

## **Prompts Renewed Call for Congressional Action on RU486 New Study Details Dangers of RU486**

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Two doctors who have examined over 600 reports of "adverse events" among U.S. women who have taken RU486 say they have found not only a dangerous pattern of problems among patients but also considerable deficiencies in the reporting of those complications.

Obstetrician/gynecologists Margaret Gary and Donna Harrison spoke on Capitol Hill on February 1, 2006. They discussed their findings, reported in the February 2006 issue of *The Annals of Pharmacotherapy*, at a press conference in which several members of Congress expressed their support for a bill that would pull RU486 from the market and investigate how such a dangerous drug came to be approved.

Ten women are now known to have died after taking RU486, including five in the U.S. Four women in California and one in Canada died from rare bacterial infections following their chemical abortions, while one RU486 patient from Tennessee died after her undetected tubal pregnancy ruptured. A woman in France died from a heart attack, while a teen in Sweden bled to death and two British patients died for reasons unknown after taking the abortion pill. NRLC has a fact sheet you can download at [http://www.nrlc.org/factsheets/FS15\\_pilldanger.pdf](http://www.nrlc.org/factsheets/FS15_pilldanger.pdf).

### **Congress Urged to Act**

Dr. Gary's and Dr. Harrison's February 1, 2006, press conference on Capitol Hill was hosted by Representative Roscoe Bartlett (R-Md.), one of the sponsors of "Holly's Law," named for Holly Patterson. Holly, a California teenager, died in 2003 after taking the abortion pill.

The bill, H.R. 1079, would suspend government approval for RU486 and investigate exactly how the dangerous drug came to be approved during the Clinton Administration.

Congressman Bartlett told reporters that "RU486 always kills babies. Today, we present stronger evidence that RU486 kills and injures women.

"It is unacceptable for the FDA to expose women to the risk of serious injury, especially deadly infections whose symptoms are similar to any RU486 abortion when we have documented cases of medical professionals who have failed to diagnose them," he said.

Bartlett added, "Responsible manufacturers pull drugs from the market. However, RU486's [American distributor], Danco, is a shell company. Its only product is RU486. That is why Congress must act and approve Holly's Law to protect women's lives and health from this dangerous drug."

Other legislators, such as Rep. Chris Smith (R-NJ), Jean Schmidt (R-Ohio), Joe Pitts (R-PA), and Pete Hoekstra (R-MI), as well as several representatives of pro-life or pro-family groups, spoke at the press conference or issued statements of support.

As of February 27, Holly's Law had 80 cosponsors in the House, while a companion bill sponsored by Senator Jim DeMint (R-SC), S. 511, had 12 cosponsors in the Senate.

Bartlett urged voters to contact their representatives and urge them to support Holly's Law. For information on

how to send an e-mail or fax to your U.S. House member and U.S. senators in support of this legislation, go to the Legislative Action Center on the NRLC web site at <http://www.capwiz.com/nrlc/issues/>.

## **Alarming Results**

Dr. Gary's and Dr. Harrison's report, "Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient," examined the 637 "adverse event reports" (or AERs) received by the U.S. Food and Drug Administration (FDA) from September 2000 to September 2004 for RU486. An additional 250 adverse event reports were received by the FDA from September 2004 to July 2005, but were not analyzed in this study.

The AERs examined in Gary and Harrison's study represented 607 unique patient incidents. The adverse responses included events ranging from hemorrhage, infection, and ruptured ectopic pregnancy—the most common complications—to heart attack, pulmonary embolism, pancreatitis, and allergic reactions. Several patients also had pregnancies that were not "successfully" aborted.

Drs. Gary and Harrison used the National Cancer Institute's coding criteria to rank the AERs by severity. They found that nearly half of those events could be ranked as "severe" (224 events) or "life threatening or disabling" (64 events), while another five had to be coded as "death[s] related to adverse event(s)."

All told, AERs indicated that one teen died and over 200 patients suffered from severe (168) or life threatening (42) hemorrhages. Three women in this initial group of AERs died of infections, but at least 47 other patients suffered from infections that could be called severe (43) or life threatening (4).

AERs indicate that 17 patients had undetected ectopic or tubal pregnancies at the time they took the abortion pill (RU486 does not abort ectopic pregnancies). Eleven of these ectopic pregnancies ruptured and one of these women died.

At least 40% of all patients represented by the AERs were hospitalized for treatment, including 12 admissions to the intensive care unit. Sixty-eight women received transfusions and 235 emergency surgeries were performed, including 218 emergency D&Cs to stop hemorrhages. Two of the women died on the operating table.

Information was often incomplete or lacking on AER forms, but Drs. Gary and Harrison looked for indications of fetal status or outcome in the 278 cases where the abortion drug "failed." In 21% of those cases (58), ultrasound documented fetal viability at the follow-up visit. In 66% of cases (184), there was simply no documentation one way or the other regarding fetal outcome.

As alarming as this data is, Drs. Gary and Harrison note that most of the AERs simply did not provide enough information to accurately code the severity of the adverse event being analyzed. In some cases, the authors say, "The deficiencies were so egregious ... as to preclude analysis."

Potentially more troubling, they point out, is that AER systems typically only uncover a fraction of complications that actually occur. Dr. Gary told a reporter for WebMD Medical News (12/29/05), "The FDA reports that only about 1% to 10% of adverse events for any given drug are ever reported."

Dr. Gary said that in this case, the numbers may be even worse, because "women may be even less likely to report problems because they may be ashamed."