Misleading Leadership

The Deliberate Deception of Recommendation 5.5

Arland K. Nichols

Mr. Nichols is the national director of HLI America, an educational initiative of Human Life International. Many of his articles may be found at www.hliamerica.org, and he may be reached by email at anichols@hli.org.

Abstract

On August 1, 2011, the Department of Health and Human Services accepted the Institute of Medicine's recommendation that all Food and Drug Administration—approved contraceptives and sterilization procedures be made available to women without incurring out-of-pocket costs. The Institute of Medicine and the Department of Health and Human Services have deliberately misled the American people by claiming that this mandate would not include abortifacient drugs, that conscientious objection would be honored, and that this provision is essential to preserving the health of women. The author rebuts each of these claims by appeal to the scientific, medical, legal, and political facts surrounding these claims. In doing so, he argues that the recommendations include at least three abortion-inducing contraceptive methods. Likewise, he illustrates that the current administration has shown no will to protect the inviolable right of conscience of both individuals and institutions. Finally, he draws the reader's attention to the known deleterious side effects of oral contraception, emphasizing that these recommendations ultimately encourage women to use drugs that put them at a greater risk of harm. The author concludes that the Institute of Medicine and the Department of Health and Human Services have neglected their responsibility to American women and have misled and deceived the American people.

As the Patient Protection and Affordable Care Act was nearing passage, Senator Barbara Mikulski (D-Maryland) secured an amendment—the “Mikulski Women’s Preventive Health Care Amendment”—that gave the Department of Health and Human Services (HHS) the authority to delineate preventive care uniquely necessary for women.¹ The secretary of HHS, Kathleen Sebelius, tasked the Institute of Medicine (IOM) with undertaking a systematic review of those preventive services that should be covered, without payment, for all women. On July 19, 2011, the IOM submitted a 210-page report recommending eight preventive services.² Seven of these recommendations involve important screening, counseling, and testing for common health risks facing women. Recommendation 5.5, unfortunately, was a recommendation of a different kind. It stated, “Women will have access to all Food and Drug Administration (FDA)—approved contraceptive methods, sterilization procedures, and patient education and counseling. These recommendations do not include abortifacient drugs.” On August 1, 2011, in a quietly made announcement in the corner of the HHS website, the federal government accepted the IOM recommendations wholesale.³

The decision by the Department of Health and Human Services to mandate coverage of contraception and sterilization is a tragedy in many ways. This mandate characterizes pregnancy as a disease, unjustly discriminates against Christians who find contraception and sterilization to be morally repugnant, and brings significant costs to women and society in general. This bill is not good for Catholics, American women, or the common good of our country. To add insult to injury, HHS has misled the public on three matters of great import. The IOM and HHS have claimed that the health of women necessitated each of the recommendations, that abortifacient drugs are not included under Recommendation 5.5, and that conscientious objection will be honored. This article will explore these three areas of deception.

“These Recommendations Do Not Include Abortifacient Drugs”

The *Ethical and Religious Directives for Catholic Health Care Services* are very clear: “Catholic health-care institutions may not promote or condone contraceptive practices. Direct sterilization of either men or women, whether permanent or temporary, is not permitted in a Catholic health-care institution.”⁴ There can be no equivocation: The mandate to fund contraception and sterilization is directly contrary to the explicit teaching of the Catholic Church and, in so doing, sets up a conflict between the State and the last provider of health care in the United States.

Though much could be said concerning contraception and sterilization as such, we direct our attention to the last sentence of Recommen-

dation 5.5: “These recommendations do not include abortifacient drugs.” Such a claim is made possible only by ignoring the abortion-inducing effect of some FDA-approved contraceptives, and by accepting the common, but no less inaccurate, claim that life begins at implantation rather than conception. Ultimately, the claim of Recommendation 5.5 amounts either to deliberate deception or complete ignorance of the facts.

It is instructive first of all to take a quick glance at both the science of embryonic life and at the dynamics of how these drugs work to prevent pregnancy. Once a tiny human being comes into existence at the moment of fertilization, the woman is pregnant; that is, she is with child, even if that child has not yet implanted. As neuroscientist and anatomist Maureen Condic has noted, “The embryo comes into existence at sperm-egg fusion, a human organism is fully present from the beginning, controlling and directing all of the developmental events that occur throughout life.”⁵ After fertilization, this new human being may take a week or so to travel to the uterus where he will implant. An increasingly common medical definition of pregnancy employs an implantation-based definition that, at best, uses the phrase “established pregnancy” in reference to the state of the mother once a child has implanted on the endometrial lining of her uterus.⁶ The term “established pregnancy” can be deceptive; it is important to recall that life does not begin at implantation, but at fertilization. Not only can this language be misleading, it is also fraught with a moral lassitude toward the new human being. This new “human being is to be respected and treated as a person from the moment of conception; and therefore from that same moment his rights as a person must be recognized, among which in the first place is the inviolable right of every innocent human being to life.”⁷ The dignity of every human being, regardless of his size or location, must be honored as the *imago Dei*.

The IOM’s claim distracts from the fact that some FDA-approved contraceptives do have methods of action that are abortion-inducing.⁸ *Dignitas personae* characterizes these methods as “interceptive” if they interfere with the ability of the embryo to implant and “contragestative” if they cause the death of the embryo following implantation.⁹ One of the methods of contraception most promoted by the IOM because of its effectiveness in preventing pregnancy is the use of intrauterine devices. An intrauterine device functions, in part, as an interceptive “contraceptive method” by agitating the uterine lining to such a degree that once conceived the child is unable to implant on the endometrial lining of the uterus. That is, intrauterine devices function so as to directly induce abortions. *Dignitas personae* offers criticism of such interceptive methods: “[A]nyone who seeks to prevent the implantation of an embryo which may possibly have been conceived, and who therefore either requests or prescribes such a pharmaceutical, generally intends abortion.”¹⁰ The Church’s teaching is clear: directly and voluntarily causing the death of such an innocent and vulnerable human being constitutes a direct abortion, regardless of the means employed.¹¹

Furthermore, the IOM ignores that both Plan B and Ella, which are considered FDA-approved contraceptive methods, also have potential abortion-inducing methods of action. Plan B, composed of two 0.75 mg pills of levonorgestrel, primarily functions so as to prevent a woman from ovulating (at least if it is administered during the preovulatory phase of her cycle).¹² The medical consensus indicates that Plan B (levonorgestrel) does not act as a contragestative; that is, it does not kill an embryo that has already implanted. However, studies indicate that Plan B may also have a secondary effect if a woman has a breakthrough ovulation in spite of the administration of Plan B.¹³ When ovulation and subsequent fertilization occurs in spite of the administration of Plan B, the drug can act as an interceptive abortifacient. Yeung et al. suggest that this is due to a reduction of the luteal phase length and function, as well as a reduction of glycodeilin-A in the endometrium. They state that Plan B “interferes with the normal development and function of the corpus luteum; a dysfunctional corpus luteum then leads to an impaired endometrium that interferes with embryonic implantation.”¹⁴ They argue that “no evidence exists to contradict this interceptive effect” and suggest that “levonorgestrel is estimated to act as an abortifacient 3–13 percent of the time when it is administered in the preovulatory period.”¹⁵ This potential abortion-inducing effect is acknowledged by Barr Pharmaceuticals (the manufacturer of Plan B), the *Physicians’ Desk Reference*, (PDR) and the FDA, the latter of which states, “Plan B One-Step is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization. . . . In addition, it may inhibit implantation (by altering the endometrium). It is not effective once the process of implantation has begun.”¹⁶ As the evidence suggest, Plan B may at times, act as an abortifacient; and when this abortion-inducing possibility is not excluded, dispensing this drug is contrary to Catholic teaching.

Ella, approved by the FDA in August 2010, is composed of thirty mg of a chemical compound (ulipristal acetate) similar to that used in RU-486 (the “abortion pill”). It is known to be a progestin inhibitor, which is effective for up to five days after sexual intercourse.¹⁷ It also is an interceptive abortifacient, which, as the FDA states, works by means of “alterations to the endometrium that may affect implantation.”¹⁸ This, the FDA says, “may also contribute to efficacy.” The European Medicines Agency also stresses this interceptive method of action: “Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin and maintain pregnancy are not synthesized.”¹⁹ Ella works as a contragestative as well. For this reason (likely due to concerns for maternal health), the FDA stresses that ella should not be used if there is a “known or suspected pregnancy.”²⁰ Recognizing that there is “no doubt that ulipristal acts as an abortifacient,” the American Association of Prolife Obstetricians and Gynecologists asserts that “Ulipristal’s ability to destroy established pregnancies, as well as prevent implantation, makes it an embryocidal drug.”²¹

It is clear, from the testimony of medical science, that Plan B, ella, and intrauterine devices all have the potential to act as abortifacients. They all have a method of action that prevents a child who is dependent upon a hospitable womb from implanting so that he might continue to undergo and direct his own development. In addition, ella acts against the child that has already implanted. Nonetheless, HHS has ignored these facts, has deliberately misled the public about the scientific and medical realities of such abortion-inducing FDA-approved contraceptives, and has mandated their cost-free provision. If such a mandate were enjoined upon Catholic hospitals, it would place them in a precarious position by forcing them to meet the demands of the mandate, violating the *Ethical and Religious Directives* that say that “abortion . . . is never permitted. Every procedure whose sole immediate effect is the termination of pregnancy before viability is an abortion, which, in its moral context, includes the interval between conception and implantation of the embryo.”²² Thus, a directive requiring physicians to prescribe potentially abortion-inducing contraceptive methods would place their souls in great peril. *Dignitas personae* puts it this way: “the use of means of interception and contragestation fall within the sin of abortion and are gravely immoral. Furthermore, when there is certainty that an abortion has resulted, there are serious penalties in canon law.”²³ This HHS mandate, therefore, amounts to a direct attack upon the teachings of the Catholic faith and against the medical institutions founded in the spirit of that faith. Could our government really perpetrate such an offense?

Disregard for the Rights of Conscience

The second claim made at the time of the HHS announcement was that conscientious objection would be respected for those who are opposed to these mandates due to religious conviction. Unfortunately, this is not the case. Perhaps this is unsurprising in light of the current administration’s fair-weather relationship with conscience protections.²⁴ After a brief time in office, President Obama proposed to rescind, by Presidential Order, the strong and reasonable protections for conscience rights enacted in the preceding administration.²⁵ Strong conscience protections are necessary because discrimination in the medical field is increasingly common in spite of such amendments as the Church Amendment, the Weldon Amendment, and the Coats-Snowe Amendment.²⁶ While these amendments express a long-held American respect for conscientious objection, they are insufficient because they do not contain within them means by which complaints of discrimination may be filed. Furthermore, enforcement of these laws has been exceedingly rare.²⁷

The proposed rescission predated President Obama’s much maligned visit to the University of Notre Dame. There, he assured the class of 2009 that he was committed to “honor the conscience of those

who disagree with abortion, and draft a sensible conscience clause, and make sure that all of our health-care policies are grounded in clear ethics and sound science.”²⁸ In spite of his pledge at the university of Our Lady, he significantly weakened the conscience protections enacted by President Bush, thus weakening federal protections of the right of conscience for religious groups and individuals.²⁹ The regulations protect neither the free exercise of religion, nor the individuals or Catholic institutions that conscientiously object to a number of morally offensive medical practices, thus paving the way for unjust discrimination.

It was in this milieu, on August 1, 2011, that HHS released their “Affordable Care Act Rules on Expanding Access to Preventive Services for Women,” which included an “interim final rule . . . to give religious organizations the choice of buying or sponsoring group health insurance that does not cover contraception if that is inconsistent with their tenets.”³⁰ The criteria to meet this exemption delineated by the administration include the following: The primary purpose of the organization must be to inculcate religious values, its employees must primarily be those who share the tenets of the faith, and the organization must primarily serve its own members.³¹ This, on its face, may appear to be a goodwill gesture toward those who conscientiously oppose the new law based on their deeply held religious or moral convictions. But a closer look reveals otherwise: The four qualifying criteria for exemption are so narrow that conscience protections are limited to very few Catholic or Christian organizations, leaving the remaining objecting organizations and individuals forced to pay for contraception, surgical sterilizations, and abortion-inducing drugs. Furthermore, the guidelines offer no opportunity for objection by individuals.

For all practical purposes, this would exclude nearly all of the 250 Catholic universities in the United States, countless Catholic social agencies, and more than 2,200 Catholic hospitals and clinics that would not meet these criteria. Because they do not have faith-formation as their primary mission, do not exclusively employ Catholic employees, nor require those they serve to be baptized Catholics, this could have the effect of forcing these institutions to violate their moral and ethical commitments, refuse insurance, or shut their doors. Furthermore, the criteria limit and implicitly redefine and confine religion to worship and faith-formation alone. Such government overreach may end up preventing these Catholic-sponsored institutions from serving the oft-neglected communities they minister to—much as we have seen with Catholic adoption agencies in recent years. As John Haas, president of the National Catholic Bioethics Center, notes, federal respect for conscience “is necessary to ensure our viability in providing continued service to the underserved.”³² Furthermore, the criteria delineated by HHS would eliminate a number of other conscientious objectors such as Americans United for Life and the Heritage Foundation, which are not “religious

employers.” Jeanne Monahan of the Family Research Council has noted that the administration has only

offered a fig leaf of conscience protection for certain churches that fulfill very specific criteria. However, religious groups that provide social services [or] engage in missions work to people of different religious faiths, [and] religious health insurance companies, let alone religious health-care providers and individuals in such health plans, are not protected from any discrimination whatsoever.³³

The HHS continues the offense by seeking to justify these “conscience protections” by appeal to state law.

In its fact sheet, HHS noted that the proposed conscience exemptions are modeled after those used in twenty-eight states. It also invited the public to comment “as we work to strike the balance between providing access to proven prevention and respecting religious beliefs.”³⁴ Here one might make two observations. First, the National Catholic Bioethics Center reports, “The actual fact, however, is that there are only seven states with such provisions,” not twenty-eight as claimed by HHS. Furthermore, the National Catholic Bioethics Center notes that many states have enacted conscience protections that are significantly more robust than those provided by HHS.³⁵ Second, it is instructive to survey the history of the Obama administration in responding to public comments and finding a median between pro-choice ideology and the beliefs of Catholics and other social conservatives: In light of this history, it is safe to say that for all practical purposes, this administration’s “decision” on this issue appears to be a foregone conclusion, made prior to any so-called “dialogue.”³⁶ As Sister Mary Ann Walsh of the United States Conference of Catholic Bishops bluntly noted, “Health and Human Services must think Catholics and other religious groups are fools.”³⁷

In spite of promises to the contrary, this administration has shown no will to substantially protect consciences. Though one may hold out hope, clearly precedent does not bode well. It remains highly unlikely that the current administration will provide robust conscience protections for both organizations and individuals who are opposed to funding these mandates or providing the services required by them. This seems increasingly clear, especially in light of the clamor that continues to come from organizations like Planned Parenthood and the National Abortion Rights Action League, organizations to which the current administration is beholden.³⁸

This inevitable opposition makes it even more essential that Catholics and all people of goodwill support the “Rights of Conscience Act” currently being proposed in both the House of Representatives and the Senate. Introduced in the House of Representatives in March of 2011 by Jeff Fortenberry (R-Nebraska), who anticipated the issues we face today, this act has gained the support of a coalition of groups including the United States Conference of Catholic Bishops, Christus Medicus Foundation, Family Research Council, Catholic Medical Association,

and Human Life International. This act would protect both individuals and institutions from being coerced to perform actions to which they have a fundamental and well-grounded objection. As Daniel Cardinal DiNardo has noted, “The Administration’s failure to create a meaningful conscience exemption to the preventive services mandate underscores the need for Congress to approve the Respect for Rights of Conscience Act.”³⁹ This disregard for conscience rights underscores the importance of reminding American Catholics that the true nature of the conscience rests in the proper use of reason to know and act on what is true and good, not in superficial convictions, feelings, and preferences. After all, if the conscience merely amounts to superficial conviction, why should the federal government honor it?

“Help Keep Them Healthy”

The Insidious Danger of Recommendation 5.5

Those who advocated for Recommendation 5.5 have regularly claimed that its inclusion as a preventive service was necessary to secure the health and well-being of women. HHS claimed that they had “directed the Institute of Medicine, for the first time ever, to conduct a scientific review and provide recommendations on specific preventive measures that meet women’s unique health needs and help keep them healthy.” Kathleen Sebelius, secretary of HHS, wrote, “These historic guidelines are based on science and existing literature, and will help ensure women get the preventive health benefits they need.”⁴⁰ Susan F. Wood of the Jacobs Institute of Women’s health said, “[C]ontraception should be based on the evidence as outlined by IOM, which shows that contraception for women is indeed safe and effective prevention.”⁴¹ IOM committee chairwoman Linda Rosenstock claimed, “Each recommendation stands on a foundation of evidence supporting its effectiveness.”⁴² This claim that the recommendations were evidenced-based and necessary for the good of women has hushed politicians and other civil leaders who fear political ramifications if they should, by questioning the recommendations, appear to be anti-science or, worse, misogynistic. In touting science as the basis for this document, the authors have tacitly inferred that anyone who disagrees with it is motivated by political ideology and does not have the best interest of women in mind. However, there is ample evidence that the conclusions of the IOM harm the health of the very women they purport to defend.

Since the “preventive service” offered by Recommendation 5.5 is of a different kind than the other seven—involving the administration of drugs and surgeries—a host of other considerations should naturally arise, namely, the health risks associated with those drugs or surgeries. Unfortunately very little consideration is given to these risks in the IOM report. Only one paragraph in the 210-page report addresses risks associated with this recommendation, and even that paragraph only says that women under thirty-five die as a result of giving birth more often

than because of contraception. Yet this statistic is misleading, as many of the negative health effects of contraceptives become apparent only later in a woman's life; and furthermore, the cause of death during pregnancy is primarily attributed to some underlying unresolved malady such as diabetes or obesity. The committee also brushes aside the death rates of women who smoke and use oral contraception. The failure to even pause and address the seriousness of this is unconscionable, given that 18.5 percent of women in America smoke.⁴³ The report claims instead that "side effects are generally considered minimal."⁴⁴ In support of such a sweeping statement, one would expect a host of peer-reviewed studies to be cited. The actual citation, however, lists only three "educational pamphlets" from the American College of Obstetricians and Gynecologists and one fairly dated study.

This particular citation should raise the ire of any observant reader. The public was assured, upon the passage of the IOM's mandates, that the report was an "exhaustive review of the scientific evidence," and yet one of the primary cruxes of the committee's argument—and one which furthermore directly impacts the longevity of millions of American women—rests squarely upon the support of educational pamphlets. These pamphlets, available online, are promotional brochures that do not cite even one study.⁴⁵ Interestingly, the pamphlets themselves state that "the average readability level of the series . . . is grade six to eight." An undergraduate using such sources in a composition class would likely find their grade docked; certainly the IOM's use of this amateurish secondary material is completely unacceptable.

It is evident that more rigorous peer-reviewed studies concerning the potentially negative side effects of chemical contraception should have been brought to bear on such an important issue. Instead, after quickly explaining away the side effects that are mentioned, one paragraph is devoted to the noncontraceptive benefits of contraception. To this end, the report places a great deal of emphasis on an ongoing study that has not yet been published, but that is likely to indicate that oral contraception prevents ovarian cancer. While numerous studies do indicate that oral contraception does reduce the risk of ovarian cancer, the decision to include mention of only this particular cancer is circumspect. If oral contraception increases the risk of other cancers, ignoring those other cancers in their report would indicate a commitment to selectively emphasize sympathetic findings and subjective bias. So, what of the assertion that cancer risks are reduced, and that side effects, in general, are minimal? Though space does not permit an exhaustive survey of the studies, I will briefly identify some of the major side effects that were completely ignored by the IOM.

- Breast cancer is the most common form of invasive cancer in women, and combined oral contraceptives increase breast cancer risk.⁴⁶ Breast cancer accounts for 26 percent of cancers in women, while ovarian cancer accounts for 3 percent. Further-

more, 15 percent of cancer deaths in women are caused by breast cancer and 6 percent of deaths are caused by ovarian cancer.⁴⁷ In spite of ardent claims to the contrary, there is a rapidly increasing collection of studies indicating that the risks of breast cancer for contraceptive users is higher than nonusers.⁴⁸ These studies have been published in the most prestigious journals, including *Cancer Epidemiology Biomarkers and Prevention*, *Breast Journal*, *Mayo Clinic Proceedings*, *Journal of the American Medical Association*, *New England Journal of Medicine*, and *British Medical Journal*. The World Health Organization's International Agency for Research on Cancer recognizes that synthetic estrogen is a Group 1 carcinogen for numerous cancers including breast cancer.⁴⁹ Those most at risk for developing breast cancer as a result of contraceptive use are women who begin contraceptive use before their first full term pregnancy, women who have a family history of breast cancer, and women who smoke. In short, there are numerous studies that show that the breast cancer-contraceptive link is very real. On the other hand, one of the most effective ways to reduce breast cancer risk is to have a child, and to do so before twenty-five years of age.⁵⁰ Furthermore, the National Cancer Institute at the National Institutes of Health emphasizes that studies also indicate a greater risk of other cancers including cervical and liver cancer.⁵¹

- Stroke risk is also much higher for users of oral contraception. Studies reveal increased risk in the range of 1.5 to 4 times greater risk in those who use oral contraceptives.⁵² Data vary depending on the type of contraceptive, how long it was used, and a number of other factors. The *Physicians' Desk Reference* indicates that risks are even greater for women who smoke, are obese, get migraines, are older, or are hypertensive. Studies indicating an increased risk of stroke have been published in such journals as *Journal of Neurology*, *Neurosurgery and Psychiatry*, *Journal of the American Medical Association*, *Blood: Journal of the American Society of Hematology*, and *Stroke: Journal of the American Heart Association*.
- Deep vein thrombosis is increasingly a concern for users of oral contraception. The *Physicians' Desk Reference* states the following: "An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established."⁵³ Users of the pill, the *Physicians' Desk Reference* emphasizes, are three times more likely to develop superficial venous thrombosis, and have a four to eleven times greater risk for deep vein thrombosis or pulmonary embolism. Further, the risk goes up by a factor of 1.5 to 6 for those women who are genetically predisposed to the disease. In mid-2011 the FDA announced a safety review of the most popular oral contraceptive, which was once aggressively marketed directly to teenagers

and young adults under the trade names of Yaz, Yasmin, and Beyaz. These oral contraceptives contain drospirenone, which, according to two recent studies published in *British Medical Journal*, increase risk of blood clots two- to threefold compared to the risk associated with other (second- and third-generation) oral contraceptives. As the FDA states, “All birth control pills pose a risk of blood clots. Several epidemiological studies have reported that the risk of blood clots for women who use birth control pills containing drospirenone is higher than that for women who use birth control pills containing the progestin levonorgestrel.”⁵⁴ Finally, a recent Centers for Disease Control *Morbidity and Mortality Weekly Report* states that after giving birth, women should not use combined oral contraceptives for forty-two days. The report says, “[E]vidence from thirteen studies showed that the risk for [blood clots] among women within the first forty-two days postpartum is twenty-two-fold to eighty-four-fold greater than the risk among nonpregnant, nonpostpartum reproductive age women.”⁵⁵ The risk is highest immediately after delivery, declining rapidly during the first twenty-one days, but not returning to baseline until forty-two days postpartum in most studies.” In spite of the increased risk of blood clots attributed to use of combined oral contraceptives, these risks go entirely unmentioned in the IOM’s report.⁵⁶

- Numerous studies have revealed that oral contraceptive users have a greater risk of heart attack than non-users and that arteries develop plaque at a faster rate for users of oral contraception, though most studies indicate that the risks vary according to the generation of oral contraceptive used. A 2007 study presented at the annual meeting of the American Heart Association showed that there was a 20–30 percent increase in the occurrence of arterial atherosclerosis for every decade of oral contraceptive use, with carotid and femoral arteries developing plaque at a higher rate with use of combined oral contraceptives.⁵⁷ A study first published in 2001 reported that users of second-generation oral contraception were 2.5 times more likely to have a heart attack, though the authors note that risks associated with third-generation oral contraceptives are inconclusive and did not pose a statistically significant risk.⁵⁸ If other risk factors were involved such as hypertension, smoking, or diabetes the risk was elevated by a factor of 13.6, 17.4, and 24.7 respectively. Many more similar studies have been published in journals including the *Journal of Clinical Endocrinology and Metabolism*, the *European Heart Journal*, and the *Canadian Medical Association Journal*.

I have drawn attention to only four significant side effects of oral contraceptive use, but peer-reviewed studies indicate reasons to be concerned about a number of other side effects. Though studies often pro-

vide discordant results, a number of studies indicate (though perhaps not always conclusively) increased risk of loss of bone mass in teenagers (and a subsequent increased risk of osteoporosis),⁵⁹ clinical depression,⁶⁰ weight gain,⁶¹ and higher rates of sexually transmitted diseases.⁶² In spite of the wealth of evidence available, the IOM committee and the source material they chose to consult completely ignored the mountain of studies that give strong indications that there are in fact grave risks associated with oral contraceptive use. One cannot help but wonder how it was that these studies indicating serious risks for women were missed, ignored, or swept under the rug by the IOM.⁶³

Conclusion

A closer look at the claims made by the IOM and HHS leads me to share the conviction of Daniel Cardinal DiNardo, who said, “I can only conclude that there is an ideology at work in these recommendations that goes beyond any objective assessment of the health needs of women and children.”⁶⁴ In allowing ideology to direct their research, the members of Sebelius’s IOM committee have misled the American people about the abortion-inducing effect of FDA-approved contraceptives, they have not protected the consciences of American citizens, and they have put the lives of millions of American women at risk by placing a federal imprimatur on drugs that have very well-documented deleterious side effects. Our public officials—elected and appointed—are called to ensure the safety and security of Americans. They have power and prominence so as to further the well-being of citizens, not to further the aims of ideology. In this case, HHS and IOM have neglected their responsibility and have misled and deceived the American people.

Notes

¹ Barbara Mikulski, “Mikulski Applauds Institute of Medicine’s Comprehensive Recommendations for Women’s Prevent Screening and Care to Be Covered under the Affordable Care Act,” press release, July 19, 2011, <http://mikulski.senate.gov/media/pressrelease/7-19-2011-1.cfm>.

² Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps* (Washington, D.C.: The National Academies Press, 2011), <http://www.iom.edu/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx>.

³ Department of Health and Human Services, “Affordable Care Act Ensures Women Receive Preventive Services at No Additional Cost,” news release, August 1, 2011, <http://www.hhs.gov/news/press/2011pres/08/20110801b.html>.

⁴ United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th ed. (Washington, D.C.: USCCB, 2009), dirs. 52–53.

⁵ Maureen Condic, “When Does Life Begin?: A Scientific Perspective,” (New York: Westchester Institute for Ethics and the Human Person, 2008), 12,

http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf.

⁶ For a wonderful review of the language used in modern day medical texts, see Christopher M. Gacek, "Conceiving Pregnancy," *National Catholic Bioethics Quarterly* 9 (2009): 543–553.

⁷ Congregation for the Doctrine of the Faith, *Donum vitae* (1987), I, n. 1.

⁸ One observes that there are a number of studies that indicate that oral contraception may also have an abortifacient method of action by altering the endometrial lining of the uterus. While noted, this is not the focus of this essay.

⁹ Congregation for the Doctrine of the Faith, *Dignitas personae* (2008), n. 23.

¹⁰ Ibid.

¹¹ See John Paul II, *Evangelium vitae*, n. 57: "I confirm that the direct and voluntary killing of an innocent human being is always gravely immoral. The deliberate decision to deprive an innocent human being of his life is always morally evil."

¹² Plan B, marketed as "Plan B One Step," may also be taken as a single dose of 1.5 mg of levonorgestrel.

¹³ The author notes that there are some, including within the Catholic scholarly community, who suggest that an abortifacient effect is extremely unlikely. Perhaps most notable is Rev. Nicanor Pier Giorgio Austriaco, O.P. See his "Is Plan B an Abortifacient?" *National Catholic Bioethics Quarterly* 7 (2007): 703–707.

¹⁴ P. Yeung, E. Laetham and J. Tham, L.C., "Argument against the Use of Levonorgestrel in Cases of Sexual Assault," *Catholic Health Care Ethics: A Manual for Practitioners*, ed. Edward J. Furton (Philadelphia: National Catholic Bioethics Center, 2009), 144.

¹⁵ Ibid., 146.

¹⁶ Federal Drug and Administration, "Plan B One-Step: Highlights of Prescribing Information," http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf; and also *Physician's Desk Reference*, 63rd ed. (2009), 1045.

¹⁷ Deacon Thomas J. David Jr. explains, "However, ulipristal acetate is a selective progesterone receptor modulator, which means that it attaches to the receptors to which progesterone normally attaches, preventing the hormone from having its effect." Thomas J. David Jr., "Plan B Agnostics," *National Catholic Bioethics Quarterly* 10(2010):771.

¹⁸ Food and Drug Administration, "Highlights of Prescribing Information: ella," http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

¹⁹ European Medicines Agency, "Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone," (2009): 8 http://www.ema.europa.eu/docs/en_GB/document_library/EPAR__Public_assessment_report/human/001027/WC500023673.pdf.

²⁰ Food and Drug Administration, "Highlights of Prescribing Information: ella."

²¹ American Association of Pro-Life Obstetricians and Gynecologists to the FDA, June 2, 2010, "Comment to Docket No. FDA-2010N-0001," http://www.aaplog.org/wp-content/uploads/2010/06/AAPLOG-Ulipristal-Comments_2010.pdf.

²² United States Conference of Catholic Bishops, *Ethical and Religious Directives*, dir. 45.

²³ Congregation for the Doctrine of the Faith, *Dignitas personae*, n. 23.

²⁴ See Family Research Council, "FRC Condemns Obama Administration's Weakening of Conscience Protections for Medical Professionals," press release, February 18, 2011, http://www.bizjournals.com/prnewswire/press_releases/2011/02/18/DC51343; John Haas, president, National Catholic Bioethics Center, to Charles E. Johnson, U.S. Department of Health and Human Services, April 2, 2009, <http://www.ncbcenter.org/Document.Doc?id=39>; or Catholic Medical Association, "Catholic Medical Association Deplores Assault on Conscience Rights by the Obama Administration," press release, June 24, 2009, http://www.cathmed.org/issues_resources/publications/press_releases/cma_deplores_assault_on_conscience_rights_by_obama/.

²⁵ To read the proposed rescission, see Department of Health and Human Services, 45 CFR Part 88, "Rescission of the Regulation Entitled 'Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law'; Proposal," http://www.freedom2care.org/docLib/20090313_HHS_rescission_notice.pdf.

²⁶ See, e.g., the recent requirement that nursing students at Vanderbilt University perform abortions during residency, Steven Ertelt, "Vanderbilt University Requires Nursing Students to Do Abortions," *LifeNews.com*, January 11, 2011, <http://www.lifenews.com/2011/01/11/vanderbilt-university-requires-nursing-students-to-do-abortions/>; see also the case of Cathy DeCarlo, who was coerced into assisting in an abortion at Mount Sinai Hospital in spite of her well-known objection to abortion, Alliance Defense Fund, "NY nurse forced to participate in abortion files additional suit against Mt. Sinai Hospital," April 29, 2010, <http://www.alliancedefensefund.org/News/PRDetail/2895>.

²⁷ See M. Casey Mattox and Matthew Bowman, "Your Conscience, Your Right," *Linacre Quarterly* 77 (2010): 187–197. Bowman and Mattox provide an excellent summary of the necessity of conscience protections that include a reporting mechanism and enforcement of the laws that protect consciences.

²⁸ President Barack Obama, "Obama's Commencement Address at Notre Dame," *New York Times*, May 17, 2009, <http://www.nytimes.com/2009/05/17/us/politics/17text-obama.html>.

²⁹ To read the new regulations, see Department of Health and Human Services, "Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws," *Federal Register* 76 (2011): 9968–9977, http://www.nacua.org/documents/FR_HHSRescissionProviderConscienceClause.pdf.

³⁰ Department of Health and Human Services, "Fact Sheet: Affordable Care Act Rules on Expanding Access to Preventive Services for Women," <http://www.healthcare.gov/news/factsheets/womensprevention08012011a.html>.

³¹ Department of the Treasury, Department of Labor, and Department of Health and Human Services, "Department Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act," *Federal Register* 76 (2011): 46621–46626, <http://www.gpo.gov/fdsys/pkg/FR-2011-08-03/pdf/2011-19684.pdf>.

³² John Haas, president, National Catholic Bioethics Center, to Charles E. Johnson, U.S. Department of Health and Human Services, April 2, 2009, <http://www.ncbcenter.org/Document.Doc?id=39>.

³³ Family Research Council, "FRC Opposes HHS Mandated Coverage of Abortifacients under Obamacare," press release, August 1, 2011, <http://www.frc.org/newsroom/frc-opposes-hhs-mandated-coverage-of-abortifacients-under-obamacare>.

³⁴ Department of Health and Human Services, "Fact Sheet: Affordable Care Act Rules."

³⁵ National Catholic Bioethics Center, "The NCBC Expresses Dismay over the Disregard for Conscience in New HHS Regulations Regarding Contraceptive Coverage," press release, August 2, 2011, <http://www.ncbcenter.org/page.aspx?pid=482&storyid1277=138&ncs1277=3>.

³⁶ Consider President Obama's speech to the Democratic National Committee on October 4, 2011: "No longer can insurance companies *discriminate against women* just because you guys are the ones who have to give birth. . . . Darn tooting. *They have to cover things* like mammograms and contraception as preventive care," emphasis added. The White House, Office of the Press Secretary, "Remarks by the President at a DNC Event," October 4, 2011, <http://www.whitehouse.gov/the-press-office/2011/10/04/remarks-president-dnc-event-1>.

³⁷ Sister Mary Ann Walsh, "HHS Makes In-Your-Face Effort to Undermine Constitution's Religious Freedom," August 1, 2011, blog USCCBlog, <http://usccbmedia.blogspot.com/2011/08/hhs-makes-in-your-face-effort-to.html>. This article was completed prior to the administration's decision to leave the interim rule substantially unchanged in January of 2012. Following the cacophony created by that decision, President Obama announced, by press conference, an "accommodation." However, the "accommodation" was nothing more than an accounting and public relations gimmick as the law went on the books of the federal register unchanged. Though a new comment period has been announced, it is difficult to see this as anything but political posturing.

³⁸ Consider the comments made by Kathleen Sebelius at an October 2011 National Abortion Rights Action League Pro-Choice America fundraiser: "We've come a long way in women's health over the last few decades, but we are in a war." She promised that the Obama Administration "will be fighting with you [NARAL] every step of the way," while sarcastically stating, "Wouldn't you think that people who want to reduce the number of abortions would champion the cause of widely available, widely affordable contraceptive services? Not so much." Carla K. Johnson, "Sebelius: GOP wants to roll back women's health," *Star Tribune* (Minneapolis), October 5, 2011, <http://www.startribune.com/printarticle/?id=131165228>.

³⁹ United States Conference of Catholic Bishops, "HHS Mandate for Contraceptive and Abortifacient Drugs Violates Conscience Rights," press release, August 1, 2011, <http://usccb.org/news/2011/11-154.cfm>.

⁴⁰ HHS, "Affordable Care Act Ensures Women Receive Preventive Services."

⁴¹ Susan Wood, "Statement from Dr. Susan Wood Regarding IOM Report that Recommends Eight Additional Women's Health Preventive Services for Cover-

age,” statement, July 21, 2011, <http://www.jiwh.org/content.cfm?sectionid=100>.

⁴² The National Academies, “IOM Report Recommends Eight Additional Preventive Health Services to Promote Women’s Health,” press release, July 19, 2011, <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=13181>.

⁴³ Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (Washington, D.C.: The National Academies Press, 2007), 62, <http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A-Blueprint-for-the-Nation.aspx>.

⁴⁴ IOM, *Clinical Preventive Services for Women*, 105.

⁴⁵ See for example, American College of Obstetricians and Gynecologists, “Birth Control Pills,” education pamphlet AP021.

⁴⁶ See Angela Lanfranchi, “Normal Breast Physiology: The Reasons Hormonal Contraceptives and Induced Abortion Increase Breast-Cancer Risk,” *Linacre Quarterly* 76 (2009): 236–249.

⁴⁷ Ahmedin Jemal et al., “Cancer Statistics, 2008,” *CA: Cancer Journal for Clinicians* 58 (2008): 71–96, <http://onlinelibrary.wiley.com/doi/10.3322/CA.2007.0010/pdf>.

⁴⁸ Newspapers and the Internet are littered with various sources claiming that the breast cancer–contraceptive link is a farce. Two examples will suffice: Women to Women, “Does the Pill Cause Breast Cancer?” (2011), <http://www.womentowomen.com/sexualityandfertility/faq4-does-the-pill-cause-cancer.aspx>; and Dawn Stacey, “Top 10 Pill Myths” (2011), <http://contraception.about.com/od/contraceptionmyths/tp/pillmyths.htm>.

⁴⁹ International Agency for Research on Cancer, “Agents Classified by the IARC Monographs, Volumes 1–105,” <http://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf>.

⁵⁰ Lanfranchi, “Normal Breast Physiology,” 242–243.

⁵¹ National Cancer Institute, “Fact Sheet: Oral Contraceptives and Cancer Risk” (2012), <http://www.cancer.gov/cancertopics/factsheet/Risk/oral-contraceptives>.

⁵² The risk of stroke, like other side effects, tends to be impacted by the type or “generation” of oral contraceptive that is used. Jeanet Kemmeren et al., “Risk of Arterial Thrombosis in Relation to Oral Contraceptives (RATIO) Study: Oral Contraceptives and the Risk of Ischemic Stroke,” *Stroke: Journal of the American Heart Association* 22 (2002): 1202–1208, <http://stroke.ahajournals.org/cgi/content/full/33/5/1202>.

⁵³ *Physicians’ Desk Reference*, 63rd ed., 807.

⁵⁴ Food and Drug Administration, “FDA Drug Safety Communication: Safety Review of Possible Increased Risk of Blood Clots with Birth Control Pills Containing Drospirenone,” safety announcement, May 31, 2011, <http://www.fda.gov/Drugs/DrugSafety/ucm257164.htm>. In September of 2011 the FDA announced that it continues to be concerned by the increased risks of this fourth generation of birth control pills as they cite an addition 1.5-fold risk for women who use them. However, the final conclusions have not yet been announced. Food and Drug

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⁵⁵ Centers for Disease Control, "Update to CDC's U.S. Medical Eligibility Criteria for Contraceptive Use, 2010: Revised Recommendations for the Use of Contraceptive Methods During the Postpartum Period," *Morbidity and Mortality Weekly Report* 60 (2011): 878, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6026a3.htm?s_cid=mm6026a3_w.

⁵⁶ For the implications this silence has upon women's health throughout the world see, Arland K. Nichols, "Newest Forms of 'the Pill' Pose Great Risk to Women's Health," *LifeWatch* (November 23, 2011), <http://www.hliamerica.org/wp-content/blogs.dir/1/files/2012/02/The-Pill.pdf>.

⁵⁷ Greg Burke, "Notes & Abstracts: Medicine," *National Catholic Bioethics Quarterly* 8(2008): 148.

⁵⁸ Bea C. Tanis et al., "Oral Contraceptives and the Risk of Myocardial Infarction," *New England Journal of Medicine* 345 (2001): 1787–1793, <http://www.nejm.org/doi/pdf/10.1056/NEJMoao03216>.

⁵⁹ See Delia Scholes et al., "Oral Contraceptive Use and Bone Density Change in Adolescent and Young Adult Women: A Prospective Study of Age, Hormone Dose, and Discontinuation," *Journal of Clinical Endocrinology and Metabolism* 96 (2011): 1380–1387.

⁶⁰ See Marie-Alberte Boursiquot, "The Real Risks of Oral Contraceptives," *Linacre Quarterly* 78 (2011): 100–103.

⁶¹ Ibid.

⁶² See, e.g., Joan Claire Robinson, "The Pill and HIV/AIDS," *Ethics and Medics* 35.12 (December 2010):2–3.

⁶³ For insight into the motivations behind the IOM report, see my "Promised Objectivity: Americans Receive Planned Parenthood Ideology," *Public Discourse* (September 28, 2011), <http://www.thepublicdiscourse.com/2011/09/4031>.

⁶⁴ United States Conference of Catholic Bishops, "Bishops Pro-life Chair Strongly Opposes Recommended Mandate for Birth Control, Sterilization in Private Health Plans," July 19, 2011, <http://usccb.org/news/2011/11-143.cfm>.