FDA

TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

T96-61
Sept. 18, 1996

Lawrence Bachorik
(301) 443-1130

FDA ISSUED APPROVABLE LETTER FOR MIFEPRISTONE

The Food and Drug Administration today issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. As announced by the Population Council, the Agency has determined that the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision. Additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made. The following can be used to answer questions:

An FDA advisory committee voted 6-0 (with two abstentions) on July 19, 1996, that clinical data show that the benefits of a mifepristone and misoprostol regimen for terminating early pregnancy outweigh its risks. The studies presented to the Committee involved women treated under close medical supervision within 49 days of the beginning of their last menstrual period. The data come from two French trials, involving 2,480 women, that

-MORE-

showed the combination of mifepristone and misoprostol, an oral prostaglandin, to be about 95 percent effective.

In addition, the Population Council, a non-profit research organization, presented to the Committee preliminary safety data from U.S. trials, involving more than 2,000 women. Trials were conducted in the U.S. to complement the European data and to confirm whether the drug regimen could be safely used in the American medical system.

The regimen used in the clinical trials consisted of 3 tablets (600 milligrams) of oral mifepristone followed two days later by 2 tablets (400 micrograms) of oral misoprostol.

Adverse events seen in clinical trials include painful contractions of the uterus, nausea, vomiting, diarrhea, pelvic pain and spasm, and headache. A very small percentage of patients in the clinical trials required hospitalization, surgical treatment, and/or blood transfusions.

The Population Council's new drug application was filed on March 18, 1996. Under the Prescription Drug User Fee Act, priority drugs such as mifepristone have a six-month goal for initial Agency action.

####

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017

Sandra P. Arnold
Vice President, Corporate Affairs

July 26, 1996

Health Science Administrator
US Food and Drug Administration
Center for Drug Evaluation and Research
5600 Fishers Lane, HGD021
Rockville, Maryland 20857

Dear :

Enclosed as you have requested are copies of the slides used by Dr. Ann Robbins, Dr. Irving Spitz, Dr. C. Wayne Bardin, and Dr. Beverly Winikoff at the meeting of the Advisory Committee on July 19. Let me draw your attention to the annotation in the lower right hand corner of each slide, indicating that the information is unpublished, and, in the case of Beverly Winikoff's slides, both preliminary and unpublished.

Since we wish to preserve the right to publish the data, we would prefer that the copies be used only to complete the FDA record of the event, as you and I have discussed, and not released to the press or others. In addition, the preliminary nature of the results reported by Dr. Winikoff make an even more compelling case for limiting the distribution of the information.

Thank you once again for the great care with which you and others managed the proceedings on the 19th. We are of course delighted with the results, and were very pleased with how smoothly everything functioned. We know that this doesn't happen by accident!

Please don't hesitate to contact me if there is anything further I can help you with.

Very truly yours,

Sandra Arnold

Enclosures

APPEARS THIS WAY
ON ORIGINAL

Telephone: (212) 339-0500 Telex: 9102900660 POPCO Facsimile: (212) 755-6052 Cable: POPCOUNCIL NEW YORK

History of the Use of Mifepristone Plus Misoprostol for Medical Abortion

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Developmental Milestones in the Marketing of Mifepristone for Pregnancy Termination

1970 — Identification of the progesterone receptor (PR)

1982 — Initial report of medical termination of pregnancy with mifepristone, the first PR antagonist.

1983 — The Population Council files IND for clinical trials of mifepristone in the the U.S.

1988 — Marketing approval in France and China

1991 — Marketing approval in the United Kingdom

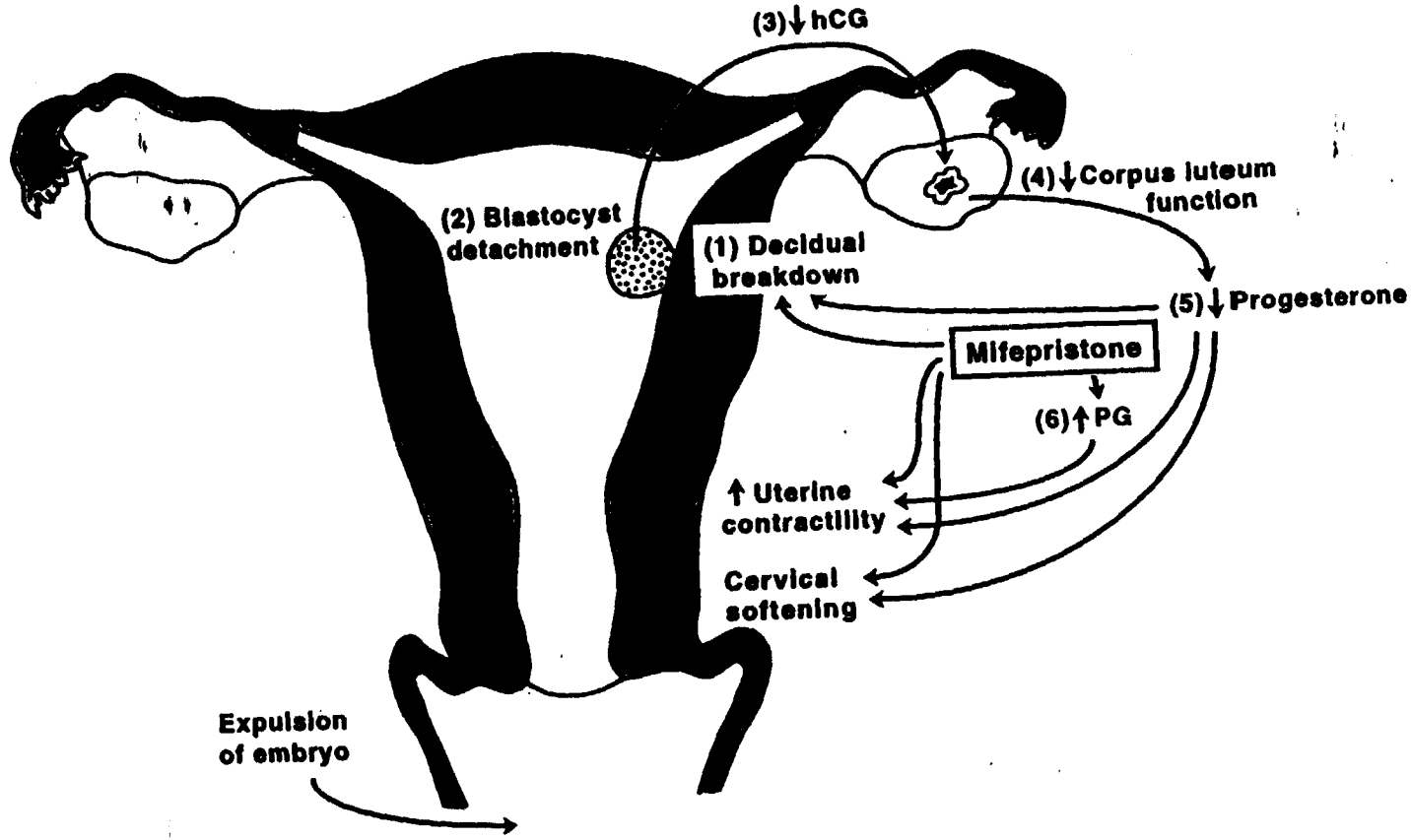
1992 — Marketing approval in Sweden

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

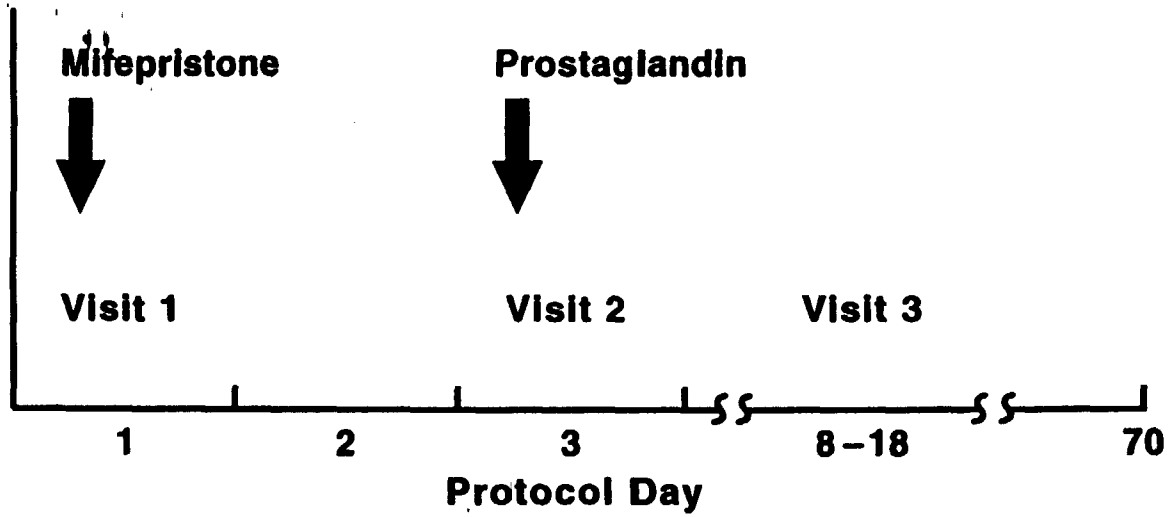
Clinical Development of Mifepristone

- Initial report of pregnancy termination with mifepristone
- Selection of a single 600 mg dose of mifepristone
- The addition of a prostaglandin increases efficacy
- Demonstration of serious adverse events with sulprostone
- Clinical trials with mifepristone and misoprostol in France

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

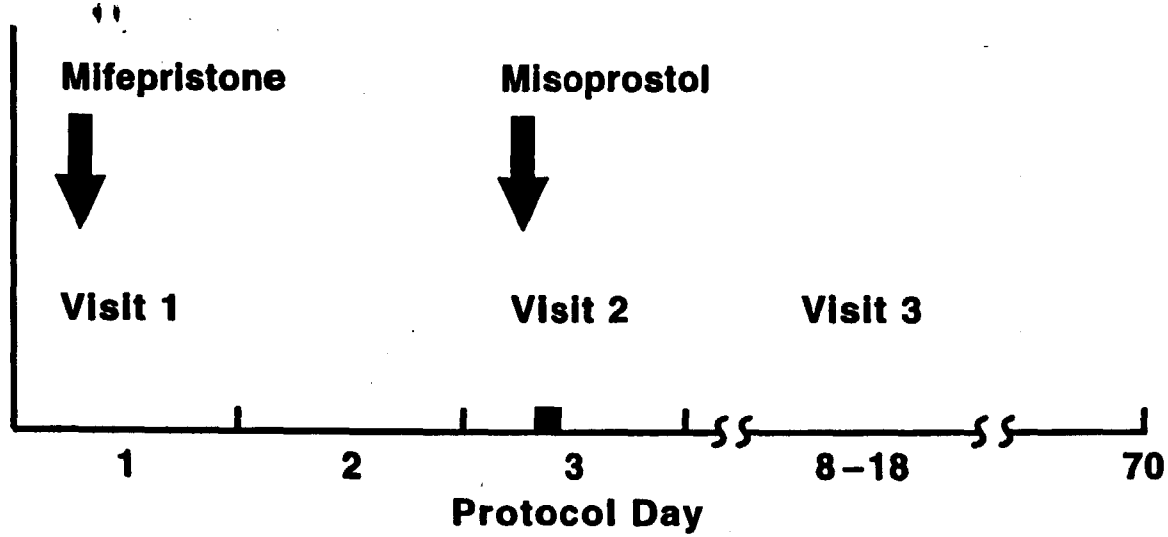


The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

French Studies of Mifepristone and Misoprostol



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Registration of Mifepristone in the U.S. by The Population Council

May 1994: • **The Population Council is granted U.S. rights for the use of Mifepristone**

U.S. Clinical Trial **New Drug Application**

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

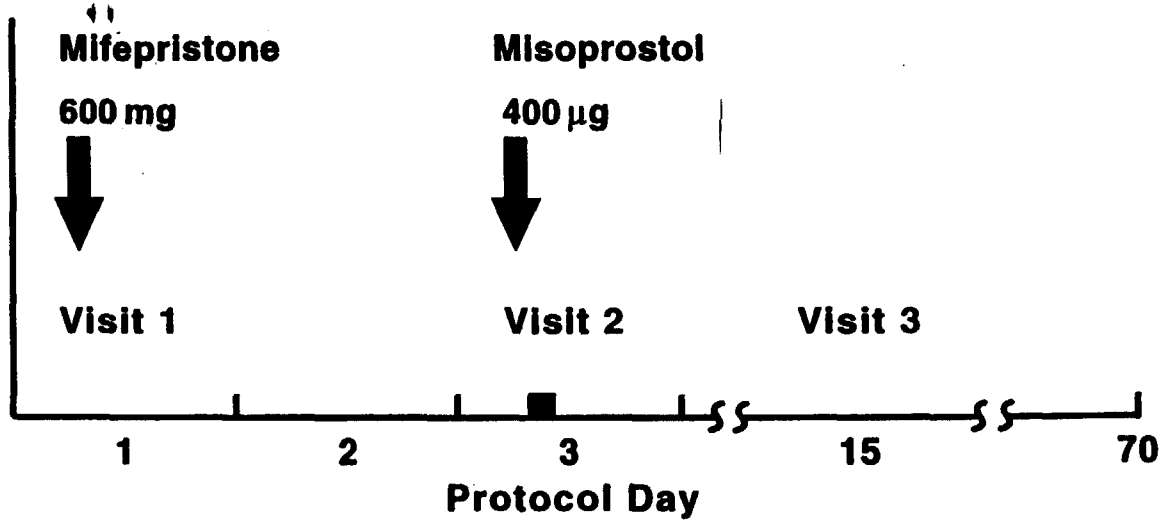
Registration of Mifepristone in the U.S. by The Population Council

U.S. Clinical Trial

- Initiated Fall 1994
- 2121 women enrolled
- ≤ 63 days of gestation
- 17 clinical sites
  - — geographically distributed
  - — variety of provider settings

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

U.S. Clinical Trial



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Registration of Mifepristone in the U.S. by The Population Council

New Drug Application

Summer 1994:	• Pre-NDA meeting with the FDA • NDA preparations begin
Fall-Winter 1994:	• Obtain database for French trials • Audit/validation of the database • Full re-analysis of the French database
Summer 1995:	• Cut-off date for information to be included in the NDA
Fall-Winter 1995:	• Final production of NDA begins
Spring 1996:	• NDA submitted to the FDA
Summer 1996:	• FDA audits French pivotal trial sites and data

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Clinical Features of the NDA

- **Background: efficacy and safety data**
  - **— mifepristone alone**
  - **— mifepristone + other prostaglandins**
- **Pivotal trials: efficacy and safety data**
  - **— mifepristone + misoprostol**
  - **— two French studies**
  - **— 2480 subjects**
- **International safety data**
  - **— other clinical trials**
  - **— compassionate use**
  - **— post-marketing surveillance**

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Effectiveness of Mifepristone Plus Misoprostol for Medical Abortion

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Study Regimens

- **Mifepristone alone**
- **Mifepristone and Prostaglandins**
  - **— Sulprostone or Gemeprost**
- **Mifepristone and Misoprostol**

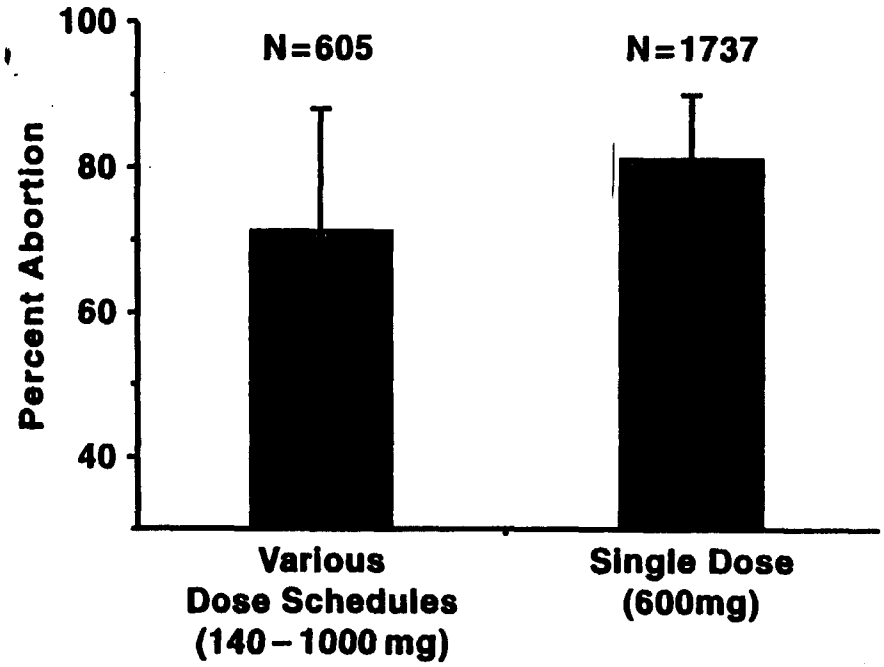
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

The first published study showed pregnancy termination in 9 of 11 women with duration of gestation of less than 56 days following mifepristone administered in a dose of 200 mg daily for 4 days.

(Herrmann et al, 1982)

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Complete Medical Abortion after Mifepristone Alone
Duration of Gestation ≤ 49 Days



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Uterine activity is controlled by a balance between the intrinsic inhibition of progesterone and stimulation by prostaglandins.

(Csapo, 1973)

Mifepristone increases the sensitivity of the myometrium to prostaglandins.

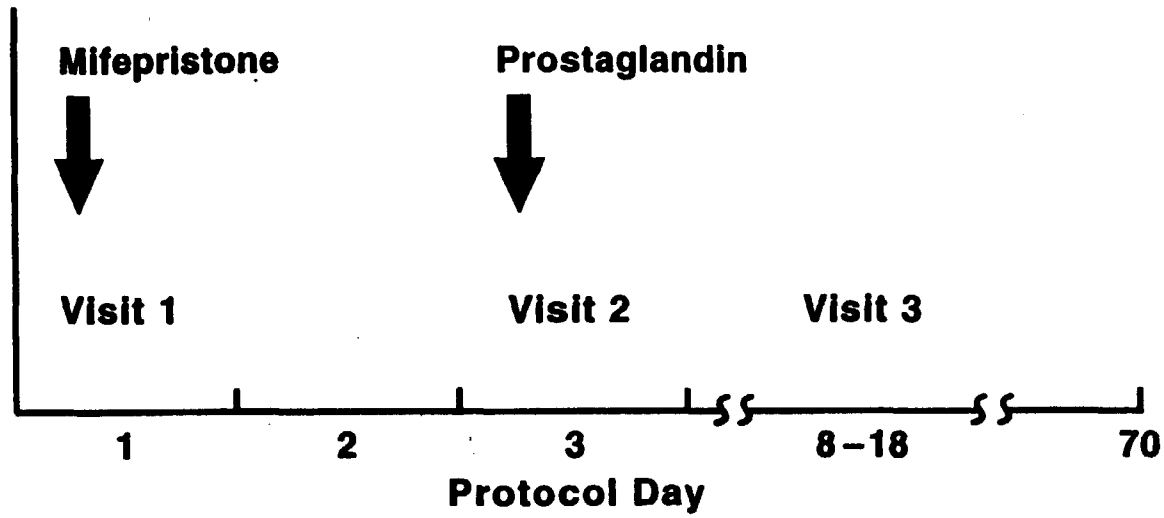
(Bygdeman and Swahn, 1985)

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Prostaglandins Used

	Sulprostone	Gemeprost	Misoprostol
Type of analog	PGE_2	PGE_1	PGE_1
Mode of administration	parenteral	vaginal suppository	oral
Refrigeration	yes	yes	no
Cost	$$$$	$$$$	$
Available in US	no	no	yes

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pregnancy Termination with Mifepristone and Prostaglandins: Literature Review

Duration of Gestation ≤ 49 Days

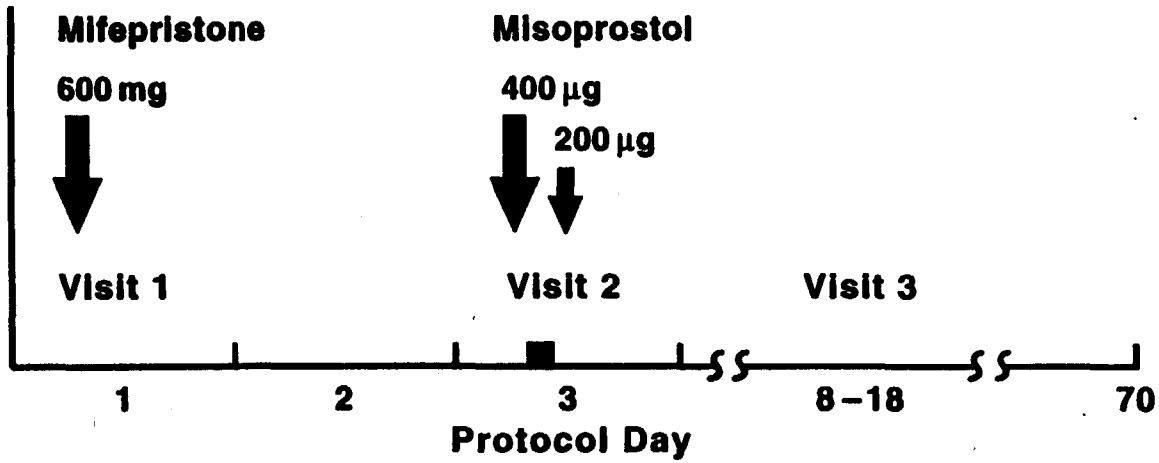
Prostaglandin	No. enrolled	Successful medical abortion (%)
Sulprostone	> 15,000	95.7
Gemeprost	> 2,000	95.5
Mifepristone alone	> 1,700	81.0

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pivotal Studies

- Study I: gestation (days) ≤ 49
- Study II: gestation (days) ≤ 49
  50 – 63

] extra dose] efficacy] safety



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pivotal Studies

	Study I	Study II
Duration of gestation	≤ 49 days	≤ 63 days
Day 1: mifepristone	600 mg	600 mg
Day 3: misoprostol	400 μg	400 μg; if no abortion in 3 hours another 200 μg
Follow up	day 8 – 15	day 10 – 18

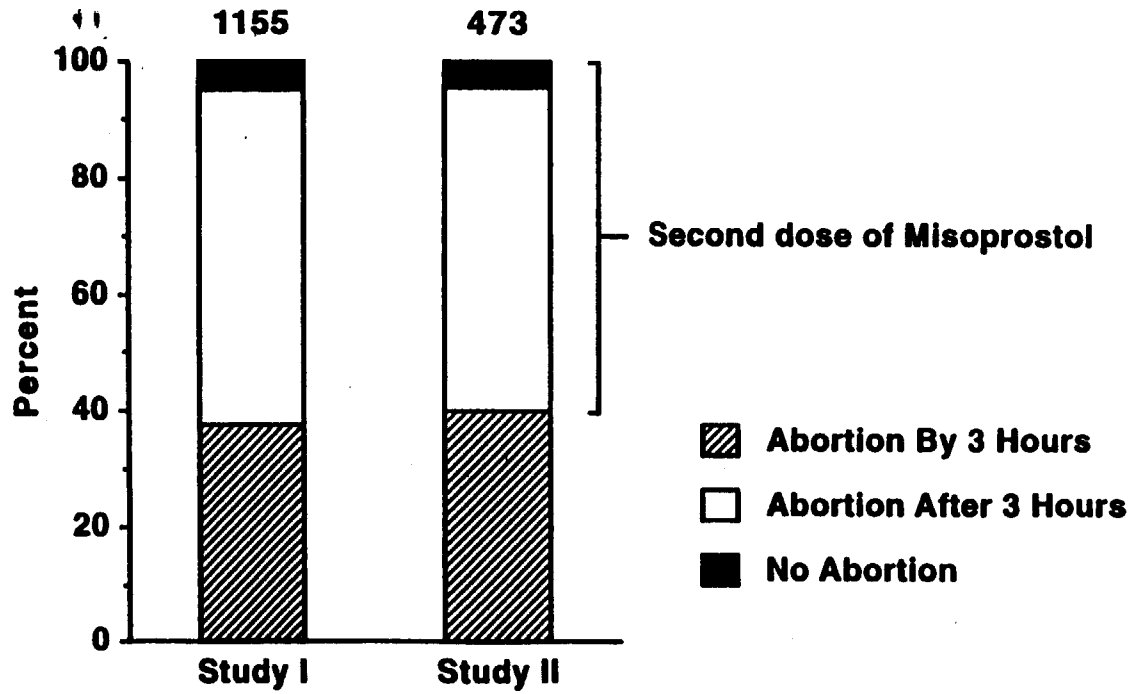
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pivotal Studies

	Study I	Study II	Total
Total no. women enrolled	1286	1194	2480
No. women with gestation ≤ 49 days	1189	492	1681
No. women with gestation ≥ 50 days	16	612	628

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Outcome Analysis of Women Who Received Misoprostol
Duration of Gestation ≤ 49 Days



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pivotal Studies:
Complete Medical Termination of Pregnancy:
Duration of Gestation ≤ 49 Days

- **Total evaluated: 1681**
- **Complete medical abortion: 95.5%**

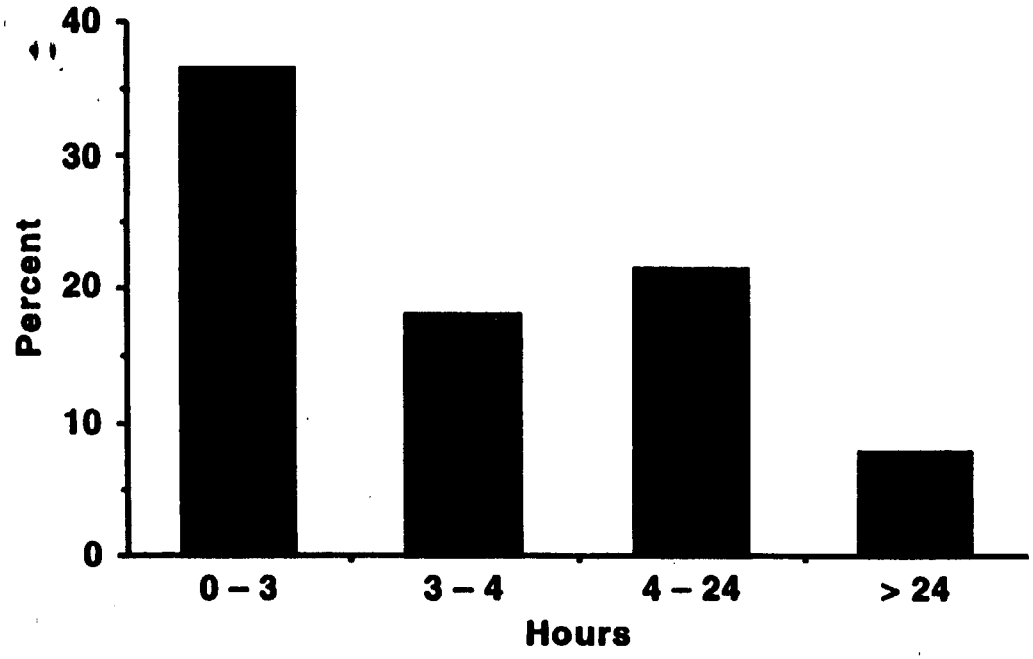
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Pivotal Studies:
Failure of Medical Termination of Pregnancy:
Duration of Gestation ≤ 49 Days

- **Total evaluated: 1681**
- **Continuing pregnancy: 1.3%**
- **Incomplete abortion: 2.9%**
- **D & C / VA for bleeding: 0.3%**

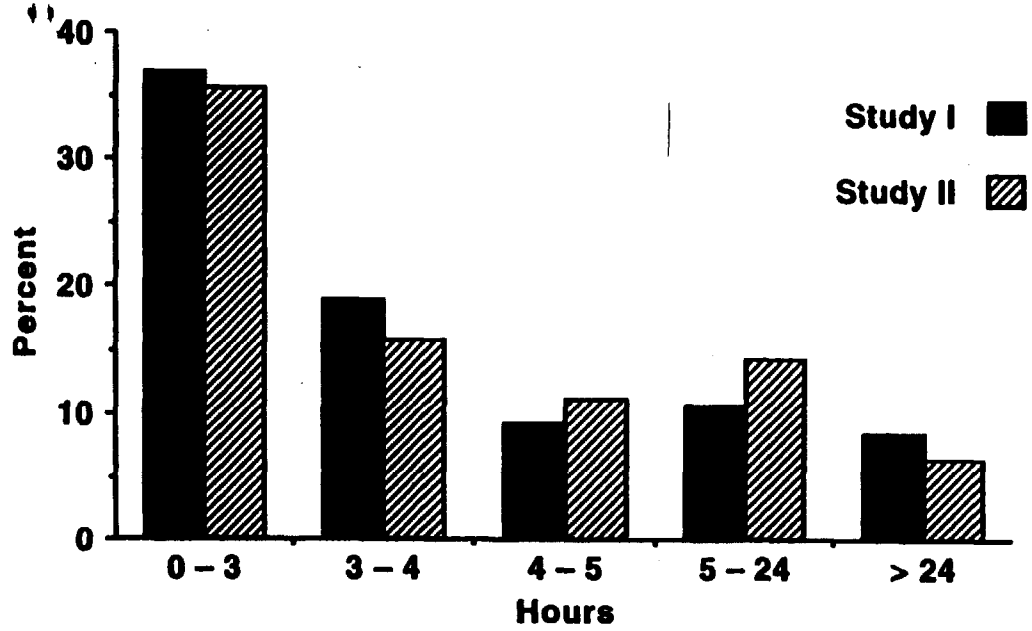
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Time of Expulsion After Misoprostol
Duration of Gestation ≤ 49 Days



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Time of Expulsion
Effect of a Second Dose of Misoprostol
Duration of Gestation ≤ 49 Days



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

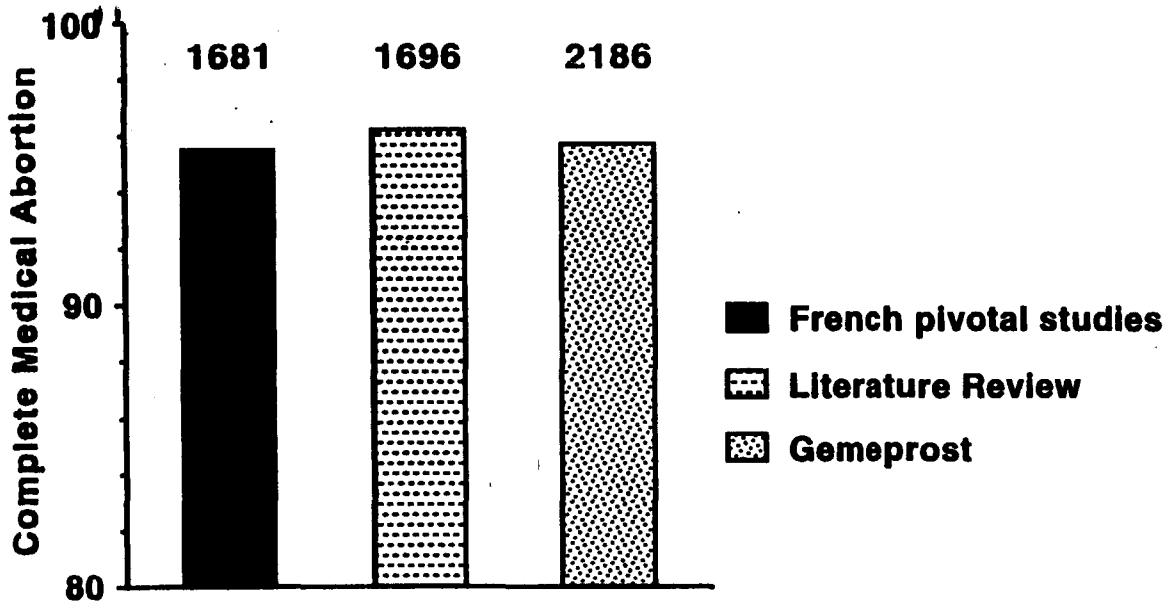
Patient Characteristics Evaluated

- age
- height
- weight
- body mass index
- gravity
- parity
- number of previous abortions
- duration of gestation

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Summary of Efficacy

Duration of Gestation ≤ 49 Days



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Conclusion

It is concluded that Mifepristone plus Misoprostol is effective for the medical termination of pregnancy in women with duration of gestation of 49 days or less.

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Safety of

Mifepristone Plus Misoprostol

for Medical Abortions

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Medical Termination of Pregnancy Requires:

- Withdrawal of the progesterone support of the endometrium
- Increased contraction of the myometrium

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Contraction of the Myometrium

- Contraction is regulated by the balance between the inhibitory action of progesterone and the stimulatory action of prostaglandins
- During pregnancy progesterone suppresses contractions
- Mifepristone increases the action of prostaglandins

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Rationale for Reporting Adverse Events for the Mifepristone / Misoprostol Combination

- There is evidence for synergy between mifepristone and misoprostol
- Symptoms of pregnancy are increased by both drugs
- No multicenter studies of oral misoprostol alone during pregnancy

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Overview of Safety / Adverse Events

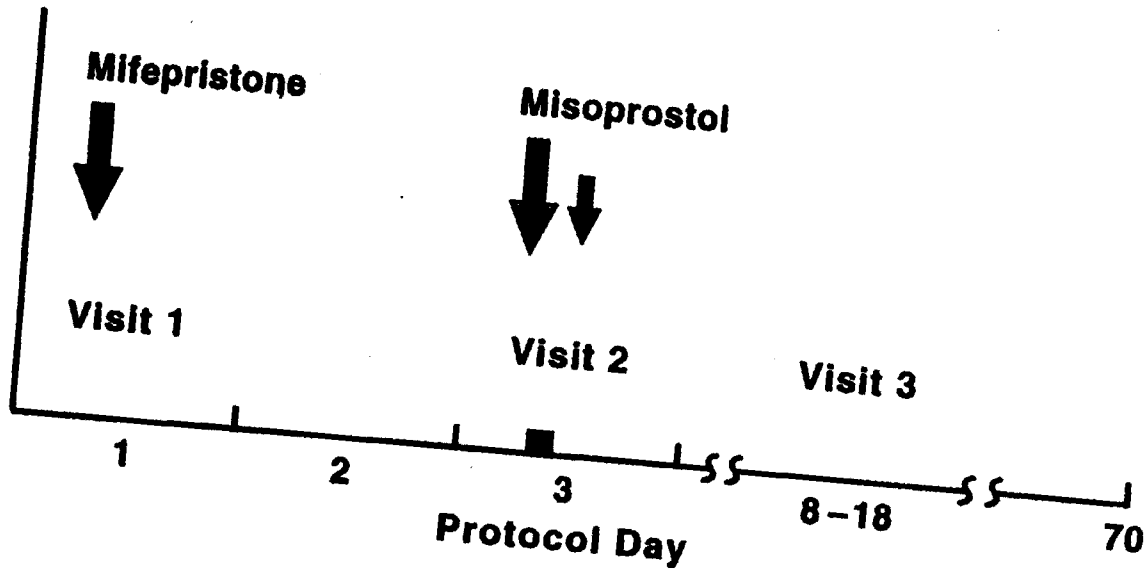
- Animal studies showed no toxic effects
- In humans, there were no deaths or serious cardiovascular outcomes
- In humans, no unexpected adverse events occurred
- Virtually all adverse events were related to the pharmacological actions of the regimen and some of these actions are essential for efficacy

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Severe Adverse Events

Severe as judged by women	Severe medical outcome
• bleeding	• cardiovascular event
• uterine contractions	• hospitalization
• nausea / vomiting	• surgery
• diarrhea	• blood transfusion

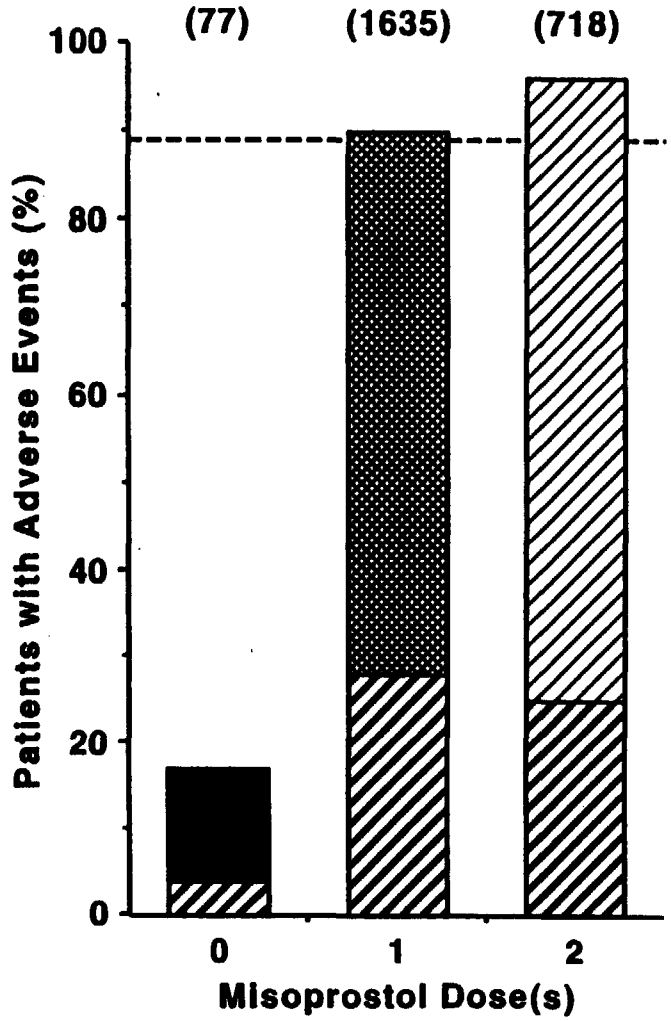
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



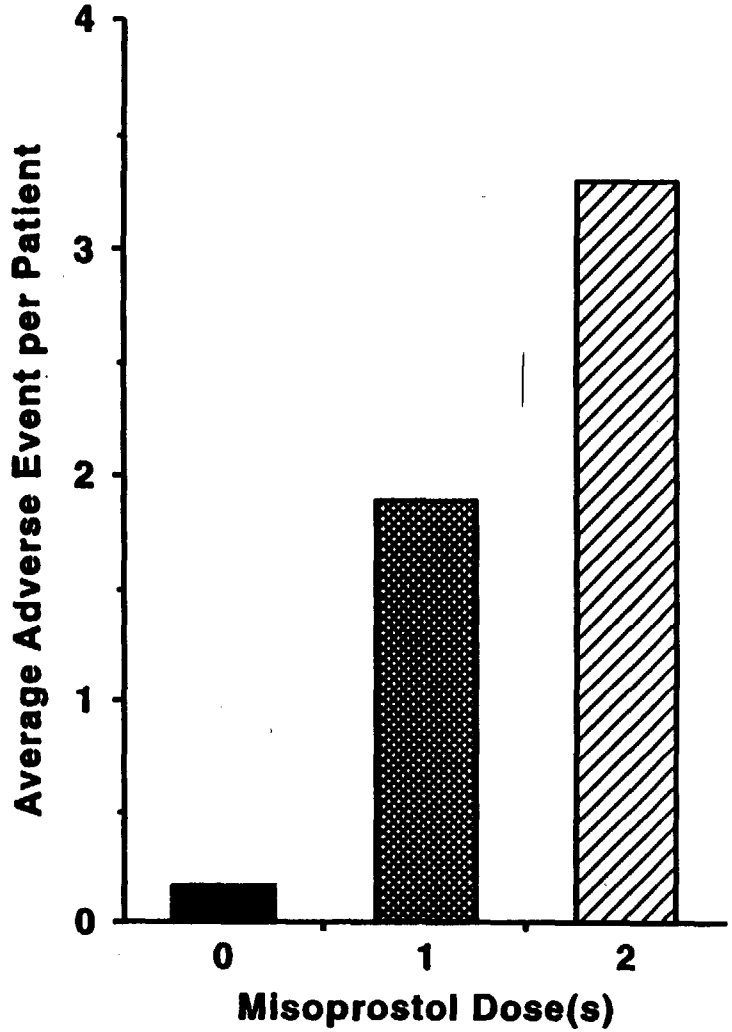
MIF 003040

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

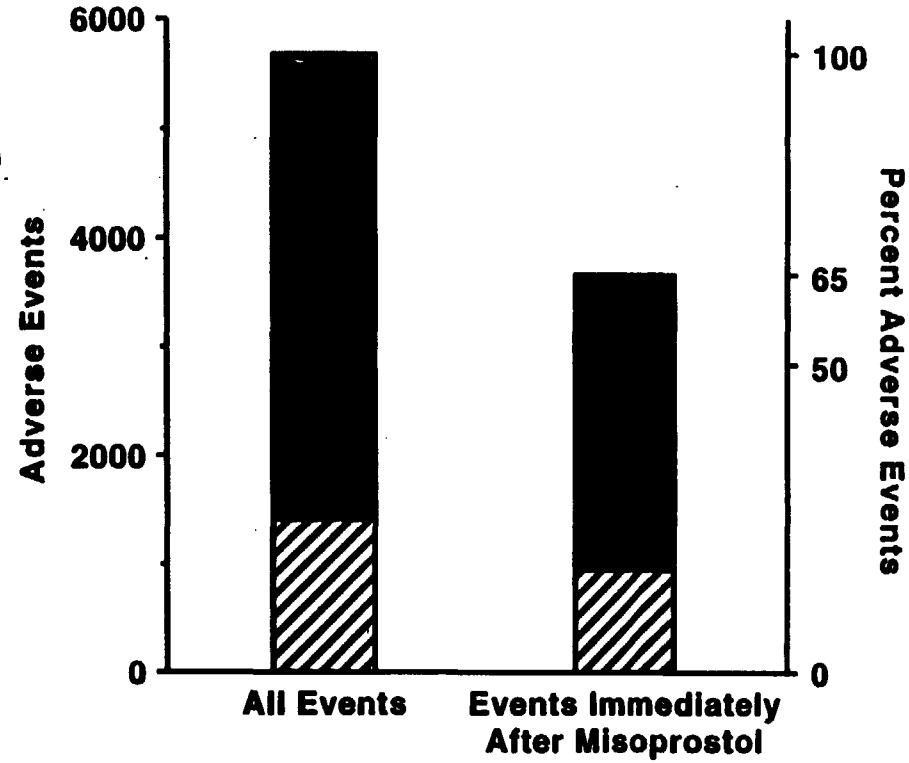
All Patients



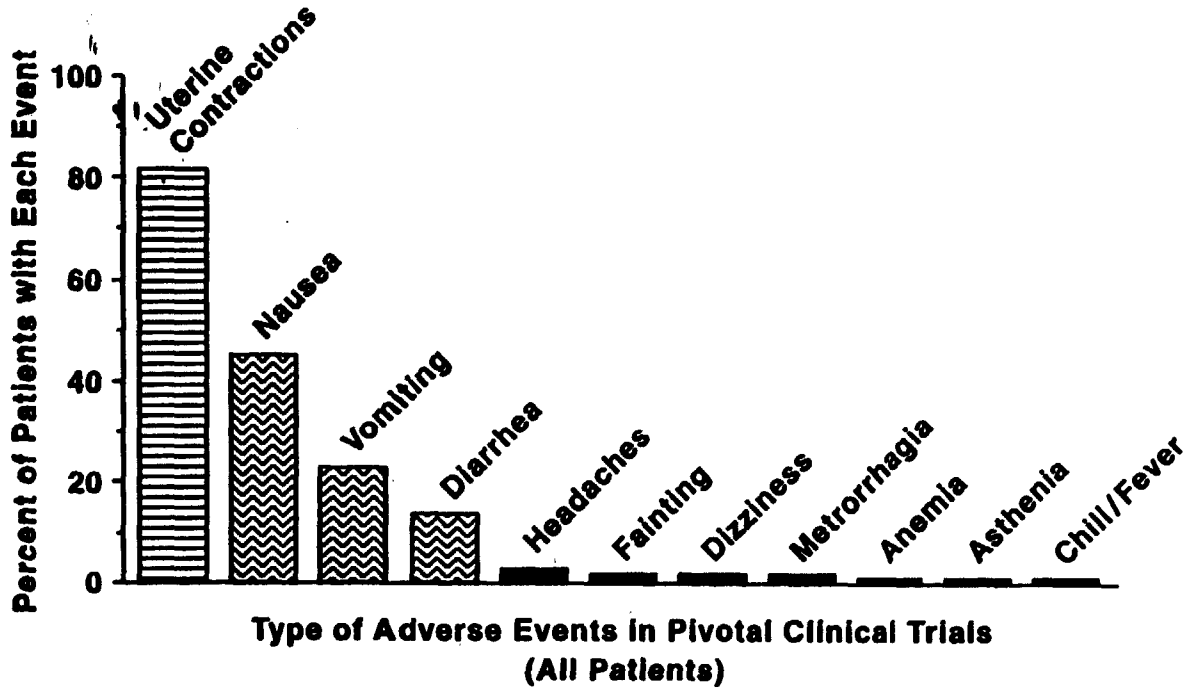
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



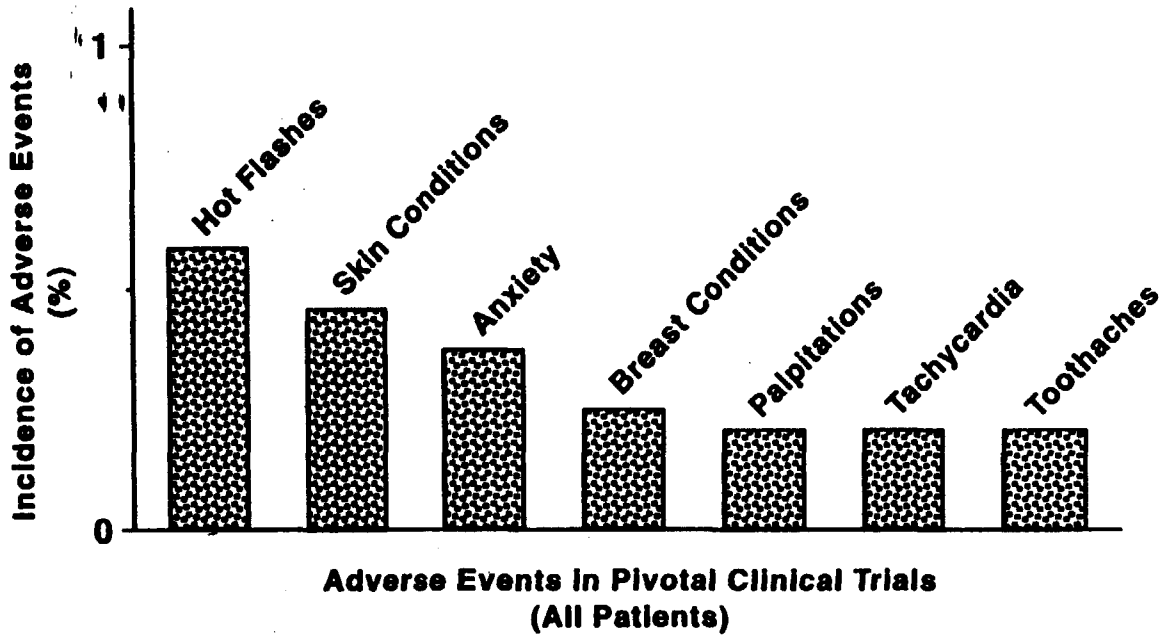
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



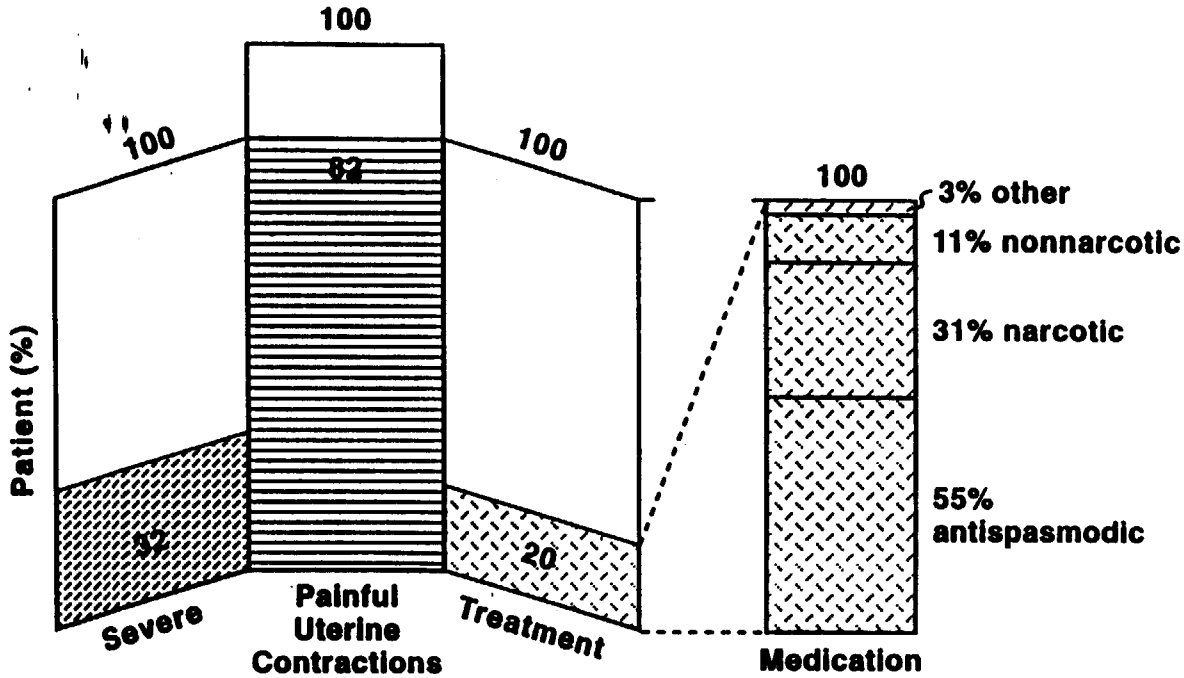
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



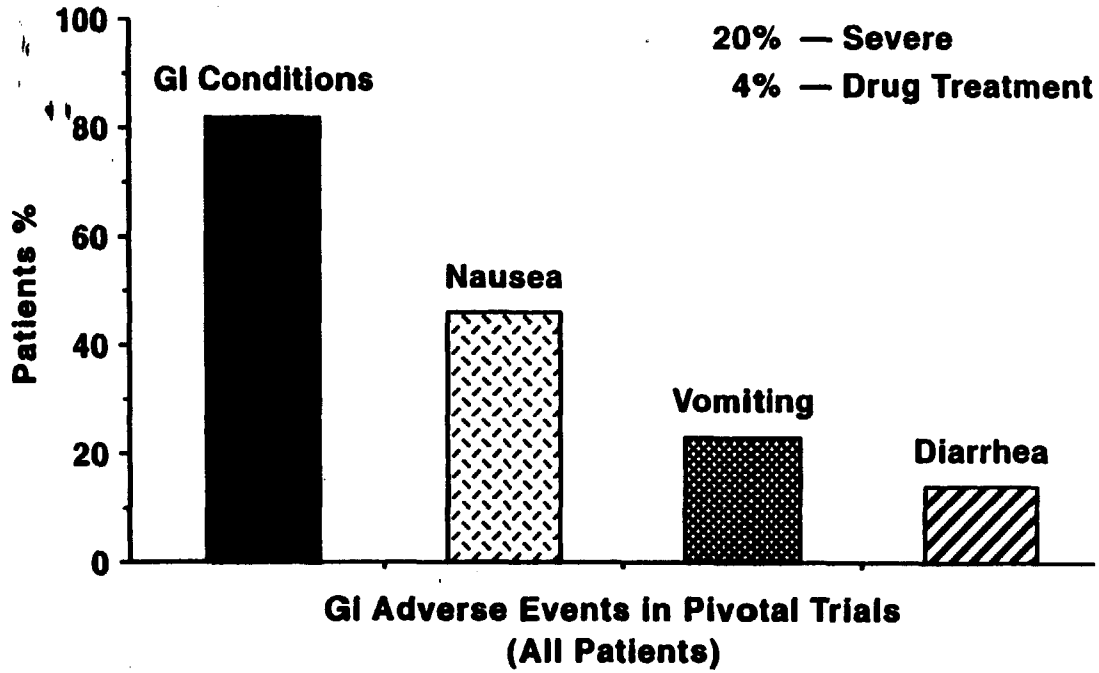
The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

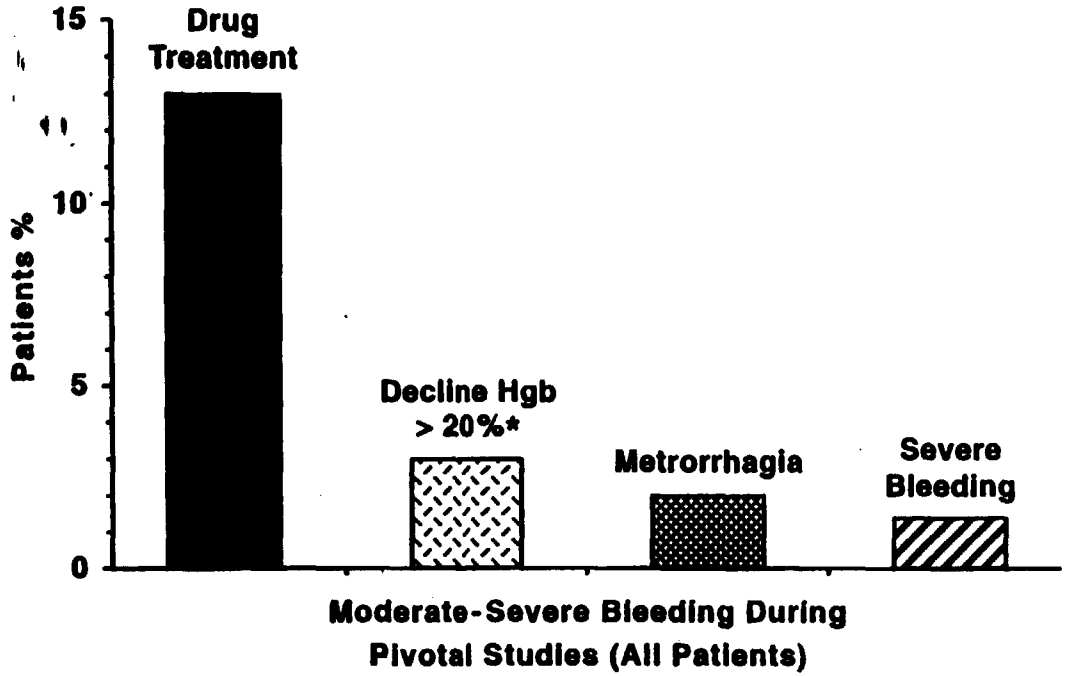


The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Bleeding Expected as Part of Treatment Procedure

- 96.6% of all patients bleed
- 33% bleed prior to misoprostol
- Mean duration — 9.1 ± 0.09 days
- Longest duration — 69 days

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee



* at 8–18 days

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Treatment for Severe Bleeding Events

Treatment	No. Patients
Hospitalization	21
Surgery	15
Transfusion	4

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Cardiovascular Events

Event	Number	(Severe)
• Decline in BP > 20%	420 *	
Hypotension	7	(1)
• Increase in BP > 20%	396 **	
Hypertension	8	
• Tachycardia	5	(1)

*17% **16%

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Comparison of Serious Adverse Events (SAE)* in the U.S. Clinical Trial and NDA Pivotal Trials

	U.S.	French
No. subjects enrolled	2121	2480
No. of hospitalizations	26 (1%)	21 (1%)
No. of transfusions	4 (<1%)	4 (<1%)
No. of subjects with hemorrhage	41 (2%)	52 (2%)
Surgical intervention for bleeding	32 (2%)	15 (1%)

*reported on Medwatch form to the FDA

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Conclusions

- **The risk of adverse events has been determined in two pivotal studies. As a result, labeling has been written that informs women about the risks of this regimen.**

- **The most frequent adverse events, painful uterine contractions and GI symptoms, were expected outcomes of the regimen.**

- **65% of events were immediately after misoprostol at the 2nd visit.**

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Conclusions

- 80% of women required no pain medication.
- Bleeding occurred in all women with a successful outcome. Rarely, excessive bleeding requiring hospitalization, transfusion or curettage occurred.
- Cardiovascular events including clinical hypertension, hypotension, and tachycardia were rare and only 2 were considered severe — these resolved without long term consequences.

The Population Council
Unpublished data
Presented July 19, 1996
to FDA advisory committee

Acceptability of Mifepristone Plus Misoprostol for Medical Abortion

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Best Features (Previous Studies)

- No surgery
- No anaesthesia
- No pain / comfortable
- Natural
- Less risk
- Easy / convenient
- Private
- Very early

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Do Different Kinds Of Women Have Different Reactions?

- There were no differences by race, ethnicity or method of payment for medical care
- Analysis not yet done by geography

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Acceptability of Mifepristone / Misoprostol to Providers

- Focus group of providers in each clinic
- 78 Providers: MDs, RNs, other clinicians, counselors, administrators
- 17 Clinics
- 15 States

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Acceptability of Mifepristone / Misoprostol to Patients

- Almost 800 women seeking abortion
- ≤ 49 days LMP
- Study volunteers
- 17 clinics / 15 states
- About one third minority

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Careful Introduction

- Extensive provider education in medical abortion
- Distributed directly to providers
- Physicians who have had training in:
  - — dating of pregnancy
  - — diagnosis of ectopic pregnancy
  - — surgical abortion
- Physicians with access to facilities for surgical abortion and emergency treatment

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Drug Administration

- Stocks of drug in secure location
- Record kept of each dose administered
- Patient information in each package
- Administration of medication on site and under supervision

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

General Reactions to Medical Abortion Experience

- Majority of women (~60%) prefer medical regimen in most studies
- Very high levels of satisfaction
- Very high willingness to use again and recommend to others

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

How Does This Compare to Previous Abortion Experience?

- More than 9 of 10 reported this as more satisfactory
- About two thirds of women for whom it failed reported it as more satisfactory

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

How Satisfactory Was This Abortion Procedure?

- More than nine out of ten women were very satisfied or satisfied
- Less than 3 in a hundred were unsatisfied, half of these women experienced treatment failure
- Even among those for whom it did not work, two thirds were very satisfied or satisfied

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Mifepristone / Misoprostol for Early Abortion: A New Type of Therapy

- Women like this method (overwhelmingly)
- Very different experience / technology from available alternatives
- U.S. women react similarly to women in other places
- Providers want to offer it

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

- **Mifepristone / misoprostol is a safe, effective, and highly acceptable therapy for women seeking early abortion.**

- **U.S. physicians want to offer it, thereby increasing access to services.**

- **Women will have more choice, and abortions will be earlier and therefore safer.**

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Measures Of Acceptability

- Was it what you expected?
- How does it compare to previous experience?
- Would you use it again?
- Would you recommend it to others?

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Acceptability Studies of Early Medical Abortion Outside U.S. 1979 – 1993

- 12 reports
- 6 countries
- Generally small cohorts (< 100)
- Experimental regimens
- Findings consistently and strongly support very high preference by women

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

A New Method:
Issues For Providers

- **May be time consuming: extra time for counseling**
- **Not used to waiting for results of treatment**
- **Not used to observing patient bleeding**
- **May be complicated to serve medical and surgical abortion patients simultaneously**
- **Need for extra space and bathrooms**

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Perceptions Of Bleeding

- Most common answer was that both length and amount were "as expected"
- Next most common answers were longer and more than expected
- Women for whom method failed tended to report more and longer bleeding

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Perceptions Of Pain

- More than half of women reported the experience as less painful than expected
- The next most common response was that the experience was "as expected"

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Provider Attitudes to the New Method

- Providers want to offer this method
- Providers think women like this method
- Providers feel they get better at giving the method with practice
- Providers become even more positive about the method with experience

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Providers Become Even More Positive about Method with Experience

- "I really didn't expect to like this... I thought it would be very time consuming and I was really amazed at how easy it was and how much women liked it." (MD)
- "Most of us said that we'd never do it... And then I realized, no, I'd take mifepristone... I'd rather do this instead of taking my chances with who knows who out there [surgically]." (MD)
- "... that was the learning experience for me — was that this was a plus for so many women..." (Counselor)

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Providers Feel They Get Better at Giving the Method with Practice

- "... the learning curve just in dealing with this from the clinic's point of view, from the doctor's point of view... I learned a lot..." (MD)
- "... I definitely noticed a big shift as we all got familiar with it as a clinic. Overall, I think patients did better because of what we could provide with our knowledge." (Study Coordinator)
- "... we weren't very efficient at the beginning... at the end it was beautiful because we'd hardly done as well at the beginning as we did at the end." (Health Worker)

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Providers Think Women Like This Method

- **Most providers thought women preferred it overall**

- **"Even the ones that failed and even the ones I thought had a terrible experience in terms of the physical symptoms, for the most part said, 'I would do it again... I like this method'." (Nurse Practitioner)**

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Providers Want to Offer This Method

- "I desperately want it here... I would offer the option." (Senior Clinician)

- "The best thing was to be able to answer the phone and be able to tell people who were really scared about having a surgical procedure that there was another alternative." (Administrative Coordinator)

- "I had spent the previous twenty-two years working for an abortion clinic doing surgical abortion... and had listened to women ask, 'Isn't there some other way?'" (Office Manager)

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Patient Reactions: Control / Autonomy

- "It offers a lot more control."
- "*You* take the medication."
- "Your body does it itself."
- "I was the primary person knowing when I was actually aborting."
- "This was more *my body* discharging it than someone going in."

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Potential to Increase Access to Services

1995

- **33% of all U.S. OB / GYNs provide abortion services**
- **66% increase in OB / GYN providers if mifepristone / misoprostol were available in U.S.**

The Population Council
Preliminary / unpublished data
Presented July 19, 1996
to FDA advisory committee

Patient Reactions:
Avoidance Of Surgery / Anaesthesia

- "I didn't like the idea of a surgical abortion."
- "I don't like any type of surgery at all."
- "I've had anaesthesia. I didn't like it."
- "Anything that didn't involve anaesthesia."
- "I want to try it anyway, even if I have to go through the other at the end..."

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Patient Reactions: "Natural"

- "I've had a miscarriage before. It's just like having a miscarriage."
- "It doesn't make you nervous."
- "More humane."
- "It felt like my period, so it felt like a natural process."

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Reasons Patients Value Medical Abortion

- Avoids surgery
- More "natural"
- Preserves control / autonomy

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Unwanted pregnancy is a serious and stressful problem for women

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Was Your Experience Similar to What You Thought Would Happen?

- Half thought it was just what they expected
- One third thought it better
- One in eight thought it worse

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Was There Any Problem with the Timing or Place of the Abortion?

- Less than one in twenty-five said there was a problem

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Would You Choose the Same Procedure Again?

- More than 9 in 10 said "yes"
- More than three quarters of women for whom it failed said "yes"

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

Would You Recommend This Method To A Friend Or Relative?

- Almost everyone said "yes"
- More than four out of five of women for whom it failed said "yes"

The Population Council
Preliminary/unpublished data
Presented July 19, 1996
to FDA advisory committee

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017

Sandra P. Arnold
Vice President, Corporate Affairs

July 26, 1996

Dr. David Kessler
Commissioner
US Food and Drug Administration
5600 Fishers Lane
Room 14-18
Rockville, Maryland 20857

Dear Dr. Kessler,

The Population Council would like to thank you and your associates at the FDA for the care with which the July 19th meeting of the Reproductive Health Advisory Committee to evaluate the safety and efficacy of mifepristone was planned and conducted. It has been a pleasure to work with the FDA staff members, and the meeting was testimony to the skill and effort that everyone put into it.

We are of course quite pleased with the outcome. We also particularly appreciate your personal involvement in opening the meeting and participating actively throughout it. Thank you very much for devoting your time and effort to this issue and this meeting.

We are looking forward to our continuing interface with you and your associates as the remaining steps in the evaluation of the mifepristone New Drug Application are carried out.

Thank you once again.

Very truly yours,

Sandra Arnold

APPEARS THIS WAY
ON ORIGINAL

Telephone: (212) 339-0500 Telex: 9102900660 POPCO Facsimile: (212) 755-6052 Cable: POPCOUNCIL NEW YORK