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New American

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Is the Biden Administration Promoting Abortion via Contraceptives?

Since the U.S. Supreme Court ended federal protections for abortion last June, the Biden administration has been promoting the idea that women's access to contraceptives is in jeopardy. In remarks last July when he issued his Executive Order on Protecting Access to Reproductive Healthcare Services, Biden vowed, "My administration will also protect a woman's access to medications that are approved by the Food and Drug Administration — the FDA — like contraception, which is essential for preventative healthcare."

However, no state abortion laws ban birth control. Is Biden's argument just a red herring, or is it concealing a veiled admission of abortifacient potential in contraceptives?



Hidden agenda? President Biden issued an executive order last July that erroneously implies that June's Roe v. Wade reversal imperils women's access to contraceptives.

A recent FDA announcement helps answer that question. On December 23 the agency issued a Decisional Memorandum about levonorgestrel emergency contraception (LNG-EC), well known by the brand name Plan B One-Step. It is an over-the-counter "morning after" pill that women can take within 72 hours of intercourse.

The FDA's memorandum revealed plans to update Plan B patient safety information by removing facts about its abortifacient potential from the medication's labeling. According to traditional product literature, the drug releases a synthetic hormone, levonorgestrel (LNG), which works in three ways.

First, it discourages ovulation — the release of an egg from an ovary. If a woman doesn't ovulate, she can't get pregnant.

Next, it discourages fertilization of a released egg by impeding movement of both egg and sperm. If the egg and sperm can't meet, no pregnancy occurs.

A third mechanism of action is that the contraceptive can interfere with a woman's uterine lining, preventing a developing baby from implanting in the womb. In medical language this developing baby is known as a blastocyst, and some refer to it as a fertilized egg — an erroneous term because if it is fertilized, it isn't an egg anymore. Regardless of the terminology employed, uterine damage from LNG affects pregnancy post-fertilization (i.e., *after* conception, when unique DNA is present and a new life already exists). In other words, the drug can cause an abortion.

Not anymore! FDA now says Plan B One-Step *cannot* cause abortion, and the drug's former product labeling has caused "consumer confusion." Updates to the literature — which were requested by the

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drug manufacturer — are intended to "reduce barriers to use of the legally marketed approved product," reads the memorandum.

It's interesting timing: SCOTUS hands down a ruling that supposedly affects sales of a pharmaceutical drug, and FDA erases verbiage that could affect Big Pharma's bottom line. So much for informed consent.

FDA excuses itself by arguing that the "science has evolved since original approval" of the drug, so an update to the product's accompanying literature is warranted. However, of the 64 references listed in the Decisional Memorandum, none were published within the last five years. Fifty-five of them are more than a decade old, and 23 of them predate 2003. So much for late-breaking research influencing patient safety updates.

Category X

Missing from the memorandum's citations is a March 2015 study on LNG published in the journal *Experimental and Therapeutic Medicine*. It identifies the contraceptive as an FDA Pregnancy Category X medication, noting that "Category X drugs can be traded illegally via the internet for the purpose of early pregnancy termination."

FDA introduced its pregnancy categories in 1979, and Category X is the highest-risk. It is applied to any drug proven to cause fetal abnormalities or other adverse reactions in pregnancy — risks that "clearly outweigh potential benefits," explains the U.S. Department of Health & Human Services' Chemical Hazards Emergency Medical Management website. All progestins (i.e., hormonal contraceptives) — of which LNG is one example — are classified as Category X.



Contraceptive or abortifacient? Patient safety information accompanying the most popular over-thecounter contraceptive pill, Plan B One-Step, is getting an overhaul since the U.S. Supreme Court removed federal protections for abortion. (AP Images)

Abortifacient

Though the classification hasn't changed, an updated information page on the FDA website outright denies that LNG is an abortifacient. The agency insists, "Evidence does not support that the drug affects implantation or maintenance of a pregnancy after implantation, therefore it does not terminate a



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pregnancy."

Incidentally, that statement contains a blatant admission that pregnancy exists prior to implantation. It is an important point, since some abortion advocates still erroneously cling to the argument that life begins not at conception, when unique DNA is created, but only at some arbitrary threshold such as implantation or the even more ambiguous and changeable "age of viability."

However, the claim that the drug does not affect implantation is demonstrably false. For instance, the National Library of Medicine relates that one of the ways LNG works is "by changing the lining of the uterus (womb) to prevent development of a pregnancy." (Notice that it does not say "to prevent pregnancy," but "to prevent *development* of a pregnancy" — an important distinction.)

Numerous scientific studies support the National Library's statement. The journal *Endocrinology* included a February 2020 investigation titled "Levonorgestrel Inhibits Embryo Attachment by Eliminating Uterine Induction of Leukemia Inhibitory Factor," and its authors noted the importance of their research to the "understanding of contraceptive action." FDA's December memorandum actually mentioned this study, but brushed it aside as having insignificant clinical relevance.

The FDA is not alone in its disdain for research that condemns LNG as an abortion-inducing drug. The May 2014 issue of *Linacre Quarterly* published "Levonorgestrel in cases of rape: How does it work?" which featured a comprehensive review of studies into LNG's mechanisms of action. "The literature on LNG-EC contradicts the commonly held belief, and subsequent bioethical conclusions, that this drug primarily works to prevent ovulation and fertilization," the article states.

It's obvious from related studies that LNG certainly affects the endometrial lining and therefore implantation. A 2006 study published in the journal *Contraception* noted that LNG-EC "is associated with significant but transient changes in menstrual patterns in a significant proportion of users." FDA's memorandum ignored that research altogether.

However, the federal judiciary acknowledges LNG's abortifacient properties. In the 2014 case *Burwell v. Hobby Lobby*, the U.S. Supreme Court struck down ObamaCare's 2012 contraceptive mandate, which forced all insurance companies to provide contraceptives free of charge. Pro-life employers and individuals objected to being forced to pay into health plans that offer abortifacient drugs.

LNG was one of the contraceptives specifically named. The case included an *amicus curiae* brief by several national physician organizations. Experts from these groups explained that not only did FDA acknowledge that "Plan B may prevent a fertilized egg from attaching to the womb (implantation)," but the drug manufacturer also admitted that its product worked by "altering the endometrium, which may inhibit implantation."

For a more in-depth explanation of how the drug works, *The New American* turned to Dr. Christina Francis, CEO of the American Association of Pro-Life Obstetricians and Gynecologists. "Plan B is a highdose progestin [synthetic progesterone] that, if taken at a point in a woman's cycle that is 2 to 4 days prior to the peak of her luteinizing hormone (LH) levels, will delay or prevent ovulation, which in turn prevents conception," Francis relates. "However, taking Plan B too close to or after this LH peak may not prevent conception but instead only lower the woman's levels of progesterone — the hormone that allows the embryo to implant and grow. This means that Plan B has the potential not only to prevent the creation of a new human life but also to end that life in its earliest stages."



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Survey of Research

Independent studies confirm Francis' account. In 2016, an international team of researchers published findings in the *Linacre Quarterly*. They sought to compare pre- and post-fertilization effects of Plan B One-Step. The drug's ability to prevent fertilization would classify it as a contraceptive; its action ending pregnancy after conception would define it as an abortifacient as well.

Their "Lay Summary" concluded that Plan B

was originally thought to work by preventing fertilization. Recent research has cast doubt on this. Our review of the research suggests that it could act in a pre-fertilization capacity, and we estimate that it could prevent ovulation in only 15 percent or less of cases. The drug has no ability to alter sperm function and limited ability to suppress ovulation. Further, data suggest that when administered pre-ovulation, it may have a post-fertilization MOA [mechanism of action].

In other words, they concluded that LNG is an ineffective contraceptive but may snuff out newly conceived life.

These findings do not surprise Dr. Ingrid Skop, senior fellow and director of medical affairs for the prolife Charlotte Lozier Institute. "Plan B's primary mechanism of action is delay of ovulation. Unfortunately, that is the reason it does not work well as a contraceptive," she told *The New American.* "If a woman ovulated shortly before the act of unprotected intercourse, she is likely to become pregnant."

She went on to confirm that FDA's decision to rewrite Plan B patient safety information is unjustified. "Any progestin-containing contraceptive has the potential to interfere with implantation if the primary mechanism fails to prevent ovulation and fertilization occurs, because the progestin may also cause the uterine lining (endometrium) to be less hospitable to the developing embryo," she explained. "I am not aware of any recent evidence that this endometrial effect cannot ever occur, as the FDA implies."

Unfortunately, due to technological limitations, researchers lack absolute data to confirm the frequency of this phenomenon. "We do not know how often [failed implantation] occurs, because we do not have tests sophisticated enough to detect the embryo before implantation," says Skop.

Subjective Truth

Though the frequency of failed implantation may remain unknown, FDA bureaucrats are not alone in denying the reality that LNG can cause it. The 2016 *Linacre* researchers complained that the abortifacient potential of the drug is "frequently ignored" in studies, and they cited several examples. Curiously, each of their examples is creditably referenced in the FDA's Decisional Memorandum. Even more interesting is the fact that the 2016 *Linacre* report is also listed among references, but cited nowhere else within the memorandum.

"Women deserve complete and accurate information about emergency contraceptives, including how they work and what their risks are," Francis says. "Denying this fact contradicts the available evidence and denies women accurate information about this drug's effect on her body and potentially her child."

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Skop agrees. "Knowledge of this potential effect is an important component of informed consent counseling," she notes. "It is not appropriate to change labeling of a pharmaceutical product without clinical evidence in pursuit of political goals."

However, Skop adds another twist to this tangled web. She points out that state laws define abortion only as "an action taken to end a known pregnancy. Even the most sensitive pregnancy test cannot detect BHCG [the pregnancy hormone] until several days after implantation." In other words, state abortion laws cannot restrict access to Plan B or other contraceptives, because no "known pregnancy" exists when they are used.

Yet thanks to the FDA's recent updates, pro-life laws are demonized, important research is suppressed, and users of the drug are denied informed consent. At least sales of Plan B One-Step won't suffer.



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