

THOMAS MORE SOCIETY

A National Public Interest Law Firm

June 10, 2010

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Dear Tom:

This letter contains relevant information about the administration of abortifacients outside the personal presence of the physician.

“Abortion” is defined in Iowa law as “the termination of a human pregnancy with the intent other than to produce a live birth or to remove a dead fetus.” IOWA CODE § 146.1 Only physicians may perform abortions. *Id.* § 707.7(3) (Class “C” felony).

The regimen established by the FDA and the manufacturer of RU-486 (Danco Laboratories) make it crystal clear that both Mifeprex (mifepristone) and misoprostol, which is taken two days after Mifeprex, are to be ingested *in the presence of the physician who has administered them.* According to the FDA,

The approved Mifeprex regimen for a medical abortion through 49 day’s pregnancy is:

- Day One: Mifeprex Administration: 3 tablets of 200 mg of Mifeprex *orally at once*
- Day Three: Misoprostol Administration: 2 tablets of 200 mcg of misoprostol *orally at once*
- Day 14: Post-Treatment: the patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medical abortion treatment failures.

<http://www.fda.gov/Cder/Drug/infopage/mifepristone/default.htm> (emphasis added).

In a question and answer guide regarding Mifeprex, the FDA notes that mifepristone is supplied directly to physicians who meet certain qualifications and that it is not available in pharmacies or legally available over the Internet. Further physicians who meet those qualifications “must agree to other responsibilities, such as dispensing the Medication Guide” <http://www.fda.gov/Cder/Drug/infopage/mifepristone/qa2007.htm> The Medication Guide, which is provided to the patient, specifies that the tablets of Mifeprex (mifepristone) and misoprostol are to be taken “*at your provider’s office.*” <http://www.fda.gov/cder/foi/label/2005/020687s0131bl.pdf>, p. 17 (Medication Guide) (emphasis added). This requirement is repeated in the directions for Dosage and Administration, which note that “[t]reatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient,” and specify that “Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies.” *Id.* at 13. The Patient Agreement expressly states:

I understand that I will take Mifeprex *in my provider’s office* (Day 1).

I understand that I will take misoprostol *in my provider’s office* two days after I take Mifeprex (Day 3).

Id. at 19 (Patient Agreement), ¶¶ 5, 6 (emphasis added). The prescribing physician is required to administer Mifeprex in a manner consistent with the foregoing specifications. <http://www.fda.gov/Cder/Drug/infopage/mifepristone/prescriberagreement.pdf> (Prescriber’s Agreement).

In light of the foregoing, the administration of a drug to a pregnant patient for the purpose of terminating a pregnancy (with an intent “other than to produce a live birth or to remove a dead fetus”) constitutes an “abortion,” as that term is defined in Iowa law. IOWA CODE § 146.1. The administration of such a drug may be performed only by a physician, *id.* § 707.7(3), and, under the protocol established by the manufacturer of RU-486, must be done in the physician’s presence. The Michigan Attorney General has concluded that the administration of mifepristone constitutes an “abortion” under the applicable laws of the State of Michigan. *See* <http://www.ag.state.mi.us/opinion/datafiles/2000s/op10152.htm> (March 13, 2001).

Very truly yours,

Paul Benjamin Linton

Special Counsel

Thomas More Society