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New Studies Show All Emergency Contraceptives Can Cause Early Abortion

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Whether the plaintiff is Hobby Lobby, the Little Sisters of the Poor or one of the hundreds of other plaintiffs suing the Obama Administration, what's primarily at stake in the challenges to the HHS "contraceptive mandate" is, of course, whether the federal government can lawfully force employers to violate their conscience by requiring them to provide insurance coverage for all forms of "contraception" approved by the federal Food and Drug Administration (FDA).

The lawsuits are about religious liberty and conscience rights. They are not about "sex" (as Linda Greenhouse asserts). Nor are they about the use of contraceptives per se because, in fact, many plaintiffs taking part in the 90-plus lawsuits do not in principle object to contraceptive use. It is likely that all plaintiffs *do* object, however, to abortion-inducing drugs and they rightly believe that some forms of "contraception" have post-fertilization mechanisms of action (MOAs) that can cause the death of a human embryo. This is especially true with emergency "contraceptives."

Yet despite all the considerable evidence regarding the abortifacient effect of emergency contraceptives (EC), mandate proponents—Lillian Tamayo, President and CEO of Planned Parenthood of South Florida, for example—continue to deride those who contend that ECs can induce abortion. Her view is valid only if one accepts the Orwellian-newspeak-definition of conception—"the implantation of a fertilized ovum"—adopted by the American College of Obstetricians and Gynecologists (ACOG) in 1965 to obscure the reality that all hormonal contraceptives are potentially abortifacient. For the rest of the world, fertilization and conception are synonymous and mark the beginning of a new living organism.[i]

According to the ACOG view, pregnancy begins only when an embryo implants in the uterine lining (endometrium), so that causing the death of a week-old child by means that include blocking implantation is not an abortion. A 2012 ACOG Committee Opinion expresses this clearly: "Emergency contraception is not effective after implantation;

therefore it is not an abortifacient." This statement is doubly misleading because mifepristone (or RU-486, the "abortion pill") is also used as an EC in several countries. It effectively kills embryos for six weeks *after* implantation, and it is, perhaps, only a matter of time before the FDA approves RU-486 for EC use.

This sort of doublespeak concerning conception, pregnancy and abortion inevitably requires further terminology-twisting. One can no longer refer to embryo implantation as that implies the presence of a human being; the embryo is instead called a "fertilized egg," although he is a unique human being with his own complete set of DNA. In his first hours of existence, the embryo even signals the mother to get her immune system to stand down, prompting her body to release Early Pregnancy Factor, an immunosuppressive protein that is detectable in maternal blood as early as 24 hours after fertilization.

Nonetheless, many people, including Pam Belluck, a former *New York Times* reporter, ignore such facts and instead accept the statements of contraceptive proponents at face value. She suggests that believing EC to be abortion-inducing "is probably rooted in outdated or incorrect scientific guesses about how the pills work."

To the contrary. The latest studies, using precise and rigorous methods to assess the MOAs of emergency contraceptives, provide conclusive evidence that pre-ovulatory (i.e., contraceptive) MOAs (for example, delay or inhibition of ovulation and interference with sperm mobility) cannot alone account for the relative efficacy of ECs in preventing established (implanted) pregnancies.

A look at the current state of the science regarding the three most common types of emergency contraception available in the United States is instructive: the Copper-T IUD (marketed as ParaGard® T 380A Intrauterine Copper Contraceptive), Ulipristal acetate (marketed as Ella® and ellaOne®), and levonorgestrel EC or LNG-EC (marketed as Plan B®, Plan B One-Step® and Next Choice®).

Paragard T 380: Although the Copper-T IUD is used far less frequently than Plan B (due to its $475 cost and safety fears), we'll address it first because its MOAs have never been disputed. Paragard emits copper ions, creating an environment toxic to sperm, ova, and embryos. The FDA lists three MOAs—"interference with sperm transport or fertilization, and prevention of implantation."[ii] But when Paragard is used as an "emergency contraceptive" and inserted 1-5 days after intercourse, sperm have long since arrived in the upper fallopian tube/oviduct and fertilization may already have taken place. Sperm have been found in the fallopian tubes within five minutes to two hours after insemination.[iii] *Managing Contraception* (11th ed.) concedes as much: "In the month that [Paragard] is inserted as an emergency contraceptive, it may act by interfering with implantation."[iv] Embryos unable to implant die.

Ella® (ellaOne®): Nor is there serious scientific dispute over the anti-implantational MOA of Ella (Ulipristal acetate). Ella's FDA-approved Drug Label states "alterations to the endometrium that may affect implantation may also contribute to efficacy." Ella and RU-486 act by blocking progesterone receptors in the endometrium. This action can prevent the endometrium from becoming capable of receiving and nurturing the embryo. It thwarts implantation and, in the more potent formulation of RU-486, can deprive an implanted embryo (up to nine weeks' gestational age) of the oxygen and nutrition it needs to survive. Two little-known aspects of Ella bear mentioning. An analysis of pooled data from three trials, published in November 2013 by Vivian Brache and colleagues,[v] found that Ella delayed ovulation for five days in 58.8% (20/34) of cycles. In addition to a 41.2% failure rate in delaying ovulation (potentially allowing fertilization to occur), there is another great drawback with the use of Ella as EC. Because Ella only delays, but does not disrupt, ovulation, it will eventually occur after a prolonged fertile period. Unprotected intercourse during the prolonged fertile period can result in an unexpected pregnancy in the same cycle (before onset of menses).[vi]

Plan B: Early research speculating on the MOAs of LNG-EC produced more confusion than clarity. Many factors contributed to the incoherence, e.g., small subject pools, imprecise dating of key events in the patients' reproductive cycles, and a widespread, flawed assumption that the MOAs present with daily use of LNG or other progestin-only pills (mainly thickening of cervical mucus to impede sperm mobility) would also occur with one-time, post-coital EC use.

To assess both Plan B's MOA and efficacy, one must determine for each patient in the study—(1) whether or not unprotected intercourse occurred during the six-day fertile period of the menstrual cycle (when a woman is capable of becoming pregnant), and (2) whether EC was administered prior or subsequent to the peak level of luteinizing hormone (LH peak), which triggers ovulation in about 24 hours. Transvaginal ultrasound (TVUS) measurement of the dominant ovarian follicle, along with ascertaining urinary levels of LH and estrogen, yields precise dating of anticipated ovulation. TVUS observation of the ruptured ovarian follicle from which the ovum emerged, is the best means of determining that ovulation occurred. Earlier studies used less precise tools. Two recent literature reviews critique the older studies and also report on the findings of new, larger studies which used more accurate methods. All point to Plan B's having a predominantly post-fertilization (abortifacient) MOA when it is given during a woman's fertile period.

The first review, published in *Gynecological Endocrinology*[vii] by Bruno Mozzanega and Erich Cosmi (Department of Gynecology and Obstetrics, University of Padua), unsparingly critiques a Joint Statement of the International Consortium for Emergency Contraception (ICEC) and the International Federation of Gynaecology and Obstetrics (FIGO). The Joint Statement declared that the "primary and possibly only" MOA of LNG-EC is the "inhibition or delay of ovulation" and that "LNG-ECPs cannot prevent implantation." Mozzanega and Cosmi explain that ICEC/FIGO's conclusions were derived from a review of only seven studies with a combined total of only 142 patients,

who were further stratified into different subgroups (making statistically meaningful conclusions impossible). Flawed methodology marked some of the seven studies; "conclusions" were contradicted by actual findings in others; and larger, more rigorous studies were ignored completely.

In December 2013, Rebecca Peck, MD and Rev. Juan R. Vélez, MD, PhD published an exhaustive review of the scientific literature on Plan B's MOAs. After pointing out the errors and inconsistencies in studies purporting to show that Plan B has only or mainly pre-ovulatory (contraceptive) MOAs, the authors examine several large and rigorous studies that demonstrate Plan B's high likelihood of post-fertilization (abortifacient) MOAs.

Interim and final results of one of the largest studies to date were published in 2010 and 2011 by Gabriela Noé and colleagues. Noé et al. were able to calculate the efficacy of LNG-EC given before and after ovulation among patients who requested EC at family planning clinics. In the 2010 paper, 86% of the women who had intercourse during their fertile period and who received LNG-EC *before* ovulation, nevertheless ovulated. This contradicts the notion that ovulation delay or inhibition is Plan B's only or primary MOA. Had they not taken EC, 13 pregnancies would have been expected to occur among these women, but not one expected embryo survived to implant. In contrast, among women who had intercourse during their fertile period and received LNG-EC on their day of ovulation or later, seven pregnancies would have been expected (in the absence of EC) and six established pregnancies resulted. This suggests that LNG-EC is largely ineffective in preventing an established pregnancy if taken at or after ovulation.
Their final findings, published in 2011, are based on data from 450 women. Among those who had intercourse during their fertile period and who were given LNG-EC prior to ovulation, 80% nevertheless ovulated. A contraceptive failure rate of 92% occurred among a subset of women who had intercourse two days before ovulation and received LNG-EC promptly. Sixteen pregnancies would have been expected among the group of

women who received EC pre-ovulation. No established pregnancies occurred, i.e., no embryos survived to implant. In the group that received LNG-EC after ovulation, however, 8.7 pregnancies could have been expected and 8 occurred.

To summarize: It is possible that Plan B may delay ovulation when given before or at the beginning of the fertile period, when the chance of pregnancy is slim to none, and therefore, it is not "needed" to prevent pregnancy. When given after intercourse in the fertile period and before the LH peak that triggers ovulation, Plan B fails to act as a contraceptive 80-92% of the time; it acts instead as an abortifacient, eliminating all embryos likely to have been conceived. When given on the day of ovulation or later to prevent pregnancy from intercourse during the fertile period, it almost always fails to prevent established pregnancies.

Peck and Vélez also reviewed other studies whose findings suggest that Plan B has post-fertilization MOAs that may result in the death of an embryo prior to implantation. Among these findings are: slowed transport of the embryo to the uterus resulting in an ectopic pregnancy or the embryo's delayed arrival in the uterus (after the brief four-day implantation window); diminished luteal (post-ovulatory) levels of LH and progesterone that prevent the changes to the endometrium needed to permit implantation; a shortened luteal phase (indicating that something is awry and the endometrium did not become hospitable to implantation and pregnancy support); and direct changes to the endometrium that block implantation.

The November 2013 Brache et al. analysis of pooled EC studies compares the efficacy of LNG (Plan B), Ulipristal acetate (Ella), a third EC (meloxicam), LNG+meloxicam, and placebo. Their findings lend support to the conclusions of Peck/Vélez and Mozzanega/Cosmi that Plan B is only minimally effective in delaying ovulation when given in the fertile period immediately preceding ovulation. Brache et al. found that Plan B was no more effective than a placebo in delaying/inhibiting ovulation. In fact, it was

even less effective than placebo because the progesterone in Plan B helped to trigger ovulation within 48 hours.

Given the dangers to the future of conscience rights posed by the Affordable Care Act, an honest debate over the "contraception mandate" is a necessity. But that debate can only take place by calling things what they are instead of attempting to redefine them into things they are not. Numerous studies have shown that the most popular emergency contraceptives can cause the death of embryos. For the sake of full and accurate informed consent for patients and for the sake of the integrity of the medical profession and research community, this reality must be acknowledged. Only then will we be able to make informed decisions about our personal healthcare and healthcare policy.

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[i] E.g., ""The development of a human begins with fertilization, a process by which the spermatozoon from the male and the oocyte from the female unite to give rise to a new organism, the zygote;" [Sadler, T.W. *Langman's Medical Embryology*. 7th edition. Baltimore: Williams & Wilkins 1995, p. 3]; "Although life is a continuous process, fertilization is a critical landmark because, under ordinary circumstances, a new, genetically distinct human organism is thereby formed.... The embryo now exists as a genetic unity;" [O'Rahilly, Ronan and Muller, Fabiola. *Human Embryology & Teratology*. 2nd edition. New York: Wiley-Liss, 1996, pp. 8, 29; "Zygote. This cell, formed by the union of an ovum and a sperm (Gr. *zyg tos*, yoked together), represents the beginning of a human being. The common expression 'fertilized ovum' refers to the zygote." [Moore, Keith L. and Persaud, T.V.N. *Before We Are Born: Essentials of Embryology and Birth Defects*. 4th edition. Philadelphia: W.B. Saunders Company, 1993, p. 1];

[ii] FDA-approved Drug Label (through June 10, 2013). On June 11, 2013, the F.D.A. approved a manufacturer-requested change to ParaGard's label, adding "possibly" before "prevention of implantation."

[iii] A list of studies can be found in footnote 106 of R. Peck and J. Vélez, "The Postovulatory Mechanism of Action of Plan B: A Review of the Scientific Literature," *The National Catholic Bioethics Quarterly* 13.4 (Winter 2013):000-000; available at *http://ncbcenter.org/document.doc?id=584;* accessed January 9, 2014.

[iv] M. Zieman and R.A. Hatcher, *Managing Contraception* (Tiger, GA: Bridging the Gap Foundation, 2012), p. 76.

[v] V. Brache et al., "Ulipristal Acetate Prevents Ovulation More Effectively than Levonorgestrel: Analysis of Pooled Data from Three Randomized Trials of Emergency Contraception Regimens," *Contraception* 88.5 (November 2013) 611-618.

[vi] Brache et al., 616-617.

[vii] B. Mozzanega and E. Cosmi, "How Do Levonorgestrel-Only Emergency Contraceptive Pills Prevent Pregnancy? Some Considerations," G*ynecological Endocrinology* 27.6 (June 2011) 439-442.