DANCO LABORATORIES

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July 19, 2005

Dear Health Care Provider:

Danco Laboratories is providing you with important new safety information regarding Mifeprex® (mifepristone), indicated for the termination of pregnancy in patients who are ≤ 49 days pregnant, dated from the first day of their last menstrual period (LMP). From September 2000, when Mifeprex® was approved in the United States for marketing, through June 2005, more than 460,000 women have used Mifeprex® in the U.S.

Safety Information

Providers offering Mifeprex® should be aware that, as with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of Mifeprex®. No causal relationship between these events and the use of Mifeprex® and misoprostol has been established. Since Food and Drug Administration (FDA) approval of the Mifeprex® and misoprostol regimen almost five years ago, we have received reports of five deaths from serious bacterial infection and sepsis following treatment with Mifeprex® and misoprostol. All of these cases had atypical presentations of infection. One of these occurred during a clinical trial in Canada in 2001. The other four cases were reported from California – two in late 2003, one in early 2004, and one in mid-2005. The bacteria identified in the first three cases were *Clostridium sordellii.* The organisms in the other two cases are unknown at this time. These patients received intra-vaginal misoprostol (800mcg), but no causal relationship between vaginal use of misoprostol and an increased risk of infection or death has been established.

Patients with serious bacterial infections (e.g. *Clostridium sordellii*) and sepsis can present without fever, bacteremia or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. *Clostridium sordellii* infections have also been reported following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

While it is known that menstruation, childbirth and abortion (whether spontaneous, surgical or medical) create conditions that increase the risk of infections, we do not believe that the Mifeprex® and misoprostol regimen presents any special risk of infection. Nonetheless, all providers of medical abortion and emergency room health care providers must have an elevated index of suspicion to rule out sepsis in patients who present with the signs and symptoms listed above, or who complain of general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after administration of misoprostol.

This new safety information is included in the updated BOXED WARNING and WARNINGS section of the Mifeprex® Prescribing Information as well as in the MEDICATION GUIDE and PATIENT AGREEMENT, copies of which are enclosed. Updated versions of the Mifeprex® Prescribing Information and Medication Guide are available on Danco's website (www.earlyoptionpill.com).

Patient Counseling

We would like to remind you of the importance of helping your patients understand the benefits and risks of the Mifeprex® regimen, including the new safety information presented in this letter and the revised Medication Guide. During the first office visit, please give the patient a Medication Guide and Patient Agreement to read and review. If she decides to end her pregnancy with the Mifeprex® regimen, you should ask her to sign the Patient Agreement. Please advise patients to report abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea), with or without fever, if they experience these symptoms more than 24 hours after taking misoprostol. Also, please advise your patients to take their Medication Guide with them if they visit an emergency room or another health care provider who did not prescribe Mifeprex®, so that provider will be aware that the patient is undergoing a medical abortion.

Approved Regimen

As a reminder, the FDA approved regimen for administration of Mifeprex® is:

- 600 mg Mifeprex taken orally in the office or clinic on Day 1
- 400 mcg of misoprostol taken orally in the office or clinic on Day 3
- Follow-up visit on approximately Day 14

Reporting Adverse Events and On-going Pregnancy

We would also like to remind you to report serious adverse events and any ongoing pregnancies following treatment with the Mifeprex® regimen to us. 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)

For more information about Mifeprex®, please visit our web site at 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