BUC & BEARDSLEY
919 EIGHTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006-5503

WRITER'S TELEPHONE
202-736-3610

TELEPHONE
202-736-3600
FACSIMILE
202-736-3608

October 27, 2006

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Chairman:

The enclosed letter from Dr. Richard Hausknecht, Medical Director of our client, Danco Laboratories LLC ("Danco"), responds to the questions in your September 13, 2006 letter to him.

As you will see, in response to certain questions, Dr. Hausknecht has referred you to this cover letter. The reason for his doing so arises from his and Danco's need for confidentiality in certain areas. As you are aware, Danco and everyone associated with the company are faced with the very real threat of violence against them and their workplaces by certain anti-abortion groups and individuals who have publicly threatened Danco and others associated with Mifeprex®. Danco's location, the identity and location of its contract manufacturing facilities, and the identity and locations of other companies and people associated with Danco are subjects of continuing probing by these groups who wish to identify and locate them so they can carry out their threats. To prevent such groups from identifying and locating these individuals and their workplaces, Danco keeps confidential and does not release to the public the names or the locations of those associated with it, nor any information which could lead those bent on violence to the individuals and facilities they have threatened. The Food and Drug Administration also keeps such information confidential, and its doing so has been upheld by the courts. Judicial Watch, Inc. v. FDA, 449 F.3rd 141 (D.C. Cir. 2006). The Court of Appeals has held that information about or leading to the identity and location of Danco and individuals and facilities associated with it could properly be kept confidential as a privacy matter because of the threat of abortion-related violence. The District Court also found that the threat of abortion-related violence was an appropriate basis for refusing to disclose confidential commercial information. 407 F. Supp. 70 (D.D.C. 2005) Danco has therefore instructed Dr. Hausknecht to respectfully decline to answer questions in a manner that would disclose the identity or location or lead to the identity or location of Danco itself and individuals and facilities associated with it.

Danco believes Dr. Hausknecht's responses provide the information necessary to satisfy the public interest in the answers to the questions in your letter, while at the same time honoring the legal and moral obligations of Danco and Dr. Hausknecht to individuals associated with the

development, manufacture, and distribution of Mifeprex, who face a threat of physical danger from abortion-related violence.

Your letter also requests copies of Danco's tax returns and information contained in those returns. As a privately held company, Danco has kept such information confidential. Danco therefore respectfully requests that the Subcommittee withdraw its request for this information.

Respectfully submitted,

Nancy L. Buc

Danco Laboratories, LLC P.O. Box 4816, New York, New York 10185

October 26, 2006

The Honorable Mark E. Souder
Chairman
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Congress of the United States
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Mr. Chairman:

I am responding to the questions in your September 13, 2006 letter to me.[1] Each response is stated to the best of my knowledge, information, and belief.

The questions are set forth in bold type, my answers in standard type.

1. What is your title at Danco, and what, specifically, do your responsibilities entail?

I am a consultant for Danco Laboratories LLC ("Danco") serving as its Medical Director. My responsibilities include management of the Adverse Event Program, pursuant to which I review adverse event information received by Danco, prepare and submit to FDA adverse event reports, as appropriate, and conduct follow up on such reports, as appropriate. I also provide scientific/medical input in reproductive health-related issues, and respond to medical questions from physicians and other healthcare providers.

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1. The Subcommittee agreed to extend the time for my response to October 27, 2006. Letters dated September 19, 2006 and October 16, 2006 from Buc & Beardsley to Kimberly Craswell, Office Clerk (attached).

2. **Do you currently or did you at any time, either prior to or during your employment with Danco, receive payment of money, favors, travel, accommodations, or any other compensation of any form, for any reason, from Population Council, Planned Parenthood, National Abortion Federation, NARAL, or any other interest group, pharmaceutical company, medical association, or organization other than Danco? If so, which organizations, and why?**

I was employed as the Medical Director of Planned Parenthood New York City from approximately 1996 – 1999. I have received honoraria on two occasions (in 2003 and 2005) from NAF for lectures at its annual national meeting. I received an honorarium for lecturing for Planned Parenthood Connecticut in 2006. I received compensation from The Population Council for participation as an investigator in a clinical trial.

3. **What was the rationale, legal or otherwise, for withdrawing from a Congressional investigative hearing in which your company's product, which is implicated in 8 deaths, 9 life-threatening situations, 232 hospitalizations, 116 transfusion cases, and 88 infections, was a focus? If your lawyers recommend your withdrawal, what was their reasoning?**

Let me first note that to use the word "implicated" in connection with these adverse events states or suggests that Mifeprex® caused such events; there is no scientific basis for such a statement or suggestion.

After initially telling the Subcommittee staff person who contacted me that I would accept the Subcommittee's invitation to testify, I decided upon further reflection not to do so.

4. **Since its inception, Danco has been affiliated with the Population Council, an advocacy group involved in the development of population control technologies throughout the world, particularly in the third world. Please explain in detail Danco's relationship to the Population Council from Danco's inception until now.**

I do not believe that the description of the Population Council in the question provides an accurate or complete picture. As the Population Council's website states, the Council is an international nonprofit organization that conducts biomedical, social science and public health research on a wide range of topics including, among others, reducing

neonate and infant mortality, improvement of obstetric care and post-partum care for mothers and newborns, developing strategies to support orphans and other children affected by AIDS, and encouraging abandonment of female genital cutting, as well as examining and improving family planning programs in developing countries.

Danco has a license from the Population Council to market mifepristone in the United States.

5. **It seems Danco was created for the sole purpose of providing chemical abortion to American women by producing Mifeprex. Please name all individuals, corporations, interest groups, government agencies, or other entities which were involved in creating Danco, by providing financial support, consulting, legal services, and any other support.**

Danco was created to bring Mifeprex to the United States, both for medical abortion and to treat other non-pregnancy-related conditions. Also, please see counsel's cover letter.

6. **In addition to chemical abortion being far more dangerous, painful, and inconvenient than surgical abortion in the early weeks of pregnancy, it is our understanding that it is also more expensive.**

I am unaware of any scientific evidence that the medical termination of intrauterine pregnancy ("medical abortion") is any more, let alone far more, dangerous, painful, or inconvenient than surgical abortion.

   a. **What is the standard cost charged by Danco to distributors for one dose of Mifeprex (at both the 200 and 600 mg level), and by physicians to patients?**

      The list price for a pack of 3 - 200 mg Mifeprex tablets is $270. I have no information about physicians' charges to patients.

   b. **What is the cost of a surgical abortion in the case that chemical abortion fails?**

      I have no information about prices charged by providers of surgical abortion.

7. **Often contraceptive suppliers who provide large quantities of product are able to secure reduced rates from distributors in order to increase profits.**

    a. **Is this also the case with chemical abortion? Does Danco supply any providers with Mifeprex at a reduced rate? If so, please list all providers receiving a reduced rate.**

    Danco offers a discount to nonprofit customers and certain high volume customers.

    b. **What benefit does Danco receive in return for the reduced rate?**

    Offering discounts to non-profit organizations and volume discounts is standard in the pharmaceutical industry.

8. **It is our understanding that Danco is incorporated in the Cayman Islands.**

    a. **Is Danco in fact incorporated in the Cayman Islands? If not, where is Danco incorporated?**

    Danco is not incorporated in the Cayman Islands. It is incorporated in the United States.

    b. **Where are Danco's manufacturing facilities?**

    Please see counsel's cover letter.

    c. **Why, if Mifeprex is available only in the United States, would Danco be incorporated in a foreign country?**

    Danco is not incorporated in a foreign country. It is a U.S. corporation.

9. **How many people does Danco employ in the United States? How many people does it employ overall?**

    In the United States and overall, Danco employs six people.

10. **It has been reported that Mifeprex is produced in China at a facility which initially failed FDA inspections several times, leading to significant delays in the availability of Mifeprex chemical abortion in the United States.**

    FDA cannot approve a New Drug Application ("NDA") if "the facilities and controls used for the manufacture, processing and packaging of [such] drug are inadequate to preserve

its identity, strength, quality, and purity." 21 U.S.C. § 355 (b)(1)(D). FDA's approval of the Mifeprex NDA means that FDA was satisfied that the statutory standard was met.

a. Did or does Danco use a Chinese manufacturing facility to produce Mifeprex?

Please see the cover letter from counsel.

b. Does Danco monitor the safety of the manufacturing facilities for Mifeprex? If so, how does it go about doing this, and how often does it do this?

As the sponsor of the NDA for Mifeprex, Danco is responsible for on-going compliance with FDA's regulations for Good Manufacturing Practices, 21 C.F.R. pts. 210 and 211, which implement provisions of the Food, Drug, and Cosmetic Act directed at drug safety. These "GMP" regulations impose a variety of requirements for manufacturing drugs, including production and process controls, laboratory controls, equipment, and records and reports.

c. Does the FDA monitor these facilities? If so, how? How often?

Under the Food, Drug, and Cosmetic Act, FDA has the authority to inspect facilities at which drugs are manufactured. 21 U.S.C. § 374. It has inspected the manufacturing of Mifeprex on several occasions.

11. Does Danco produce any drugs other than Mifeprex?

Danco does not market any drugs other than Mifeprex.

a. Does it have any plans to expand its operations? If so, what are the plans?

Danco is interested in developing mifepristone for other uses.

12. Five women who have taken Mifeprex have subsequently died of C. sordellii infection.

a. Is Danco aware of any other death from infection by C. sordellii associated with the use of Mifeprex?

No.

b. Is Danco aware of any other deaths by infection associated with the use of Mifeprex?

Danco is aware that a woman died from infection with *Clostridium perfringens* following a medical abortion with Mifeprex. No causal connection between Mifeprex and the death has been established.

c. What, specifically, has Danco done to investigate the link between Mifeprex and C. sordellii? Other infections?

Danco has been working with and continues to work with FDA, Centers for Disease Control ("CDC"), healthcare providers, and other medical experts to try and understand the circumstances surrounding these infections that have occurred after childbirth, miscarriage, medical abortion and other ob/gyn-related conditions. Danco obtained and provided FDA with important information about some of the deaths, and continues to respond to questions from FDA.

d. If there have been any studies or other actions, please name the dates, parameters, and results of such actions.

On May, 11, 2006, CDC, NIH, and FDA held a public workshop on emerging clostridial diseases, the goal of which was to develop a surveillance and research strategy surrounding *Clostridium difficile* and *Clostridium sordellii*.

13. If the FDA revoked the approval of Mifeprex for safety concerns related to the 8 deaths, 9 life-threatening situations, 232 hospitalizations, 116 transfusion cases, and 88 infections associated with the use of Mifeprex, would Danco survive as a company? Why or why not?

If FDA withdrew the approval of Mifeprex, Danco would not be able to market Mifeprex in the U.S. and would not receive revenue from that source. Whether the company would remain viable based on its other drug development programs would remain to be seen.

14. What circumstances, if any, would prompt Danco to refuse to provide Mifeprex to a physician? Has Danco ever cut off sales or refused to provide Mifeprex to a physician?

Mifeprex is not provided to a prescriber unless s/he has signed and submitted an FDA-approved Prescriber's Agreement. As to the second question, prescribers who failed to pay their bills or failed to provide licensing information have had their accounts suspended or terminated.

15. The FDA regulations imposed on the marketing of Mifeprex include the requirement that physicians report all adverse events to Danco.

FDA regulations do not require that physicians report all adverse events to Danco or FDA.

a. What are the details and protocols of your adverse event reporting system?

I review and analyze adverse event information received by Danco from any source including healthcare providers (such as doctors and nurses), patients, physician consultants, manufacturers and marketers of other products, scientific and medical literature, and clinical and non-clinical studies. I evaluate this information to determine what kind of adverse event report, if any, is required to be made to FDA, and fill out FDA's MedWatch Form (FDA Form 3500), if appropriate. A MedWatch Form is submitted to FDA as either a 15-day report or a periodic report, as appropriate. Certain information not reported as a 15-day or a periodic report is included in the annual report to FDA. I also follow up on adverse event information, as appropriate.

b. What would be the usual procedure by which an adverse event would come to your attention?

Danco receives adverse event information via U.S. mail, overnight courier (such as Federal Express), e-mail, fax, or telephone.

c. What proactive measures does Danco take to ensure all adverse events are being reported to the FDA, if any?

Please note that because there is no requirement for physicians or other healthcare providers to report "all adverse events" to Danco or to FDA, the information that Danco receives (see response to question 15a, above) does not necessarily include information about "all adverse events."

Physicians are encouraged to report adverse events to Danco or FDA in several ways:

1. Each shipment of Mifeprex is accompanied by the FDA-approved Prescribing Information, which contains the following:

> Adverse events, such as hospitalization, blood transfusion, ongoing pregnancy, or other major complications following the use of Mifeprex and misoprostol must be reported to Danco Laboratories. Please provide a brief clinical and administrative synopsis of any such adverse events in writing to:
>
> Medical Director
> Danco Laboratories, LLC
> P.O. Box 4816
> New York, NY 10185
> 1-877-4-Early Option (1-877-432-7596)
>
> For immediate consultation 24 hours a day, 7 days a week with an expert in mifepristone, call Danco Laboratories at 1-877-4-Early Option (1-877-432-7596).

2. The Prescriber's Agreement, which each prescriber must sign and submit before receiving any shipment of Mifeprex, provides Danco's address, 24-hour phone number, and e-mail address and states as follows:

> While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.

3. In Dear Doctor letters to customers (April 19, 2002, November 15, 2004, and July 19, 2005) and to Emergency Room Directors (November 15, 2004 and July 19, 2005). Each of these letters includes a reminder to physicians to report serious adverse events to Danco. One example of the reminder follows:

> 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 patient.
>
> 4. In an "Alert for Healthcare Professionals, Mifepristone (marketed as Mifeprex)" on its website, FDA states "To report any unexpected adverse or serious events associated with the use of [Mifeprex], please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm."

d. Have there been any instances where an adverse event was not reported by Danco to the FDA? What were they?

I believe any adverse event required to be reported has been reported.

16. In an apparent effort to capture reports on the anticipated adverse events that are the result of taking Mifeprex, the FDA's priority approval of Mifeprex included a requirement that prescribing physicians "[m]ust report any hospitalization, transfusion or other serious events to the sponsor or its designate." There is evidence that physicians are not reporting serious events.

The FDA's approval of Mifeprex was not a "priority," "accelerated," or "fast track" approval.

With respect to the statement that there is evidence that "physicians are not reporting serious events," I am not aware of any evidence that physicians are not reporting those serious adverse events of which they become aware.

a. **Planned Parenthood, for example, refers women who receive Mifeprex chemical abortions to a hotline number to call if they experience problems, rather than a number to reach their prescribing physician. That arrangement opens a loophole whereby prescribing physicians many remain unaware of adverse events that take place after they administer the abortion pill, alleviating them of reporting requirements. In light of this, how can Danco assure the public that prescribing physicians are actually reporting all events to Danco?**

Planned Parenthood has in place a separate system for collecting and providing to Danco information from Planned Parenthood clinics about adverse events related to Mifeprex. As a separate matter, neither Danco nor any other pharmaceutical company can ensure that every adverse event is reported to it or FDA, and they are not required to do so.

b. **Danco is required to report all adverse events to the FDA. Is Danco following this requirement? What evidence can Danco provide the Subcommittee which would demonstrate that Danco is reporting all adverse reported to it? This priority approval requirement under Subpart H is meaningless if physicians and emergency rooms are not reporting all adverse events to Danco, as they are required under FDA regulations to do. What does Danco do to ensure that physicians adhere to these reporting requirements? How often are these measures implemented? Please provide any documentation which would provide insight into the nature and frequency of these measures.**

Please see my responses to Question 15 and Question 16 above.

17. **The FDA has acknowledged the deaths of five women by infection associated by the use of Mifeprex, yet the FDA and other claim there has been no causal link established between Mifeprex chemical abortion and C. sordellii infection. If a causal link between the use of Mifeprex and the fatal C. sordellii infection was established, would Danco withdraw Mifeprex from the Market? If not, under what circumstances would Danco withdraw Mifeprex from the market?**

As the question recognizes, FDA and others, including experts from CDC, have stated that no causal link has been established between Mifeprex and *C. sordellii* infection.

The question of the circumstances under which Danco would withdraw Mifeprex from the market is too hypothetical to be answered.

18. The consensus among scientists who presented at the May 11, 2006 CDC conference was that mifepristone compromises the immune response, which would explain the 5 reported deaths by C. sordellii infection, 88 other reported infections, and several of the other nine life-threatening events.

I respectfully disagree that the consensus was as stated in the question. To the contrary, the consensus at the conference was that there is a lack of data about the cause, risk factors, or mechanism of action of *C. sordellii*.

a. What is Danco's opinion on the work of physicians like Dr. James McGregor, Dr. Esther Sternberg, and Dr. Ralph Miech, which identify a mechanism by which Mifeprex inhibits the immune system?

There are no scientific data identifying such a mechanism of action.

b. In what ways, specifically, might this research be refuted? Are there any methodological flaws, or flaws in the analysis of the data? If not, doesn't this work have serious implications for our understanding of Mifeprex's safety?

There are no scientific data supporting the hypothesis to evaluate or refute.

19. Despite the multitude of known adverse events associated with Mifeprex chemical abortions and acknowledged by the FDA, including 8 deaths, 9 life-threatening situations, 232 hospitalizations, 116 transfusion cases, 88 infections, and the fact that it is at least ten times more fatal than early surgical abortion,[2] it is still available on the market. Furthermore, the FDA's Medical Review, finalized on November, 1999 stated,

> **"[t]his method of pregnancy termination is of limited value because of the relatively short window of opportunity, [sic] in which it can be employed. Its safety and effectiveness is based on its use during the seven weeks following the first day of the**

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2. **[The following footnote is from the question in Chairman Souder's letter.] The mortality rate for women who procure a surgical abortion is 0.1 in 100,000 during the first eight weeks of pregnancy, the period for which RU-486 is available to women. Dr. Michael Green, based on usage rates of 460,000 and 4 deaths, suggested that the risk of death from chemical abortion is ten times greater. *See*, Michael F. Green, M.D., *Fatal Infections Associated with Mifepristone-Induced Abortion*, Dec. 1, 2005, N. ENGL. J. MED 353;22 *at* 2318. Current numbers suggest, however, eight deaths in the United States, while, according to the manufacturer, 575,000 women have used the drug. This works out to 1 in about 71,875, or 1.39 for every 100,000, suggesting a Mifeprex fatality rate that is fourteen times greater than that with surgical abortion during the eight weeks of pregnancy.**

last menstrual period. This means that most women would not suspect that they are pregnant and have a confirmatory pregnancy test until at least four weeks after the beginning of their last menses. This then, leaves only a three week period for the women to secure this method of abortion.

"Another disadvantage of this method …is the need for at least three visits to the medical facility [sic] including at least a four hours [sic] stay after the administration of the misoprostol.

"In addition, medical follow-up is required to ensure that surgical termination is performed in case the medical termination attempt fails since misoprostol has been reported to be teratogenic in humans …

"[In a study comparing medical and surgical abortion,] [t]he medical regimen had more adverse events, particularly bleeding, than did surgical abortion. Failure rates for medical abortion exceeded those for surgical abortion …Specific symptoms and adverse events, include cramping, nausea, and vomiting, were far more frequent among the medical than the surgical abortion patients …Three patients (all medical abortions) received blood transfusions. This is a serious potential disadvantage of the medical method. On the whole, medical abortion patients reported significantly more blood loss than did surgical abortion patients.

"[In another study of 377 patients comparing mifepristone to surgical abortion} [f]our mifepristone patients required curettage for acute bleeding while no surgical patients did. Nine mifepristone patients required curettage to manage ongoing pregnancy while no surgical patients did. Five mifepristone patients required suction curettage because of incomplete abortion while no surgical patients did. Fourteen mifepristone and eight surgical patients required suction curettage for persistent bleeding…Mifepristone patients experienced significantly longer postprocedure bleeding than did surgical patients…Mifepristone patients reported significantly longer bleeding in all three gestational age groups. Overall, mifepristone abortion patients reported significantly higher levels of pain, nausea, vomiting, and diarrhea during the actual abortion than did surgical patients…Mifepristone patients were routinely offered oral narcotics for expulsion-related pain, and 78.5% used them. Mifepristone patients reported more problems during the follow-up interval than did surgical patients. Post-abortion pain occurred in 77.1% of

mifepristone patients compared with only 10.5% of surgical patients. Nausea or vomiting in the follow-up interval was common in the mifepristone group, but rare among surgical patients."

To an outside observer, it seems the only benefit of choosing Mifeprex is the opportunity to avoid a surgical procedure that is less painful, more convenient, quicker, and exponentially safer than its chemical alternative. Please explain Danco's perspective about what benefits a women might gain from choosing a Mifeprex chemical abortion and explain how these benefits outweigh the increased inconvenience, the increased discomfort, and the increased danger of deadly infection, massive hemorrhage, and death associated with Mifeprex.

The question includes a multitude of assumptions and implicit and explicit assertions which are incorrect. Without attempting to parse each and every one, I note several as follows. No causal connection has been found between Mifeprex and any death. The numbers cited regarding various adverse events reflect reports made to FDA, none of which is a determination of a causal connection. Also, there is no requirement of a 4-hour stay after the administration of misoprostol in the FDA-approved regimen.

To answer the question as to why women choose Mifeprex, a number of studies document that many women offered a choice of a medical or surgical abortion choose medical abortion. For example, in a review of 12 published studies on patient attitudes toward medical abortion, the author concluded that, in most trials that offered a choice between surgical abortion and medical abortion, 60-70% chose medical abortion (Winikoff, B. et al., Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol: Results of a Large Multicenter Trial in the United States, *Arch Fam Med* 360, July/Aug 1998). Those studies did not collect data on the reason for each woman's choice, but there are several studies that have investigated the reasons many women choose medical abortion over surgical abortion. Some of those reasons are personal control, avoidance of surgery, privacy, and naturalness (e.g., Fielding et al., Having an Abortion Using

Mifepristone and Home Misoprostol: A Qualitative Analysis of Women's Experiences, *Perspectives on Sexual and Reproductive Health* 34(1): 34 – 40, 2002).

20. Please provide detailed summaries of all postmarket studies which Danco has conducted on Mifeprex, for any reason, the purpose of each study, and the results, specially noting for the Subcommittee which of these studies were required by the FDA.

FDA's approval of Mifeprex included a requirement that Danco conduct two post marketing studies. The first is a pregnancy outcome follow-up study of women who continued to be pregnant for at least one month after any Mifeprex exposure. The second is a prescriber monitoring study that was designed primarily to assess the relationship between patient outcome and whether the prescriber (a) provided surgical intervention if the medical abortion was not successful, or (b) referred patients to another healthcare provider for surgical abortion if the medical abortion was not successful.

Danco designed and implemented a protocol and is currently conducting the pregnancy follow-up study. Danco has determined that as of this time, very few pregnancies were continued for at least one month. The company has also designed and implemented a protocol for the prescriber monitoring study. Thus far, few Mifeprex prescribers have expressed an interest in participating in the study.

Danco provides updates to FDA on these two studies, including in Annual Reports.

21. Please explain in detail Danco's risk management plan for Mifeprex, FDA's efforts to ensure its implementation, and Danco's compliance with the risk management plan. Please provide any relevant documentation.

In addition to risk management practices required of all sponsors of new drugs under FDA's regulations (21 C.F.R. § 314.80), FDA's letter approving Mifeprex restricted distribution in a number of respects that are components of Danco's risk management plan.

Copies of the approval letter and other documents on this issue (e.g., Prescriber Agreement, Patient Agreement, and Medication Guide) are attached.

a. How often does FDA conduct investigations into Danco's compliance with the restrictions and regulations imposed with the approval of Mifeprex?

I am aware of five such FDA audits. I do not know if FDA has performed other investigations of Danco's compliance that do not involve such audits.

b. Which restrictions and regulations do these investigations cover?

I do not know what the audit teams' charters have been, but when auditing Danco, FDA has generally reviewed adverse event reporting records. FDA has also reviewed shipping and storage records, and Prescriber Agreement records.

c. Do they investigate compliance with all regulations during every investigation, or only some?

With respect to Danco, and as far as I know, other drug companies, only some.

d. If only some, which restrictions or regulations, and how often?

See b above.

e. Who conducts the investigations, and how are they conducted?

FDA personnel perform the audits under FDA's procedures for performing audits.

f. What are the specific dates and parameters of each investigation the FDA has conducted?

FDA audited Danco March 6-13, 2006, September 20-28, 2004, and in June 2002. FDA audited Danco's logistics partner in 2002 and the authorized distributor in 2002.

g. What were the results for each investigation? Did the FDA notify Danco that it was in full compliance with all restrictions and regulations? If not, of which restrictions or regulations was Danco considered noncompliant?

No warning letters have been issued or enforcement action taken in connection with these audits. It is not FDA's practice to notify companies that they "are in full compliance with all restrictions and regulations." No questions were raised by FDA about compliance with restrictions on distribution. Certain questions were raised about 21 C.F.R. § 314.80. FDA provided Danco with a copy of its inspectional observations from each audit of Danco on an FDA Form 483. Danco believes that most of these inspectional observations were inappropriate. FDA had no inspectional observations and no Form 483 was issued by FDA after the inspection of the logistics partner.

22. Is Danco notified in advance each time FDA investigates Danco's compliance, or has Danco been subject to unannounced compliance checks for any restriction/ regulation imposed with the Mifeprex approval?

Certain audits have been announced in advance.

a. If such unannounced compliance checks/ investigations have occurred, please provide dates and the subject or regulation/ restriction(s) investigated.

An unannounced FDA audit of Danco occurred in September 2004. FDA reviewed adverse event reporting records.

23. Has Danco or the Population Council been subject to any lawsuits related to Mifeprex? If so, when, and on what grounds?

Danco and Population Council have been named in three cases. One was filed in September 2004, one in December 2004, and one in September 2005. All allege personal

injury. Danco and the Council have denied the allegations. It is possible that Population Council has been named in other lawsuits of which I am unaware.

24. The September 28, 2000 memo accompanying the Subpart H approval of Mifeprex says, "The signed [patient] agreement form will be given to the patient for her reference and another kept in the medical record. The Population Council has committed to auditing prescribers to ascertain whether they have obtained signed copies of the Patient Agreement forms."

The language about auditing prescribers pertains to one of the Phase IV ongoing study commitments. In that prescriber monitoring study (which is described in my response to Question 20) one of the secondary objectives was to assess the frequency at which patients and providers sign a Patient Agreement form.

a. Has Danco Laboratories performed any of the aforementioned audits? How often? When?

No, because the study has not been enrolled.

b. Has Danco shared the results of these audits with the FDA?

Not applicable.

c. Please provide a summary of all findings.

Not applicable.

25. The approval of Mifeprex included a requirement that Danco have the ability to track Mifeprex usage "to the patient level."

a. Does such a tracking system exist?

Yes.

b. If so, what are the exact numbers of unique patients who have taken the drug, and individual doses dispensed to patients? Please break the numbers down by year.

The tracking system is not designed to and does not yield this information. Danco estimates that approximately 650,000 women have used Mifeprex in the United States since approval in 2000.

c. If Danco does not have exact numbers as required in the approval for Mifeprex, please explain in detail why not.

The approval does not require that Danco have exact numbers.

26. If there is a reliable tracking system in place, why does Danco estimate usage of its product? Why doesn't Danco use the requirement to track its product to the patient level to calculate precise usage numbers? Couldn't estimated usage numbers result in potential chemical abortion patients perceiving a lower risk associated with the use of Mifeprex? Shouldn't Danco take appropriate steps to ensure patients are giving fully-informed consent?

As to the first two questions, please see the answers to Question 25 above. Danco believes patients are given accurate risk information.

The concept of "fully-informed consent" applies to subjects in a clinical trial, not to patients to whom an approved drug is prescribed by their physician. Patients receive an FDA-approved Medication Guide and Patient Agreement before deciding whether to take Mifeprex. If a patient decides to use Mifeprex for a medical abortion, she reads and signs an FDA-approved Patient Agreement, acknowledging among other things, that she has read the Medication Guide and discussed the risks and benefits with her provider.

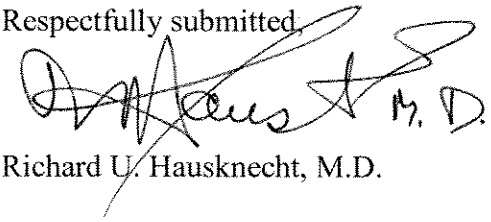
27. The Mifeprex label suggests that infections and hemorrhage are expected complications of chemical, surgical, and spontaneous abortion alike. Data shows, however, that chemical abortion is associated with a much higher risk of infection, hemorrhage, and death than its counterparts at the early stages of pregnancy. Isn't this label, then, misleading? Shouldn't Mifeprex labeling reflect the fact that chemical abortion is far more dangerous than surgical or spontaneous abortion? If not, why not?

The label is not misleading. There is no need or requirement to provide comparison to alternative treatments. There is no evidence that medical abortion is associated with a higher, much less "much higher," risk of infection, hemorrhage, and death than surgical abortion. The FDA-approved Mifeprex Prescribing Information provides extensive information about the drug, including safety and efficacy data, and the FDA-approved Medication Guide describes the possible risks and side effects in lay terms for patients.

28. What were Danco's profits for each of the past six years since its inception? Please provide to the Subcommittee copies of all annual company reports and/or all I.R.S. tax fillings by Danco for the past six years.

Please see counsel's cover letter.

Respectfully submitted,



Richard U. Hausknecht, M.D.

BUC & BEARDSLEY
919 EIGHTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006-5503

WRITER'S TELEPHONE
202-736-3622

TELEPHONE
202-736-3600
FACSIMILE
202-736-3608

September 19, 2006

Ms. Kimberly Craswell
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Congress of the United States
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: Letter to Richard Hausknecht, M.D.
dated September 13, 2006
Extension of Time to Respond

Dear Ms. Craswell:

On behalf of our client, Danco Laboratories, LLC, and its Medical Director, Dr. Richard Hausknecht, I am writing to confirm that the Subcommittee has agreed to extend the time for response to the above-referenced letter to October 13, 2006.

Very truly yours,

Deborah Livornese

BUC & BEARDSLEY
919 EIGHTEENTH STREET, N.W.
SUITE 600
WASHINGTON, D.C. 20006-5503

WRITER'S TELEPHONE
202-736-3622

TELEPHONE
202-736-3600
FACSIMILE
202-736-3608

October 16, 2006

Ms. Kimberly Craswell
Subcommittee on Criminal Justice,
Drug Policy and Human Resources
Committee on Government Reform
House of Representatives
Congress of the United States
2157 Rayburn House Office Building
Washington, DC 20515-6143

Re: Letter to Richard Hausknecht, M.D.
dated September 13, 2006
Extension of Time to Respond

Dear Ms. Craswell:

On behalf of our client, Danco Laboratories, LLC, and its Medical Director, Dr. Richard Hausknecht, I am writing to confirm that the Subcommittee has agreed to extend the time for response to the above-referenced letter to October 27, 2006.

Very truly yours,

Deborah Livornese

NDA 20-687

SEP 28 2000

Population Council
Attention: Sandra P. Arnold
Vice President, Corporate Affairs
1230 York Avenue
New York, NY 10021

Dear Ms. Arnold:

Please refer to your new drug application (NDA) dated March 14, 1996, received March 18, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MIFEPREX™ (mifepristone) Tablets, 200 mg.

We acknowledge receipt of your submissions dated April 19, June 20, July 25, August 15 and September 16 and 26, 1996; January 30, March 31, July 28, August 5, September 24, November 26, 1997; January 30 (2), February 19, April 27, June 25, October 26, December 8, 1998; February 8 and 22, March 31, April 28, May 10 and 20, June 3 (2), 15, 23, 25, and 30, July 14 (2) and 22, August 3, 13, 18 and 30, September 3, 8, 13 and 30, October 5, 26 and 28, November 16 and 29 (2), December 6, 7 and 23, 1999; and January 11, 21 and 28 (2), February 16 and 24, March 3, 6, 9, 10, 30 and 31 (2), April 20, May 3, 11 and 17, June 22 and 23, July 11, 13, 25 and 27, August 18, 21 and 24, September 8, 12, 15 (2), 19 (2), 20, 21, 22, 26 (2), and 27 (2), 2000. Your submission of March 30, 2000 constituted a complete response to our February 18, 2000 action letter.

This new drug application provides for the use of Mifeprex™ for the medical termination of intrauterine pregnancy through 49 days' pregnancy.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to approve Mifeprex™ (mifepristone) Tablets, 200 mg, for use as recommended in the agreed upon labeling text. The application is approved under 21 CFR 314 Subpart H. Approval is effective on the date of this letter. Marketing of this drug product and related activities are to be in accordance with the substance and procedures of the referenced regulations.

The final printed labeling (FPL) [including the professional labeling (Package Insert), the Medication Guide required for this product under 21 CFR Part 208, the Patient Agreement Form, and the Prescriber's Agreement Form] must be identical to the submitted draft labeling (Package Insert, Medication Guide, Patient Agreement Form, and the Prescriber's Agreement Form submitted September 27, 2000; and the immediate container and carton labels submitted July 25, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative

purposes, this submission should be designated "FPL for approved NDA 20-687." Approval of this submission by FDA is not required before the labeling is used.

Under 21 CFR 314.520, distribution of the drug is restricted as follows:

Mifeprex™ must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex™.
- Must provide each patient with a Medication Guide and must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and Patient Agreement, give her an opportunity to read and discuss both the Medication Guide and the Patient Agreement, obtain her signature on the Patient Agreement and must sign it as well.
- Must notify the sponsor or its designate in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an ongoing pregnancy, which is not terminated subsequent to the conclusion of the treatment procedure.
- Must report any hospitalization, transfusion or other serious events to the sponsor or its designate.
- Must record the Mifeprex™ package serial number in each patient's record.

With respect to the aspects of distribution other than physician qualifications described above, the following applies:

- Distribution will be in accordance with the system described in the March 30, 2000 submission. This plan assures the physical security of the drug product and provides specific requirements imposed by and on the distributor including procedures for storage, dosage tracking, damaged product returns, and other matters.

We also note the following Phase 4 commitments, specified in your submission dated September 15, 2000. These commitments replace all previous commitments cited in the September 18, 1996 and the February 18, 2000 approvable letters. These Phase 4 commitments are:

1. A cohort-based study of safety outcomes of patients having medical abortion under the care of physicians with surgical intervention skills compared to physicians who refer their patients for surgical intervention. Previous study questions related to age, smoking, and follow-up on day 14 (compliance with return visit) will be incorporated into this cohort study, as well as an audit of signed Patient Agreement forms.

2. A surveillance study on outcomes of ongoing pregnancies.

You have agreed to provide the final Phase 4 protocols for these studies within six months.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

We also remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call [redacted]

Sincerely,

/S/

[redacted]
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

To set up your account:

1

Read the Prescriber's Agreement on the back of this Account Setup Form.

2

Complete and sign this form.

3

Fax the completed Account Setup Form to the Danco distributor at 1-866-227-3343. Your account information will be kept strictly confidential.

4

The distributor will call to finalize your account setup and take your initial order.

5

Subsequent orders may be phoned in and are usually shipped within 24 hours.

6

Unopened, unused product may be returned for a refund or exchange up to a year after the expiration date.

MIFEPREX™
(Mifepristone) Tablets, 200 mg

ACCOUNT SETUP FORM

MIFEPREX™ (Mifepristone) Tablets, 200 mg; NDC 64875-001-03

Billing information

Bill to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

Shipping information (❑ Check if same as above)

Ship to Name _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Attention _____

Additional site locations

I will also be prescribing Mifeprex* at these additional locations:

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Name _____ Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

(Any additional sites may be listed on an attached sheet of paper.)

Request additional materials

❑ Medication Guides ❑ Patient Agreements

❑ State Abortion Guidelines ❑ Patient Brochures

Establishing your account (required only with first order)

Each facility purchasing Mifeprex must be included on this form (see additional site locations box above) before the distributor can ship the product. Please read the Prescriber's Agreement on the reverse of this form and sign below.

By signing below, you acknowledge receipt of the Prescriber's Agreement and agree that you meet these qualifications and that you will follow these guidelines for use.

Print Name _____ Signature _____

Medical License # _____ Date _____

Fax this completed Account Setup Form to the authorized distributor. Fax: 1-866-227-3343

Please fax any questions to the above number or call 1-800-848-6142.

*Mifeprex is a trademark of Danco Laboratories, LLC.

OWEB

MIFEPREX™

(Mifepristone) Tablets, 200 mg

PRESCRIBER'S AGREEMENT

We are pleased that you wish to become a provider of Mifeprex* (Mifepristone) Tablets, 200 mg, which is indicated for the medical termination of intrauterine pregnancy through 49 days from the first day of the patient's last menstrual period (see full prescribing information). Prescribing Information, Mifeprex Medication Guides and PATIENT AGREEMENT forms will be provided together with your order of Mifeprex.

Prior to establishing your account and receiving your first order, you must sign and return this letter to the distributor, indicating that you have met the qualifications outlined below and will observe the guidelines outlined below. If you oversee more than one office facility, you will need to list each facility on your order form prior to shipping the first order.

By signing the reverse side, you acknowledge receipt of the PRESCRIBER'S AGREEMENT and agree that you meet these qualifications and that you will follow these guidelines for use. You also understand that if you do not follow these guidelines, the distributor may discontinue distribution of the drug to you.

Under Federal law, Mifeprex must be provided by or under the supervision of a physician who meets the following qualifications:

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the prescribing information of Mifeprex. The prescribing information is attached to this letter, and is also available by calling our toll free number, 1-877-4 Early Option (1-877-432-7596), or logging on to our website, www.earlyoptionpill.com.

In addition to these qualifications, you must provide Mifeprex in a manner consistent with the following guidelines.

- Under Federal law, each patient must be provided with a Medication Guide. You must fully explain the procedure to each patient, provide her with a copy of the Medication Guide and PATIENT AGREEMENT, give her an opportunity to read and discuss them, obtain her signature on the PATIENT AGREEMENT, and sign it yourself.
- The patient's follow-up visit at approximately 14 days is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications. You must notify Danco Laboratories in writing as discussed in the Package Insert under the heading DOSAGE AND ADMINISTRATION in the event of an on-going pregnancy which is not terminated subsequent to the conclusion of the treatment procedure.
- While serious adverse events associated with the use of Mifeprex are rare, you must report any hospitalization, transfusion or other serious event to Danco Laboratories, identifying the patient solely by package serial number to ensure patient confidentiality.
- Each package of Mifeprex has a serial number. As part of maintaining complete records for each patient, you must record this identification number in each patient's record.

Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

PATIENT AGREEMENT
Mifeprex® (mifepristone) Tablets

1. I have read the attached MEDICATION GUIDE for using Mifeprex* and misoprostol to end my pregnancy.
2. I discussed the information with my health care provider (provider).
3. My provider answered all my questions and told me about the risks and benefits of using Mifeprex and misoprostol to end my pregnancy.
4. I believe I am no more than 49 days (7 weeks) pregnant.
5. I understand that I will take Mifeprex in my provider's office (Day 1).
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3).
7. My provider gave me advice on what to do if I develop heavy bleeding or need emergency care due to the treatment.
8. Bleeding and cramping do not mean that my pregnancy has ended. Therefore, I must return to my provider's office in about 2 weeks (about Day 14) after I take Mifeprex to be sure that my pregnancy has ended and that I am well.
9. I know that, in some cases, the treatment will not work. This happens in about 5 to 8 women out of 100 who use this treatment.
10. I understand that if my pregnancy continues after any part of the treatment, there is a chance that there may be birth defects. If my pregnancy continues after treatment with Mifeprex and misoprostol, I will talk with my provider about my choices, which may include a surgical procedure to end my pregnancy.
11. I understand that if the medicines I take do not end my pregnancy and I decide to have a surgical procedure to end my pregnancy, or if I need a surgical procedure to stop bleeding, my provider will do the procedure or refer me to another provider who will. I have that provider's name, address and phone number.
12. I have my provider's name, address and phone number and know that I can call if I have any questions or concerns.
13. I have decided to take Mifeprex and misoprostol to end my pregnancy and will follow my provider's advice about when to take each drug and what to do in an emergency.
14. I will do the following:
    - contact my provider right away if in the days after treatment I have a fever of 100.4°F or higher that lasts for more than 4 hours or severe abdominal pain.
    - contact my provider right away if I have heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours).
    - contact my provider right away if I have abdominal pain or discomfort, or I am "feeling sick", including weakness, nausea, vomiting or diarrhea, more than 24 hours after taking misoprostol.
    - take the MEDICATION GUIDE with me when I visit an emergency room or a provider who did not give me Mifeprex, so that they will understand that I am having a medical abortion with Mifeprex.
    - return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant.
    - return to my provider's office about 14 days after beginning treatment to be sure that my pregnancy has ended and that I am well.

Patient Signature: _____

Patient Name (print): _____

Date: _____

The patient signed the PATIENT AGREEMENT in my presence after I counseled her and answered all her questions. I have given her the MEDICATION GUIDE for mifepristone.

Provider's Signature: _____

Name of Provider (print): _____

Date: _____

After the patient and the provider sign this PATIENT AGREEMENT, give 1 copy to the patient before she leaves the office and put 1 copy in her medical record. Give a copy of the MEDICATION GUIDE to the patient.

Rev 2: 7/19/05

MEDICATION GUIDE

Mifeprex® (MIF-eh-prex)
(mifepristone)

Read this information carefully before taking Mifeprex* and misoprostol. It will help you understand how the treatment works. This MEDICATION GUIDE does not take the place of talking with your health care provider (provider).

What is Mifeprex?

Mifeprex is used to end an early pregnancy. It blocks a hormone needed for your pregnancy to continue. It is not approved for ending later pregnancies. Early pregnancy means it is 49 days (7 weeks) or less since your last menstrual period began. When you use Mifeprex (Day 1), you also need to take another medicine misoprostol, 2 days after you take Mifeprex (Day 3), to end your pregnancy. But, about 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Prompt medical attention is needed in these circumstances. Serious infection has resulted in death in a very small number of cases in which misoprostol was used in the vagina. There is no information that vaginal use of misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your provider. Your provider's telephone number is _____.

Be sure to contact your provider promptly if you have any of the following:

Heavy Bleeding. Contact your provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical abortion/D&C) to stop it.

Abdominal Pain or "Feeling Sick". If you have abdominal pain or discomfort, or you are "feeling sick", including weakness, nausea, vomiting or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

Fever. In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your provider right away. Fever may be a symptom of a serious infection or another problem (including an ectopic pregnancy).

Take this MEDICATION GUIDE with you. When you visit an emergency room or a provider who did not give you your Mifeprex, you should give them your MEDICATION GUIDE so that they understand that you are having a medical abortion with Mifeprex.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

Talk with your provider. Before you take Mifeprex, you should read this MEDICATION GUIDE and sign a statement (PATIENT AGREEMENT). You and your provider should discuss the benefits and risks of your using Mifeprex.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take it if:

- It has been more than 49 days (7 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- Your provider has told you that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next 2 visits.
- You cannot easily get emergency medical help in the 2 weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Tell your provider about all your medical conditions to find out if you can take Mifeprex. Also, tell your provider if you smoke at least 10 cigarettes a day.

How should I take Mifeprex?

- **Day 1 at your provider's office:**
  - Read this MEDICATION GUIDE.
  - Discuss the benefits and risks of using Mifeprex to end your pregnancy.
  - If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT.
  - After getting a physical exam, swallow 3 tablets of Mifeprex.
- **Day 3 at your provider's office:**
  - If you are still pregnant, take 2 misoprostol tablets.
  - Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your provider may send you home with medicines for these symptoms.
- **About Day 14 at your provider's office:**
  - This follow-up visit is very important. You must return to the provider about 14 days after you have taken Mifeprex to be sure you are well and that you are not pregnant.
  - Your provider will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your provider will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your provider about them because they may interfere with the treatment. Ask your provider about what medicines you can take for pain.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss with your provider if you should stop breastfeeding for a few days.

What are the possible and reasonably likely side effects of Mifeprex?

Cramping and bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must return to your provider on Day 3 and about Day 14. See "How should I take Mifeprex?" for more information on when to return to your provider. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take on Day 3. Bleeding or spotting can be expected for an average of 9–16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of ending the pregnancy.

Other common symptoms of treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. Your provider will tell you how to manage any pain or other side effects.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

* * *

Medicines are sometimes prescribed for purposes other than those listed in a MEDICATION GUIDE. For more information, ask your provider for the information about Mifeprex that is written for health care professionals. Ask your provider if you have any questions.

This MEDICATION GUIDE has been approved by the U.S. Food and Drug Administration.

Rev 2: 7/19/05

Danco Laboratories, LLC

P.O. Box 4816
New York, NY 10185

1.877.4 EARLY OPTION
(1.877.432.7596)

www.earlyoptionpill.com