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**Full Disclosure: Blurry or
Broken Language and the
Beginning of Human Life**

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Maureen L. Condic, PhD. *The Science and Politics of Cloning: What the News Was All About*, On Point Series 2

Charles A. Donovan, *Multi-State Health Plans: A Potential Avenue to Tens of Thousands of Publicly Subsidized Abortions*, Only Point Series 3

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Editor's Note: The following is an excerpt from the brief amicus curiae of Americans United for Life (AUL) in Conestoga Wood Specialties Corporation v. Sebelius, in support of a petition for writ of certiorari in the U.S. Court of Appeals for the Third Circuit. The brief was filed on behalf of seven medical and bioethics groups in the United States. The text below refers to "Petitioners" (Conestoga) and "Respondents" (the Obama Administration in the form of Secretary of Health and Human Services Kathleen Sebelius and others).

The case involves the preventive services mandate (the "Mandate") from the U.S. Department of Health and Human Services under the Affordable Care Act, and the question presented is whether the federal government may compel a commercial enterprise with religious or conscientious objections to certain drugs and devices used to prevent conception and/or induce early abortions to provide or arrange for insurance coverage of such drugs and devices for its employees. The brief is excerpted here because of its clear and concise framing of evidence and arguments regarding the abortion-inducing mode of action of various drugs and devices that are involved in this and related litigation across the United States.

The Charlotte Lozier Institute (CLI) thankfully acknowledges the permission of AUL to reprint this excerpt. CLI has edited the excerpt only to renumber footnotes and to remove headings required for a legal brief that are not necessary for presentation as an independent article. For more information about AUL and to obtain a full copy of this amicus brief and related materials, visit www.aul.org.

A New, Distinct Human Organism Comes into Being at Fertilization

It is undisputed that a new, distinct human organism comes into existence during the process of fertilization.¹ Scientific literature states the following:

- "The fusion of sperm and egg membranes initiates the life of a sexually reproducing organism."²
- "The life cycle of mammals begins when a sperm enters an egg."³
- "Fertilization is the process by which male and female haploid gametes (sperm and egg) unite to produce a genetically distinct individual."⁴

¹ See, e.g., Condic, When Does Human Life Begin? A Scientific Perspective (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wpcontent/uploads/2012/06/wi_whitepaper_life_print.pdf; George & Tollefsen, EMBRYO 39 (2008).

² Marsden et al., Model systems for membrane fusion, CHEM. SOC. REV. 40(3):1572 (Mar. 2011) (emphasis added).

³ Okada et al., A role for the elongator complex in zygotic paternal genome demethylation, NATURE 463:554 (Jan. 28, 2010) (emphasis added).

⁴ Signorelli et al., Kinases, phosphatases and proteases during sperm capacitation, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012) (emphasis added).

- “The oviduct or Fallopian tube is the anatomical region where every new life begins in mammalian species. After a long journey, the spermatozoa meet the oocyte in the specific site of the oviduct named ampulla, and fertilization takes place.”⁵
- “Fertilization – the fusion of gametes to produce a new organism – is the culmination of a multitude of intricately regulated cellular processes.”⁶

The government’s own definition attests to the fact that life begins at fertilization. According to the National Institutes of Health, “fertilization” is the process of union of two gametes (i.e., ovum and sperm) “whereby the somatic chromosome number is restored and the development of a new individual is initiated.”⁷ Thus, in the context of human life, a new individual human organism is initiated at the union of ovum and sperm. One textbook similarly explains: Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to produce a single cell – a zygote. This highly specialized, totipotent cell marked the beginning of each of us as a unique individual.⁸

Thus, a new human organism is created before the developing embryo implants in the uterus – i.e., before that time at which some people consider a woman “pregnant.” Respondents [HHS] and their amici have at times tried to blur this distinct line with semantics of when “pregnancy” begins. Relying on a definition of pregnancy that begins at “implantation,” Respondents argue that “emergency contraceptives” are not “abortifacients.” However, this is a nonresponse to the concern that a drug or device can work after fertilization, by blocking the implantation of a developing human embryo. Such drugs might not end a “pregnancy” under Respondents’ definition, but it does end the life of a unique human being. What Petitioners [AUL et al.] – and Amici – conscientiously oppose is not simply the ending of a “pregnancy,” but this ending of human life.

Drugs and Devices Defined by the FDA as “Emergency Contraception” Have Post-Fertilization Mechanisms of Action

Drugs and devices with post-fertilization (i.e., life-ending) mechanisms of action are included in the FDA definition of “contraception.” Even though these drugs or devices may end a developing, distinct human being’s life by preventing implantation, they are labeled by the FDA as “contraception.” However, referring to such drugs as “contraception” is deceiving in that it infers only the prevention of fertilization. But the FDA’s criterion in categorizing a drug as “contraception” is whether a drug can work by preventing “pregnancy” – which the FDA defines as beginning at “implantation,” not fertilization.⁹

⁵ Coy et al., Roles of the oviduct in mammalian fertilization, REPRODUCTION 144(6):649 (Oct. 1, 2012) (emphasis added).

⁶ Marcello et al., Fertilization, ADV. EXP. BIOL. 757:321 (2013) (emphasis added).

⁷ National Institutes of Health, Medline Plus Merriam-Webster Medical Dictionary (2013), <http://www.merriamwebster.com/medlineplus/fertilization> (emphasis added).

⁸ Moore & Persaud, THE DEVELOPING HUMAN 16 (7th ed. 2003) (emphasis added).

⁹ For an overview of how the definition of “pregnancy” has changed, see Gacek, Conceiving Pregnancy: U.S. Medical

Thus, drugs that interfere with implantation – which occurs after fertilization and the creation of a new human organism – are categorized as “contraception.” Promoting the Mandate, Respondent Kathleen Sebelius, Secretary of Health and Human Services (HHS), admitted that the FDA’s definition of “contraception” extends to blocking the implantation of an already developing human embryo: “The Food and Drug Administration has a category [of drugs] that prevent fertilization and implantation. That’s really the scientific definition.”¹⁰ Respondent Sebelius stated that under the new Mandate, “[t]hese covered prescription drugs are specifically those that are designed to prevent implantation.”¹¹ Respondents know and admit that these drugs work after fertilization.

In his most recent study on “emergency contraception,” Dr. James Trussell, whose research on “contraception” is cited by the FDA, states: “To make an informed choice, women must know that [emergency contraception pills] . . . may at times inhibit implantation. . . .”¹² Although an advocate of “emergency contraception,” Dr. Trussell believes that the scientific difference between a drug that prevents fertilization of an egg and one that may also prevent implantation of a unique human organism is significant enough that it must be disclosed to a potential user. He has also stated that these post-fertilization effects “should certainly be [acknowledged and] celebrated, because without them the [contraceptive] method would not provide as much benefit as they do.”¹³ In other words, if fertilization has occurred, the method provides “benefit” by preventing implantation.

Strikingly, Dr. Warren Wallace, a physician at Northwestern University Medical School who has “prescribed emergency contraceptives,” and who was called to testify in support of a law restricting rights of conscience protections for the prescription of “emergency contraception,” testified that “there is a new unique human life before” the implantation of an embryo.¹⁴

Moreover, a new drug classified by the FDA as “emergency contraception” – Ulipristal Acetate (ella) – is actually an abortion-inducing drug, because it can kill an embryo after implantation. An understanding of these post-fertilization mechanisms of action, discussed below, demonstrates that “emergency contraception” can end the life of an already developing human organism.

Dictionaries and Their Definitions of Conception and Pregnancy, FRC INSIGHT PAPER (Apr. 2009), <http://downloads.frc.org/EF/EF09D12.pdf>.

¹⁰ Wallace, Health and Human Services Secretary Kathleen Sebelius Tells iVillage “Historic” New Guidelines Cover Contraception, Not Abortion (Aug. 2, 2011), <http://www.ivillage.com/kathleen-sebelius-guidelines-cover-contraception-not-abortion/4-a-369771> (emphasis added).

¹¹ Id. (emphasis added).

¹² Trussell et al., Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy (Office of Population Research at Princeton University June 2010).

¹³ Raymond et al., Embracing post-fertilisation methods of family planning: a call to action, J. FAM. PLAN. REPROD. HEALTH

CARE (2013), http://press.psprings.co.uk/jfprhc/september/jfprhc_100702.pdf.

¹⁴ Transcript of Bench Trial at 91-92, 111, Morr-Fitz, Inc. v. Quinn, 2012 IL App. (4th) 110398 (Ill. App. Ct. Sept. 20, 2012).

Plan B Can Prevent Implantation

In 1999, the FDA approved the distribution of the drug known as Plan B. Although called “emergency contraception,” the FDA’s labeling acknowledges that Plan B can prevent implantation of an already developing human embryo.¹⁵ Further, the FDA states on its website, “[i]f fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation).”¹⁶ The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step.¹⁷

Under Respondents’ Mandate, Petitioners are forced to pay for Plan B, despite its life-ending effect on already formed unique human organisms, in violation of Petitioners’ genuinely held religious beliefs.

Ulipristal Acetate (ella) can prevent implantation or kill an implanted embryo. In 2010, the FDA approved the drug Ulipristal Acetate (ella) as another “emergency contraceptive.” Importantly, ella is not an “improved” version of Plan B; instead, the chemical make-up of ella is similar to the abortion drug RU-486. Like RU-486, ella is a selective progesterone receptor modulator (SPRM) – “[t]he mechanism of action of ulipristal (ella) in human ovarian and endometrial tissue is identical to that of its parent compound mifepristone.”¹⁸ This means that though labeled as “contraception,” ella works the same way as RU-486. By blocking progesterone – a hormone necessary to build and maintain the uterine wall during pregnancy – ella can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by essentially starving it to death. Put another way, ella can abort a pregnancy, whether you define “pregnancy” as beginning at fertilization or at implantation.¹⁹

Studies confirm that ella is harmful to a human embryo.²⁰ The FDA-approved labeling notes that ella may “affect implantation”²¹ and contraindicates use of ella in the case of known or

¹⁵ Plan B Approved Labeling, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf.

¹⁶ FDA, FDA’s Decision Regarding Plan B: Questions and Answers (updated Apr. 30, 2009), <http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm>.

¹⁷ Duramed Pharmaceuticals, How does Plan B One-Step work? (2010), <http://www.planbonestep.com/faqs.aspx> (explaining that Plan B can work “by preventing attachment (implantation) to the uterus (womb)”).

¹⁸ Harrison & Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 ANNALS PHARMACOTHERAPY 115 (Jan. 2011).

¹⁹ See Gacek, *Conceiving Pregnancy*, supra.

²⁰ European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone 16* (2009), http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf.

²¹ ella Labeling Information (Aug. 13, 2010), http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

suspected pregnancy. A study funded by ella's manufacturer explains that SPRMs (drugs that block the hormone progesterone), "including ulipristal acetate," can "impair implantation."²² While the study theorizes that the dosage used in its trial "might be too low to inhibit implantation,"²³ it states affirmatively that "an additional postovulatory mechanism of action," e.g., impairing implantation, "cannot be excluded."

Thus, ella has the potential to destroy a human embryo. At the FDA advisory panel meeting for ella, Dr. Scott Emerson, a professor of Biostatistics at the University of Washington and a panelist, raised the point that the low pregnancy rate for women who take ella four or five days after intercourse suggests that the drug must have an "abortifacient" quality.²⁴

In short, ella goes beyond any other "contraceptive" approved by the FDA at the time of the Affordable Care Act's enactment. By approving ella as "contraception," the FDA removed, not simply blurred, the line between "contraception" and "abortion" drugs because ella can work by ending an established "pregnancy."

Further, though "indicated" for contraceptive use, mandated coverage for ella opens the door to the funding (through health insurance) of purposeful off-label abortion usage of the drug. Already, ella is available for sale online, where a purchaser need only fill out a questionnaire to obtain the drug, with no physician or pharmacist to examine the patient, explain the risks in person, or verify the identity and intentions of the purchaser. Thus, contrary to their religious and conscientious beliefs, Petitioners are required to pay for ella – an abortion-inducing drug – under Respondents' mandate.

Intrauterine Devices May Also Prevent Implantation

Copper Intrauterine Devices (IUDs) are heavily promoted as another form of "emergency contraception." IUDs can block the implantation of a human embryo after fertilization.²⁵

²² Glasier et al., Ulipristal acetate versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis, 375 THE LANCET 555 (Jan. 2010).

²³ In the Glasier study, "follow-up was done 5-7 days after expected menses. If menses had occurred and a pregnancy test was negative, participation [in the study] ended. If menses had not occurred, participants returned a week later." Considering that implantation must occur *before* menses, the study could not, and did not attempt to, measure an impact on an embryo prior to implantation or even shortly after implantation. *ella* was not given to anyone who was known to already be pregnant (upon enrollment participants were given a pregnancy test and pregnant women were excluded from the study). The only criterion for *ella* "working" was that a woman was not pregnant in the end. Whether that was achieved through blocking implantation, or killing the embryo after implantation, was not determinable.

²⁴ See Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf>.

²⁵ See Department of Health and Human Services, *Birth Control Methods* (Nov. 21, 2011), <http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf> ("If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus.").

In his study on “emergency contraceptives,” Dr. Trussell concludes that “[i]ts very high effectiveness implies that emergency insertion of a copper IUD must be able to prevent pregnancy after fertilization.”²⁶ Put another way, IUDs are so effective because they do not just prevent conception – they can kill an already developing human embryo. Once again, under Respondents’ Mandate – and contrary to their religious and conscientious beliefs – Petitioners are required to pay for devices that can kill human embryos.

²⁶ See Trussell, *Emergency Contraception*, *supra* (emphasis added).