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Centers for Medicare and Medicaid Services
Department of Health & Human Services
ATTN: CMS-9940--P
PO Box 8010
Baltimore, MD 21244-1850

SUBJECT: File Code CMS-9940-P
Comments on Proposed Regulations at 45 CFR Parts 147, 148, and 156
RIN 0938-ARS-50
Coverage of Certain Preventative Services under the Affordable Care Act

Dear people,

Our organization is composed of lawyers and of people interested in legal issues, especially those affecting the life issues of abortion, choice, sterilization, informed consent, medical ethics, and right to life. We are filing the following comments as allowed for in the Federal Register on the Regulations referenced above in the "Subject" line. These are due by October 21, 2014 in your offices. We are sending these by regular mail, with a postage label of when they were sent.

These comments pertain to the Administrative Regulations which have been proposed following the Burwell vs. Hobby Lobby case, the decision issued by the U.S. Supreme Court on June 30, 2014. That case was precipitated by the Regulations proposed in File Code CMS-9968-P, Proposed Regulations at 45 CFR Parts 147, 148, and 156, RIN 0938-AR42. Those regulations, despite the many comments that were filed, had failed to protect the rights of many individuals and entities who objected to any involvement in the so-called Contraceptive Mandate which provided coverage of Certain Preventative Services under the Affordable Care Act.

We did file comments in that proceeding and also proposed a general regulation which if it had been adopted would have eliminated much of the legal wrangling that has consumed so

much time, resources, judicial assets, and money. Hopefully, there will be more openness by all now to our recommendations.

Our Comments will have Seven Parts: 1. Introduction; 2. Some Background on Medical Ethics and Law; 3. Some Background on Principles of Religious Freedom in America; 4. General Comments; 5. Specific Comments; 6. Our Proposal; and 7. Conclusion.

We will begin with some Background.

PART ONE: INTRODUCTION

Initially the Federal Government and your Departments had provided a very limited exemption of certain religious organizations from being forced to comply with the law in providing through medical insurance plans certain services which they found directly contradicted their strongly held religious doctrines, dogmas, and beliefs.

These services had been lumped under the category of "contraceptive services." This is actually a misleading designation and misnomer. These services are described as "All FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity…" (From Explanation of terms, Paragraph B in Section III, Provisions of the Proposed Rules from File Code CMS-9968-P, Regulations at 45 CFR Parts 147, 148, and 156, RIN 0938-AR42.) Comment: Note how "contraceptive methods" is mixed with sterilization. This may cause confusion. Also "contraceptive methods" includes far more than "contraception" as explained below. Again this can be confusing.

Thus the term "Contraceptive coverage" depends upon what has been approved by the FDA. (Does this embrace future items that will be approved by the FDA? None of the proposed regulations answer this.) This includes various means which do have a contraceptive effect. Some religious groups object to being forced to provide this alone. There are, moreover, various contraceptive methods which also can be abortifacient, meaning they bring about early abortions of newly formed human beings. These can operate in ways of directly attacking this new human life and killing this life, or of indirectly attacking this new human life.

"Contraceptive" should be understood as meaning these devices and pills that prevent the human sperm from penetrating the human egg in a process of conception. If there is no conception, the pill or other device has worked "contra" to conception. Since no human being has been conceived or begun, there is no abortion or killing of a new human life.

But a number of the pills and other devices approved by the FDA reportedly have other effects beyond "contraceptive." The term has been used of "abortfacient," meaning that the pill or other device works on and attacks the newly conceived human life and ends that life.

Thus the same pill or device can have both contraceptive effects and abortion effects.

Also these pills and devices can carry out the killing of these new human lives by making the womb unreceptive to implantation of the new human life. This is equivalent to an abortion. Besides the fact that artificial contraception can have very serious side effects for the

women using these, in many cases these prevent "nidation," bringing about what some doctors call a micro-abortion when the tiny human being is sloughed-off, and perishes.

The initial regulations published by the Federal government and your Departments exempted some religious groups, such as churches themselves, from having to provide such services in their health insurance coverage which services directly contradicted the strongly held religious principles of these churches.

Many individuals and groups criticized this overly restrictive exemption policy because while some religious organizations would be exempt, the exemption did not cover other religiously based groups—especially religious groups providing extensive social and medical services to the general public or those engaged in various educational activities. The exemption was not extensive enough to cover them. These religiously-based organizations who had strong religious positions would be forced into participating in and providing such medical coverage for these alleged "preventative services" which violated their religious positions.

In response the Federal government and your Departments did broaden the exemption in these proposed rules. While this was a welcome step forward by the Federal government and your Departments, this still was not adequate to protect our nation's long-held commitments to religious freedom and freedom of conscience. There were still organizations and entities who were being forced to participate in activities contrary to their religious principles.

In our previously filed comments, we urged that there should be a broad-based exemption not only for all non-profit groups objecting to the Mandate but all profit-making groups as well. In our view, religious beliefs and practices trump dollar bills. So we in our prior comments asked what about entities that are not non-profit? We understood that the proposed rules would not allow these entities any kind of exemption. Why was this "line in the sand" drawn? What distinguishes non-profit groups from profit-making entities in relation to a commitment to religious principles? How do profit-making entities differ from non-profit entities? Are profit-making groups not allowed to also adhere to religious views, doctrines, and principles? This appears to be a discrimination that is unfair, unwarranted, illegal, and unconstitutional.

But your agency seemingly disregarded our questions and our comments. Regulations were approved that were not broad enough in protecting the religious rights and liberties of various profit-making entities.

It turned out, however, that our previously filed comments and regulations had some validity.

On June 30, 2014, our Supreme Court ruled 5 to 4 in favor of the owners Green Family and their company Hobby Lobby in a historic victory for religious liberty. (Burwell v. Hobby Lobby, 523 U.S.____, 2014.) Hobby Lobby cannot be discriminated against in asserting their rights to freedom of religion. Here is some of the Court's reasoning. It begins with the requirement of accommodation contained in RFRA which recalls some of the accommodation ideas of Title VII in the Civil Rights Act for employment to protect the religious and other rights of employees in the work place.

Under RFRA, a Government action that imposes a substantial burden on religious exercise must serve a compelling government interest, and we assume that the HHS regulations satisfy this requirement. But in order for the HHS mandate to be sustained, it must also constitute the least restrictive means of serving that interest, and the mandate plainly fails that test. There are other ways in which Congress or HHS could equally ensure that every woman has cost-free access to the particular contraceptives at issue here and, indeed, to all FDA-approved contraceptives. (Page 8 of Hobby Lobby decision.)

The Court declared that the profit-making status of Hobby Lobby did not invalidate their protection under RFRA and that the corporation as "a person" under our laws could claim rights under RFRA. While promoting public health care is "a compelling government interest," The Affordable Health Care must employ the "least restrictive means" for implementing this interest. The Court found that the HHS Contraceptive Mandate failed to do this.

HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. As we explained above, HHS has already established an accommodation for nonprofit organizations with religious objections. See *supra*, at 9–10, and nn. 8–9. Under that accommodation, the organization can self-certify that it opposes providing coverage for particular contraceptive services. See 45 CFR §§147.131(b)(4), (c)(1); 26 CFR §§54.9815–2713A(a)(4), (b). If the organization makes such a certification, the organization's insurance issuer or third-party administrator must "[e]xpressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan" and "[p]rovide separate payments for any contraceptive services required to be covered" without imposing "any cost-sharing requirements . . . on the eligible organization, the group health plan, or plan participants or beneficiaries." (Page 49 of Hobby Lobby decision.)

The Supreme Court thus upheld the right of Hobby Lobby to assert their religious principles and not be forced to provide contraceptive services violating their religious convictions. HHS cannot deny these organizations, even though they are profit-making, the legal protection afforded by RFRA. The Government must look for other means to provide such services and cannot force these companies to take part in providing that which contravenes their basic religious principles.

Your agency is now proposing new regulations which are intended to implement the Supreme Court's Hobby Lobby decision. (Comment: Again we hope that the Hobby Lobby holdings will be fully implemented. But we are concerned. While we will explain these concerns more fully below, let us point out that you are proposing rules which seem to follow Hobby Lobby, but in our view violate that decision's intent, spirit, and holdings.)

Before we present our GENERAL COMMENTS and our SPECIFIC COMMENTS on the newly proposed regulations, we would like to again review (as we did in our Comments filed before) some materials on the ethical, medical, and historical aspects of these issues. These should assist your agency in drafting proper, appropriate, and just regulations on these issues. We review these ethical and medical issues in PART TWO below. It also is beneficial to review various aspects of religious freedom, the Constitution, and our history as well as some case law. This is presented in PART THREE below. PART FOUR and PART FIVE provide our general comments and our specific comments on the proposed regulations. Our Coalition then has a comprehensive proposal that would resolve these issues which we submit at PART SIX below, including our rationale for this proposal and its advantages.

PART TWO: SOME BACKGROUND ON MEDICAL ETHICS AND LAW

This topic has a vast literature and has occupied the time of many great thinkers and medical personnel. We cannot naturally cover all of this. However, we would like to provide two very important medical items which are very pertinent to the proposed regulations. The first is the more than two-thousand-year-old Hippocratic oath which doctors as well as medical personnel have generally followed in their practices. The second is the basic principle applicable to physicians as well as all medical personnel urging them to "Do No Harm" in their practices. These principles, of course, apply to medical institutions, hospitals, and others involved in providing medical care. This would also seem to cover medical insurance providers.

The first item we present is the Hippocratic Oath. This was initially formulated in Ancient Greece, amazingly enough in societies where such evils as slavery and infanticide were commonly practiced. Unwanted babies as well as babies born with various defects were exposed in the wild elements and perished. Wars were waged to capture vulnerable peoples who would then become the slaves for their conquerors. In societies where such evil practices flourished, it is amazing that the Hippocratic Oath with its commitment to respecting all human life could be born and take root.

Here is one translation of pertinent parts from the Hippocratic Oath:

"I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art. I will not cut persons laboring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females or males, of freemen and slaves."

This Oath has been one of the most important fundamentals of medical ethics throughout the centuries. Its teachings on abortion are quite clear. The doctor is not to perform these.

While not harming the patient is implicit in the Oath, this section does not explicitly make "doing no harm" the first concern of the Hippocratic physician. The Hippocratic writing *Epidemics* is considered the more likely source for the direct statement on this:

With regard to the dangers of these cases, one must always attend to the seasonable concoction of all the evacuations, and to the favorable and critical abscesses. The concoctions indicate a speedy crisis and recovery of health; crude and undigested evacuations, and those which are converted into bad abscesses, indicate either want of crisis, or pains, or prolongation of the disease, or death, or relapses; which of these it is to be must be determined from other circumstances. The physician must be able to tell the antecedents, know the present, and foretell the future - must mediate these things, and have two special objects in view with regard to disease, namely, **to do good or to do no harm.** The art consists in three things - the disease, the patient, and the physician. The physician is the servant of the art, and the patient must combat the disease along with the physician.

Embedded in this "do no harm" principle as well as in the Hippocratic Oath is that each human being—notice "freemen and slaves" are included—has a value and worth that is not dependent upon the whims and wishes of others. A patient is immeasurably valuable in and of himself and herself.

A good summary of all of this medical background is contained in the Book, "The Battle for America's Soul, Healthcare, the Culture War, and the Future of Freedom" by C.L. Gray, MD, at pages 34 to 36.

Born in 460 B.C., Hippocrates of Cos rapidly rose to assume the honor of the most famous member of the Asclepiads, the family of physicians revered since the Trojan War. Both Plato and Aristotle wrote of Hippocrates with great respect. This Father of Medicine's contributions have lasted nearly two and a half millennia. Hippocrates steered the focus of the physician toward the afflicted patient. He also paved the way for the scientific method in medicine emphasizing observation, attention to detail, and treatment based on these findings.

Hippocrates' greatest contribution to western civilization set a patient-centered standard for medical ethics. Though some historians argue that Hippocrates did not write much of the Hippocratic Corpus himself, none debates its profound impact. Hippocratic medicine emphasized several concepts, however, the "greater good" of society held no place in Hippocratic thought. The physician's commitment to the well-being of the individual patient formed the central theme of Hippocratic medicine:

1. " Primum non nocere-First, do no harm." This powerful statement served as the bedrock of Hippocratic medical ethic. Though written nearly 2,500 years ago, "First do no harm" concisely articulates the American expectation of modern medicine.
2. "The physician sees terrible things, touches what is loathsome, and from others' misfortunes harvests troubles of his own." Quoting Hippocrates, twentieth century historian Oswei Temkin recalled the lifelong commitment of a physician to the Patients; highest good even at considerable personal expense.
3. "For if love of men is present, love of the art is also present." Quoting Hippocrates. Temkin wrote of the Hippocratic physician's love for the patient.
4. "I will not give poison to anyone asked to do so, nor will I suggest such a plan. Similarly I will not give a pessary to a woman to cause abortion. But in purity and in holiness I will guard my life and my art." The Hippocratic Oath itself memorialized the sanctity of life from conception to natural death. Ancient medicine struggled with the lack of adequate treatment for severe pain. Some patients who preferred voluntary death to ongoing agony requested that physicians provide medications to commit suicide. In this context "I will not give poison to anyone thought asked to do so" gives insight into Hippocrates' underlying philosophy. Even when faced with a patient's uncontrolled pain, Hippocrates refused to participate in physician-assisted suicide.
5. "In name there are many doctors, but in fact there are a very few." Again quoting Hippocrates, Temkin noted the rarity of the truly excellent physician.
6. Ludwig Edelstein quoted the ancient Greek physician and anatomical scholar, Erasistratus, to demonstrate the high moral calling of the physician:

   Most fortunate indeed, wherever it happens that the physician is both, perfect in his art and most excellent in his moral conduct. But if one of the two should have to be missing, then it is better to be a good man devoid of learning than to be a perfect practitioner of bad moral conduct, and an untrustworthy man--if indeed it is true that good morals compensate for what is missing in art, while bad morals can corrupt and confound even perfect art."

7. Temkin describe how Hippocrates distanced the practice of medicine from monetary reimbursement:

   He values his reputation, and he claims a right to his fee.

   But whenever the need arises, his concern for the fee must yield to consideration for the patient's welfare. He does not worry his sick patients by arguing about his fee; he considers their circumstances and their means, and even assists aliens who lack resources. Nor is he so hardened as to refuse help to recalcitrant patients.

Not only did these new standards set the Hippocratic physician apart in the ancient world, they framed the bedrock of modern medicine in America.

These medical principles also find their expression in our legal principles. Our own Declaration of Independence demonstrates this when it declares:

We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness.--That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed….

Thus, for example, the right to life of each of us begins at the moment of creation by the Creator. Notice that this right to life comes from "their Creator," not any government Notice, also, that all these rights including life are "inalienable."

Why do we begin with these medical principles and our own Declaration of Independence? Simple. It is important to know these beginnings. These can help us as we sort our way through today's medical, insurance, and medical situations as well as consider the multiple provisions of such legal provisions as Section 2713 of the Public Health Service Act, the Patient Protection and Affordable Health Care Act, proposed regulations on the so-called Contraceptive Mandate, and related legal sections.

Let us next consider some background about religious freedom and the freedom of conscience in our own American history.

PART THREE: SOME BACKGROUND ON PRINCIPLES OF RELIGIOUS FREEDOM IN AMERICA

Here below is an excellent summary about the historical context of religious freedom in America. This Article is entitled "Religion in Colonial America" and was written by Lawanda Brewer, Heather Jaques, Ranada Jones, and Joshua King who were students at the University of North Carolina at Pembroke in 2001:

Many people came to America to search for religious freedom. Their hope was to escape the religious persecution they were facing in their countries. The one thing they did not want to do was to establish a church like the Church of England. The colonists wanted a chance to worship freely and have an opportunity to choose which religion they wanted to take part in. Upon arriving in America (the Pilgrims being the first to arrive in 1620), the journey began for the search of the "perfect" religion that could satisfy the needs of the people.

Many religious groups (such as the Quakers and Puritans) formed the first 13 colonies on the basis of their religious beliefs. Although the plan was to escape persecution, there was actually some amount of persecution happening in the colonies. One example of this persecution would be with the Puritans. The Puritans wanted everyone to worship in the Pur0itan way. In order to ensure that Puritanism dominated the colonies, nonconformists were fined, banished, whipped, and even imprisoned for not conforming to the way of the Puritans. Eventually this persecution was ended and other religions began to appear.

The Anglicans were already established in most of the colonies and were even part of the group of people that were "persecuted" by the Puritans. However, after the dispersement of the Puritans, the number of other religions in the colonies began to increase. Baptists appeared in a majority of the colonies, Roman Catholics and

Protestants organized in Maryland and even some German religions surfaced in a few of the colonies. Later came the Lutherans, who formed in the German communities in Pennsylvania, and the Presbyterians, who even had an appearance in the Massachusetts Proposals of 1705.

Religious diversity had become a dominant part of colonial life. The colonies were a patchwork of religiously diverse communities and, as a result, the population of America increased quickly. People from all over the world wanted the freedom that was found in America and they began to move their homelands to America. Groups such as the Scotch-Irish were among the first to begin that emigration to America. As a result, religious persecution was beginning to diminish and religious freedom began to replace it.

Religion also became a dominant part of American politics. The Cambridge Platform was established in the 1640's. This document was a part of the Puritan theology and adopted the Westminister Confession. Then, in 1649, the Act Concerning Religion was enacted. This act has even been considered one of the greatest additions to the freedom of religion in America. Later political documents included the Massachusetts Proposals and the Adopting Act of 1729. The Bill of Rights added to religious freedom with the First Amendment.

These help us understand our historical beginnings on religious freedom. Here are more helpful materials from Wikipedia located on the internet concerning the "History of Religion in the United States." This also presents some legal background on cases concerning the freedom of religion:

North America as a religious refuge: 17th century

Many of the British North American colonies that eventually formed the United States of America were settled in the 17th century by men and women, who, in the face of European religious persecution, refused to compromise passionately held religious convictions and fled Europe.[2]

The first amendment to the US Constitution states "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof" The two parts, known as the "establishment clause" and the "free exercise clause" respectively, form the textual basis for the Supreme Court's interpretations of the "separation of church and state" doctrine.

On August 15, 1789 Madison said, "he apprehended the meaning of the words to be, that Congress should not establish a religion, and enforce the legal observation of it by law, nor compel men to worship God in any manner contrary to their conscience...."[61]

All states disestablished religion by 1833; Massachusetts was the last state. This ended the practice of allocating taxes to churches.

Supreme Court since 1947

The phrase *"separation of church and state"* became a definitive part of Establishment Clause jurisprudence in *Everson v. Board of Education*, 330 U.S. 1 (1947), a case that dealt with a state law that allowed government funds for transportation to religious schools. While the ruling upheld the state law allowing taxpayer funding of transportation to religious schools as constitutional, *Everson* was also the first case to hold the Establishment Clause applicable to the state legislatures as well as Congress, based upon the due process clause of the Fourteenth Amendment.[62]

In 1962, the Supreme Court extended this analysis to the issue of prayer in public schools. In Engel v. Vitale 370 U.S. 421 (1962), the Court determined it unconstitutional for state officials to compose an official school prayer and require its recitation in public schools, even when it is non-denominational and students may excuse themselves from participation. As such, any teacher, faculty, or student can pray in school, in accordance with their own religion. However, they may not lead such prayers in class, or in other "official" school settings such as assemblies or programs.

Currently, the Supreme Court applies a three-pronged test to determine whether legislation comports with the Establishment Clause, known as the "Lemon Test". First, the legislature must have adopted the law with a neutral or non-religious purpose. Second, the statute's principal or primary effect must be one that neither advances nor inhibits religion. Third, the statute must not result in an excessive entanglement of government with religion.

All of these materials should be helpful for drafting an appropriate set of regulations.

PART FOUR: GENERAL COMMENTS

The following are our general comments on the proposed rule-making.

General Comment 1: We have presented extensive materials to your Agency in our past comments on the ethical, medical, legal, and historical issues involved. We urge you to incorporate these materials into whatever work you do on the regulations. At present, the regulations you are proposing do not adequately incorporate these materials. For example, the Supreme Court has already ruled that closely held non-profits do have rights of religious freedom and liberty to object to the Contraceptive Mandate. This can be based on the RFRA law as well as First Amendment grounds. We urge the agency to review the other materials we have presented above and insure that these guide the authors of these proposed regulations.

General Comment 2: Why are you restricting the exemption from the Contraceptive Mandate to only closely-held profit making companies? Why this emphasis on "closely held"? We find nothing in Hobby Lobby where the Court limited their ruling in that way. In fact, there is a discussion that companies that are not closely held may never get to a point of claiming religious rights because of the diversity and number of their owners and shareholders. But nowhere does the Supreme Court state that the "widely held" companies could not assert their religious rights including under RFRA.

General Comment 3: Also there is the whole problem of defining "closely held." This is more a term of art, rather than logic, law, and science. Suppose one defines a loosely held entity as one having 20 stockholders or less. What about a company that has twenty-one stockholders? Does one additional stockholder destroy the entity's status as a closely-held entity, and thus deprive them forever of asserting and defending their religious freedoms and principles? That does not seem very reasonable, nor even fair and just. Suppose this entity with twenty-one stockholders is kept from being able to gain an exemption because they have more than the allowed twenty. What happens if one of the twenty-one sells all their shares to someone else in the twenty, so that now there are only twenty shareholders? Can this entity now with only twenty shareholders claim the exemption? Such an example shows how questionable is this approach to implementing the Hobby Lobby precedent.

General Comment 4: How do other business entities that are not corporations with shareholders fit into the regulations you are now proposing? We have other business entities such as partnerships. They could have many partners. Can they claim an exemption from the Contraceptive Mandate? Again the newly proposed rules do not seem to cover this.

General Comment 5: If the new rules continue to insist that only closely-held entities are allowed the accommodation and if there are restrictive attempts at defining this term of "closely held," we predict this will only cause more confusion, strife, and further expensive and time-consuming litigation. We are thus proposing in PART SIX below a fairly extensive regulation which will allow any entity to claim the exemption from the Contraceptive Mandate based on

their sincerely held religious views. Our proposal will avoid needless litigation while also fully adhering to the principles and lessons gained from all the ethical, medical, historical, and legal materials we have presented above.

General Comment 6: The term "religious" also should be used in the broad sense, as used for example in the law related to conscientious objectors. We provide some of this below.

The United States has confronted this issue [of conscientious objection to serving in the military in a war] from its founding. Those individuals satisfying certain legal criteria have been labeled conscientious objectors. (Since there is no draft at present in the United States, the following is somewhat academic.) Our present military policy defines conscientious objection as follows: "A firm, fixed, and sincere objection to participation in war in any form or the bearing of arms, by reason of religious training and/or belief." (DOD 1300.6)

This definition has further evolved both by military policy and by court cases and our legal system. For example, "religious" does not mean the individual must belong to a particular religious sect like Jehovah Witnesses, or the Quakers, or Seventh Day Adventists. The "religious" requirement can be satisfied by an individual holding moral and ethical beliefs that have the same force in a person's life as the more normal religious beliefs. Thus an agnostic, or even an atheist, can qualify as a conscientious objector
(This is taken from a forthcoming speech by Attorney Joseph Meissner at LAWASIA Conference in Bangkok in October 2014.)

While Hobby Lobby has a definite religious position, we do not view this as restricting the basis on which others can claim the accommodation. If conscientious objection can be based on closely-held sincere beliefs which may not be based on strict religious dogmas, so should the right of an entity to claim the accommodation from the Contraceptive Mandate be similarly allowed. Thus, for example, an atheist entity should not be precluded from claiming an exemption so long as they have moral and ethical beliefs which are equivalent to the normal religious beliefs held by an entity such as Hobby Lobby.

General Comment 7: The Contraceptive Mandate applies not only to contraceptives and sterilization but also includes "patient education and counseling for all women with reproductive capacity…" What is included in this "patient education and counseling"? Where do these materials come from? Are these objective, scientifically and medically based materials? Do these include any ethical and moral items? Do these materials provide information on the various contraceptive means, including the fact that some of them may operate as abortifacients? Do these materials cover various methods for contraception, which should include natural family planning? It would seem that all the available options should be provided and not just those dependent on a pill or device. Furthermore, especially with any items which are used as "morning after" methods, is there information on how these operate so that women can make informed choices? Furthermore, when explaining that a device or pill may have an abortifacient aspect, do these materials contain information about human development including how a new human life begins at conception? Do these materials refer women to various counseling agencies including those that promote respect for all human life, including the unborn child? We urge your agency to provide answers for these questions as well as opportunities for all to participate in gathering and providing the materials for "patient education and counseling."

These are our General Comments. We now turn to our Specific Comments addressing particular parts of the proposed regulations.

PART FIVE: SPECIFIC COMMENTS

The following specific comments relate to particular sections of the proposed rules. We refer to these by page, column, and location in the column.

Specific Comment 1: (See page 51118, third column): Consider the terms "women's preventive health services," and "certain contraceptive services." These are really misnomers. More is covered under these rubrics than just "prevention" and "contraceptive." A better term is needed which will insure that people understand all that is covered under these terms.

Specific Comment 2: (Page 51118, bottom, third column): This phrase appears: "while respecting certain closely held, for-profit entities religion-based objections to contraceptive coverage…." Already, unfortunately this language is troubling. Why cannot non closely-held entities entertain similar religious-based objections? Is this grounded on some language in the Hobby-Lobby case? Then please cite to that language. Just because an entity is "widely-held" should not take away their rights under the Religious Freedom Restoration Act.

Specific Comment 3: (Page 51119, top of first column): This Proposed regulation is requesting input for any additional steps "that could be taken to provide the full range of FDA-approved contraceptives." Presumably this includes those that are abortifacient. These Regulations should be requesting what "additional steps" should be taken in order to insure that people are aware of the abortifacient effects of some of the FDA-approved contraceptives. Many people may object to these so-called "contraceptives" because they oppose killing other human beings, even those at the first stages of a human being's development. Furthermore, the regulations should also be asking what else can be done to protect the religious freedom and rights of various entities, rather than simply limiting the search to only recommending other means to provide for contraceptive coverage. Finally, the word "full range" is used. Does this include means of contraception based upon natural family planning? Or are only pills and devices included for welcomed input? This is troubling because almost all of the pills and various devices can have serious side-effects and women deserve to be warned of these in advance of using these.

Specific Comment 4: (Page 51120, first column, bottom): There is a discussion of the "definition of a religious employer." There were various criteria at one point in the regulatory history for how someone was required to establish their eligibility as a "religious employer" in order to seek the accommodation and exemption. Thankfully such a rigid approach has been dropped. However, we would urge that it is not necessary to use the term "religious employer." Any employer claiming a right to the accommodation based upon their sincere religious principles should be eligible. This should include employers of all profit-making entities, and not just the closely held entities.

Specific Comment 5: (Page 51121, first column, middle): There is meant to be a summary of the Hobby Lobby case and decision. Unfortunately, this explanation seems to imply that the Supreme Court has only upheld the rights of closely-held entities to claim the exemption and accommodation. We do not read the Court's decision so narrowly. We would

request that the authors of these proposed regulations point out where in the Hobby Lobby decision that accommodation is so limited to only closely-held entities. If this limitation is not in the decision, then the authors of these proposed regulations need to explain rationally and clearly why they are limiting those profit-making entities who can claim the accommodation to only those that are "closely held."

Specific Comment 6: (Page 51121, second column, middle): Again this seeks comments on ways for insuring full contraceptive coverage. But what about seeking comments on how religious freedom and First Amendment rights can be protected for the issue of Contraceptive Coverage? Is there an assumption that some medical coverage is more important than the First Amendment or religious freedom? We are not arguing this issue at this time, but only pointing out perhaps some biases in the proposed regulations. We have also cited extensive historical materials above to demonstrate that in American history and in the establishment of this country our Founders held religious freedom as a paramount value. Some acknowledgement of these might be helpful if they were referred to in these proposed regulations.

Specific Comment 7: (Page 51121, second column, lower middle): Again the agency is limiting the regulations to serving only one purpose, namely, providing contraceptive coverage. Again it seems as though protecting religious freedom is not worthy of consideration in these proposed regulations. Perhaps these regulations would be strengthened if there were references in them to the U.S. Constitution, the First Amendment, and our history, aa well mention of such ethical norms as the Hippocratic Oath and the "Do No Harm" standard.

Specific Comment 8: (Page 51121, third column, top): Here is the fundamental error of these proposed regulations. The agency is limiting those eligible under the Hobby Lobby decision to only "closely held entities." Nowhere in these proposed regulations is this particular restriction rationally and reasonably explained. To repeat what we said earlier: Why are the claims to religious rights and protection under RFRA limited only to closely-held entities? The agency must answer this question before trying to implement the Hobby Lobby decision in relation to the Contraceptive Mandate.

Specific Comment 9: (Page 51122, first and second column): The agency now tries to define "closely held." We have urged that there is an easy way to deal with this problem by regulating that all nonprofits—closely held and "widely held"--can claim an accommodation on the basis of their sincerely-held religious principles. Such a proposal which we outline at PART SIX would avoid all these problems. We also point out that many widely-held profit making entities have all sorts of views on issues from climate change and the environment to race relations and globalization which they promote and support. So why cannot such corporations also have views regarding "Contraceptive Coverage" and religious freedom which they support? Before excluding such corporations from being able to claim an accommodation on Contraceptive Coverage, this agency needs to explain such a constraint.

The proposed regulations discuss two ways of defining "closely held." One relies upon setting the number of stockholders. The other discusses "specified fraction of ownership" interest. Neither of these are even mentioned in the Hobby Lobby decision, let alone endorsed by it. Secondly, there is a discussion about other areas of Federal law which use such ways of defining "closely-held." But what do these have to do with the Contraceptive Mandate and

religious freedom? Are the definitions used elsewhere in Federal Law set up to serve the same goals and functions as are needed here? Remember what happens here is that if an entity claims the accommodation on the basis of its sincerely held religious principles, it will have no protection of its religious freedom if it does not qualify under whatever definition is established by this agency for closely-held entities. In the other areas of Federal law cited in this discussion, it seems like the definition of closely-held pertains to "taxation of real estate investment trusts, passive activity losses, and certain income from foreign entities." Undoubtedly these are important issues, but is the agency really equating these tax issues to the religious rights claimed by those objecting to being forced to support the Contraceptive Mandate which may result in killing innocent human beings at an early stage in human development? If an entity fails to qualify as closely held entities on various tax claims, it may wind up paying some more dollars to support our Federal government. But if an entity fails to qualify as closely held for purposes of the Contraceptive Mandate, it suffers the loss of religious freedom and First Amendment rights. Hopefully this difference between these various situations is apparent enough to call into question deciding what is closely-held by simply referring to other legal areas that use such terminology.

The agency at this time is asking for comments on whether closely held should be defined in terms of number of stockholders or "minimum concentration of ownership." To insure that religious rights and freedoms are fully protected, we endorse the approach of defining closely held in terms of number of stockholders. To insure again that religious freedom is protected, we recommend that the number of shareholders for closely-held entities be set at 999.

Finally, we want to comment on the seeming restriction that the agency is adopting that only entities for which "no active trading market exists" can qualify for the exemption. Where does this restriction appear in the Hobby Lobby case? Why is this restriction even necessary? The agency needs to justify this. Even entities that experience an "active trading market" should not lose their claims to freedom of religion on this basis.

Specific Comment 10: (Page 51122, second column, middle): The agency is asking for comments taking into account various factors which include "the experience regarding accommodations of religion and religious beliefs in various contexts and the rationales for the scope and operations of such accommodations." We have already pointed out the context of conscientious objection in national defense matters. Here the CO accommodation is allowed to all and religion is broadly defined to include more than just religious sects or religious dogmas. Even an atheist can be a CO. So too, here, the accommodation should be broadly and widely available.

Another area of religious accommodation occurs in the work place. For claims under Title VII of the Civil Rights Act of 1964, religion is pertinent and employers are required to make accommodations for the religious beliefs and practices of their employees as well as applicants for jobs at the employer's company. Here, too, the protection available under Title VII is very broad in order to protect claimants' religious freedoms. This should also apply in the area of the Contraceptive Mandate.

Finally, while the agency at least is seeking comments related to religion, this still is not a broad enough recognition of religion and religious freedom on this issue. It is not just an "accommodation" which is being made to some entity raising some kind of nuisance claim. Entries should not be required by their government to participate in activities which they consider to violate fundamental principles and beliefs of theirs. The agency should not only

consider how Contraceptive coverage is provided, but also how the agency is insuring that religious freedom and First Amendment rights are being protected by these proposed rules.

Specific Comment 11: (Page 51122, third column, top): Here the proposed regulations discuss the need to validate the actions by an entity in seeking an accommodation and whether these accord with an entity's governing rules or pertinent State laws. We hope this does not mean the agency will be interfering in the internal processes, governing structure, and internal operations of an entity. While the agency may want to insure that an entity's pronouncements are the actual pronouncements of that entity, we suggest that self-certification should be used to validate an entity's decision in seeking an accommodation from the Contraceptive Mandate. This should be the only documentation requested and needed.

Specific Comment 12: (Page 51123, second column, lower half): Here the agency discusses all the reasons allegedly why contraception coverage is necessary. For example, women who experience an unintended pregnancy may not be motivated to discontinue certain habits such as smoking or consuming alcohol. What is the comprehensive basis for proving such a statement? Also supposedly babies born from an unintended pregnancy may have lower than normal birth weights. Again what is the basis for this? One or two citations hardly seem like an adequate basis. It may turn out that other factors account for this, including the financial status and poverty of the mother, the lack of adequate income, lack of sufficient diets, and the lack of available medical facilities.

Finally, the following statement "there are significant cost savings to employers from the coverage of contraceptives" deserves some comment. " What is being compared? Is this the costs for having a baby? The cost of taking care of the elderly also is more costly if the elderly continue living than if we find some way to interrupt their lives like contraceptives interrupt the onset of a pregnancy. But more to the point, what kind of cost-benefit analysis is being presented here? The agency needs to explain this statement in order to avoid confusion and misinterpretation about the ultimate goals of the Affordable Health Care Act.

Specific Comment 13: (Page 51125): This page carries a discussion of the number of entities which may seek this new accommodation based on the Hobby Lobby case. The number given is 71 entities may seek this accommodation. It is not apparent why any such number is needed. Also hopefully this is not intended as some kind of limit on how many entities may apply for this accomm0dation.

This completes for now the specific objections and comments we have for the newly proposed regulations.

PART SIX: OUR PROPOSAL FOR CONTRACEPTIVE COVERAGE

We have provided some background on medical ethics and some background on the historic and legal developments concerning religious liberty in America. How should these be applied in this current situation? What kind of proposal should our country and your Departments construct for "contraceptive coverage" and an administrative mandate for "contraceptive coverage" ? What are the essential elements for regulations which will preserve

the time-honored medical ethical principles and remain true to our own historical principles of freedom of religion and freedom of conscience?

Here are some of the essential guidelines for fitting regulations.

First, no proposal should require anyone—including medical personnel, medical institutions, religious institutions of any kind, any medical health insurers, any medical health plans, and any entity including both non-profit and profit-making—to participate in any activities that relate to abortion, cause abortions, or lead to abortions contrary to their principles and doctrines. This includes both small sized closely-held profit-making companies, medium size profit-making companies, and large profit-making companies, including those with many, many stockholders. It also includes profit-making companies whether these are individuals, or partnerships, or corporations as well as any other businesses.

It is not just a question of providing money or being taxed to support these activities. All of these people and entities should not be required to be involved in abortifacient activities in any way. This guideline emerges from the medical ethical principles and the Hippocratic Oath presented above.

Second, no entity and no individual should be forced to be involved in any way in contraceptive activities that violate their fundamental principles. This particularly would relate to any organization that has any involvement with religion. But it also would apply to groups whose activities and conduct are founded upon deeply held moral and ethical principles. Thus an "atheist" profit-making hospital--even if owned by many shareholders as opposed to a closely-held one--that opposes abortion should not be required to provide any kind of medical coverage for its employee, staff, or clientele that violates its anti-abortion position.

Third, since the present definition of "Contraceptive coverage" in the proposed regulations could also require providing medical coverage for pills and devices that may have an abortifacient effect besides a contraceptive effect, individuals and entities should not be required to be involved in any way with providing medical insurance coverage for these, contrary to their principles.

Fourth, various individuals and entities oppose the use of the means for artificial contraceptive. This is neither the place nor the time to become involved in a discussion about the justification for this position. Unfortunately, our society may not be ready for discussions which challenge our whole modern cultural approach to sexuality, marriage, and the marriage act that leads to the joining of a sperm from a human male and the egg from a human female in the conceiving of new human life. Questions could be asked to proponents of the unrestrained use of contraceptives about any linkages between such cultural lifestyles and the growing sense of selfishness, lack of commitment, and "loose life styles" that permeate our society. Suffice it to say that a number of religious groups have very strong dogmas contrary to artificial contraception. In order to protect their religious freedom and protect their freedom of conscience, they should not be required to participate in any way in activities that violate their principles. This same reasoning applies to protecting the principles of individuals and entities, including profit-making, that question unjustified sterilizations.

Fifth, America's long standing commitment to religious freedom and the protection of religious diversity should lead to the formulation of regulations which provide the widest possible scope for exemptions from being forced to provide such "contraceptive coverage" as this is defined in the proposed regulations. Not only should all religious groups be exempt, including those serving the general public with charitable activities, but also groups based on

non-religious ethical principles and profit-making entities should be permitted to be eligible for an exemption.

Sixth, we are all aware of how some have tried to destroy the voting rights of people by attaching all sorts of conditions and restrictions on exercising such rights. These obstructive activities rightfully must be opposed. Similarly, the exercise of an exemption for freedom of religion and conscience must not be undermined by bureaucratic restrictions and complex eligibility procedures. Simple self-declarations and self-certifications should be sufficient to obtain the exemption. Furthermore, these should not require the individual or entity to refer anyone to some administrator or third-party for such services who will provide the objectionable services.

Seventh, based on America's religious history and our commitment to religious liberty and freedom of conscience, this exemption from providing "contraceptive coverage" should be as broad as possible. This would accord with our Bill of Rights, including the First Amendment, which provides for the separation of church and state.

Based on these essential guidelines, here is our proposal for the regulation and exemption. The proposal is very simple:

"Any entity, employer, organization, individual, or any other person who is required to provide health coverage as required under the Patient Protection and Affordable Care Act and the related Statutes, whether for themselves, for their employees, or for others would be able to opt out of providing coverage for contraception, abortificients, and sterilizations. This "freedom of choice" option would not have to be based on any particular religious claim, nor any particular religious eligibility, nor any number of shareholders, nor any number of owners. This "freedom of choice" option could be exercised on the basis of ethical beliefs and principles. This option would be available to any entity whatever its business form and organization, including non-profit entities as well as profit-making entities, Furthermore, this option would be exercised through self-certification."

There are many advantages to providing this "Freedom of Choice" option and inserting the necessary language for such an exemption at all the relevant sections of the proposed rules. Here are some of these advantages.

a. This will be extremely easy to administer. This is always an advantage in any governmental program

b. The various governmental agencies administering the Act will not find themselves enmeshed in any sorting through of the religious beliefs and dogmas of groups exercising this option and the exemption including their staff, their employees, and the clientele they serve.

c. This broad exemption and option will avoid an excessive entanglement of government with religion.

d. This proposal also takes into account that there are those who may not have religious grounds but whose strong ethical "non-religious" principles lead them to rejecting any participation in the alleged "contraceptive coverage."

e. This "freedom of choice" proposal insures that our government and its departments remain true to America's historic commitment of protecting freedom of conscience and religious liberty.

f. By including this comprehensive exemption, the Affordable Health Care plan fits into our commitment to strong ethical principles in our medical institutions as well as our religious institutions.

g. Most important of all in terms of the proposed "Freedom of Choice option" and resulting exemption, any group or individuals with strong religious and ethical principles will not be compelled to participate in any activities, including medical insurance plans and medical coverages, nor any referral mechanisms which run counter to their fundamental religious views and beliefs.

PART SEVEN: CONCLUSION

We urge our Federal Government and the various agencies and departments to protect the freedom of religion for all our citizens as well as protect the rights and freedom of conscience for all. No person or entity of any kind should be forced to participate in any way in activities which violate their principles, doctrines, and beliefs, whether religious or ethical. This includes being compelled to provide for insurance through medical plans for so-called "contraceptive coverages." We urge the Federal Government to adopt our proposed "Freedom of Choice" option and exemption for all, including nonprofit or profit making entities. We urge that this option and exemption be available to all by a very simple self-certification process. It is our considered view that such a "Freedom of Choice" option and exemption best corresponds with our highest ethical and medical principles as well as our Nation's commitment to the principles of religious freedom and liberty inherent in American history and contained in our Constitution.

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Respectfully submitted,

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