurance plans. The IOM panel was reminded by AUL and others that the "preventive services" provision was, as its author Senator Mikulski stated, "strictly concerned" with "preventing *diseases*." The IOM panel was also reminded that Senator Mikulski made assurances that abortion would not be covered "in any way." Further, at every meeting it was explained to the IOM panel that *ella*, newly approved by the FDA as a so-called "emergency contraceptive," can end even an "established" pregnancy.

Despite this knowledge, in July 2011, during the IOM committee's press conference to announce the release of its report, Dr. Linda Rosenstock (the committee chair) explained, unequivocally, that the drug *ella* was included in her committee's recommendation. Though Dr. Rosenstock stated her committee considered "every" comment that was made before them, the IOM report utterly failed to address the serious concerns repeatedly presented at the meetings about *ella*'s abortion-inducing quality. Nowhere in its 250-page report did the committee even mention *ella*'s life-ending mechanisms of action.

Also absent from the 250-page report was any mention that other FDA-labeled "contraceptives," including Plan B, can work by preventing the implantation of an already developing human embryo – another fact presented at every meeting, a fact that the FDA notes in its labeling of the drugs, and an established fact that HHS has included in its information on "birth control" methods.

Further, the IOM's own Report acknowledged that the panel would have considered abortion *per se* as a "preventive service" had it not been otherwise constrained by the Affordable Care Act: "Finally, despite the potential health and well-being benefits to some women, abortion services were considered to be outside of the project's scope, given the restrictions contained in the [Affordable Care Act]."[55]

While HHS can cite the IOM panel as recommending the inclusion of *ella* and other life-ending drugs and devices in a coercive mandate being forced on nearly all Americans, it is indefensible to omit the important fact that the recommendation was, as Dr. Lo Sasso describes, "filtered through a lens of advocacy"—a lens so warped, it would equate destruction of human life with disease prevention.

c. *HHS improperly bypass of the Administrative Procedures Act's (APA) notice-and-comment period requirements.*

The ANPRM announced that it was "*designed to encourage maximum input"* and that HHS "*also intend[ed] to hold listening sessions to ensure all voices are heard.*" This assertion

[55] *Clinical Preventive Services for Women: Closing the Gaps*, INSTITUTE OF MEDICINE (July 19, 2011) at 21.

undermined HHS' earlier determination to bypass the APA's important notice-and-comment requirements in its interim final rule because it had

> *[D]etermined that an additional opportunity for public comment would be impractical and contrary to the public interest.*

The very fact that HHS continues to suggest revisions demonstrates that HHS wrongly rushed the original process and public comment would not have been "contrary to the public interest."

Moreover, in the ANPRM, HHS noted that, in accord with a February 2012 announcement, it had recently held meetings with "religious organizations, insurers, women's groups, insurance experts, and other interested stakeholders." These meetings, the ANPRM stated

> *[B]egan to provide more detailed information on how health coverage arrangements are currently structured, how religious accommodations work in States with contraceptive coverage requirements, and the landscape with respect to religious organizations that offer health benefits today.*

HHS essentially admitted that it did not know what would seem to be crucial details before it issued the coercive HHS mandate. Further, the questions asked in the ANPRM highlighted several other factors that would have been in the public's best interest to comment on and evaluate *before* HHS forced its final rule.

Unfortunately, even after notice and comment on the ANPRM, the now-proposed NPRM continues to suggest only insufficient, untimely solutions.

However, it is not too late for HHS to redress the problems of its coercive, anti-life coverage mandate. AUL implores HHS to provide comprehensive conscience protections for all Americans and to immediately rescind the mandate's inclusion of drugs and devices with known life-ending effects, including the abortion-inducing drug *ella*.

Sincerely,

/s/ Denise M. Burke
Vice President of Legal Affairs
Americans United for Life

/s/ Anna Franzonello
Staff Counsel
Americans United for Life