



SUBMITTED VIA EMAIL

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**Re: file code CMS-9992-IFC2**

To whom it may concern:

Americans United for Life is deeply concerned about the guidelines and regulation concerning preventive services for women that was issued by the Health Resources and Services Administration (HRSA) and the Department of Health and Human Services (HHS) on August 1, 2011.

The HRSA exceeded or abused 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*.

The HRSA mandate, which will coerce the consciences of many Americans by requiring they pay for drugs and devices they have an ethical, moral, or religious objection to, was based on an ideologically-driven recommendation from the Institute of Medicine.

In addition, the “accommodation” for a narrowly-defined set of “religious employers” suggested by HHS fails to protect the conscience rights of many Americans, disrupts conscience protection laws of several states, and violates the principles of longstanding protections in federal law.

This comment addresses both the inappropriate over-reach of the HRSA mandate and the insufficiency of the conscience “accommodation” suggested by HHS.

**1. 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*.**

The statutory language of Section 2713(a)(4), which was added to the Affordable Care Act<sup>1</sup> by amendment on December 3, 2009 and requires private insurance plans to cover certain preventive services, does not require the inclusion of “contraception” as a covered service. Further, statements offered by the amendment’s author as well as statements offered during the Senate floor debate over the addition of Section 2713(a)(4) to the Act demonstrate that the amendment was intended to prevent *diseases*, not to end pregnancies. Specifically, abortion was not intended to be included under the amendment “in any way.” Thus, the legislative history of the amendment suggests that by mandating coverage for “all Food and Drug Administration (FDA) approved contraceptives,” which includes the abortion-inducing drug *ella*, the HRSA abused or exceeded its discretion.

**a. Section 2713(a)(4) of the Affordable Care Act does not explicitly include contraception, and the Senate floor debate over the addition of Section 2713(a)(4) to the Act demonstrates that it the amendment was intended to prevent *diseases*, not to end pregnancies.**

Senator Barbara Mikulsi (D-MD), who offered the amendment which became Section 2713(a)(4) of the Affordable Care Act, issued a press release providing the following description of her amendment:

Services that would be covered under the Mikulski Amendment are likely to include cervical cancer screenings for a broad group of women; annual mammograms for women under 50; pregnancy and

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<sup>1</sup> Pub. L. 111-148 (2010) [hereinafter ACA].

postpartum depression screenings; screenings for domestic violence; and annual women's health screenings, which would include testing for diseases that are leading causes of death for women such as heart disease and diabetes.<sup>2</sup>

In her prepared floor statement, Senator Mikulski again emphasized that her amendment was meant to cover life-saving, disease-preventing services, concluding:

Often health care doesn't cover basic women's health care like mammograms and cervical cancer screenings. My amendment is about saving lives and saving money to give women access to comprehensive preventive services that are affordable and life saving.<sup>3</sup>

Further, during a debate over the amendment on the Senate Floor on December 3, 2009, Senator Mikulski had the following exchange with Senator Robert Casey (D-PA) in which she 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):

Mr. CASEY. There is one clarification I would like to ask the Senator. I know we discussed it during the HELP markup and it was not clarified at that time and thus I chose to vote against the amendment because of the possibility that it might be construed so broadly as to cover abortion. But I understand that the Senator has now clarified specifically that this amendment will not cover abortion in any way. Specifically, abortion has never been defined as a preventive service and there is neither legislative intent nor the language in this amendment to cover abortion as a preventive service or to mandate abortion coverage in any way. I ask the Senator is that correct?

Ms. MIKULSKI. Yes, that is correct. This amendment does not cover abortion. Abortion has never been defined as a preventive

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<sup>2</sup> Press Release, Senator Barbara Mikulski, Mikulski Puts Women First in Health Care Debate (November 30, 2009), *available at* <http://mikulski.senate.gov/media/record.cfm?id=320304> (*last visited* Sept. 20, 2011).

<sup>3</sup> *Id.*

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.<sup>4</sup>

First, pregnancy is not a disease and it is, thus, illogical to include elective contraceptive-coverage through an amendment “strictly concerned” with preventing diseases. Moreover, it is directly contrary to Senator Mikulski’s assurance that abortion would not be covered “in any way” to include abortion-inducing drugs, such as *ella*, in preventive care and screenings.

**b. Contrary to the stated intent of Section 2713(a)(4), HRSA’s mandated coverage for the “all FDA-approved contraceptives” inappropriately includes drugs and devices with known life-ending mechanisms of action, including the abortion-inducing drug *ella*.**

The guidelines issued by the HRSA mandating coverage for contraceptives clarifies that its definition is broad: “All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.” Such a definition includes drugs and devices with known life-ending mechanisms of action, including the abortion-inducing drug *ella*.

Like the abortion drug RU-486, Ulipristal Acetate (*ella*) is a selective progesterone receptor modulator (SPRM). Despite its “indication” for use as “emergency contraception,” *ella* – like RU-486 – can induce an abortion.<sup>5</sup> This is because an

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<sup>4</sup> Cong. Rec. S12274 (daily ed. Dec. 3, 2009) (colloquy between Sen. Mikulski and Sen. Casey), available at <http://thomas.loc.gov>. On December 1, 2009, Senator Mikulski stated: “There are no abortion services included in the Mikulski amendment. It is screening for diseases that are the biggest killers for women – the silent killers of women. It also provides family planning – but family planning as recognized by other acts.” Cong. Rec. S12028 (daily ed. Dec. 1, 2009) (statement of Senator Mikulski), available at <http://thomas.loc.gov>.

<sup>5</sup> “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).

SPRM “works” by blocking progesterone, a hormone that is necessary for pregnancy.<sup>6</sup> By blocking progesterone, *ella* can kill a human embryo even after implantation.

Studies confirm that *ella* is harmful to an embryo.<sup>7</sup> The FDA’s own labeling notes that *ella* may “affect implantation,”<sup>8</sup> and contraindicates (or advises 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 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.<sup>9</sup>

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<sup>6</sup> 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](http://www.plannedparenthood.org/ppaz/images/Arizona/web-AB_by_Pill_E(1).pdf) (last visited Sept. 1, 2011). (“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.”)

<sup>7</sup> 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](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf) (last visited Sept. 27, 2011). See also *ella* Labeling Information (Aug. 13, 2010), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s0001bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s0001bl.pdf) (last visited Sept. 27, 2011).

<sup>8</sup> *ella* Labeling Information (Aug. 13, 2010), available at [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022474s0001bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s0001bl.pdf) (last visited Sept. 27, 2011).

<sup>9</sup> 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 Sept. 26, 2011). “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. ...” “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

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.<sup>10</sup> Intrauterine Devices (IUDs) are also acknowledged to work not only by preventing conception, but by blocking implantation.<sup>11</sup> Other hormonal contraceptives are also argued to change the endometrial lining making a woman’s uterus “hostile” for the implantation of a human embryo.<sup>12</sup> The more “effective” a contraceptive drug or device is generally coincides with a mechanism of action other than preventing conception.

Notably, *ella*’s deadliness goes beyond that of any other “contraceptive” approved 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<sup>13</sup>; the FDA-approved “contraceptive” *ella* can work by ending an “established” pregnancy.

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individual women included. So it is very hard to comment on where those women actually were.”

<sup>10</sup> Plan B Approved Labeling, *available at*

[http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2006/021045s011\\_Plan\\_B\\_PRNTLBL.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf) (last visited Sept. 27, 2011). The FDA’s labeling acknowledges that Plan B can prevent implantation of a human embryo.

<sup>11</sup> See <http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf> (last visited Sept. 27, 2011). 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.”

<sup>12</sup> See e.g. Frye, *An Overview of oral contraceptives: Mechanisms of action and clinical use*, 66 *Neurology* S29 (2006). “[C]hanges in the endometrium may affect survival of a blastocyst within the uterus or prevent implantation.” See also Larimore & Sanford, *Postfertilization Effects of Oral Contraceptives and Their Relationship to Informed Consent*, 9 *ARCH FAM MED.* 126 (2000). Citing the Food and Drug Administration “approved product information” for oral contraceptives in the Physician’s Desk Reference, “Although the primary mechanism of action is inhibition of ovulation, other alterations include changes in the cervical mucus, which increase the difficulty of sperm entry into the uterus, and changes in the endometrium, which reduce the likelihood of implantation.”

<sup>13</sup> For an overview of the “changed” definition of pregnancy, see Christopher Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, FRC

Though “indicated” for contraceptive use, mandated coverage for *ella* opens the door to off-label 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 not precedent for its inclusion even in government healthcare programs. Only approved by the FDA in August 2010, there can be no reliance argument made on a history of taxpayer-funding for the abortion-inducing drug *ella* through government programs that cover other contraceptives.

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

The Institute of Medicine (IOM), 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.<sup>14</sup>

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INSIGHT PAPER (April 2009), *available at* <http://www.frc.org/life--bioethics> (last visited Sept. 1, 2011).

<sup>14</sup> 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](http://www.nap.edu/catalog.php?record_id=13181) (last visited Aug. 1, 2011).

Several members of the IOM panel have direct ties to Planned Parenthood, the nation's largest abortion provider,<sup>15</sup> which stands to gain financially from the IOM recommendation, as well as other openly pro-abortion organizations.<sup>16</sup>

A look at the organizations invited to present at the IOM's three public meetings on the preventive services mandate underscore its advocacy-based bias.<sup>17</sup>

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.

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<sup>15</sup> 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 Sept. 27, 2011); 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](http://www4.uwm.edu/secu/news_events/sph-dean/Peck-cv.pdf) (last visited Sept. 27, 2011); Dr. Carol Weisman served as a member of the Affiliate Medical 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](http://www.pennstatehershey.org/c/document_library/get_file?folderId=229089&name=DLFE-25907.pdf) (last visited Sept. 27, 2011).

<sup>16</sup> 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](http://orwh.od.nih.gov/about/Garcia%20(updated%202-18-10)--edited%20clean%20copy.pdf) (last visited Sept. 27, 2011); 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 Sept. 27, 2011); 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 Sept. 27, 2011). 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 Sept. 27, 2011); 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 Sept. 27, 2011); and 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 Sept. 27, 2011).

<sup>17</sup>The IOM meeting information and agendas are available at <http://iom.edu/Activities/Women/PreventiveServicesWomen.aspx> (last visited Sept. 27, 2011).

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.”<sup>18</sup> 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.”<sup>19</sup>

Thus, it is unsurprising with an ideologically-stacked deck, that nearly every invited presenter urged the inclusion of *all FDA-approved contraceptives* in the mandate, without addressing any conscience concerns for Americans who oppose drugs and devices with life-ending mechanisms of action.

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 ACA.”<sup>20</sup>

## **2. HHS’ proffered conscience “accommodation” for a narrowly defined set of “religious employers” is inadequate.**

The HHS regulation’s proposed exemption fails to protect the serious and legitimate conscience concerns of many Americans. Instead, it disrupts the conscience protections contained in the laws of several states. The narrowly defined “accommodation” has no precedent in federal law; rather, a mandate including sterilization and abortion-inducing drugs violates the principles of long-standing federal laws protecting conscience rights.

### **a. The conscience exemption adopted by HHS fails to protect the conscience of many Americans**

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<sup>18</sup> National Women’s Law Center, *Our Issues, Abortion*, available at <http://www.nwlc.org/our-issues/health-care-%2526-reproductive-rights/abortion> (last visited Sept. 27, 2011).

<sup>19</sup> Guttmacher Institute, *Mission*, available at <http://www.guttmacher.org/about/mission.html> (last visited Sept. 27, 2011).

<sup>20</sup> *Clinical Preventive Services for Women: Closing the Gaps*, INSTITUTE OF MEDICINE (July 19, 2011) at 21.

HHS has suggested a limited exception to the HRSA mandate, exempting a narrowly defined category of “religious employers.” However, by adopting such a narrow definition, most religiously-affiliated schools, hospitals, and charitable organizations would not be included in the exception’s protection. Moreover, non-religiously affiliated institutions – whose pro-life consciences are nonetheless violated by the mandate – are unquestionably left unprotected by the limited conscience protection.

**b. The guidelines and regulation issued by HRSA and HHS disrupt 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 requirement to insurance plans that offer prescription coverage. (Therefore allowing an employer the option, albeit a difficult choice, to drop prescription coverage altogether.) In addition, multiple states explicitly exclude certain specific FDA-labeled “contraceptives” from its mandate. Moreover, many states with religious employer exemptions adopt a more expansive definition than that provided for by the HHS regulation. Thus, the guidelines and regulation issued by the HRSA and HHS extend beyond any coercive measure enacted by the states. Further, the mandate stands in direct opposition to the duly enacted law of Mississippi which protects the conscience rights of healthcare payers. Thus, the HRSA mandate and narrow HHS “accommodation” supplants the reasoned judgment of the states with an ideologically-driven coercive measure.

The state of Mississippi has chosen to statutorily protect the conscience rights of its healthcare payers. The Mississippi law is comprehensive, and its right to decline to pay applies to any healthcare service that violates the payer’s conscience, “A health-care payer has the right to decline to pay, and no health-care payer shall be required to pay for or arrange for the payment of a health-care service that violates its conscience.”<sup>21</sup> The mandate imposed by HRSA stands in direct opposition to Mississippi’s duly enacted law.

HHS is correct that the vast majority of states that have enacted contraceptive coverage laws contain an exemption for religious employers. However, many of these states define “religious employer” more broadly than HHS, and thus the mandate and regulations would trump their state protections as well. For example,

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<sup>21</sup> Miss. Code Ann. § 41-107-9 (2004).

Nevada law exempts insurers “affiliated with a religious organization,”<sup>22</sup> while Missouri exempts *anyone* (not limited to religious employers) with a “moral, ethical, or religious” conscientious objection<sup>23</sup> and *any* health carrier “owned, operated, or controlled ... by an entity that is operated pursuant to moral, ethical or religious tenets...”<sup>24</sup> Missouri’s reasoned judgment to protect the conscience rights all its citizens would be eviscerated by the HHS rule.

Moreover, in the states that have adopted the narrow definition of religious employer proposed by HHS, their contraceptive mandates only apply to plans that offer prescription coverage. That means that employers still have the choice (admittedly a tough decision) to not offer prescription coverage. In contrast, the HRSA guidelines apply to nearly *all* insurance plans and the Affordable Care Act does not offer many organizations and individuals (without a penalty) a similar escape from its coercive measure. Even currently “grandfathered” plans will be subjected to the mandate if any number of changes is made to their plans.<sup>25</sup>

In addition, 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, Arkansas clearly excludes from its mandate so-called “emergency contraception”: “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.**”<sup>26</sup> North Carolina likewise excludes emergency contraception,<sup>27</sup> while Texas’ law 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. Georgia law, for example, states, “Likewise, nothing contained in this Code section shall be construed to require any insurance company to provide coverage

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<sup>22</sup> Nev. Rev. Stat. § 689A.047 (1999).

<sup>23</sup> Mo. Rev. Stat. § 376.1199 (2001).

<sup>24</sup> *Id.*

<sup>25</sup> See <http://www.ncsl.org/documents/health/GrandfatheredPlans.pdf>. (*last visited* Sept. 27, 2011). It is estimated that anywhere from 20 to 51 percent of small employer plans and 23 to 66 percent of large employer plans will retain their “grandfather” status by 2013. See [http://www.healthreform.gov/newsroom/keeping\\_the\\_health\\_plan\\_you\\_have.html](http://www.healthreform.gov/newsroom/keeping_the_health_plan_you_have.html).

<sup>26</sup> Ark. Stat. Ann. §23-79-1103-1104 (2005).

<sup>27</sup> N.C. Gen. Stat. § 58-3-178 (1999). The law excludes “The prescription drug marketed under the name “Preven” or any “equivalent drug product” as defined in G.S. 90-85.27(1).”

for abortion.”<sup>28</sup> Maine’s law states that the mandate “may not apply to prescriptions designed to terminate a pregnancy.”<sup>29</sup> Rhode Island’s law includes, “[p]rovided, that nothing in this subsection shall be deemed to mandate or require coverage for the prescription drug RU 486.”<sup>30</sup> Keeping in mind that these laws, explicitly excluding the abortion drug RU-486, pre-date the approval of a substantially similar drug, *ella*, the HRSA/HHS mandated coverage preempt the principles, if not the letter, of these laws.

In addition, while the HRSA guidelines require inclusion of sterilization as a covered service, the Illinois’ contraceptive mandate states, “Nothing in this Section shall be construed to require an insurance company to cover services related to permanent sterilization that requires a surgical procedure.”<sup>31</sup>

Contrary to the HHS regulation’s insinuation that its “accommodation” draws it in line with the majority of states, the HRSA and HHS guidelines and regulation are a nation-wide evisceration of existing state laws.

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

The Affordable Care Act, states explicitly that “Nothing in this Act shall be construed to have any effect on Federal laws regarding – (i) conscience protection...”<sup>32</sup> 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 the *Roe v. Wade* case.<sup>33</sup> In 1973, Congress passed the first of the Church Amendments (named for its sponsor, Senator Frank Church).<sup>34</sup> 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

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<sup>28</sup> Ga. Code § 33-24-59.6 (1999).

<sup>29</sup> Me. Rev. Stat. Ann. Tit. 24 §2332-J (1999).

<sup>30</sup> R.I. Gen. Laws § 27-18-57 (2000).

<sup>31</sup> Ill. Rev. Stat. ch. 215 § 5/356z.4 (2003).

<sup>32</sup> ACA §1303(c)(2)(A)(i).

<sup>33</sup> 410 U.S. 113 (1973).

<sup>34</sup> 42 U.S.C. 3001-7.

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 objection, because of religious belief or moral conviction, 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.<sup>35</sup>

In contrast to the principles of these federal laws which recognize a right not to be coerced into participating in abortion, sterilization, and other services “contrary to his religious or moral convictions,” the HRSA mandate leaves most Americans no option but to be on an insurance plan that covers the abortion-inducing drug *ella*, sterilization, and other “contraceptive” items and services to which he or she may have a sincerely held ethical, moral, or religious objection. The HRSA mandate is not a question of taxpayer-funding, but applies to all health insurance plans.

## **Conclusion**

On September 9, 2009, President Obama addressed a joint session of Congress to outline his vision for a healthcare bill, and to clear up any “misunderstandings” about existing proposals.<sup>36</sup> Of particular note the President asserted, “And one

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<sup>35</sup> Consolidated Appropriations Act 2008, Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).

<sup>36</sup> President Obama’s address in its entirety, President Barack Obama, *Remarks by the President to a Joint Session of Congress on Health Care*, September 9, 2009, available at [www.whitehouse.gov/the\\_press\\_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care/](http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-to-a-Joint-Session-of-Congress-on-Health-Care/).

more misunderstanding I want to clear up—under our plan, no federal dollars will be used to fund abortions, and federal conscience laws will remain in place.”<sup>37</sup>

Unfortunately, the HRSA guidelines and HHS regulation concerning preventive services fly in the face of the President’s assurance, as well as the very words of the Affordable Care Act and its legislative history.

It is not a tiny minority that stands in opposition to the HRSA mandate. In fact, more Americans oppose the mandate than support it. According to a Rasmussen poll, 46 percent oppose forcing “contraceptive” coverage, while only 39 percent approve.<sup>38</sup> Nor is this an issue of women versus men. Women’s opinion, according to the Rasmussen poll, was nearly evenly split. Only 40 percent of women approve, while 42 percent of women oppose the mandate. Even these numbers fail to tell the entire story, considering Rasmussen did not mention that abortion-inducing drugs and devices, such as *ella*, are included in mandate.<sup>39</sup>

In accord with the language and history of the Affordable Care Act and the weight of public opinion, Americans United for Life implores HHS to repeal the HRSA guidelines mandating coverage for all FDA approved contraceptives and sterilization.

The damage done by the mandate will be hard to counteract once the insurance market stops accommodating conscience rights. Thus, immediate action on the part of HHS is necessary to address the inappropriate HRSA mandate.

Sincerely,

/s/ Anna Franzonello  
Staff Counsel  
Americans United for Life

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<sup>37</sup> *Id.*

<sup>38</sup> See *39% Say Health Insurance Companies Should Be Required to Cover Contraceptives*, RASMUSSEN 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](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* Sept. 27, 2011).

<sup>39</sup> *Id.* Rather, the question posed 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?”