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CONTACT: MICHELLE GRESS (202) 225-2577

Drug Policy Chairman tells FDA that health and safety of women necessitates physician role in emergency contraception

FDA should not allow over-the-counter sales of powerful Plan B drug

Washington, DC (August 26, 2005) – U.S. Rep. Mark Souder (R-IN), Chairman of the House Drug Policy Subcommittee, today asked the Food and Drug Commissioner, Lester M. Crawford, not to allow over-the-counter sales of the emergency contraceptive drug known as "Plan B."

Representative Souder emphasized in a letter to Commissioner Crawford that the health and safety of women and adolescent girls would be jeopardized if such a powerful drug were made available without physician supervision.

"Although emergency contraceptive drugs such as Plan B contain the same hormones that compose standard oral contraceptives, emergency contraceptives contain a much higher dosage than oral contraceptives," said Representative Souder, noting the dangerous possible side effects of prescription-only oral contraceptives include increased risk of developing liver tumors, liver cancer, breast cancer, heart attack, stroke or serious blood clots.

"[O]ver-the-counter availability of Plan B would remove the necessary safety precautions required for standard oral contraceptives, and would allow the widespread distribution of this powerful drug without any physician supervision and without any checks on the frequency of use for any particular patient."

Representative Souder also noted British reports linking higher rates of sexually transmitted disease with over-the-counter sales of emergency contraception, and the potential link between emergency contraceptive use and ectopic pregnancies as additional concerns justifying physician oversight.

"[Based on the known health risks for prescription-only oral contraceptives and the lack of information available on adolescent use of emergency contraceptives, I would be very disappointed if the FDA approved over-the-counter sales of this drug. Such a decision would expose women and girls to grave risks without any physician supervision." wrote Representative Souder.

A copy of Representative Souder's letter is available by calling Michelle Gress at 202-225-2577.