DANCO LABORATORIES

PO Box 4816
New York, NY 10185

infoline
1.877.4.EARLY OPTION

www.earlyoptionpill.com

April 19, 2002

Dear Health Care Provider:

This letter is to inform you of new safety information with regard to prescribing Mifeprex® and to remind you of your responsibility to report certain events and provide patient counseling, as stated in your Prescriber's Agreement.

New Safety Information

We have received a small number of reports of ruptured ectopic pregnancies (including one death from hemorrhage due to a ruptured ectopic pregnancy). As you will recall, Mifeprex* and misoprostol are not an effective treatment of ectopic pregnancy. Confirmed or suspected ectopic pregnancy is a contraindication for the use of Mifeprex and should be ruled out prior to initiating Mifeprex treatment. Because ectopic pregnancy may be present despite your best efforts to rule it out before starting Mifeprex treatment, you should be mindful of the possibility of an ectopic pregnancy throughout the treatment period and have a plan for its management.

Two cases of serious systemic bacterial infection (one fatal) following treatment with Mifeprex and misoprostol have been reported. While it is known that menstruation, childbirth and abortion (whether spontaneous, surgical or medical) create conditions that can result in infection, we do not believe that Mifeprex and misoprostol present a special risk of infection. Although serious infection in medical abortion is rare, we ask that you be alert to this possibility if your patients report symptoms or have signs of infection.

We have also received a report of myocardial infarction occurring in a 21 year old woman three days following use of Mifeprex and misoprostol.

No causal relationship between any of these events and use of Mifeprex and misoprostol has been established.

Approved Regimen

As a reminder, the Food and Drug Administration (FDA) approved regimen for administration of Mifeprex is:

- 600 mg Mifeprex taken orally in the office or clinic
- 400 mcg of misoprostol taken orally in the office or clinic 48 hours after the Mifeprex.

The FDA has not reviewed or approved other dosing regimens for early termination of pregnancy.

* Mifeprex is a registered trademark of Danco Laboratories, LLC.

Reporting Adverse Events and On-going Pregnancy

We would like to remind you to report any Serious Adverse Events (SAEs) associated with Mifeprex use to the address below. Serious adverse events include death, hospitalization, blood transfusion, and other major events. In the case of on-going pregnancy following treatment with the Mifeprex regimen (approximately 1%), you should also notify us if the patient chooses to proceed with her pregnancy.

Please provide a brief clinical synopsis by writing, calling, or emailing:

Medical Director
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
Medicaldirector@earlyoptionpill.com
Toll free at 1-877-4 Early Option (1-877-432-7596)

We may need to contact you to obtain additional information, so please include your contact information. The following information is helpful when you report adverse events: age of patient; gestational age; dosages and means of administration of all medications, including concomitant medications; clinical information on the patient, including relevant past medical history, laboratory results, and health care course; and final outcome of the patient.

Patient Counseling

We would like to remind you of the importance of helping your patients understand the benefits and risks of the Mifeprex regimen. During the first of three office visits, please give the patient a Medication Guide to read, as well as a Patient Agreement to read and sign. (These materials are included with each Mifeprex order. If you need additional copies, please contact our authorized distributor.)

As you are aware, bleeding and cramping are a normal part of the process; women can expect bleeding or spotting for an average of 9 to 16 days. Women may experience bleeding that is similar to, or greater than, a heavy period. In the U.S. clinical trials, about 1 out of 100 women required a surgical procedure, identical to the procedure for miscarriage, to stop heavy bleeding. If you do not plan to provide this procedure yourself, you must have made arrangements with someone who will and provide this contact information to your patient. Other side effects that may occur include nausea, headache, vomiting, diarrhea, dizziness, fatigue and back pain.

For more information about Mifeprex, visit www.earlyoptionpill.com or call the 24-hour hotline, toll-free at 1-877-4 Early Option (1-877-432-7596). If you have an emergent question, a physician will usually return your call within the hour. For general questions, our Medical Director typically returns calls within 24 hours.

Sincerely,
Danco Laboratories, LLC