Stop the bloodshed and pass Holly's Law

By Susan E. Wills, Washington Times, February 5, 2006

Last Wednesday, Rep. Roscoe Bartlett held a briefing to publicize risks to women from RU-486 abortions and garner support for the "RU-486 Suspension and Review Act of 2005" (H.R. 1079), also called "Holly's Law."

Mr. Bartlett, Maryland Republican, first introduced this measure in November 2003 when there were four known fatalities associated with RU-486 abortions: Holly Patterson, the California teen for whom the law is named, and women from Tennessee, Canada and England.

Since then another five girls and women have died following RU-486 abortions: a Swedish teen, an Englishwoman and three more Californians.

Holly's Law is a very modest bill. It provides only for the *temporary* suspension of the Food and Drug Administration (FDA) approval of RU-486 and for a review by the Comptroller General limited to the agency's adherence to applicable regulations in its process of approving the drug.

We can expect the usual canard from pro-choice groups claiming opposition to RU-486 is based on "politics" rather than women's health and sound science. Once again they have it backward. The FDA approval of RU-486 was rife with flagrant departures from regulatory standards and reeked of abortion politics. The result has been a disaster for women's health.

More than 800 Adverse Event reports to FDA chronicle fatalities, near-fatalities, hospitalizations of up to a week, heart attacks, ruptured ectopic pregnancies, failed and incomplete abortions, serious-to-lethal infections, women who lost consciousness at home and required sutures to close head wounds, and hemorrhaging so extreme some women required replacement of half to all their blood volume. These cases may represent only a fraction of complications because the FDA doesn't mandate reporting by providers.

Dr. Michael Greene calculates the risk of death from infection following RU-486 abortions as tenfold the mortality rate from all causes in surgical abortions in early pregnancy (New England Journal of Medicine, December 2005).

This estimate does not take into account potential deaths from ruptured ectopic pregnancy, hemorrhaging and heart attack.

The FDA deviated from its procedures and failed in at least four ways to protect women's health.

(1) The FDA abandoned its "gold standard" for drug approval -- requiring two randomized, blind, controlled clinical trials. Its regulations state: "Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness." It settled instead for one uncontrolled American trial and a French trial which, under FDA's statistical review, revealed *un embarrass d'evidence* of falsification. Lab reports were missing and wrongly dated (e.g., dates of two reports changed to make it appear they were separate new reports). There were missing ultrasounds, pages missing from files, unreported surgical abortions, underreported side effects (e.g., "patient bleeding with two subsequent aspirations; convulsions reported as fainting; an expulsion that was actually a surgical evacuation").

(2) In approving RU-486, the FDA used its "fast track" regulatory authority under "Subpart H," which applies only to drugs needed to treat "serious or life-threatening illnesses" and the new drugs provide a "meaningful therapeutic benefit to patients over existing treatments." Other drugs approved under Subpart H treat AIDS, leprosy, sepsis and some cancers. Note to FDA: Pregnancy is *not* a disease, and RU-486 has *no* therapeutic benefit over existing (surgical) abortion.

(3) Taken alone, RU-486 is dangerously ineffective. A second drug, misoprostol ("Cytotec"), is needed to induce contractions to expel the dead embryo, but Cytotec's manufacturer repeatedly warned against its use in abortion. Immediately after the patent expired, the FDA took the astonishing step of approving the new use for misoprostol with RU-486, without *any* drug application having been filed.

(4) The FDA prescribed regimen for using RU-486/misoprostol lacked safeguards present in clinical trials, e.g. by not requiring ultrasonography to rule out ectopic pregnancy and pinpoint gestational age. With longer gestation, effectiveness plummets and adverse events increase dramatically. RU-486 fails to terminate ectopic pregnancies; by masking their symptoms, physicians can overlook this life-threatening condition.

FDA reluctance to suspend the drug temporarily is puzzling. Doctors involved in the U.S. drug trials of RU-486 may provide the answer. Dr. Carolyn Westhoff stated: "One of my real, and I think realistic, hopes for this method is that it will help get abortion back into the medical mainstream and out of this ghettoized place it's been in" (M. Talbot, "The Little White Bombshell," New York Times Magazine, July 11, 1999).

Dr. Eric Schaff, objecting to an early FDA proposal requiring doctors dispensing RU-486 to be trained in surgical abortion, explained: "The whole idea of [RU-486] was to increase access. ... [The FDA proposal] kills the drug if it can't be used by primary care providers"

(I. Stolberg, the New York Times on-line edition, June 8, 2000). Rather than killing "the drug," the FDA's flawed approval and subsequent inaction is killing children and their mothers. Congress must put a stop to this.

SUSAN E. WILLS
Associate director for education at the U.S. Conference of Catholic Bishops Secretariat for Pro-Life Activities

Secretariat for Pro-Life Activities
United States Conference of Catholic Bishops
3211 4th Street, N.E., Washington, DC 20017-1194 (202) 541-3070