PRESS RELEASE

The NCBC Responds to FDA Action on Plan B One-Step Label

February 2, 2023

CONTACT: John Brehany (215) 871-2015; jbrehany@ncbcenter.org

The National Catholic Bioethics Center (NCBC) has released "FDA Change of Plan B One-Step Label: Points to Consider," which highlights recent changes to the labeling of Plan B One-Step made by the US Food and Drug Administration (FDA).

Many may have failed to note the significance of the FDA's actions. They were announced on December 23, 2022, the Friday afternoon before the Christmas weekend. In its published materials, the FDA stated more strongly than it has in the past that Plan B One-Step and similar, generic levonorgestrel-based drugs used for "emergency contraception" (LNG-EC), have no connection to abortion or abortifacient mechanisms of action.

Unfortunately, the FDA did not address all factors relevant to how LNG-EC can impact human life after fertilization. The FDA argues that LNG-EC works by preventing or delaying ovulation rather than by causing any postovulatory effects on fertilization or implantation. However, the FDA ignored well-known data and concerns that LNG-EC often fails to prevent ovulation but still prevents pregnancy depending on when it is given. This important issue was not resolved and concerns about LNG-EC's post-fertilization effects remain. The NCBC therefore maintains its longstanding position that Catholic health care institutions and professionals should engage in testing to ensure with moral certitude (that is, by excluding any reasonable doubts) that, at a minimum, LNG-EC is not dispensed when it most likely could not prevent ovulation but may cause the death of an embryo.

Dr. Joseph Meaney, NCBC President, notes that "Catholic health care institutions have long provided compassionate care, including clinical and forensic services, to victims of sexual assault. They support the right of a victim to defend herself against an attacker and a potential fertilization resulting from sexual assault. At the same time, there is a profound moral duty to avoid interventions that would be expected to cause the death of an innocent human being."

In the charged political climate following the overturn of *Roe v. Wade*, and in the wake of the FDA's recent action, some states may try to enact laws requiring LNG-EC to be administered upon patient request after a negative pregnancy test. This would prevent the assessment required to enable each victim to give informed consent and make it impossible to ensure that LNG-EC is not dispensed when it most likely could not prevent ovulation but may cause the death of an embryo. Any legislation proposed to expand the availability of LNG-EC should ensure that the clinical judgment, conscience, and religious liberty rights of health care professionals and institutions are respected.

FDA Change of Plan B One-Step Label: Points to Consider

Bioethics On Air episode 106: Changing the Messaging and Mechanisms of Plan B - Part 1.

Bioethics On Air episode 107: Changing the Messaging and Mechanisms of Plan B – Part 2.

<u>The National Catholic Bioethics Center</u> (NCBC) is a nonprofit research and educational institute committed to providing education, guidance, and resources to the Church and society to uphold the dignity of the human person in health care and biomedical research.