



The Credibility Crisis at the FDA

An unfortunate result of the response to the COVID-19 pandemic has been a crisis of [credibility](#) of many government, scientific, and health care institutions. There is neither time nor space to explore the issue here. I will focus instead on how the US Food and Drug Administration (FDA) is adding fuel to this crisis. The FDA recently changed its Drug Facts Label for Plan B One Step (PBOS), known to the public as Plan B “emergency contraception,” in ways that create suspicion that this process was not so much guided by objective scientific facts as it was by political pressure and other extraneous factors.

The National Catholic Bioethics Center (NCBC) issued a [press release](#) on February 2nd noting that the FDA removed language “that, since 2006, had stated that PBOS ‘may inhibit implantation (by altering the endometrium).’ The FDA’s action has created the impression that PBOS and similar, generic levonorgestrel-based drugs used for ‘emergency contraception’ (LNG-EC) have no effect on the survival of a human being conceived following sexual assault.”

The FDA did this late Friday afternoon on the [23rd of December](#) 2022. One could hardly pick better timing to “bury” an important announcement. The Christmas weekend and end of year holiday travel and celebrations meant a minimum of people would be paying attention. This is only one of several factors that led many to question the motivations for and timing of this FDA action.

It is important to acknowledge that the science regarding the exact mechanism of action of Plan B and other drugs using levonorgestrel has been difficult to establish. The main point is that levonorgestrel is very effective at preventing pregnancy if taken within 72 hours of “unprotected” sex, even though it is often not able to stop ovulation when taken in the period of the cycle just preceding the release of an ovum from the ovary. If in these cases it does not prevent pregnancy by suppressing ovulation, how does it work?

Here we run into a major ethical problem for scientific research. Catholics and those who are pro-life cannot in good conscience conduct scientific research on human subjects to confirm that a drug has abortifacient effects. They would run the unacceptably strong risk of directly killing human embryos as part of their research. At the same time, scientists who have no ethical qualms about killing human embryos, or companies that produce these drugs, have no incentive to prove that what may be happening is an early abortion in some users of Plan B, namely, those who have had sexual intercourse and released an egg despite taking the drug.

With the Dobbs Supreme Court decision this past summer, which reversed *Roe v. Wade* and allowed states to severely restrict or ban abortion, concern mounted among some that Plan B and similar [drugs](#) could be affected by abortion bans. Quite a bit of verbal gymnastics was

required to maintain the position many liberals are now taking on Plan B. First, they affirm that “emergency contraception” cannot cause abortions. The very word contraception means preventing conception, but the scientific question is whether what may be happening is not the prevention of conception but the killing of a newly conceived human being. They further obscure the matter by redefining the beginning of pregnancy, and the word conception, so that it refers to when a human embryo implants in the uterine lining.

Given this “verbal engineering,” pro-life medical professionals have advised that we stop advocating for the defense of life from conception to natural death in public debate and legislation. The scientific term conception has had its meaning changed. Instead, the word fertilization is preferred to make clear that we are talking about the scientific fact that a unique new human being comes into existence with the fusion of the nuclei of the sperm and the egg at what everyone used to call conception. This fusion occurs days prior to implantation.

The FDA participates in this deadly deceptive game of redefinition when they say an abortifacient drug or device kills a growing human being who has implanted in the mother’s uterus. By that definition Plan B and other drugs or devices would clearly not be abortifacient, even if they killed human beings before implantation. The hubris of thinking that they can simply make the reality of a serious ethical issue go away by redefining terms is breath-taking. Objective reality exists and using word games to deceive in serious matters is a grave violation of ethics.

This is a desperate attempt to obscure the truth. Human life begins at conception (fertilization) and any killing of human beings at any stage of life once conceived should be treated as morally, ethically, and legally equivalent to abortion. That is the logical consequence so many are determined to avoid. Some do not hesitate to lie or manipulate science and the law to achieve their ends.

I wish that all really would “follow the science,” as the popular but [misleading](#) meme proclaims. This would do a world of good in discussions of abortion, transgenderism, and many other bioethical controversies. Notably, the FDA changed its guidance on Plan B without offering credible scientific evidence to buttress their new assertion that it only acts by preventing ovulation. In fact, one of the key studies they use to support their contraceptive claim suggests the exact opposite. In our recent [NCBC statement](#) we point out this glaring problem.

Data from the 2011 study from Noé et al. demonstrate that of 103 women who received LNG-EC and had sexual intercourse during Days -5 to -1, sixteen pregnancies would have been expected without LNG-EC and yet zero (0) pregnancies occurred.[11] As noted above, Noé’s study showed that 80% of these 103 women ovulated even after taking LNG-EC. These realities are striking. That LNG-EC *both* fails to prevent ovulation and yet still prevents pregnancies strongly suggests that it has harmful effects on early human life after fertilization and prior to implantation.

Also highly significant is that in 2005 and 2010 the FDA rejected requests to change their guidance on the possibility of an abortifacient mechanism of action of Plan B. Now they reverse

their position on the issue without any new scientific evidence to support the change? Given the stridently pro-abortion and “reproductive rights” advocacy of the Biden Administration, one is left with serious questions about the credibility of the FDA’s proclamation.

For more information on this topic and other questions raised by the FDA’s proclamation on Plan B, please see our recent [press release](#) and longer [statement](#).