RU 486 (MIFEPRISTONE OR MIFEPREX)

Nature of the Drug.

RU 486 (mifepristone or mifeprex) is an abortifacient drug which was approved by the United States Food and Drug Administration (FDA) in September 2000. The Clinton Administration put the testing and approval process for this drug on a fast track usually reserved for new potentially life-saving drugs needed by large numbers of patients with life-threatening illnesses.

Mifepristone (commercial name Mifeprex) works by blocking the action of the hormone progesterone in a pregnant woman's body. Progesterone helps the uterine lining grow and provide a nutrient-rich environment for the developing human being upon implantation. By blocking implantation, RU 486 causes an early abortion. In this "chemical abortion" procedure, a second drug called prostaglandin is also taken to bring on uterine contractions to expel the fetus.

Safety Record.

To date (August 18, 2013), at least 36 maternal deaths, including 15 in the United States, are known to have resulted from the use of RU 486.[1] Two board certified obstetrician gynecologists conducted a study evaluating FDA "adverse event" reports collected from September 2000 to September 2004 on 607 patients who experienced complications from using RU 486.[2] The authors graded the seriousness of the complications using criteria developed by the National Cancer Institute and found that:

Of 641 complications:

- .6% (less than 1%) were mild
- 53.7% were moderate
- 34.9% were severe
- 10.0% were life-threatening or disabling and
- .8% (n =5) resulted in death.

Hence, almost half, or 45.7% of the complications were severe or worse. The authors note that the most frequent serious and life-threatening adverse events were:

- hemorrhage (210 patients),
- infection (46 patients), and
- undiagnosed ectopic pregnancies (17 patients).

Other diagnoses included heart attack, blood clot in the lungs, acute pancreatitis, precipitation of a sickle cell crisis, exacerbation of Crohn's disease, and drug interaction resulting in liver failure. To treat these complications:

- 513 surgical procedures needed to be performed,
- 68 women needed transfusions, and at least
- 40% of the patients required hospitalization.

In the 94 cases where RU 486 failed to cause a complete abortion,

- 58 reported the fetus was still alive on the second visit, and
- 36 reported the fetus was dead or fetal parts were retained in the womb.

The study authors further state, "With mifepristone abortions, the rate of failure to cause a complete termination of pregnancy increases dramatically, along with hemorrhagic events [bleeding], as the gestational age and the size of the placenta increases."[3]

Clinical trials of RU 486 in the U.S. indicate that the failure to completely abort is

- 8% at 49 days of gestation or less,
- 17% AT 50-56 days since the last menstrual period, and
- 23% at 57-63 days since the last menstrual period.

A second FDA study found 2,207 adverse events from the use of mifepristone through April 30, 2011. The report listed 14 deaths, 612 cases (27.7% of the adverse events) requiring hospitalization, 339 women (15.4%) requiring blood transfusions, and 58 undetected ectopic pregnancies.[4] Renate Klein, a pro-choice biologist and social scientist who wrote a book about the dangers of RU 486, estimates that only 1% to 10% of complications are reported to the FDA, so the number of adverse events may be much higher than the 2,207 figure.[5]

Another study reviewed the results of the drug's use at 317 Planned Parenthood clinics during 2009 and 2010.[6] The 233,805 first-trimester medical abortions yielded the following adverse results:

- 1,530 adverse events were reported, which included over 1,100 cases where women had an ongoing pregnancy that wasn't terminated after two attempts with medication. In addition :
    - 385 women had a serious side effect, including
    - 238 who had to go to emergency rooms for treatment,
    - 135 who were admitted to a hospital,
    - 114 who required a blood transfusion,
    - 57 who required intravenous antibiotics, and
    - 1 woman who died because of an undetected ectopic pregnancy.

(The above events total to more than 385 because some women experienced more than one even.)

Protocol for the Drug's Use.

The usual protocol for RU 486 calls for the two drugs to be administered at 36 to 48 hour intervals. However, some facilities have been administering them only 24 hours apart, or simultaneously. A study of 1,223 patient charts at Boston Medical Center found that those patients who were given the two drugs simultaneously required surgical intervention about two times more often than those who got them 24 hours apart.[3] The simultaneous group had a 77% abortion completion rate while the other group had an 84% abortion completion rate. The study concluded that "simultaneous administration was associated with increased risk of surgical intervention."

As disturbing as the results of the FDA study are, the authors note that the FDA's Adverse Event Reporting systems "typically detect only a small percent of events that actually occur."[7] Randall O'Bannon, Ph.D., director of research and education for the National Right to Life Committee agrees that the number of women who have suffered RU 486 complications is probably much higher than that reported. He notes that (as is also true for surgical abortions):

- few women return to the abortionists to have complications treated,
- when they go to emergency rooms or their family doctor, they may not report the abortion, and if an infection results, any ensuing death may be reported as being due to the infection, and not to the abortion that caused it,

- the hospital, doctor or health clinic that treated the woman may not report that the complications were due to the use of RU 486.

Further, O'Bannon maintains that Danco Laboratories, RU 486's manufacturer, used data gathering procedures that exaggerate how many women actually use RU 486 and underestimate the number of women suffering complications. Hence, the number of women safely using RU 486 may be grossly overestimated.

Thus, it seems that the commercial that stated, "It's not nice to fool Mother Nature" contains a good deal of wisdom. In trying to circumvent Mother Nature (or God) in matters such as induced abortion, we tend to create more problems than we solve.

Effect of RU 486 Can Be Reversed.

RU 486 (Mifepristone) works over a period of 36-72 hours. If the woman changes her mind about the abortion, and the child is still alive, its effect can be reversed. Dr. Mary Davenport, President of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG) notes that if the woman receives shots of progesterone, they will overwhelm the RU 486 and keep the lining of the womb intact. She and a colleague report that out of six women who attempted reversal of RU 486, four successfully went on to have term babies.[8] For more information, readers may go to abortionpillreversal.com.

References

1. See Steven Ertelt, "Abortion Drug Has Killed 29 Women, European Maker Tells Italy's Government," LifeNews.com (July 31, 2009) and Food and Drug Administration, "Mifepristone U.S. Postmarketing Adverse Events Summary through 4/30/2011." The FDA included six more women in its April 2011 report, giving us at least 35 and the Cleland et al. article in *Obstetrics & Gynecology* added one more for a total of 36 (see reference 4 below).
2. Margaret M. Gary and Donna J. Harrison, "Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient," *The Annals of Pharmacotherapy*, Vol. 40 (February, 2006):191-197.
3. Richard Hyer, "ACOG 2009: Simultaneous Administration of Mifepristone and Misoprostol for Early Medical Abortion Increases Risk for Surgical Intervention," *Medscape Medical News*, May 5, 2009. (Accessed online 6/3/09).
4. U.S. Food and Drug Administration, "Mifepristone U.S. Postmarketing Adverse Events, Summary Through 04/30/2011."
5. Renate Klein et al., *RU 486: Misconception, Myths and Morals,* Spinifex Press: N. Melbourne, Australia, 2013.
6. See Kelly Cleland et al., "Significant Adverse Events and Outcomes After Medical Abortion," *Obstetrics and Gynecology* 121(1):166-171 (January 2013) and a report of the article by Genevra Pittman, "Medical Abortions Are Safe: Study," Business and Financial News, Reuters.com (December 20, 2012) Preprint report.
7. Gary and Harrison, p. 194. (See reference 2).
8. George Delgado and Mary L. Davenport, "Progesterone Use to Reverse the Effects of Mifepristone," *The Annals of Pharmacotherapy* 46 (December, 2012). Published on line, November 27, 2012, theannals.com,doi: 10.1345/aph.1R252

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