WH Counsel - Michelle Aronowitz 62024

994-7025

Maria - FYI —

This is what the groups are sending up to the Hill - Looks like they have changed their message a bit and are focusing on the process not being over yet. NARAL told me the manufacturer has several weeks to file a response w/ the FDA and make its case against the restrictions. early optin - not reassuring'

correct the hysteria   groups divided   'messaging'   Heather   credibility integrity

Online Advertisers Are Negotiating Deal On Privacy Rules With U.S. Regulators

By GLENN R. SIMPSON
Staff Reporter of THE WALL STREET JOURNAL

WASHINGTON – The online-advertising industry is moving toward a deal with federal regulators to develop new voluntary privacy rules.

Negotiations involving online advertisers, the Commerce Department and Federal Trade Commission are aimed at devising a self-regulatory framework that would put new restraints on so-called online profiling, the practice of gathering information—sometimes surreptitiously—about consumers' Web-surfing habits and other preferences.

Industry and government officials familiar with the talks say progress has been made in developing new "principles" regarding disclosure of such practices, and in giving consumers the opportunity to exclude themselves from scrutiny. While the principles are voluntary, once they are agreed to and published by the firms, the FTC will have the power to enforce them under existing trade-practices laws.

"We're very pleased with the progress," said Daniel Jaye, chief technology officer and co-founder of ad-server Engage Inc., of Andover, Mass., who has worked on the issue through an industry group called the Network Advertising Initiative.

The negotiations are crucial for the infant online-advertising industry, which has suffered from depressed stock prices and public mistrust because of several controversies over information practices. But the Clinton administration also sees a chance to use the talks to leverage a broader round of reforms regarding information-handling practices on the Internet. There are only about a dozen Internet ad-serving firms, but they have contracts with virtually every commercial enterprise on the Web. Under one aspect of the agreement being negotiated, the ad-serving firms will pledge to only do business with firms that promise contractually to abide by their privacy standards.

The other key areas of progress so far are a commitment by the NAI to enhance the quality of notice that consumers get regarding their privacy policies, and better choices about participation. The notices, which today are sometimes hard to find and difficult to decipher, will now be posted more prominently and in clear language. Similarly, consumers will have a clearer opportunity to "opt out" or "opt-in" on surveillance, which is most often done through the placement of a software program known as a "cookie" on a computer user's hard drive. The cookies can record preferences and habits, as well as where a user travels online.

In addition, there will be a single "gateway" page where consumers can go to opt out of profiling by all of the NAI companies. Along with Engage, firms include **Doubleclick** Inc. and **24/7 Media** Inc., both based in New York.

People familiar with the talks said they are optimistic that a resolution can also be found for perhaps the most controversial practice: the matching of offline data about consumers with their online surfing habits.

Negotiators had sought to reach a deal by today in time for the release of a new report on profiling by the FTC, but were unable to finish. Mr. Jaye said they now hope to finish by the end of the month. In testimony before Congress today, Jodie Bernstein, director of the FTC's bureau of consumer protection, is expected to comment on the talks.

The FTC will make legislative recommendations on profiling "after it has an opportunity to fully consider the self-regulatory proposals and how they interrelate with the commission's previous views and recommendations in the online privacy area," a draft of Ms. Bernstein's testimony states. The FTC has already recommended that Congress give it considerable new authority to regulate Internet privacy.

THE WALL STREET JOURNAL
TUESDAY, JUNE 13, 2000

Abortion-Rights Leaders Fight FDA Limits on RU-486

Meeting Will Plot Strategy—From Lobbying to Ads—to Ensure Access

By Rachel Zimmerman
And Sarah Lueck
Staff Reporters of The Wall Street Journal

Leading abortion-rights activists plan to meet in Washington today to lay out a strategy aimed at killing the Food and Drug Administration's proposed restrictions on mifepristone, the abortion pill also known as RU-486.

Advocates say they will consider a range of options to try to stop the government from imposing rules that would effectively limit the number of doctors who could prescribe the drug. They charge that politics has eclipsed science in the case of the FDA's suggested regulations, which came to light earlier this month.

Vicki Saporta, executive director of the National Abortion Federation, said, "Everything's on the table," from lobbying members of Congress and the Clinton administration to advertising and using direct mail to get the issue on the public radar screen.

Moreover, the Center for Reproductive Law and Policy's president, Janet Benshoof, said the restrictions discriminate against pregnant women, and the organization may explore legal options if the rules take effect.

The FDA isn't discussing the proposed restrictions. But people close to the situation say the agency may require that prescribers of RU-486 be trained to perform surgical abortions; be credentialed in ultrasound administration; be trained specifically in mifepristone delivery and treatment; and have admitting privileges in a medical facility within one hour of their offices. Only physicians, not nurse practitioners, could prescribe the drug.

Certainly, the new rules would deal a big marketing blow to **Danco Laboratories** LLC of New York, the U.S. company that owns the rights to make and distribute RU-486. "Like with any drug, the greater the number of restrictions, the greater the limit on access," said Danco spokeswoman Heather O'Neill. She emphasized that negotiations between Danco and the FDA are continuing, but she added: "What they've done is more restrictive than we envisioned."

Others were more blunt. "Making the environment too restrictive will kill the drug," said Dr. Eric Schaff, a professor at the University of Rochester who ran clinical trials of the drug. For Danco, a start-up with mifepristone as its only drug, "this is a very big deal," he said.

The FDA first disclosed the possible regulations to the company in a telephone conversation, according to Ms. O'Neill. Shortly after that, on June 2, the news became widely known, when Ron Karnovsky, Danco's president and chief executive, announced the restrictions to a group of nearly 70 physicians and abortion-rights activists at an annual Population Council meeting in New York. The Population Council holds the license to the drug.

"Everyone was shocked" by the proposal, said Elizabeth Newhall, an obstetrician-gynecologist in Portland, Ore., who was at the meeting. "This was the most frustrated I've ever seen this group."

Mifepristone, in combination with another drug that causes uterine contractions, is administered in the first seven weeks of pregnancy to induce abortion.

Critics say the distribution rules being considered for RU-486 are far more severe than for comparable drugs and basically unnecessary, considering that doctors and scientists widely agree the drug has been used safely by more than 500,000 women in Europe and was declared safe and effective by the FDA in 1996.

Sara Seims, president of the Alan Guttmacher Institute, a nonprofit research and public-policy organization in New York, said that women in rural and nonurban areas will suffer if the restrictions take effect. She noted that from 1992 to 1996, the number of abortion providers fell 14%.

RU-486 faces hurdles on other fronts. GOP Rep. Tom Coburn of Oklahoma plans to introduce a measure that would prevent the FDA from using federal funds to test, develop or approve abortion drugs, spokesman John Hart said.

Congressional Democrats don't feel comfortable raising a fuss over the potential FDA restrictions—at least for now. The reason: For years, they have argued against GOP amendments, such as Rep. Coburn's, that would bar FDA approval of the abortion pill. Led by New York Rep. Nita Lowey, they have said the process shouldn't be politicized, and the agency should be left alone to reach its best scientific judgment without interference. So now, they say, they can't very well begin browbeating the FDA about imposing some strictures. At least one Democratic staffer said that she is confident that even if some restrictions are imposed, they will be removed as unnecessary over time.

People in the antiabortion camp think the FDA's proposed rules don't go far enough, though they're a step in the right direction. "This has outraged Planned Parenthood," said Scott Weinberg, spokesman for the American Life League. While not commenting about RU-486, FDA officials say the agency isn't influenced by political concerns and makes its decisions based on science.

The Long Road

Since it was first introduced in the U.S. in 1994, RU-486 has encountered major obstacles.

- **MAY 17 1994:** France's Roussel Uclaf donates U.S. patents for RU-486 to a New York's Population Council research group, setting the stage for U.S. clinical trials of the drug.
- **MARCH 18, 1998:** The Population Council files an application to the FDA for the drug.
- **JUNE 25, 1998:** The U.S. House of Representatives votes 223-202 to bar the FDA from testing or approving drugs to induce abortion, including RU-486.
- **JULY 19:** An FDA advisory panel recommends that the agency approve RU-486 but recommends that the agency monitor the distribution and credential system for the drug.
- **FEB. 18, 2000:** The FDA informs Danco Group, the marketing agent for RU-486, that it will approve the pill once labeling and other specifics are ironed out.
- **JUNE 2:** At a Population Council meeting in New York, abortion rights activists and providers are briefed on proposed FDA restrictions on RU-486.
- **JUNE 13:** Leading abortion-rights activists meet in Washington to plan a strategy to fight and kill the FDA's proposed restrictions on RU-486.

THE WALL STREET JOURNAL
TUESDAY, JUNE 13, 2000

Ann Lewis —

Medical community

Their ability to
offer options to patients

get doctors out in front
MC's

Waxman

Nancy Tilkin - worked to get Henry Waxman

WH can't step on FDA process

way to move to new —
this assignments

politics can't override safety
push safety & good healthcare

RU-486. Representatives Carolyn Maloney, Louise Slaughter and Lynn Woolsey requested a meeting with the FDA about the proposed restrictions on distribution of RU-486. They were told that the FDA would not discuss an ongoing drug approval. Instead, these members are now hosting a briefing next week for pro-choice members about the FDA approval process, with representatives from Danco and the Population Council, which share the U.S. rights to distribution of RU-486. The pro-choice groups and some representatives, including Nita Lowey, believe such a meeting is a bad idea because it could give the impression that the scientific process is being politicized. The timing is unfortunate; next week, during consideration of the Agriculture Appropriations bill, Rep. Coburn may offer an amendment to bar the FDA from using funds to test, develop, or approve RU-486. Opponents of the amendment will charge that he is politicizing the process, but he may counter that supporters of RU-486 are doing the same.

"Coleman, Clare" <Clare.Coleman@mail.house.gov>
06/23/2000 03:10:07 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP

cc:
Subject: RE: mifepristone action

Slaughter sent a letter in March with about 75 members -- we didn't sign it so they have never shared a copy of the letter or the pro-forma response that they got from FDA. Woolsey has backed off sending a Dear Colleague around for a letter to Henney demanding answers, but Maloney refused to back down from having this mifepristone-specific meeting.

-----Original Message-----
From: Heather_H._Howard@opd.eop.gov
[mailto:Heather_H._Howard@opd.eop.gov]
Sent: Friday, June 23, 2000 2:21 PM
To: Coleman, Clare
Subject: FYI: mifepristone action

Lauren forwarded this to me. What is the Slaughter letter the email refers to? Have they backed off on demanding the meeting you called about yesterday?
---------- Forwarded by Heather H. Howard/OPD/EOP on 06/23/2000 02:20 PM ----------

Lauren M. Supina
06/23/2000 12:26 PM

Record Type: Record

To: Heather H. Howard/OPD/EOP@EOP

cc:
Subject: FYI: mifepristone action

---------- Forwarded by Lauren M. Supina/WHO/EOP on 06/23/2000 12:27 PM ----------

Lauren M. Supina 06/23/2000 12:26

Record Type: Record

To: Heather H. Howard/OPD/EOP@EOP

cc:
Subject: FYI: mifepristone action

---------- Forwarded by Lauren M. Supina/WHO/EOP on 06/23/2000 12:27 PM ----------

"Coleman, Clare" <Clare.Coleman@mail.house.gov>
06/23/2000 12:03:55 PM

Record Type: Record

To: Lauren M. Supina/WHO/EOP

cc:
Subject: FYI: mifepristone action

This was sent to the Women's Caucus, and the Pro-Choice Caucus.

> -----Original Message-----
> Sent: Friday, June 23, 2000 11:37 AM
> Subject: MEMBERS Meeting, Tuesday 6/27 at 1pm
>
> Reps. Maloney, Woolsey, and Slaughter have invited some experts to talk
> about the FDA approval process, the history and status of RU-486 (the
> public info as we know it), and to answer any questions your boss may have
> about this subject.
>
> Please join us:
> Tuesday, June 27
> 1:00 p.m.
> 2456 Rayburn
>
> We have assembled a terrific panel of speakers, including:
>
> Sandra Arnold, Vice President of Corporate Affairs, Population Council
>
> Kay Holcombe, former Senior Health Policy Staff of the House Commerce
> Committee, formerly with the Food and Drug Administration and the Public
> Health Service
>
> Nancy Buck, Attorney/Consultant, formerly with the Food and Drug
> Administration

>
> I will be faxing copies of some background materials for your bosses:
> *a flyer about the meeting
> *the Washington Post article about leaked info on RU-486
> *a Washington Post article about the delay in approving RU-486
> *a copy of a recent letter organized by Rep. Slaughter on the status
> of RU-486
> *a letter from several pro-choice organizations on the status of
> RU-486
>
> Hope to see you then.
>
> NOTE: This is a Members Meeting, but staff may attend if accompanying the
> member.

June 6, 2000

Gov't Eyes Abortion Pill Regs

Filed at 5:28 p.m. EDT

By The Associated Press

WASHINGTON (AP) -- The government is considering rules for use of the abortion pill RU-486 that could restrict access to that early-abortion option, Planned Parenthood's director said Tuesday.

The Food and Drug Administration said in February it would approve the sale of RU-486, also known as mifepristone, once some final, but undisclosed, requirements were met.

The pill's sponsor, the nonprofit Population Council, last week told abortion providers the FDA is proposing some curbs on the pill's use, said Gloria Feldt, national president of Planned Parenthood.

''We are deeply concerned that FDA is considering restrictions that in my view would virtually assure that very few doctors would ever make mifepristone available,'' Feldt said Tuesday. Planned Parenthood is a family planning group that favors abortion rights.

She said the biggest concern is an FDA proposal that physicians allowed to administer RU-486 must be part of a registry, which she said would deter doctors worried about anti-abortion violence from offering the pill.

Feldt said the FDA also is considering long-term health tracking of at least some RU-486 recipients, something she called unnecessary because half a million European women have used the pill successfully since 1988.

FDA officials declined comment.

"Some of the FDA's recent proposals are more restrictive than we had expected," said Sandra Waldman, speaking for the Population Council. She would not be more specific.

But Waldman stressed that FDA discussions over the pill's use have just begun and no requirements are complete.

Studies show RU-486 is 95.5 percent effective in causing abortion when taken within the first 49 days of pregnancy. But a very small percentage of patients required additional surgical treatment or blood transfusions, something the FDA must consider in determining how the pill should be used. One question is how to ensure women return for an exam to be sure the pregnancy was terminated.

The nonprofit Population Council in 1994 received U.S. marketing rights to RU-486 from the original French manufacturer, which feared an anti-abortion boycott.

6/14

RU-486

Gunther Heather (AGI)

Danco - farming out 6 legal memos

Heather Barnstn - looking at restrictions in other countries

Pop Council doing information sharing

legal memos on restrictions

going to put these memos into one document

Citizen's Petition - CCRP

lay out legal arguments -

FDA has a time limit where to respond

- might provide basis for lawsuit later

also - submit legal memos to HHS general counsel/FDA

1993 - POTUS stmt - must free science from politics

NEWS

LOWEY: ABORTION-PILL RULES ENDANGER DOCS

By DEBORAH ORIN

WASHINGTON - Pro-choice advocates yesterday feared that the Clinton administration's plan to allow sale of the RU-486 abortion pill not only is too restrictive, but could also put doctors' lives at risk.

"Approving the drug means nothing if American women won't have access to it," said pro-choice Rep. Nita Lowey (D-Westchester).

"The requirement that there be a national registry of doctors permitted to use it would be taken as providing right-wing extremists with a hit list. We have to remember that doctors [who do abortions] already have been murdered."

Allison

The Food and Drug Administration's preliminary plan would require such a registry and limit use of the pill to doctors trained in surgical abortions with admitting privileges at hospitals less than an hour from their offices.

The pill, also known as mifepristone, is for women up to 49 days pregnant. It makes it difficult for a fertilized egg to attach to the uterus while a second drug triggers contractions.

In an odd twist, right-to-life advocates praised the pro-choice Clinton administration's preliminary plan because it is restrictive.

"RU-486 is not a magical pill that causes the baby to vanish," said Janet Parshall of the Family Research Council. "A woman taking this abortion drug experiences cramping and bleeding and sometimes even has to get a surgical abortion."

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973-3070

THE WHITE HOUSE

WASHINGTON

June 7, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: HEATHER HOWARD

CC: MELANNE VERVEER
SHIRLEY SAGAWA
LISSA MUSCATINE
ANN O'LEARY

SUBJECT: RU-486

As you know from news reports, pro-choice groups (Planned Parenthood, NARAL, National Abortion Federation and the Feminist Majority Foundation) are concerned that the FDA is considering placing restrictions on access to RU-486 (Mifepristone). I wanted to provide you with some background and context:

- Mifepristone is used in the first seven weeks of pregnancy. It has been shown in studies to be effective in ending pregnancy, but a small percentage of women require additional medical treatment such as blood transfusions or surgical procedures. It has been used over 500,000 times in Europe over the past 12 years.

- In 1989, the Bush Administration banned the importation of Mifepristone. In 1993, President Clinton reversed the importation ban. In 1998 and 1999, the Administration successfully fought for removal of an appropriations provision that would have prohibited the FDA from testing, developing or approving Mifepristone. We may face a similar amendment as early as next week when the House considers the Agriculture appropriations bill.

- In 1996 and again in February 2000, the FDA issued an "approvable" letter for Mifepristone, indicating that final approval was contingent upon additional information about manufacturing practices and labeling.

- Danco Laboratories – the company licensed for U.S. manufacture and distribution – is negotiating the conditions for the drug's manufacture, labeling and distribution. They claim that the FDA is considering requiring restrictions that would seriously limit access, including:

    - Requiring a "black box" to highlight certain warnings. According to the groups, the only other non-scheduled drug with such a black box is thalidomide.
    - Requiring that it only be distributed by "qualified physicians" who are trained and certified to distribute it, and who are trained and authorized to perform surgical

abortions. This would be problematic for two reasons: first, because it limits the number of doctors who would be able to prescribe, since there are already far too few doctors performing surgical abortions; second, because it would require a registry to keep track of who is authorized to distribute the drug, which would discourage doctors who fear anti-choice violence.

- Requiring that Misoprostol, the second pill taken to induce contractions, be taken in a doctor's office, which would require women to make a second trip and would in particular limit the access of rural women.

We do not know whether the conditions being considered by the FDA are reasonable, but we do know that the process is ongoing. The FDA is in negotiations with Danco, and Danco will have an opportunity to respond to these proposals within the next few weeks, and will be able to make their arguments based on the science. It is very important that the FDA's scientific approval process be credible; we should not interfere and politicize the issue. For this reason, we have had no contact with the FDA. Today's press reports are unfortunate because they politicize an issue that should be about the science.

Our message should be:

- We do not want women to face unnecessary access barriers, but we do want appropriate safety precautions.
- The FDA is doing what it should be doing at this stage in the review process -- it is in negotiations with Danco about manufacturing and distribution issues. Danco will have an opportunity to be heard and present its arguments. The FDA's final decision must be based on the science.
- RU-486 is an important, non-surgical option for women early in their pregnancies and will not result in more abortions.

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Urgent – Important Information

To: Chiefs of Staff and Reproductive Health Staff

From: Alice Travis Germond, Executive Vice President, NARAL
Gloria Feldt, President, Planned Parenthood Federation of America
Vicki Saporta, Executive Director, National Abortion Federation
Eleanor Smeal, President, Feminist Majority Foundation

Date: June 7, 2000

Subject: Mifepristone (RU 486) Approval

In 1996, the Food and Drug Administration (FDA) issued an "approvable" letter for mifepristone, finding it safe and effective, and indicating that final approval is contingent upon additional information about manufacturing practices and labeling. Also known as RU 486, mifepristone is an effective early option for nonsurgical abortion, and has been used safely for nearly two decades in European countries.

Today it is being reported that the FDA is discussing with Danco Laboratories - the company licensed for United States manufacture and distribution - certain conditions concerning the drug's labeling, distribution and manufacturing. The conditions under discussion are very serious and, if implemented, would severely limit the drug's availability.

However, these discussions are part of the drug-approval process and are not final. At this time, we believe the manufacturer should be allowed to continue its conversation with the FDA. Mifepristone has already been used by more than 500,000 women in Europe with very high effectiveness, safety, and satisfaction rates. It also holds promise for other illnesses; it can help to induce labor, treat infertility, endometriosis, and certain types of tumors, and may be useful in treating AIDS, Cushing's disease, and glaucoma.

Today's reports further illustrate the importance of preventing anti-choice lawmakers from injecting politics into science by barring FDA funds from being used to complete mifepristone's final approval. Your opposition to Rep. Tom Coburn's amendment to the Agriculture appropriations bill is critical. Attempting to legislate any drug's approval or disapproval is inappropriate and sets a dangerous precedent of prohibiting development in certain drug categories. We urge members of Congress to stand firm against any legislative assaults of this nature. Delays in the approval process resulting from anti-choice politics will undermine reproductive health and deny American women an important health care option.

BU-486

Maray
6-7

science rules the day
Jane Heaney will make the

it's in negotiation — FDA
room for dialogue - this was just a proposal
Danco can come back

☆ don't want unnecessary barriers -
but want precautions for safety

Shelala won't meet w/ groups

people can make themselves heard through the process

we have process - not doing anything differently
don't do anything outside the norm

FAX

THE ALAN GUTTMACHER INSTITUTE
NEW YORK & WASHINGTON
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Web site: www.agi-usa.org

Date: 6/6

Number of pages including cover sheet: 6

To: Heather Howard

@ 456-2818

From: Cynthia + Heather Boonstra

___Original will not follow
___Original will follow, via _____

MESSAGE:

It's not in one tidy document but it will give you a sense of history

Mifepristone (Formerly Known As RU-486) : A Brief History

Mifepristone, also known as RU-486, is an antiprogesterone drug that blocks receptors of progesterone, a key hormone in the establishment and maintenance of human pregnancy. Mifepristone induces spontaneous abortion when administered in early pregnancy followed by misoprostol, a prostaglandin already available in the U.S, thus providing women with a medical alternative to aspiration (suction) abortion. Further, studies show that mifepristone at a substantially lower dose can be highly effective as a postcoital contraceptive when administered within five days after unprotected intercourse, thus providing women with a "morning-after pill" in case of contraceptive failure or sexual assault. Additional studies on mifepristone as a postcoital contraceptive would be necessary before any submission to the FDA for this indication could commence.

Safety, Efficacy, & Acceptability

It is estimated that approximately 600,000 women in Europe have had medical abortions using mifepristone. Between 1994 and 1995, 2121 women in Planned Parenthood and other U.S. health centers participated in clinical trials of mifepristone and misoprostol sponsored by the Population Council. The results, published in the *New England Journal of Medicine* and the *Archives of Family Medicine* in 1998, demonstrated mifepristone to be effective in terminating 92 percent of pregnancies up to 49 days in duration. Additionally, 95.7 percent of women in the same clinical trial reported that they would recommend mifepristone to others. Even among women for whom the method failed, 85.9 percent would recommend it to others. The most common side effects reported by women using mifepristone plus prostaglandin for early abortion are similar to those of a spontaneous miscarriage: uterine cramps, bleeding, nausea, and fatigue. Mifepristone is as safe as aspiration abortion; additionally, it is a completely noninvasive procedure and does not require anesthesia.

Implications

It can be surmised that when mifepristone becomes widely available, early surgical abortion as practiced today will be chosen less frequently among eligible women. Among the expected effects of such a change are these:

- More providers may be willing to offer the pharmacological regimen than currently offer surgical abortion services.
- The substitution of medical for surgical abortion may reflect a shift toward earlier pregnancy termination.
- Mifepristone may offer women more privacy in the abortion decision, along with greater personal control over the process of pregnancy termination.

Mifepristone has many potential uses beyond pregnancy termination, including the treatment of breast cancer, meningioma, Cushing's syndrome, glaucoma, and endometriosis, and the induction of labor. However, these have not yet been fully studied.

History and Current Status in the U.S.

Mifepristone/RU-486 was first approved for use in September 1988 in France, where it was developed by the pharmaceutical firm Roussel-Uclaf. In October 1988, Roussel-Uclaf, the sole manufacturer of the drug and holder of the patents, took the unprecedented action of suspending its distribution, citing protests by anti-abortion groups in the U.S., France, and West Germany. Two days later, the French Minister of Health ordered the company to resume distribution in the interests of public health. In 1991, it was approved by the United Kingdom Licensing Authority for use in Great Britain, and in 1992, it was approved for use in Sweden.

Even while the use of mifepristone was expanded to the U.K. and Sweden, however, Roussel-Uclaf announced that it had no intention of marketing the drug in the U.S. or any other country where the company perceived that political and social conditions were unreceptive to the drug. And the Bush administration, with its overall

hostility to abortion, took the additional step of placing mifepristone on a list of drugs banned by the Food and Drug Administration (FDA) from importation into the U.S. for personal use. In July 1992, Leona Benten attempted to bring RU-486 into the U.S. for personal use — the drug was seized and , in spite of a lower court ruling in Benten's favor, the Supreme Court refused to reverse the ban.

The Clinton administration, in one of its first administrative actions in January 1993, asked the FDA to reexamine the import ban. Subsequently, an FDA deputy commissioner indicated that the agency might consider clinical trials in Europe as evidence in determining the drug's safety, an important step for expediting the process of approval.

In May 1994, Department of Health and Human Services Secretary Donna Shalala announced that as a result of encouragement by the Clinton administration, Roussel-Uclaf had donated the U.S. rights for mifepristone to the Population Council, a New York-based nonprofit research institution. The Population Council conducted U.S. clinical trials from 1994-1995. Results of the Population Council clinical trials, showing mifepristone to be highly effective, safe, and acceptable for early abortion, were published in the *New England Journal of Medicine* and the *Archives of Family Medicine* in 1998. Following public hearings on the subject, the FDA Advisory Committee for Reproductive Health Drugs recommended approval of mifepristone in the summer of 1996. The FDA issued an approvable letter for mifepristone in the September 1996, indicating that the drug was safe and effective, but that the Population Council and the manufacturer needed to provide additional manufacturing, labeling, and other information in order to obtain final approval.

The Population Council granted the Danco Group, a new women's health pharmaceutical company, an exclusive license to manufacture, market, and distribute mifepristone in the United States. In 1995 and 1996, Danco entered into a series of agreements with a manufacturer to produce mifepristone. However, the manufacturer backed out of the project in early 1997. This further delayed the availability of mifepristone in the U.S. Danco has since identified manufacturers willing to produce mifepristone and is working with them towards production. Danco is providing the FDA with the information it needs to make a final review of the application.

While mifepristone awaits final approval from the FDA, medical abortion — using either mifepristone under an experimental protocol or methotrexate (a drug approved by the FDA for cancer treatment in 1953) — is increasingly available in the U.S. The Alan Guttmacher Institute reports that approximately 4200 medical abortions were performed in 1996 and, during the first half of 1997 alone, 4300 medical abortions were performed.

Selected Bibliography

"Boycott of RU-486 Firms Set." *Washington Post*, June 6, 1994, p. A4.

Glasier, Anna, et al., "Mifepristone (RU 486) Compared with High-dose Estrogen and Progestogen for Emergency Postcoital Contraception." *New England Journal of Medicine*, 327(15) October 8, 1992, 1042-1044.

Institute of Medicine. *Clinical Applications of Mifepristone (RU 486) and Other Antiprogestins: Assessing the Science and Recommending a Research Agenda*.. Washington, DC: National Academy Press, 1993.

Peyron, Rémi, et al. "Early Termination of Pregnancy with Mifepristone (RU 486) and the Orally Active Prostaglandin Misoprostol," *New England Journal of Medicine*, 328(21) May 27, 1993, 1509-1413.

Spitz, Irving, et al. "Early Pregnancy Termination with Mifepristone and Misoprostol in the United States," *New England Journal of Medicine*, 338(18) April 30, 1998, 1241-1247.

Talbot, Margaret. "The Little White Bombshell." *New York Times Magazine*, July 11, 1999, 39-43

Winikoff, Beverly, et al. "Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol: Results of a Large Multicenter Trial in the United States," *Archives of Family Medicine*, 7 July/August 1998, 360-366.

Dallard, Cynthia

From: KaiserNewsUpdate@kff.org
Sent: Tuesday, February 22, 2000 10:05 AM
To: KaiserNewsUpdate@kff.org
Subject: KAISER DAILY REPRODUCTIVE HEALTH REPORT

KAISER DAILY REPRODUCTIVE HEALTH REPORT
A news service of The Henry J. Kaiser Family Foundation
http://report.kff.org/repro/

Tuesday, February 22, 2000

ABORTION NEWS
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CAMPAIGN 2000
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IN THE COURTS
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PUBLIC HEALTH & EDUCATION
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OPINIONMAKERS
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JOB POSTING: The Kaiser Daily Report is seeking a new editor. Position requires great writing and editing skills, a strong news sense, substantial knowledge of reproductive health and HIV/AIDS issues, and a flexible attitude, as early morning and occasional weekend work is expected. If you would like to lead our efforts to publish the premier daily briefings on reproductive health care and HIV/AIDS policy, please forward a cover letter and resume to Brian Gardner at (202) 672-5700 or jobs@advisory.com. For more information about other employment opportunities with the Kaiser Family Foundation, click here or type www.kff.org/docs/about/employment.html into your Web browser.

ABORTION NEWS

#1 RU-486: FDA POSTPONES APPROVAL AGAIN

The FDA has again delayed the approval of the abortion pill RU-486, saying certain questions "need to be resolved before

final marketing approval can be granted," the Washington Post reports. Although the federal agency gave its consent on the drug's medical safety and effectiveness four years ago, the "process of finding and approving a manufacturer has been difficult, and made highly contentious by the strong opposition of antiabortion groups." Sandra Waldman, spokesperson for New York's Population Council, the group granted U.S. rights to RU-486, said of the delay, "It's disappointing, but these things happen" (Kaufman, Washington Post, 2/19). She added, "People have been waiting for this for a long time. ... But there's still reason to be optimistic. The safety and efficacy issues are out of the way. And we're trying to move this along as quickly as possible, and we're in negotiations with the FDA" (Silverman/Schwaneberg, Newark Star-Ledger, 2/19). Danco Laboratories, the pharmaceutical company contracted to manufacture and distribute the drug, "also downplayed the news, calling it 'a major step forward in the complex approval process'" (McCullough, Philadelphia Inquirer, 2/19).
Yet to be resolved are issues pertaining to the manufacturing and labeling of RU-486, Waldman said. Neither she nor the FDA would elaborate on those issues. The name and location of subcontracting companies is another possible obstacle. Such information is usually disclosed, but because the "issue has become unusually complex and political," the information has not been made public. Abortion-rights supporters say approval of RU-486 could "revolutionize the abortion debate" because the drug can be administered in doctors' offices without the "notice and controversy associated with surgical abortion clinics." But Laura Echevarria, spokesperson for the National Right to Life Committee, argued, "We believe this is a dangerous drug for mothers and obviously for the babies, and we've asked the FDA to review the whole approval process." Planned Parenthood Federation of America President Gloria Feldt expressed concerns over the influence of politics in the FDA's delays, but added, "I have no specific knowledge ... There's no reason to believe the FDA commitment to moving forward will not ultimately happen" (Washington Post, 2/19). Only after President Clinton took office in 1993 did the White House encourage the drug's developer, Roussel-Uclaf, to grant rights to the Population Council. The FDA, which was expected to issue approval this month, will have six months to act once the Population Council and Danco respond to the information request (Philadelphia Inquirer, 2/19).

#2 MEDICAL PRIVACY: CLINTON'S REGULATIONS 'DISAPPOINT BOTH SIDES'

Witnesses from "across the political spectrum" complained last week before the House Ways and Means health subcommittee about the Clinton administration's sweeping medical privacy regulations that would protect medical records stored or transmitted electronically, CongressDaily reports. Privacy advocates hailed some aspects of the proposal and criticized others, while the health industry "lauded those elements that the privacy community opposes and criticized those the privacy community supports." As a result, it appears the administration will have difficulty incorporating the more than 40,000 public comments received as of Wednesday. Even the Clinton administration voiced concern about certain aspects of the plan. Speaking for the administration, Margaret Hamburg, HHS Assistant Secretary for Planning and Evaluation, said, "Unfortunately, this leaves many entities that receive, use and disclose protected health information outside of the system of protection that we proposed to create." Calling the rules "inadequate," Hamburg said they fall short in part because they do not allow patients

Dailard, Cynthia

From: Boonstra, Heather
Sent: Tuesday, June 06, 2000 9:41 AM
To: PUBLIC POLICY; Executive Staff
Subject: Mife up-date

Kirsten Moore of RHTP reported at the recent abortion lobby meeting that the FDA met with Danco and the Pop Council late last week with new recommendations for the approval of mifepristone -- and the news is not good.

The FDA made suggestions concerning labeling and distribution. For labeling, they will not sanction home-use and recommended a "black box warning," which Kirsten surmised means a warning that the drug will be harmful to the fetus (?!). The FDA also recommends that only providers trained in surgical abortion, mifepristone-use, sonography, and with admitting privileges to a hospital within one-hour's drive can distribute mife. As for training in mife-use, the FDA asked NAF for a copy of their training materials -- if the FDA has its way, it will be up to Danco to see that providers are trained and certified.

There were questions at the small lobby meeting as to whether the FDA was authorized to require these sorts of things, especially given that the agency found earlier that mife was safe and effective. Apparently, this could be construed as the FDA extending its authority to the provision of medical services. Nancy Buck, previously with the FDA, is the lawyer working with Danco and the Pop Council to consider this argument. Danco and the Pop Council have three weeks to reply to the FDA's recommendations, which puts us at about the third week in June.

Heather

THE FIGHT FOR MIFEPRISTONE (RU 486)

1980 Researchers at Roussel Uclaf, a French pharmaceutical company, synthesize mifepristone (RU 486).

1981 The first study on the use of mifepristone to terminate early pregnancy is published.

1982 The U.S. Food and Drug Administration (FDA) issues a testing permit to the Population Council, a non-profit research organization, on the use of mifepristone as a method of early abortion.

1988 Mifepristone becomes available in France. In response to anti-abortion protests, Roussel Uclaf halts distribution of mifepristone. The French Minister of Health orders Roussel Uclaf to return the drug to the market, calling it "the moral property of women." Anti-abortion forces threaten a boycott of Roussel Uclaf's parent company. Hoechst A.G.

1989 In response to pressure from the Bush administration and anti-choice members of Congress the FDA bans the importation of mifepristone for personal use. Hoechst informs abortion opponents that it does not intend to market or distribute mifepristone outside of France.

1990 Leading scientists testify before Congress that the FDA import ban has hindered research on the broad medical benefits of mifepristone, including as a treatment for breast cancer.

Feb. 1991 The American Association for Advancement of Science (AAAS) urges the testing and use of mifepristone.

July 1991 Mifepristone is approved as an early option for nonsurgical abortion in the United Kingdom.

1991 Mifepristone is approved as an early option for nonsurgical abortion in Sweden.

July 1992 An American woman, Leona Benten, issues the first direct challenge to the FDA import alert when she returns from Europe with mifepristone. U.S. Customs officials seize the drug when Benten arrives. A U.S. District Court hears her case and examines the Aimport alert, concluding, A[T]he decision to ban the drug was based not from any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety. The U.S. Supreme Court refuses to hear her case or to order the FDA to overturn the import ban.

Oct. 1992 A study published in the New England Journal of Medicine concludes that mifepristone is a safe and effective emergency contraceptive.

Jan. 1993 President Clinton issues an Executive Order directing the Secretary of Health and Human Services to instruct the FDA to re-evaluate the mifepristone import ban and to assess ways to promote the testing, licensing, and manufacturing of mifepristone.

Sept. 1993 The Institute of Medicine (IOM) releases a report recommending expedited submission to the FDA of a New Drug Application for the use of mifepristone as an early option for nonsurgical abortion. The IOM Report also calls for U.S. research on mifepristone and other antiprogestins as contraceptives and emergency contraceptives, and as possible treatments for endometriosis, some types of breast cancer, uterine fibroids, labor management, meningiomas, and other conditions.

1994-1995 Roussel Uclaf donates U.S. patent rights for mifepristone to the Population Council. Clinical trials in the U.S. testing the combination of mifepristone and the prostaglandin misoprostol are conducted. Twenty-one hundred women in America participate in the trials.

July 1996 The FDA holds hearings on whether to approve mifepristone for use in the U.S. The FDA Advisory Committee for Reproductive Health Drugs recommends approval of mifepristone as a safe and effective early nonsurgical method of abortion. In addition, the committee concludes that the benefits of the procedure outweigh its risks

Sept. 1996 The FDA issues an "approvable letter" for mifepristone, when used in combination with misoprostol, for early abortion. The FDA determines that "the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision, but additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made."

Feb. 1997 Gedeon Richter, the European manufacturer responsible for producing mifepristone for the U.S. market, cancels its contract with the Population Council. While a new manufacturer is sought, mifepristone's introduction into the U.S. is delayed indefinitely.

April 1998 The New England Journal of Medicine reports on the clinical trials submitted to the FDA. The study finds mifepristone, in combination with a prostaglandin, is effective in medically terminating pregnancy in 92 percent of pregnancies lasting 49 or fewer days. (Women for whom the drug combination does not work may terminate the pregnancy surgically.) The study also finds this method of early nonsurgical abortion to be safe: side effects generally consist of nausea and cramping.

June 1998 U.S. Rep. Tom Coburn (R-OK) offers an amendment to the fiscal year 1999 Agriculture Appropriations bill to bar the FDA from using funds to test, develop, or approve any drug for the "chemical" inducement of abortion, including mifepristone. The amendment passes by a vote of 223-202.

July 1998 The Archives of Family Medicine reports that American women involved in clinical trials of mifepristone and misoprostol find the regimen highly acceptable. Ninety-six percent would recommend the method to a woman seeking an abortion, and over 90 percent would choose the method if they needed an abortion in the future. Even among women for whom the method failed, necessitating a traditional surgical abortion, 70 percent would try it again and 85 percent would recommend it to others.

Fall 1998 The Clinton Administration strongly opposes the inclusion of the Coburn amendment in the final Agriculture Appropriations bill and threatens to veto the bill if the ban is included. The Senate does not include a ban FDA expenditure of funds to approve medical abortion in the Agriculture Appropriations bill. A conference committee is appointed to resolve the Senate and House differences in the Agriculture Appropriations bill, and ultimately the ban is removed.

1999 For the second time, the House votes to include the Coburn amendment, banning FDA expenditure of funds to approve medical abortion, in the Agriculture Appropriations bill. The Senate does not include such a ban, and a conference committee agrees to remove the language from the final version of the bill. Austria, Belgium, Denmark, Finland, Germany, Greece, Israel, Spain, and the Netherlands approve mifepristone for marketing.

Feb. 2000 The FDA issues a second "approvable letter" for mifepristone, when used in combination with misoprostol as an early option for nonsurgical abortion. The letter indicates that additional information is required before the FDA can grant final marketing approval. Final approval is expected in 2000.

ACOG

June 6, 2000

Gov't Eyes Abortion Pill Regs

A.P. INDEXES: TOP STORIES | NEWS | SPORTS | BUSINESS | TECHNOLOGY | ENTERTAINMENT

Filed at 5:28 p.m. EDT

By The Associated Press

WASHINGTON (AP) -- The government is considering rules for use of the abortion pill RU-486 that could restrict access to that early-abortion option, Planned Parenthood's director said Tuesday.

The Food and Drug Administration said in February it would approve the sale of RU-486, also known as mifepristone, once some final, but undisclosed, requirements were met.

The pill's sponsor, the nonprofit Population Council, last week told abortion providers the FDA is proposing some curbs on the pill's use, said Gloria Feldt, national president of Planned Parenthood.

''We are deeply concerned that FDA is considering restrictions that in my view would virtually assure that very few doctors would ever make mifepristone available,'' Feldt said Tuesday. Planned Parenthood is a family planning group that favors abortion rights.

She said the biggest concern is an FDA proposal that physicians allowed to administer RU-486 must be part of a registry, which she said would deter doctors worried about anti-abortion violence from offering the pill.

Feldt said the FDA also is considering long-term health tracking of at least some RU-486 recipients, something she called unnecessary because half a million European women have used the pill successfully since 1988.

FDA officials declined comment.

"Some of the FDA's recent proposals are more restrictive than we had expected," said Sandra Waldman, speaking for the Population Council. She would not be more specific.

But Waldman stressed that FDA discussions over the pill's use have just begun and no requirements are complete.

Studies show RU-486 is 95.5 percent effective in causing abortion when taken within the first 49 days of pregnancy. But a very small percentage of patients required additional surgical treatment or blood transfusions, something the FDA must consider in determining how the pill should be used. One question is how to ensure women return for an exam to be sure the pregnancy was terminated.

The nonprofit Population Council in 1994 received U.S. marketing rights to RU-486 from the original French manufacturer, which feared an anti-abortion boycott.

Talking Points RU-486
6/7/00

BACKGROUND: The Washington Post and other media have stories today on FDA review of RU-486, a French-developed abortion bill also referred to as mifespristone. Planned Parenthood has charged that FDA will require restrictions on its usage that could limit its access. While the drug has been shown in studies to be effective in ending pregnancy, a small percentage of women require additional medical treatment such as blood transfusions or surgical procedures.

CONTACT: Larry Bachorik, FDA 301-827-6250
[Melissa Skolfield, HHS, 202-690-7850]

Q: Has FDA decided to put restrictions on RU-486?

A: FDA announced in February that RU-486 was approveable. As with any new drug under review, FDA is now discussing details of its availability and usage with the product's sponsors. That is standard operating procedure.

We cannot comment specifically on those discussions.

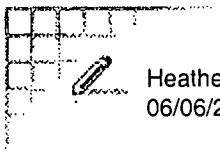
FDA is doing what it should be doing at this stage in the review process: ensuring that the drug is available and effective, but also used safely.

CHIEF OF STAFF TO THE PRESIDENT

CC: Beth Nolan
Michelle Arrowwitz
Lauren Supina
Mary Beth Cahill
Heather Howard

HHS is saying there is still no report on what actually is going on. I will keep you posted.

Maria



Heather H. Howard
06/06/2000 06:41:23 PM

Record Type: Record

To: Bruce N. Reed/OPD/EOP@EOP, Barbara Chow/OMB/EOP@EOP

cc: Ann O'Leary/OPD/EOP@EOP, Christopher C. Jennings/OPD/EOP@EOP, Devorah R. Adler/OPD/EOP@EOP, Ruby Shamir/WHO/EOP@EOP

Subject: RU-486

I wanted to let you know that I have been hearing from pro-choice groups who are very upset about what they are hearing about the FDA's final approval of RU-486, which is expected September 30th. The FDA granted approvable status in February (actually renewing the 1996 grant), but said it needed to meet some labelling and distribution conditions. The groups have gotten wind of what those conditions are and are very concerned that they will limit access to RU-486. Examples of the conditions the groups believe the FDA is considering include:

1) requiring a "black box" to highlight certain warnings (they claim the only other non-scheduled drug with such a black box is thalidomide);
2) requiring that it be distributed only by qualified physicians who are trained and certified to distribute it and who are trained and authorized to perform surgical abortions. This would be problematic first, because it limits the number of doctors who would be able to prescribe, but second, because it would require keeping track of who is authorized to distribute, which would discourage doctors who fear anti-choice violence; and
3) requiring that misoprostol, the 2nd pill taken to induce contractions, be taken in a doctor's office.

At this point, we don't know where things actually stand, and whether the FDA is just considering these among other options. But some of the groups are asking for a meeting with Podesta, and this story is on the wire:

Filed at 5:28 p.m. EDT

> By The Associated Press
>
> WASHINGTON (AP) -- The government is considering rules for use of the abortion pill RU-486 that could restrict access to that early-abortion option, Planned Parenthood's director said Tuesday.
>
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>
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>
> "We are deeply concerned that FDA is considering restrictions that in my view would virtually assure that very few doctors would ever make mifepristone available," Feldt said Tuesday. Planned Parenthood is a

Urgent – Important Information

To: Chiefs of Staff and Reproductive Health Staff

From: Alice Travis Germond, Executive Vice President, NARAL
Gloria Feldt, President, Planned Parenthood Federation of America
Vicki Saporta, Executive Director, National Abortion Federation
Eleanor Smeal, President, Feminist Majority Foundation

Date: June 7, 2000

Subject: Mifepristone (RU 486) Approval

In 1996, the Food and Drug Administration (FDA) issued an "approvable" letter for mifepristone, finding it safe and effective, and indicating that final approval is contingent upon additional information about manufacturing practices and labeling. Also known as RU 486, mifepristone is an effective early option for nonsurgical abortion, and has been used safely for nearly two decades in European countries.

Today it is being reported that the FDA is discussing with Danco Laboratories - the company licensed for United States manufacture and distribution - certain conditions concerning the drug's labeling, distribution and manufacturing. The conditions under discussion are very serious and, if implemented, would severely limit the drug's availability.

However, these discussions are part of the drug-approval process and are not final. At this time, we believe the manufacturer should be allowed to continue its conversation with the FDA. Mifepristone has already been used by more than 500,000 women in Europe with very high effectiveness, safety, and satisfaction rates. It also holds promise for other illnesses; it can help to induce labor, treat infertility, endometriosis, and certain types of tumors, and may be useful in treating AIDS, Cushing's disease, and glaucoma.

Today's reports further illustrate the importance of preventing anti-choice lawmakers from injecting politics into science by barring FDA funds from being used to complete mifepristone's final approval. Your opposition to Rep. Tom Coburn's amendment to the Agriculture appropriations bill is critical. Attempting to legislate any drug's approval or disapproval is inappropriate and sets a dangerous precedent of prohibiting development in certain drug categories. We urge members of Congress to stand firm against any legislative assaults of this nature. Delays in the approval process resulting from anti-choice politics will undermine reproductive health and deny American women an important health care option.

The FDA granted "approvable status" to Mifepristone (RU-486) in 1996 and renewed that same status in February of 2000. "Approvable status" means that the FDA found the drug safe and effective but required more information relating to manufacturing, labelling, etc. Danco has been working over the last few months to provide the FDA with the necessary information to obtain final approval on the next "action date" of the FDA, which is September 30th.

labeling + distribution conditions

It is being reported that discussions with the FDA have revealed potential new obstacles for Mifepristone. Among them are: (1) requiring a "black box" on the label to highlight certain points about Mifepristone. Such an ominous "black box" is usually required only when the safety and efficacy of the drug is in question; even the FDA admits they are not in this case. The only non-scheduled drug with such "black box" requirements is thalidomide. (2) home use of misoprostol is at serious risk, despite good data submitted to the FDA by Danco supporting its safety, efficacy, and acceptability; (3) requiring that Mifepristone only be distributed to "qualified physicians" (language changed from "provider" to "physician") who are "trained and certified" to dispense Mifepristone, "trained and authorized" to perform surgical abortions, and who have admitting privileges to a hospital within 1 hour's distance that can handle emergencies (with a letter saying so from the Chief Medical Officer of the hospital).

There's more, but these are the most egregious restrictions and if allowed to stand, represent outrageous intrusions on medical practice and will essentially kill access to Mifepristone, medical abortion for American women.

From Clinton-Gore Accomplishments:
Protected FDA's Role in Testing RU-486. In 1993, President Clinton reversed the ban on the importation of Mifepristone or RU-486. In 1998 and 1999, the President and Vice President successfully fought for removal of a provision that would prohibit the FDA from testing, developing or approving RU-486, thereby usurping the Agency's role in making scientific determinations about the effect of drugs on the safety and health of the American people.

require Danco to keep track of who is trained to distribute

ask Pharma how normal this is

misoprostol - 24 pill - & would have to go into doctor - wait there for expulsion to happen - this is what they have to do in France

FAX

THE ALAN GUTTMACHER INSTITUTE
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Date: 6/7

Number of pages including cover sheet: 4

To: Heather Howard

@ 456-2878

From: Cyn

____Original will not follow
____Original will follow, via _____

MESSAGE:

Thought you might be interested in this AGI article about harnessing support for very early abortion.

The Political Challenges And Educational Opportunities Around Very Early Abortion

By Rebekah Saul

Public attention to congressional action on abortion last year was focused almost exclusively on the Partial-Birth Abortion Ban Act—an antiabortion initiative designed to capitalize on Americans' concern over "late" pregnancy termination (*TGR*, Vol. 1, No. 6, December 1998). Meanwhile, in the shadow of the "partial-birth" debate, a congressional move that could have greatly impacted the other end of the abortion spectrum received very little attention: Last summer, the House endorsed a provision that effectively would have barred Food and Drug Administration (FDA) approval of very early, nonsurgical methods of abortion, such as mifepristone (commonly known as RU-486).

In the end, the provision failed to become law. The brief debate over the measure, however, focused less on abortion than on "science"—on the contention that congressional intervention in FDA's review of any one category of drugs (in this case, abortion-inducing drugs) would constitute an egregious and inappropriate interference with accepted scientific processes, one that could have negative consequences for a range of health conditions. During the fight, the reproductive rights community largely laid low, ceding to these more "mainstream" concerns.

With mifepristone's final FDA approval still in the offing, reproductive health supporters almost certainly will face further attempts by antiabortion lawmakers to prevent its progress—which, in turn, may yield additional opportunities to rethink legislative and public education strategies around this and other newly available methods of very early abortion. While last year's strategy, in the short term, clearly worked to sow doubts in the minds of key legislators about the wisdom of congressional meddling in the FDA drug-approval process, it did little to advance the abortion debate by increasing public understanding about very early abortion methods. It, therefore, also did little to close a troubling gap between longstanding public support for abortion as early in pregnancy as possible and the lack of congressional support for a range of new technologies that promise a potential shift in that very direction. As a long-term strategy, closing this gap, while a significant challenge, may prove critical for both reproductive health politics and the availability of reproductive health services.

Outlawing RU-486...

In an unforeseen move last June, Rep. Tom Coburn (R-OK) offered an amendment to a spending bill to prohibit the use of funds by FDA "for the testing, development or approval...of any drug for the chemical inducement of abortion." After the briefest of debates, the House approved the amendment, 223-202. The Senate declined to include a similar provision in its version of the appropriations measure, so the fate of the FDA restriction ultimately was decided by a House-Senate conference committee, which rejected it.

Though it clearly would have much broader implications, both sides of the abortion divide recognized the Coburn amendment's fundamental purpose—to derail mifepristone's long-awaited entrance into the United States. In combination with the prostaglandin misoprostol, the compound was first approved as an abortion method in France in 1988. Because the mifepristone/misoprostol regimen is a "medical"—that is to say, nonsurgical—form of abortion, and because it is effective at stages of pregnancy traditionally considered too early for effective surgical abortion, its development was considered a major reproductive health breakthrough.

Ever since mifepristone's debut in Europe, reproductive health proponents have looked forward to its advent in the United States. The drug's introduction into this country was stalled by various political maneuvers until 1993, when President Clinton effectively directed FDA to review it. In 1994, the Population Council began a year of clinical trials in the United States, which ultimately affirmed the French experience—that the drug regimen is a safe and effective method of abortion in the first seven weeks of pregnancy (measured from the beginning of a woman's last menstrual period). In 1996, the Council submitted a New Drug Application to FDA, which in turn deemed the drug "approvable," pending final information on manufacturing and labeling. Taking advantage of the delay regarding these final details, Coburn and like-minded members of Congress—who believe that abortion is murder at any stage in pregnancy—clearly aimed to stop mifepristone in its tracks.

New technologies that enable women to have abortions in the earliest stages of pregnancy could affect reproductive health politics *and* service delivery.

NEW AND RE-EMERGING VERY EARLY ABORTION TECHNOLOGIES

Mifepristone/Misoprostol Regimen—Mifepristone blocks the hormone progesterone, which is needed to maintain a pregnancy. Misoprostol, an already marketed prostaglandin, causes uterine contractions. The combined regimen has demonstrated effectiveness roughly comparable to surgical abortion, and can be used as soon as a pregnancy is detected up to 49 days from a woman's last menstrual period (LMP). Barring congressional action to the contrary, final FDA approval of the regimen is anticipated later this year.

Methotrexate/Misoprostol Regimen—Methotrexate blocks folic acid and prevents cell division; already marketed as a cancer-fighting drug, its use as an abortifacient is legal but technically "off-label." This regimen is also being used from the detection of pregnancy up to 49 days LMP.

Manual Vacuum Aspiration (MVA)—A surgical procedure that utilizes a non-electrical suction instrument to evacuate the contents of the uterus. MVA may be used throughout the first 12 weeks of pregnancy. Use of MVA was fairly widespread in the early 1970s, but technology limited early pregnancy detection, as well as detection of incomplete abortion. Improved pregnancy tests and ultrasound equipment have facilitated MVA's re-emergence as a surgical method of very early abortion.

...Or Hampering Science?

In support of the funding ban, Coburn and other congressional opponents of abortion rights maintained that approving abortion technologies is not an appropriate function for a federal agency whose mission is to promote health. Reproductive rights advocates countered that because abortion is legal in the United States, it is wholly appropriate that medical methods of abortion be considered on an equal basis with drugs used for other legal purposes.

Notwithstanding these arguments, however, a major component of the prochoice strategy was to allow questions about the appropriateness of congressional intervention in complicated scientific processes and protocols, namely, the long-established FDA drug-approval process, to dominate the debate. Indeed, a large and diverse coalition of organizations promoting biomedical research was amassed to oppose the provision on the grounds that it could have far-reaching, negative consequences on a range of health technologies, not just those relating to pregnancy termination.

While mifepristone is being reviewed by FDA in light of its efficacy as an abortifacient, these organizations pointed out, the drug also has shown promise in treating other conditions, such as Cushing's syndrome and endometriosis. Barring mifepristone's approval, then, also would slow research on alternative uses, they said. In addition, research advocates cautioned that the Coburn amendment could implicate *any* drug that causes an abortion (as a side effect, not just as its primary purpose)—for example, drugs used in chemotherapy. Fearing the Coburn amendment would effectively bar a range of important therapies, the National Coalition for Cancer Research went on record opposing it.

If Timing Matters

Downplaying the abortion issue *per se* while highlighting "larger" questions has been considered the safest, if not only, way to prevail in an antiabortion Congress on a matter impinging on reproductive choice—especially in recent years, when antiabortion advocates have focused on restrictions that are largely backed by the public. In the case of efforts to prohibit the approval of mifepristone, however, at least the *potential* for galvanizing widespread public and political support certainly exists. The drug is most effective in the first half of the first trimester and, therefore, offers women a new option for the earliest possible termination of pregnancy. Moreover, it is just one of a number of emerging technologies—surgical as well as nonsurgical—that allow women to obtain an abortion at stages traditionally considered too early for effective surgical abortion (see box).

Public opinion in the United States is highly supportive of early abortion. According to a *New York Times*/CBS poll conducted in early 1998 at the time of the 25th anniversary of the Supreme Court's *Roe v. Wade* decision, almost two-thirds of American adults believe that abortion should be legal in the first three months of pregnancy. Support for legal abortion drops precipitously after the first trimester, however. Abortion practice largely mirrors public opinion. American women overwhelmingly have abortions early in pregnancy—approximately half of all abortions occur within the first eight weeks and almost nine in 10 by the end of the first trimester. The newly emerging abortion technologies, taken together and coupled with advancements in pregnancy detection, have the potential to shift the timing of abortion in the United States even more in that direction, by increasing the percentage performed in the first half of the first trimester.

Fiction and Fact

According to the Kaiser Family Foundation, however, the American public is largely ignorant about these methods. In 1997, according to a Foundation poll, only 43% of women and 51% of men had even heard of either mifepristone or methotrexate, a long-marketed cancer-fighting drug also being used "off-label" as an abortifacient; moreover, only seven in 10 of the women who had heard of these drugs knew that they could be used as a method of pregnancy termination. It is likely that recently available *surgical* techniques of very early abortion are similarly unknown. (New data from The Alan Guttmacher Institute [AGI] indicate medical abortions constitute a small but rapidly growing fraction of all abortions; AGI estimates that, in 1996, 4,200 medical abortions were performed in the United States and that 4,300 such abortions were provided *in the first half* of 1997. No comparable information is available on the extent to which MVA is being used.)

There is also some evidence, at least in the public debate, that support for very early abortion methods, especially medical methods, may be tempered by confusion about how the methods work and, consequently, how they might affect the incidence of abortion. One myth, in the words of

Rep. Joseph Pitts (R-PA), is that they would make unwanted pregnancy "the medical equivalent of a headache: pop a pill and it will go away." The implication is that mifepristone or methotrexate, by making the procedure "easier," would diminish the seriousness with which women treat abortion.

A concerted public education campaign may be necessary to engage the public and build the bridge between theoretical support and public activism.

In reality, medical abortion is comparable to a miscarriage, but it can take considerably longer; the process can span several days and, though extremely safe, involves significant medical supervision. In terms of what's involved in the actual procedures, medical abortions and surgical abortions each have relative advantages and disadvantages from the viewpoint of the women undergoing them; experience in Europe shows that some women prefer one and some the other. In countries where it has been available, however, there is no evidence to support the notion that the availability of mifepristone increases the overall incidence of abortion; in fact, the abortion rate in France has declined more or less steadily since mifepristone's advent in 1988.

From Theory to Practice

Clearly, there is much work to be done to educate the public about the new abortion methods—how they work and how they may, and may not, impact the overall provision of abortion services—so that future attempts to restrict very early abortion methods can be fought head-on. Indeed, a concerted public education campaign may be necessary to engage the public and build the bridge between theoretical support and public activism.

Increased activism around very early abortion could have a positive, multiplier effect on reproductive health policy debates. Beyond staving off further damaging congressional action, it also could help add a new "winner" to the reproductive rights political agenda. That, in turn, could re-engage policymakers and the public in the basic right to abortion. As a bonus, prevailing on the issue of FDA approval of new abortion technologies, specifically mifepristone, could prove beneficial for a broad array of medical conditions—safeguarding, at the same time, the independence and integrity of the FDA drug-approval process itself. ⊕

Medicaid Managed Care
Continued from page 4

quate capacity—including an adequate provider network—to provide true access to the care. The problem is more complicated for services that are not included in an individual managed care contract—for example, if a plan refuses to provide family planning. In this case, the proposed regulations put the burden of ensuring access directly on the state: "The state must arrange for those services to be made available from other sources and instruct all enrollees on where and how to obtain them, including how transportation is provided."

The accessibility of family planning services to Medicaid managed care enrollees could be seriously impaired if the regulations are watered down.

Roadblocks Ahead

Assuming the regulations that ultimately are finalized closely resemble the regulations as proposed—and that several important details are addressed in the process—family planning services stand to fare well in this emerging Medicaid system. Whether that will be the case, of course, remains to be seen.

Ironically, the very clarity and detail with which the proposed regulations spell out the requirements for plans, and states, to ensure unfettered access to Medicaid-covered services may be their undoing. States had pushed for abandoning waivers in order to gain additional flexibility and the freedom to design their programs and to rid themselves of what they construed to be undue federal interference. Although Congress granted their wish and abolished the waiver requirement, in the process it established a strong set of protections for managed care enrollees; the proposed rule spells out how these protections are to be translated from legislative intent to actual practice.

Not surprisingly, some states are now alleging that the proposed regulations' requirements are too prescriptive and continue to deprive states of the flexibility they need. Thus far at least, the family planning-related provisions of the proposed rule are not at issue in this debate. However, if the concerns raised by the states lead HCFA to back down on some of the detail it built into the proposed rule, the accessibility of family planning services to Medicaid managed care enrollees—which at the moment looks so promising—could be seriously impaired. ⊕

1990	Leading scientists testify before Congress that the FDA import ban has hindered research on the broad medical benefits of mifepristone, including as a treatment for breast cancer.
February 1991	The American Association for Advancement of Science (AAAS) urges the testing and use of mifepristone.
July 1991	Mifepristone is approved as an early option for nonsurgical abortion in the United Kingdom.
1992	Mifepristone is approved as an early option for nonsurgical abortion in Sweden.

July 1992	An American woman, Leona Benten, issues the first direct challenge to the FDA import alert when she returns from Europe with mifepristone. U.S. Customs officials seize the drug when Benten arrives. A U.S. District Court hears her case and examines the Aimport alert,@ concluding, A[T]he decision to ban the drug was based not from any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety.@ The U.S. Supreme Court refuses to hear her case or to order the FDA to overturn the import ban.
October 1992	A study published in the New England Journal of Medicine concludes that mifepristone is a safe and effective emergency contraceptive.
January 1993	President Clinton issues an Executive Order directing the Secretary of Health and Human Services to instruct the FDA to re-evaluate the mifepristone import ban and to assess ways to promote the testing, licensing, and manufacturing of mifepristone.

Septembe r 1993	The Institute of Medicine (IOM) releases a report recommending expedited submission to the FDA of a New Drug Application for the use of mifepristone as an early option for nonsurgical abortion. The IOM Report also calls for U.S. research on mifepristone and other antiprogestins as contraceptives and emergency contraceptives, and as possible treatments for endometriosis, some types of breast cancer, uterine fibroids, labor management, meningiomas, and other conditions.
1994-199 5	Roussel Uclaf donates U.S. patent rights for mifepristone to the Population Council. Clinical trials in the U.S. testing the combination of mifepristone and the prostaglandin misoprostol are conducted. Twenty-one hundred women in America participate in the trials.
July 1996	The FDA holds hearings on whether to approve mifepristone for use in the U.S. The FDA Advisory Committee for Reproductive Health Drugs recommends approval of mifepristone as a safe and effective early nonsurgical method of abortion. In addition, the committee concludes that the benefits of the procedure outweigh its risks.
Septembe r 1996	The FDA issues an Aapprovable letter@ for mifepristone, when used in combination with misoprostol, for early abortion. The FDA determines that Athe submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision, but additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made.@
February 1997	Gedeon Richter, the European manufacturer responsible for producing mifepristone for the U.S. market, cancels its contract with the Population Council. While a new manufacturer is sought, mifepristone's introduction into the U.S. is delayed indefinitely.
April 1998	The New England Journal of Medicine reports on the clinical trials submitted to the FDA. The study finds

	|mifepristone, in combination with a prostaglandin, is
	|effective in medically terminating pregnancy in 92
	|percent of pregnancies lasting 49 or fewer days. (Women
	|for whom the drug combination does not work may terminate
	|the pregnancy surgically.) The study also finds this
	|method of early nonsurgical abortion to be safe: side
	|effects generally consist of nausea and cramping.
June	|U.S. Rep. Tom Coburn (R-OK) offers an amendment to the
1998	|fiscal year 1999 Agriculture Appropriations bill to bar
	|the FDA from using funds to test, develop, or approve any
	|drug for the Achemical@ inducement of abortion, including
	|mifepristone. The amendment passes by a vote of 223-202.
July	|The Archives of Family Medicine reports that American
1998	|women involved in clinical trials of mifepristone and
	|misoprostol find the regimen highly acceptable.
	|Ninety-six percent would recommend the method to a woman
	|seeking an abortion, and over 90 percent would choose the
	|method if they needed an abortion in the future. Even
	|among women for whom the method failed, necessitating a
	|traditional surgical abortion, 70 percent would try it
	|again and 85 percent would recommend it to others.
Fall	|The Clinton Administration strongly opposes the inclusion
1998	|of the Coburn amendment in the final Agriculture
	|Appropriations bill and threatens to veto the bill if the
	|ban is included. The Senate does not include a ban on
	|FDA expenditure of funds to approve medical abortion in
	|the Agriculture Appropriations bill. A conference
	|committee is appointed to resolve the Senate and House
	|differences in the Agriculture Appropriations bill, and
	|ultimately the ban is removed.
1999	|For the second time, the House votes to include the
	|Coburn amendment, banning FDA expenditure of funds to
	|approve medical abortion, in the Agriculture
	|Appropriations bill. The Senate does not include such a
	|ban, and a conference committee agrees to remove the
	|language from the final version of the bill.
	|Austria, Belgium, Denmark, Finland, Germany, Greece,
	|Israel, Spain, and the Netherlands approve mifepristone
	|for marketing.

February 2000	The FDA issues a second "approvable letter" for mifepristone, when used in combination with misoprostol, as an early option for nonsurgical abortion. The letter indicates that additional information is required before the FDA can grant final marketing approval. Final approval is expected in 2000.

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Urgent – Important Information

To: Chiefs of Staff and Reproductive Health Staff

From: Alice Travis Germond, Executive Vice President, NARAL
Gloria Feldt, President, Planned Parenthood Federation of America
Vicki Saporta, Executive Director, National Abortion Federation
Eleanor Smeal, President, Feminist Majority Foundation

Date: June 7, 2000

Subject: Mifepristone (RU 486) Approval

In 1996, the Food and Drug Administration (FDA) issued an "approvable" letter for mifepristone, finding it safe and effective, and indicating that final approval is contingent upon additional information about manufacturing practices and labeling. Also known as RU 486, mifepristone is an effective early option for nonsurgical abortion, and has been used safely for nearly two decades in European countries.

Today it is being reported that the FDA is discussing with Danco Laboratories - the company licensed for United States manufacture and distribution - certain conditions concerning the drug's labeling, distribution and manufacturing. The conditions under discussion are very serious and, if implemented, would severely limit the drug's availability.

However, these discussions are part of the drug-approval process and are not final. At this time, we believe the manufacturer should be allowed to continue its conversation with the FDA. Mifepristone has already been used by more than 500,000 women in Europe with very high effectiveness, safety, and satisfaction rates. It also holds promise for other illnesses; it can help to induce labor, treat infertility, endometriosis, and certain types of tumors, and may be useful in treating AIDS, Cushing's disease, and glaucoma.

Today's reports further illustrate the importance of preventing anti-choice lawmakers from injecting politics into science by barring FDA funds from being used to complete mifepristone's final approval. Your opposition to Rep. Tom Coburn's amendment to the Agriculture appropriations bill is critical. Attempting to legislate any drug's approval or disapproval is inappropriate and sets a dangerous precedent of prohibiting development in certain drug categories. We urge members of Congress to stand firm against any legislative assaults of this nature. Delays in the approval process resulting from anti-choice politics will undermine reproductive health and deny American women an important health care option.

Urgent – Important Information

To: Chiefs of Staff and Reproductive Health Staff

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Vicki Saporta, Executive Director, National Abortion Federation
Eleanor Smeal, President, Feminist Majority Foundation

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THE WHITE HOUSE

WASHINGTON

Office of the First Lady

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To: Ann Lewis / April Springfield

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From: Heather Howard

Number of pages (including cover): 2

Comments: I wanted you to see what message the groups are sending up to the Hill on RU-486

Urgent – Important Information

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NARAL FAX

NARAL
Reproductive Freedom & Choice

TO Heather Howard

ORGANIZATION

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THE WHITE HOUSE

WASHINGTON

June 7, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: **HEATHER HOWARD**

CC: **MELANNE VERVEER**
SHIRLEY SAGAWA
LISSA MUSCATINE
ANN O'LEARY

SUBJECT: **RU-486**

As you know from news reports, pro-choice groups (Planned Parenthood, NARAL, National Abortion Federation and the Feminist Majority Foundation) are concerned that the FDA is considering placing restrictions on access to RU-486 (Mifepristone). I wanted to provide you with some background and context:

- Mifepristone is used in the first seven weeks of pregnancy. It has been shown in studies to be effective in ending pregnancy, but a small percentage of women require additional medical treatment such as blood transfusions or surgical procedures. It has been used over 500,000 times in Europe over the past 12 years.

- In 1989, the Bush Administration banned the importation of Mifepristone. In 1993, President Clinton reversed the importation ban. In 1998 and 1999, the Administration successfully fought for removal of an appropriations provision that would have prohibited the FDA from testing, developing or approving Mifepristone. We may face a similar amendment as early as next week when the House considers the Agriculture appropriations bill.

- In 1996 and again in February 2000, the FDA issued an "approvable" letter for Mifepristone, indicating that final approval was contingent upon additional information about manufacturing practices and labeling.

- Danco Laboratories – the company licensed for U.S. manufacture and distribution – is negotiating the conditions for the drug's manufacture, labeling and distribution. They claim that the FDA is considering requiring restrictions that would seriously limit access, including:

    - Requiring a "black box" to highlight certain warnings. According to the groups, the only other non-scheduled drug with such a black box is thalidomide.
    - Requiring that it only be distributed by "qualified physicians" who are trained and certified to distribute it, and who are trained and authorized to perform surgical

abortions. This would be problematic for two reasons: first, because it limits the number of doctors who would be able to prescribe, since there are already far too few doctors performing surgical abortions; second, because it would require a registry to keep track of who is authorized to distribute the drug, which would discourage doctors who fear anti-choice violence.

- Requiring that Misoprostol, the second pill taken to induce contractions, be taken in a doctor's office, which would require women to make a second trip and would in particular limit the access of rural women.

We do not know whether the conditions being considered by the FDA are reasonable, but we do know that the process is ongoing. The FDA is in negotiations with Danco, and Danco will have an opportunity to respond to these proposals within the next few weeks, and will be able to make their arguments based on the science. It is very important that the FDA's scientific approval process be credible; we should not interfere and politicize the issue. For this reason, we have had no contact with the FDA. Today's press reports are unfortunate because they politicize an issue that should be about the science.

Our message should be:

- We do not want women to face unnecessary access barriers, but we do want appropriate safety precautions.
- The FDA is doing what it should be doing at this stage in the review process -- it is in negotiations with Danco about manufacturing and distribution issues. Danco will have an opportunity to be heard and present its arguments. The FDA's final decision must be based on the science.
- RU-486 is an important, non-surgical option for women early in their pregnancies and will not result in more abortions.

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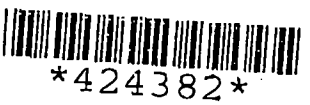
City Clerk's Office



July 11, 2000

The Honorable Bill Clinton, President
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear President Clinton:

At its meeting of June 20, 2000 the Berkeley City Council voted to urge you and the Food and Drug Administration to make it easier to obtain Mifepristone. The FDA has suggested that it might place tight restrictions on the distribution and labeling of Mifepristone, formerly called RU-486.

Mifepristone is a safe, effective, non-surgical method of early abortion that has been available and used by more than a half million women in Europe since 1981. If approved by the FDA, women would gain greater and safer access to abortion. Doctors who currently do not perform surgical abortions would be able to terminate early pregnancies making late abortion a rare event. With drug-induced abortions available in a broader range of medical settings, Mifepristone could end the violence against physicians and clinics that provide abortion services.

Berkeley City Council members feel that, if the FDA approves Mifepristone, this drug should be made available to women in the United States without undue restrictions. Denying a broader access to Mifepristone is going against the principles of the constitutional right of all women to control their reproductive lives.

Sincerely,

Sherry M. Kelly
City Clerk

cc: Councilmember Kriss Worthington
City Manager James Keene

1900 Addison Street, Berkeley, CA 94704 Tel: 510.644.6480 TDD: 510.644.6915 Fax: 510.644.8801
E-Mail: *clerk@ci.berkeley.ca.us* Website: *http://www.ci.berkeley.ca.us/clerk*

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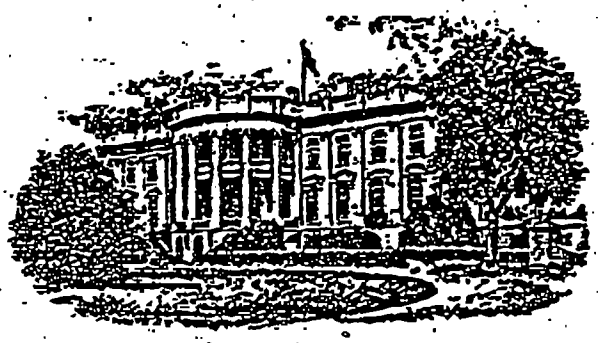

THE WHITE HOUSE
WASHINGTON

FACSIMILE / MEMO FROM AMANDA HANLIN
OFFICE OF PRESIDENTIAL LETTERS AND MESSAGES
OLD EXECUTIVE OFFICE BUILDING, ROOM 97

VOICE: (202) 456-5511 FAX: (202) 456-5426
TELEPHONE: 202.456.5492

To: Heather Howard
Fax #: 6-2878
From: AMANDA HANLIN EXT: 5492
Subject: RU486 letter
Comments:

Date: 11/15/00
Pages: 2 (INCLUDING THIS COVER SHEET)

Per my email. Thanks for your help!

Amanda C. Hanlin
11/15/2000 10:30:35 AM

Record Type: Record

To: Heather H. Howard/OPD/EOP@EOP

cc:
Subject: Mifepristone

Hi Heather,

Just wonderng if you had a chance to look at the mifepristone letter I sent you. We had to do extensive revisions since the FDA approval. I'll refax the incoming letter to you for background. Let me know if you need anything else. thanks!

Dear Sherry:

Thank you for your letter on behalf of the Berkley City Council. I appreciate knowing your thoughts, and I've shared them with members of my staff in the Domestic Policy Council.

You'll be pleased to know that on September 28, the Food and Drug Administration (FDA) approved mifepristone. After extensive review and clinical testing, the FDA found its use ~~is~~ to be safe and effective under certain prescribed conditions.

My Administration will continue working to ensure that all women have access to a full range of safe and affordable reproductive health services. I appreciate your continued involvement in this important issue. Best wishes.

Sincerely,