DEPARTMENT OF HEALTH & HUMAN SERVICES Chief of Staff

Washington D.C. 20201

FACSIMILE

OCT 26 1994

DATE OCT 26 1994

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Carol Rasco
Assistant to the President
for Domestic Policy

456-2216

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Kevin Thurm
Chief of Staff

690-6133

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

OCT 26 1994

MEMORANDUM FOR CAROL RASCO

From: Kevin Thurm

Re: Population Council Clinical Trials of RU-486

We have been notified by the Population Council that it plans to announce tomorrow, Thursday, October 27, that the clinical trials of RU-486 as an abortifacient have begun in the U.S. Attached is a summary of the announcement and associated issues.

There is no Departmental role in the press conference other than the reference by the Population Council to the Investigational New Drug approval from FDA. Please call me if you have any questions.

Update on Medical Abortion

On Thursday, October 27, 1994, in New York City, the Population Council will hold a news conference to announce that clinical trials of the abortifacient mifepristone (known in Europe as RU-486) have begun in the United States. The clinical trials became possible after the Department of Health and Human Services earlier this year helped arrange a transfer of the drug's patent rights to the Population Council, a nonprofit research organization involved in reproductive health and population issues. The clinical trials will be conducted under a protocol which has been reviewed and approved by the FDA.

The clinical trials are designed to determine the safety, effectiveness, acceptability, and feasibility of using mifepristone and prostaglandin to induce a medical abortion. Mifepristone works to interrupt an early pregnancy, and the prostaglandin -- which is administered 48 hours later -- causes the uterus to contract and expels the fertilized egg.

The combination of mifepristone and prostaglandin will be tested in 2100 American women over the age of 18 at more than a dozen sites around the United States. Clinics were selected on the basis of their ability to provide experienced scientific investigators and high quality abortion services. Trial locations include hospital-based clinics, Planned Parenthood and feminist health center facilities, and free-standing abortion clinics.

The Population Council does not intend to identify the trial sites, but individual clinics and women may choose to identify themselves.

Mifepristone in combination with a prostaglandin is approved for use in France, the United Kingdom, and Sweden. It has been used in more than 150,000 women in those countries.

As part of an agreement reached last year with Roussel-Uclaf, the Population Council is conducting the U.S. clinical trials of mifepristone and has agreed to find a manufacturer for the drug. The Population Council has also announced its intention to seek marketing approval from the FDA for mifepristone.

Other Medical Treatments

In a related matter, there has been considerable publicity recently of another method of medical abortion. The anti-metabolite drug methotrexate is being clinically tested, in combination with a prostaglandin, as an abortifacient by Dr. Mitchell Creinin and his colleagues under FDA-approved protocols at three sites around the U.S. Last week Dr. Creinin published the results of his most recent study of this drug in the Journal of the American Medical Association.

Although the preliminary results are somewhat promising, this combination has only been studied in approximately 40 women. The very limited data to date suggest that this regimen is significantly less effective than the mifepristone-prostaglandin combination that is being tested in the Population Council clinical trials. Dr. Creinin and his colleagues have urged physicians not to use this experimental treatment outside of clinical trials.

In the meantime, Dr. Richard Hausknecht, a New York City obstetrician-gynecologist, has been promoting and using the methotrexate-prostaglandin combination in his own private practice. Dr. Hausknecht has granted extensive interviews with major national newspapers and television programs, and he has distributed detailed information about his use of these drugs to thirty or forty physicians around the U.S.

Although the FDA encourages research into medical alternatives to surgical abortion, the agency has told Dr. Hausknecht of its regulatory requirement that his study be carried out only under FDA-approved clinical trials. The FDA regards the methotrexate-prostaglandin combination as experimental and has urged women not to allow this combination to be used for pregnancy termination unless the research is being carried out in an FDA-approved clinical trial.

FDA is concerned that women understand that this drug regimen is experimental -- not a proven treatment. FDA also believes that women deserve the assurance that any clinical research on this drug combination has been scrutinized by an Institutional Review Board, which concerns itself with ethical issues in clinical trials.

The FDA and the Department of Health and Human Services will continue to support research into medical alternatives to surgical abortion. The study of mifepristone and prostaglandin being carried out by the Population Council has been properly designed, and the FDA is confident that women participating in it will understand that they are undergoing an experimental procedure. FDA can offer no such assurances about Dr. Hausknecht's treatment regimen using methotrexate and prostaglandin.

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017

Statement of Margaret Catley-Carlson, President of the Population Council
Media Briefing – Mifepristone Clinical Trials*
October 27, 1994

The Population Council announces today that clinical trials of mifepristone--formerly called RU 486--are under way in the United States. The trials will involve 2100 women at over a dozen sites around the country. Enrollment of women volunteers has already started. The goal is to test the safety, efficacy, acceptability, and accessibility of nonsurgical medical abortion, leading to an application for FDA approval for marketing. We are making this announcement--which is unusual for a clinical trial and not something the Council routinely does--because of the enormous amount of media interest in all aspects of this project and because we want the method to be described in a balanced and scientific manner.

We will not identify the locations of the studies, to protect the security of the clinics and the confidentiality of the women who will volunteer for these trials. Individual clinics and women may choose to identify themselves and talk about their experiences. In selecting the clinics, the Population Council looked for institutions that could provide scientific investigators with experience in conducting clinical trials or the ability to work under trial conditions and staff experienced in providing high quality abortion services. Each potential clinic was inspected by Council monitors. We also attempted to vary the type of facility, geographic location, and clientele. We made our selection from a large group of outstanding clinics.

At the recent population conference in Cairo, the international community strongly affirmed that unsafe abortion is a major public health concern and that unwanted pregnancies should be prevented through expanded and improved family planning services. This is the Population Council's position as well. We are a research organization. We do not promote the use of abortion; we promote the use of contraception. We do not lobby for specific legislation and we are not abortion advocates. Our program supports: prevention of unwanted pregnancy through development and promotion of new safe, effective contraceptives; prevention of unsafe abortion, which is responsible for thousands of maternal deaths and illnesses, particularly in developing countries; and, because abortion exists and is legal, development of alternative safe methods.

We believe mifepristone is an important scientific advance in women's reproductive health care. Mifepristone has been shown in numerous studies to be safe and effective for early medical abortion. Over 150,000 women have used the drug safely in Europe: over 52,000 French women have used the same combination of mifepristone and prostaglandin that is being used in the U.S. We believe this will provide an equally safe alternative to surgical abortion that women can use in the earliest weeks of a pregnancy. Women who have used this regimen report it is similar to a natural miscarriage.

Medical abortion eventually will increase women's access to abortion services and give them

privacy in making their reproductive health decisions. Women will be able to obtain medical abortion at doctors' offices, free of anti-choice violence and harassment. We believe mifepristone will not lead to an increased number of abortions--it hasn't in France, where it has been available since 1989--but it will expand women's options.

American women urgently need better access to effective contraceptive methods to prevent unintended pregnancy. But when a woman does face a crisis pregnancy, she must have access to all medically safe options. The Population Council believes mifepristone can significantly expand women's reproductive choices.

*Mrs. Catley-Carlson is out of the country. The statement was read for her by Sandra Arnold, Vice President for Corporate Affairs of the Population Council.

MAY 11 1994

THE WHITE HOUSE

WASHINGTON

May 11, 1994

MEMORANDUM FOR **MACK MCLARTY**
PHIL LADER
HAROLD ICKES
LEON PANETTA
GEORGE STEPHANOPOULOS
DAVID GERGEN
JOEL KLEIN
BILL GALSTON

FROM: Carol H. Rasco

SUBJECT: RU-486

Attached, having just arrived at 5:00 p.m., is the memo requested of HHS following the briefing in my office this morning on RU-486. As I have shared with most of you and/or your representative, we need to all read this tonight and discuss it briefly among ourselves at the conclusion of the 8:00 a.m. meeting tomorrow (Thursday).

I can be reached by beeper after 8:30 p.m. tonight if we need to talk prior to the morning meeting.

Thank you.

Note to Harold: Jennifer Klein attended the briefing for Health Reform Team at the request of Greg Lawler.

MAY 11 1994

TO: Carol Rasco

FROM: Kevin Thurm

SUBJECT: RU 486

Background

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product, RU 486, which has abortifacient and potentially scores of other medical uses. The French company has engaged the Population Council, a not-for-profit organization, in over 14 months of negotiations designed to transfer Roussel Uclaf's United States patent rights to the Population Council which would then take steps to bring RU 486 to market in this country. Those negotiations are on-going.

On May 9, 1994, Roussel Uclaf wrote a letter to Secretary Shalala stating the company's wish, instead, to offer the RU 486 United States patent rights to the American government insofar as the abortifacient and other gynecological uses are concerned. The company proposes voluntarily to assign its patent rights, as so limited, to the government free of charge, asking nothing in return.

Were the government willing to accept the "gift" offer, negotiations with the Population Council would be discontinued, and the patents, as so delimited, would be made available for assignment to the United States.

Alternatively, Roussel Uclaf has advised that should its bilateral negotiations with the not-for-profit be resolved, the deal cannot be finally closed unless and until the President of the United States writes a letter to the French company asking, on behalf of the women in America, that the patents be assigned to a non-profit entity in this country.

Roussel Uclaf strongly favors the gift to the government arrangement. Your advisors strongly favor the bilateral arrangement and have taken steps consistently and firmly to so insist.

Issues for Decision

One: Whether the President is willing to write a letter to the manufacturer of RU 486 asking that the United States patents for that product be assigned to a not-for-profit entity in this country. A suitable letter might read as follows:

> It is important for the health of women in the United States that they have access to the widest possible range of safe and effective medical treatments. In support of

that goal, in January 1993, I asked the Secretary of Health and Human Services to promote the testing and licensing of mifepristone [RU 486] and other antiprogestins in the United States.

To permit the appropriate testing, development and distribution of RU 486 in the United States, I ask that your company give its mifepristone patent rights in the United States to a non-profit organization that would take all necessary steps to file a new drug application with the Food and Drug Administration [FDA], so that the FDA can determine whether the drug is safe and effective for use in the United States.

Two: If the bilateral negotiations between Roussel Uclaf and the not-for-profit entity fail, and the only option then currently on the table is the gift offer, is the government of the United States willing, and if so, under what conditions, to accept the offer of the patent rights for RU 486?

Three: If the government is not willing to accept the offer of the patent rights, on what is that decision to decline based, and how will it be communicated to the American people?

* * * * * * * * * * * * * * *

The following tabs set forth discussion of the various factors that may be brought to bear on the decision-making:

Tab 1: History and background of RU 486 in this Administration
Tab 2: Legal issues
Tab 3: Bringing RU 486 to market [timing, available entities, administrative hurdles]
Tab 4: Political considerations
Tab 5: Press strategies and concerns

The following documents are attached for your reference;

Exhibit 1: The President's Memorandum of January 22, 1993
Exhibit 2: Roussel Uclaf's May 9, 1994 letter to Secretary Shalala attaching a draft offer of the gift
Exhibit 3: Roussel Uclaf's draft letter to the President
Exhibit 4: Minutes in French and translation of the April 26, 1994 Roussel Uclaf board meeting setting out the need for a letter from the President

BACKGROUND

Roussel Uclaf, a French subsidiary of the German company, Hoechst, holds two United States patents for its product RU 486, which has abortifacient and various other medical uses. The patents will expire in the years 2000 and 2001. Hoechst, the parent company, is co-owned by the Celanese Corporation, whose direct or indirect product lines include Nike sneakers and seat belts; the company does about $8 billion worth of business per year in the United States.

On January 22, 1993, the President directed the Secretary to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU 486 or other antiprogestine" (Exhibit 1). Within the month, the FDA, through Commissioner David Kessler, requested both Roussel Uclaf and Hoechst to expedite the process and met with representatives of Roussel to discuss issues. In March 1993, Secretary Shalala wrote to the president of Hoechst urging him to eliminate all corporate barriers to introduction of RU 486 in the United States.

Roussel Uclaf identified the Population Council, a non-profit organization based in New York, as the most likely vehicle through which to produce, distribute and test RU 486; the two parties have a 1982 contract which gives the Population Council some limited rights to license Roussel Uclaf product in this country.

Over the past fourteen months, the two parties have conducted on-again/off-again negotiations over a distribution scheme, liability insurance (product and damage to property), and insurance for lost profits due to economic boycotts of non-related products. During these talks, Roussel, in addition to the three main issues, occasionally raised subsidiary matters; these bumps in the road served to delay the negotiations (some believe that Roussel was in a holding pattern in anticipation of corporate leadership changes in January and April of this year). In several newspaper stories on this issue during this period, representatives of the two parties have been quoted saying they expected a deal shortly. Obviously this has yet to materialize.

Last fall, lawyers representing Roussel Uclaf met with HHS officials to discuss ways the federal government might help the negotiations. Over a series of meetings, the corporation's lawyers presented a variety of requests, including whether the Administration would seek legislation indemnifying Roussel for all potential damages or would seize the patents. HHS officials repeatedly told Roussel's lawyers that neither was a possibility, and that the deal should be done through the private parties.

On April 14, 1994, the Secretary, along with other HHS officials, met with representatives of the two parties, including Professor

Ernst Afting (current CEO of Roussel), Dr. Edouard Sakiz (past CEO and current Board Chair of Roussel), and Margaret Carlson (head of the Population Council). The Secretary stated that the U.S. government would neither seek legislation indemnifying Roussel nor seize the patents. She made clear to the parties the importance she attached to the introduction of the product in the U.S. through an agreement between them. She ended the meeting by imposing a May 15, 1994 deadline for successful completion of their negotiations.

In light of this deadline and hearings scheduled by Congressman Ron Wyden for 10:00 a.m. on May 16 to obtain a status report, the parties have continued their negotiations. Although many issues have been resolved, some remain: the extent of insurance coverage for product liability and damage to property, and a "pull the plug" option which would give Roussel the authority to require the Population Council to withdraw the product from the market if the potential liability from all lawsuits exceeded a specified amount.

On April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing under certain circumstances the assignment of patent rights to either the United States government or to a non-profit organization (Exhibit 4). If the rights are to be given to a non-profit, the President of the United States must so request by letter on behalf of the women of the country (see draft letter in cover memo).

By letter of May 9, 1994, Roussel notified the Secretary that it was prepared to assign the patent rights (for abortifacient and other gynecological uses) to the government and attached a draft letter to the President from Professor Afting, the president and CEO of Roussel (Exhibits 2 and 3). This draft letter closely mirrored an earlier informal draft discussed with Kevin Thurm, Harriet Rabb and David Kessler during the prior week.

Discussions between the parties are scheduled to continue through the end of the week. If the private arrangement is not concluded, we must be prepared to have an answer to Roussel's letter which we believe the company would send (or at least publicize). There is some "buzz" among pro-choice and women's groups about this issue so there is a chance developments will leak before the deal is finished or the letter is formally sent.

LEGAL ISSUES DISCUSSION

I. **Gift Acceptance.** The first question is whether the government should insist that any gift be for all known medical uses, not just abortifacient and gynecological [including, perhaps, "morning after"] uses. On the one hand, the broader rights may make the patent more attractive to potential licensees. On the other hand, some potential licensees may be appropriate repositories of the government's patent rights for the designated uses, but not the full range of known medical uses. Finally, the burden of testing and bringing forward the product for abortifacient and gynecological uses may be more than enough obligation. The responsibility of pursuing research and testing on all the known medical uses to bring the promising ones to fruition may be more than the government and any licensee want to assume.

The Secretary has statutory authority to accept a gift, such as a patent, on behalf of HHS's Public Health Service. Alternatively, the directors of the national research institutes at HHS's National Institutes of Health (NIH) have statutory authority to accept gifts to support the activities of their institutes. Each option has pluses and minuses.

A. Secretarial gift acceptance. Because patents are intangible property, by statutory directive, the evidence of the gift (in this case, the original patent assignments), must be lodged with the Department of the Treasury. Treasury has the discretion to hold the property or liquidate it at HHS's request. There is unlikely to be a problem raised by Treasury, but, to date, that Department has had no part in the RU 486 issue and must be consulted should this route be chosen.

B. NIH gift acceptance. No involvement of Treasury is required. Gifts to NIH institutes must be made to support the activities of the receiving institute - so a showing of such purpose would have to be made. This is not likely to pose a problem, but no work has been done to identify a likely institute recipient or to prepare the gift justification.

Finally, with regard to gift acceptance, since Roussel Uclaf is an entity doing business with HHS, including specifically the Public Health Service and its components, the government will have to be sure that accepting the gift does not give rise to a public perception concern. There is no ethical impediment to accepting gifts from entities so positioned, but care must be taken to weigh the benefits and consequences so that the public can be assured that no favor has been curried or promised. In fact, it has not.

II. **Transfer of the Gift.** Roussel Uclaf has offered to assign its rights to the abortifacient and gynecological patent uses to the government. Were the United States to accept the assignment

from Roussel Uclaf, the government would in turn find a licensee or licensees willing and able to take responsibility for obtaining FDA approval and bringing the product to market. Although it is conceivable that the government could perform these tasks itself, only the Department of Defense now manufactures drugs on a large scale.

Since, by law, federal agencies are authorized to grant licenses in federally owned patents, were the government to have the patents by assignment, subsequent licensing arrangements are possible. Additionally, patent law provides the patent owner (or, in this case, the patent assignee) with the right to sue for patent infringement. Such capacity to bring suit could be consequential if counterfeit product began to appear in the United States.

III. **Licensing the United States Patent Rights.** Government agencies are authorized by law to grant non-exclusive, exclusive or partially exclusive licenses under federally-owned patents. Licenses to PHS-owned inventions are negotiated by the NIH Office of Technology Transfer in accordance with government-wide regulations.

Under the regulations, non-exclusive licenses can be given by the government relatively easily and directly to any applicants, generally speaking, whose capacity to act responsibly regarding the license has been demonstrated.

Exclusive or partially exclusive licenses are subject to a different, but not much more difficult process. Notice of the patent's availability must be published in the Federal Register, and a sixty day period for filing written objections must be allowed. No less than three months after the date of publication, and after consideration of any objections received, an exclusive or partially exclusive license may be granted. In that event, the agency must make determinations regarding the necessity for an exclusive license, rather than a nonexclusive one, the effect of the license on competition, and whether small business firms have been given first preference in accordance with the statute and regulations.

If and once the United States accepts the gift, it will be critically important that some bidder(s) come forward seeking a license to bring the product to market. Roussel Uclaf's efforts to shop this product around to United States pharmaceutical companies to get one or more to take up the responsibility of bringing RU 486 to market have been unsuccessful. Roussel Uclaf reports that the reluctance reflects other companies' unwillingness to bear (i) the product liability risks associated with the abortifacient or (ii) the political pressure from anti-abortion forces.

IV. **Possible United States Tort Liability.** The likelihood of United States tort liability depends, in large measure, on the

government's role in bringing RU 486 to market. Through sovereign immunity, the United States government is not subject to liability except to the extent that it consents to be sued. The Federal Tort Claims Act (FTCA) is a statutory limited waiver of sovereign immunity and, thus, acts as consent to being sued. Under the FTCA, the government is liable for personal injury caused by the negligent or wrongful act or omission of a Federal employee under circumstances where the government, if a private party, would be liable to the plaintiff. It would be unlikely for a court to allow a suit to go forward against the government under the FTCA if the government merely performed the "discretionary functions" of accepting a gift, licensing the patents, and acting on an application for FDA to approve a drug.

However, were the government to become enmeshed in facilitating or playing a direct role in the transfer of the technical background information that makes it possible actually to make RU 486, for example, the government risks being drawn into liability. An approach which limits the government's role in bringing RU 486 to market, while solving the lion's share of the potential government liability risk, creates other problems. Without the backup technical "know how," it would be years before any government licensee could create the product. Since it is unlikely that a licensee would bid for these patent rights without the actual prospect of bringing the product into existence, the United States could be left holding the patents with no licensee willing to step up and take them.

Alternatively, if a European or other off-shore manufacturer made the product in a fashion that meets FDA standards, the product is potentially importable by a government licensee. One wrinkle on this process results from the technology transfer regulations referenced above which note that normally, licensees of United States patents have to agree that the product will be produced substantially in the United States.

In short, to the extent the government refuses to become involved in actually transferring the technology, tort liability is kept at bay. But licensees may be kept at bay as well, leaving the government holding the patents with no prospect of bringing RU 486 to the women in America.

BRINGING RU 486 TO MARKET

A. Direct Patent Transfer to Population Council

If Roussel Uclaf agrees to license its patent rights in RU 486 to the Population Council, the Population Council would then have to take the following steps:

o Locate a drug manufacturer that would be willing to manufacture RU 486 for the United States market (we are advised that such a manufacturer has been identified by the Population Council).

o Obtain information from Roussel Uclaf on how Roussel Uclaf manufactures RU 486 and on its testing of the drug, so that the new manufacturer could follow parallel processes and the Population Council could refer to Roussel Uclaf's animal and human testing of RU 486 in any submission to the Food and Drug Administration. If Roussel Uclaf provides this information and technology transfer, it will significantly shorten the amount of time it will take to bring the drug to the United States market (assuming the drug is found to be safe and effective by FDA). With Roussel Uclaf's information, it might take six to twelve months for the Population Council's manufacturer to begin production of the drug, and for the Population Council to file its marketing application with the FDA. If Roussel Uclaf refuses to provide such information, it will take the Population Council eighteen months to two years to begin production, and up to five years to repeat the animal and human tests that show whether the drug is safe and effective.

Roussel Uclaf has stated that they will transfer the technology to the Population Council, but we do not consider this a strong assurance.

o Begin some clinical testing of the drug in the United States. Clinical trials, though not absolutely necessary for FDA approval, would permit women in the United States to have access to the drug, and for United States physicians to become familiar with the drug, while the Population Council prepared its marketing application for the FDA.

If Roussel Uclaf were to provide French-made RU 486 to the Population Council for the clinical trials, such trials could begin in the United States in approximately six months (five months for the Population Council to design its trials and find physicians willing to do the trials, and one month for FDA approval). If Roussel Uclaf were not willing to provide the drug for clinical trials, such trials would have to wait until (1) the Population Council's manufacturer could begin production of the drug, and (2) either Roussel Uclaf gave the Population Council its animal studies or the Population Council did its own animal studies.

Roussel Uclaf has stated that it would provide the French-made RU 486 to the Population Council for the clinical trials, but again we do not consider this a strong assurance.

o File a marketing application with the FDA. As indicated above, if Roussel Uclaf provides information and transfers its technology to the Population Council, a marketing application could be filed with the FDA within six to twelve months. FDA review would take no longer than six months. Many of the scientific decisions on the proper use and distribution of the drug have already been considered by the FDA, based on information already provided to FDA by Roussel Uclaf and the Population Council. Roussel Uclaf would not need to finish its United States clinical trials before filing a marketing application with FDA; such trials could be used to refine the use of the drug at a later time.

B. Patent Transfer to the United States

If Roussel Uclaf gives its patents to the United States, the United States would have to take the following steps:

o The United States would have to determine the scope of the rights given to the United States -- are the rights only in the abortifacient and other gynecological uses of the drug, or in all uses of the drug (e.g., gynecological uses, Cushing's disease, breast cancer).

o The United States would then need to transfer its rights in the patents to a third party. This process is discussed at Tab 2, and would take at least six months.

o The license holder would then need to take all of the steps outlined above, i.e., find a manufacturer, conduct the necessary tests, and file a marketing application with the FDA. The length of time these steps will take depends on whether Roussel Uclaf is willing to transfer its information, technology, and the drugs necessary for clinical trials to the license holder. Roussel Uclaf has advised the government that it would provide the information and French-made RU 486 for clinical trials to the United States' licensee, but it could change its mind.

It is difficult to determine whether the United States's license holder would take appreciably longer to bring RU 486 to market than the Population Council would need if the Population Council received a direct transfer of rights from Roussel Uclaf. Obviously, if the United States licensee is the Population Council, little time will be lost above that associated with the transfer of the patent rights from the United States to the Population Council. If another group becomes the United States's

licensee, that group might be able to bring the drug to the United States market slightly faster than the Population Council (if the group chosen was very familiar with the drug, had a good manufacturing facility, the cooperation of Roussel Uclaf, experience in FDA marketing applications, and excellent contacts with United States physicians) or much slower (if the group falls short on any factor).

We anticipate that if Roussel Uclaf gives its patent to the United States, it will add at least six months, and quite possibly twelve to eighteen months, onto the time needed to bring the drug to the United States market. This estimate excludes any additional time generated by litigation (see Tab 2).

POLITICAL ISSUES DISCUSSION

In viewing the various options, it is important to place them in a broader political context, particularly as they relate to health care reform, given the likelihood that Congress will narrow the current Health Security Act provisions that provide for abortions under pregnancy-related services.

Consequently, the introduction of RU 486 will take on added importance to the pro-choice and women's groups. If the Administration is viewed as closing the door or rejecting an apparently reasonable offer on RU 486, then the path toward reaching a non-confrontational agreement with the advocates on the Health Security Act could become much more difficult. It is, therefore, extremely important that the decision concerning RU 486 be placed in the context of promoting women's health and maintaining the close relationship of the Administration to these groups.

With regard to other political considerations, the acceptance of RU 486 by the federal government, as opposed to by a private non-profit organization, would most certainly lead to a floor amendment on the Labor, HHS appropriations bill, or other legislative vehicle to prohibit federal funds from being used in conjunction with RU 486. It is difficult to predict the exact nature of the amendment. However, in the last Congress, Representatives Dornan, Dannemeyer, Lent, Bartlett, Bunning and Hunter co-sponsored a bill to prohibit federal funds from being used for clinical studies of RU 486 as an abortifacient. Given the likelihood of another Hyde-type amendment on the House and Senate floors this year, as well as the expected abortion-related amendments on health care reform, the members of the House and Senate will be frustrated at having to face another abortion-related vote (on RU 486 appropriation limits). The outcome of such a vote is difficult to predict.

To date, we have worked very cooperatively with Congressman Ron Wyden, the chief Congressional advocate in providing access to RU 486 to women in this country. We expect to be able to continue this close working relationship through the upcoming hearing on May 16. Because Congressman Wyden has postponed past hearings, and is very frustrated by the fourteen months of negotiations, it is unlikely that he would be willing to postpone the May 16 hearing. He is convinced that Roussel Uclaf and Hoechst have been stalling for time, and that it is important to remain firm on the hearing date in order to force agreement or to make it clear to the American public that the companies have no intention of providing RU 486 to the American market.

Finally, regardless of the precise wording of the President's January 22, 1993 memorandum, the expectation it created among the pro-choice and women's groups is that the federal government will do everything possible to get RU 486 introduced in this country.

POLITICAL ISSUE DISCUSSION

In viewing the various options, it is important to place them in a broader political context, particularly as they relate to health care reform, given the likelihood that Congress will narrow the current Health Security Act provisions that provide for abortions under pregnancy-related services.

Because of this situation with the Health Security Act, the introduction of RU 486 will be of greater significance to the pro-choice and women's groups. If the Administration is viewed as closing the door or rejecting an apparently reasonable offer on RU 486, then the path toward reaching a non-confrontational agreement with the advocates on the Health Security Act could become much more difficult. It is, therefore, extremely important that the decision concerning RU 486 be placed in the context of promoting women's health and maintaining the close relationship of the Administration to these groups.

With regard to other political considerations, the acceptance of RU 486 by the federal government, as opposed to by a private non-profit organization, would most certainly lead to a floor amendment on the Labor, HHS appropriations bill, or other legislative vehicle to prohibit federal funds from being used in conjunction with RU 486. It is difficult to predict the exact nature of the amendment. However, in the last Congress, Representatives Dornan, Dannemeyer, Lent, Bartlett, Bunning and Hunter co-sponsored a bill to prohibit federal funds from being used for clinical studies of RU 486 as an abortifacient. Given the likelihood of another Hyde-type amendment on the House and Senate floors this year, as well as the expected abortion-related amendments on health care reform, the members of the House and Senate will be frustrated at having to face another abortion-related vote (on RU 486 appropriation limits). The outcome of such a vote is difficult to predict.

To date, we have worked very cooperatively with Congressman Ron Wyden, the chief Congressional advocate in providing access to RU 486 to women in this country. We expect to be able to continue this close working relationship through the upcoming hearing on May 16. Because Congressman Wyden has postponed past hearings, and is very frustrated by the fourteen months of negotiations, it is unlikely that he would be willing to postpone the May 16 hearing. He is convinced that Roussel Uclaf and Hoechst have been stalling for time, and that it is important to remain firm on the hearing date in order to force agreement or to make it clear to the American public that the companies have no intention of providing RU 486 to the American market.

Finally, regardless of the precise wording of the President's January 22, 1993 memorandum, the expectation it created among the pro-choice and women's groups is that the federal government will do everything possible to get RU 486 introduced in this country. Leaders of these groups will be concerned with Administration action on health care reform and other issues, including the choice to replace Justice Blackmun. Saying "no" to a facially reasonable offer by Roussel Uclaf weakens our political base and may subject the President to criticism that he is not sticking to his original position.

Given the expression of Presidential support for RU 486 in January 1993, a "yes" adds marginal political cost (separate from issues like health care reform). For 1996 purposes, we probably lose few friends and anger few voters not already positioned on this or related issues.

A "yes", however, also means the Administration will have this issue on its front burner for a significant period of time. Anticipated floor amendments in Congress, rallying at HHS or other government buildings by pro-life groups, and the necessarily public process to secure licensees will provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision and on its aftermath.

Leaders of these groups will be concerned with Administration action on health care reform and other issues, including the choice to replace Justice Blackmun. Saying "no" to a facially reasonable offer by Roussel Uclaf weakens our political base (or, to put it the other way, a "yes" will certainly energize it).

Given the expression of Presidential support for RU 486 in January 1993, a "yes" adds marginal political cost (distinct from separate issues like health care reform). We probably lose few friends and anger few voters not already positioned on this or related issues.

A "yes", however, also means the Administration will have this issue on its front burner for a significant period of time. Anticipated floor amendments in Congress, rallying at HHS or other government buildings by pro-life groups, and the necessarily public process to secure licensees will provide ample opportunity for Republicans and others opposed to the Administration to focus attention on this decision and on its aftermath.

LIST OF MEMBERS INTERESTED IN THE RU-486 ISSUE

HOUSE

Ron Wyden
Henry Waxman
Michael McNulty (D-NY)
Jim Bunning (R-KY)
Robert Dornan (R-CA)
Duncan Hunter (R-CA)

SENATE

Carol Moseley Braun (D-IL)
Paul Simon (D-IL) (wrote on behalf of constituent)
John Breaux (D-LA) (wrote on behalf of constituent)

BACKGROUND

For five years Wyden has been by far the most active and vocal Member on RU-486. He has held numerous hearings and cosponsored a bill with Waxman in the last Congress to overturn the FDA import ban. Also in the last Congress, 6 Republicans (Dornan, Dannemeyer, Lent, Bartlett, Bunning, and Hunter) cosponsored a bill to prohibit federal funds from being used for clinical studies of RU-486 as an abortifacient. No one in the Senate is consistently active on this issue.

Obviously, the womens' caucus will be interested in any actions taken on Ru-486 as will the pro-life caucus (especially Hyde, Helms, and C. Smith). However, in the last four years the Department has not received RU-486 letters from either group.

Very little mail has been received by the Clinton Administration on RU-486. A typical letter is the attached C. Moseley-Braun letter inquiring as to the status of the President's Directives.

In the Bush Administration a typical letter is the attached California delegation letter on RU-486 as an important option for American women. Also, letters often stressed the importance of allowing research on RU-486 to go forward in areas of breast cancer, glaucoma, Cushing's disease, etc.

Please let me know if I can get additional information for you.

PRESS ISSUES DISCUSSION

If negotiations with the Population Council collapse, the Clinton Administration will be left with two possible courses of action. The following is an examination of the public relations ramifications of both choices:

If the Administration decides to accept the gift of the patent from Roussel Uclaf, for purposes of insulating the White House, it should be accepted by Secretary Donna Shalala at the direction of the President of the United States and on behalf of the women in America. This could be done in a press conference on Friday, May 13, 1994, with up to four principals: Secretary Shalala, Roussel Uclaf President, Population Council (if they would agree to run the clinical trials) and possibly Congressman Ron Wyden (who has been pushing this issue on Capitol Hill).

It would be made very clear that this step is the result of the process that was set in motion by President Clinton's memorandum of January 22, 1993, and that it is being taken because it was impossible for Roussel Uclaf to come to closure with a private sector entity. Because a non-surgical (and sometimes safer) abortion alternative would thus be available to women in the United States (as it is to many women in Europe), accepting the patent gift should be touted as a reproductive rights victory for American women and another example of the Clinton Administration's commitment to deliver on its promises. However, Secretary Shalala's remarks would be tempered by caution about the long and difficult road ahead and the potential roadblocks to bringing RU 486 to the marketplace.

While it should not be a part of the formal press conference, there should be a concerted effort on the part of the HHS Public Affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against the fallout from our allies in the event efforts to get RU 486 to market become stalled in bureaucratic process, in Congress or for other reasons.

Because the Clinton Administration would actually be in possession of the RU 468 patent for a period of time while the licensing process moves foreward, during that time, the Administration may well be the focus of protest by conservative organizations that have become increasingly vocal and militant. These groups have suffered recent setbacks in court (e.g. a ruling that has imposed massive fines and barred them from physically blocking access to abortion facilities). They would welcome an extremely high visibility focal point for their activities. Protest marches in front of the White House and HHS are imaginable, and the conservative talkshow circuit would help to sustain the furor. This could go on while other abortion-related issues are before Congress, including debate on the Health Security Act and the FY 1995 enactment of the Hyde

Amendment. In the worst case, it could put the abortion issue centerstage, with the Clinton Administration as a high-profile player right up through the kick-off of the 1996 re-election campaign.

It would also be necessary to recruit a cadre of lawmakers, pro-choice and women's advocates willing and able to speak up for the Administration over the course of this heated debate. That is critically important for holding our own on the conservative talkshow circuit.

If the Administration decides to reject the gift of the patent from Roussel Uclaf, news of that decision should be disclosed in a press conference on Friday, May 13, 1994, by Secretary Shalala and FDA Commissioner David Kessler. It will be necessary to construct a rationale for why that course of action is better than the alternative one for American women. The argument will have to be that giving the patent to the United States government does not speed the drug to the American marketplace. In fact, it does just the opposite. Administrative regulatory process and the potential for legislative stonewalling could be very time consuming and could ultimately prevent the women in America from gaining access to
RU 486.

We should also highlight in the Secretary's statement the unprecedented nature of what Roussel Uclaf was attempting to position the United States to do. Never before has a patent been accepted by the government. The novelty of the situation makes the issue potentially more likely to be tied up in litigation or legislative maneuvering. One of the speakers would provide details of the formidable obstacles that may delay or even prevent the United States from moving the drug onto the market.

If Roussel Uclaf is willing to grant the United States patent rights for using RU 486 only for abortifacient and other gynecological purposes, another potential argument we could embrace is the position that we wanted more than the rights they were willing to grant because our interest in this drug goes beyond the issue of abortion, the need for which we are committed to making as rare as possible.

We would stress that a private sector deal is the only viable option for getting RU 486 quickly through clinical trials and into the market place. We should outline in detail all that the Population Council did to try and close the deal during the 14-month negotiations with Roussel Uclaf. The message, either implicitly or explicitly, is that Roussel Uclaf does not really want to close a deal with an entity that clearly has the potential to bring RU 486 to the marketplace because the company fears pressure from American conservatives.

Our position should be publicly to challenge Roussel Uclaf to go back to the bargaining table with the Population Council or to open negotiations with another entity; to stop playing games; and to get serious about responding to the request that President Clinton made of them almost a year and a half ago.

Without a doubt, a "no" will subject the Administration to a firestorm of protest by pro-choice and women's groups; and there will be few natural political allies vocally defending this decision, particularly in light of the relative difficulty of explanation.

* * * * * * *

It should be noted that Roussel Uclaf has already begun, informally, to circulate word of its potential offer to the United States. Many representatives of the pro-choice community already know about the potential gift offer. We may be forced to confront a news account of the issue prior to the Congressional hearings on May 16, 1994. Such a story will, undoubtedly, be presented from the Roussel Uclaf perspective as opposed to the Administration's point of view.

THE WHITE HOUSE

WASHINGTON

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

In Import Alert 66-47, the Food and Drug Administration ("FDA") excluded the drug Mifepristine -- commonly known as RU-486 -- from the list of drugs that individuals can import into the United States for their "personal use," although the drugs have not yet been approved for distribution by the FDA. (See FDA Regulatory Procedures Manual, Chapter 9-71.) Import Alert 66-47 effectively bans the importation into this Nation of a drug that is used in other nations as a nonsurgical means of abortion.

I am informed that in excluding RU-486 from the personal use importation exemption, the FDA appears to have based its decision on factors other than an assessment of the possible health and safety risks of the drug. Accordingly, I hereby direct that you promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption. Furthermore, if the FDA concludes that RU-486 meets the criteria for the personal use importation exemption, I direct that you immediately take steps to rescind Import Alert 66-47.

In addition, I direct that you promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 or other antiprogestins.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

William J. Clinton

ROUSSEL UCLAF

Professeur Ernst-Günter Afting
Président du Directoire

Paris, May 9, 1994

Honorable Donna SHALALA
Secretary of Health and Human Services
Room 615 F
Hubert Humphrey Building
200 Independence Avenue SW
WASHINGTON, D.C. 20201
USA

Attention : Mr. Kevin THURM

Dear Secretary Shalala,

Following various meetings with your Staff and with FDA officers, the latest on May 6, 1994 with Dr. Kessler, we would like to confirm that we are ready to assign our US patent rights on RU 486 in accordance with the attached draft letter from us to the President of the United States of America.

This document is substantially similar to the draft that was given to Mr. Kevin Thurm, on April 29, 1994, by our counsel Lester Hyman, to allow a review of the situation by your Administration.

Of course we will continue to work with you and all relevant people in a constructive spirit and we look forward to meet you personally by the end of this week, as planned.

Sincerely,

Pr. E-G. AFTING
President & CEO

cc. Dr. KESSLER

35, Boulevard des Invalides 75325 Paris Cedex 07
[illegible]

ROUSSEL UCLAF

[redacted]

Paris, May ..., 1994

Honorable William J. CLINTON
President of the United States
The White House
1600 Pennsylvania Avenue NW
WASHINGTON, D.C. 20500
USA

Attention : Ms. Nancy HERNREICH

Dear Mr. President,

You have requested that ROUSSEL UCLAF allow the RU 486 compound to be used in your country.

We have been working to react to that request in a responsible manner.

I now am pleased to inform you that we have decided to contribute mifepristone (RU 486) for abortifacient purposes (and other gynecological uses) to the people of the United States of America, completely free of charge, by voluntarily assigning our relevant patent rights to the US Government.

This an unconditional gift, we ask for nothing in return.

Sincerely,

Pr. E-G. AFTING
President & CEO

FOIA Number: 2014-0536-S

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PROJET 09.05.94

MIFEPRISTONE - ÉTATS-UNIS

Le Docteur E. SAKIZ informe le Conseil de Surveillance que son assentiment est demandé sur les décisions que le Directoire va être amené à prendre à propos de la mifépristone aux États-Unis d'Amérique, compte tenu des exigences pressantes formulées au plus haut niveau par les autorités gouvernementales fédérales de ce pays.

Étant donné les caractères très particuliers du système médical des États-Unis par comparaison à celui des pays d'Europe où la mifépristone est actuellement utilisée, et considérant également le climat hautement conflictuel créé autour de ce produit aux États-Unis, le Directoire estime que ROUSSEL UCLAF ne saurait en aucune façon s'impliquer elle-même dans la production ou la diffusion de la mifépristone aux États-Unis.

Toutefois, prenant acte de la volonté du gouvernement américain de procurer aux citoyennes des États-Unis cette alternative médicale à l'interruption chirurgicale de la grossesse, le Directoire s'est résolu à offrir au gouvernement des États-Unis de lui céder, sans rémunération, les deux brevets référencés "U.S. Patents Nos. 4,386,085 and 4,447,424".

Au cas où ce gouvernement déclinerait cette offre pour lui-même tout en la jugeant recevable par une institution qu'il désignerait à cet effet, ROUSSEL UCLAF accepterait de poursuivre dans cette voie et de passer les accords nécessaires, à condition d'en être formellement requise par une lettre officielle, portant la signature du Président des États-Unis, et d'obtenir un certain nombre de garanties contractuelles.

Le Conseil de Surveillance prend acte de cette position qui n'appelle de sa part aucune objection, et manifeste ainsi au Directoire l'assentiment de principe sollicité.

.....

[Translation of Fax from Dr. Sakiz to Mary Pendergast of draft minutes of the Supervisory Board Meeting of May 4, 1994]

MIFEPRISTONE - UNITED STATES

Dr. E. SAKIZ informed the Supervisory Board ("Conseil de Surveillance") that its assent is requested concerning decisions that the Director ["le Directoire"] is being led to take a propos mifepristone in the United States of America, taking account of pressing exigencies formulated at the highest level by authorities of the federal government of that nation.

Given the very particular characteristics of the U.S. medical system, in comparison to that of the European countries where mifepristone is currently used, and considering equally the highly conflicted climate created around this product in the U.S., the Director deems that ROUSSEL UCLAF would be in no way implicated itself in the production or distribution of mifepristone in the United States.

Nevertheless, considering the wish of the American government to procure for U.S. citizens this medical alternative to the surgical termination of pregnancy, the Director has resolved to offer to cede to the government of the United States, without remuneration, the two patents referred to as "U.S. Patents Nos. 4,386,085 and 4,447,424."

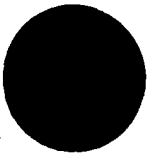
In the event that the government should decline this offer for itself and at the same time judging it receivable by an institution that it would designate to this end, ROUSSEL UCLAF would accept this path and would adopt the necessary agreements, on the condition of being formally required by an official letter, bearing the signature of the President of the United States, and of obtaining a certain number of contractual guarantees.

The Supervisory Council acknowledged this position, which generated no objections, and manifested to the Director its assent to the principle being offered.

[translated by L. Bachorik, 5/10/94]

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy



To: Chris Jennings
Jennifer Klein

Draft response for POTUS
and forward to CHR by: _____

Draft response for CHR by: _____

Please reply directly to the writer
(copy to CHR) by: _____

Please advise by: _____

Let's discuss: _____

For your information: ✓

Reply using form code: _____

File: _____

Send copy to (original to CHR): _____

Schedule ? : ☐ Accept ☐ Pending ☐ Regret

Designee to attend: _____

Remarks: _____

LEVEL 1 - 18 OF 29 REFERENCES

Public Papers of the Presidents

January 22, 1993

CITE: 29 Weekly Comp. Pres. Doc. 85

LENGTH: 1509 words

HEADLINE: Remarks on Signing Memorandums on Medical Research and Reproductive Health and an Exchange With Reporters

BODY:

The President. Please sit down, ladies and gentlemen. Today I am acting to separate our national health and medical policy from the divisive conflict over abortion. This conflict, which stems from the Roe v. Wade decision of 20 years ago, has brought to a halt promising research on treatment for serious conditions and diseases that affect millions of Americans, millions of American men, women, and children who include the members of the family and friends of mine and I'm sure virtually every other set of family and friends in the United States. We must free science and medicine from the grasp of politics and give all Americans access to the very latest and best medical treatments.

Today I am directing Secretary of Health and Human Services Shalala immediately to lift the moratorium on Federal funding for research involving transplantation of fetal tissue. This moratorium, which was first imposed in 1988, was extended indefinitely in 1989 despite the recommendation of a blue ribbon National Institutes of Health advisory panel that it be ended. Five years later, the evidence is overwhelming. The moratorium has dramatically limited the development of possible treatment for millions of individuals who suffer from serious disorders, including Parkinson's disease, Alzheimer's disease, diabetes, and leukemia. We must let medicine and science proceed unencumbered by antiabortion politics.

Today also marks the beginning of a new national reproductive health policy that aims to prevent unintended pregnancies. Our administration is committed to providing the kind of prenatal care, child care, and family and medical leave that will lead to healthy childbearing and support America's families.

As a Nation, our goal should be to protect individual freedom while fostering responsible decision making, an approach that seeks to protect the right to choose while reducing the number of abortions. Our vision should be of an America where abortion is safe and legal, but rate.

Let me also say that our administration is particularly concerned with the epidemic of teenage pregnancy. The greatest human cost of our continuing national debate over reproductive policy is borne by our children and by their children. A few teenagers choose to have and raise children, and we must help them to succeed. But for millions a teen pregnancy is unintended, leaving the young woman and her partner totally unprepared for the responsibilities of parenthood. The social and economic price paid today and for the last several years by our Nation is enormous.

So today I am also directing Secretary Shalala to act immediately to implement her intended suspension of the Title X family planning regulations that are also known as the "gag rule." For almost 5 years, HHS has prohibited

Title X recipients from providing their patients with full information and counseling concerning pregnancy. This dangerous restriction censors the medical information and advice that health care professionals can give their patients. As a result of today's action, every woman will be able to receive medical advice and referrals that will not be censored or distorted by ideological arguments that should not be a part of medicine.

I'm also ordering today the Director of the Agency for International Development to repeal immediately what has become known as the Mexico City policy, that has effectively applied the "gag rule" to organizations that receive United States funding, even when those organizations use non-AID funds for those activities. Today's actions will allow organizations that received AID funds to provide information regarding all family planning options to individuals in foreign nations. It will reverse a policy that has seriously undermined much-needed efforts to promote safe and effective family planning programs abroad and will allow us to once again provide leadership in helping to stabilize world population. Many believe that this is one of the most important environmental steps we can take.

Today I am also directing Secretary of Defense Aspin to lift immediately the near-total ban on abortions at United States military facilities and to permit them to be performed at those facilities provided that the procedure is paid for entirely with private funds. This action will allow military hospitals to perform abortions and reverse a ban that has adversely affected the lives of scores of men and women who serve our Nation around the world, or members of their families.

Finally, I am directing Secretary Shalala to instruct the Food and Drug Administration to determine whether the current import ban on the drug Mifepristine, commonly known as RUY-486, is justified and to rescind the ban if there is no basis for it. Here in the United States, RU-486 has been held hostage to politics. It is time to learn the truth about what the health and safety risks of the drug really are. If the FDA removes the ban, Americans will be able to bring the drug into the country for their personal use consistent with existing FDA policies that govern drugs not approved for distribution.

I've also ordered HHS to immediately explore the propriety of promoting testing in the United States as well as the possibility of licensing and manufacturing according to the standards which govern all other drugs so reviewed by our Government.

Taken as a group, today's actions will go a long way toward protecting vital medical and health decisions from ideological and political debate. The American people deserve the best medical treatment in the world. We're committed to providing them with nothing less.

I'd like to say in closing a special word of personal thanks to the unbelievable number of Americans from all walks of life and all different political perspectives who have children with diabetes or who, like me, have lost relatives to Alzheimer's or have friends suffering with Parkinson's and other diseases who came up to me over the last year and made a personal plea on the fetal tissue issue. Their statements to me and their life stories had a far greater impact on me even than the actions of the United States Congress, which included, as you know, a very broad spectrum of Republicans and Democrats on this issue.

I'd like now to sign these directives.

[At this point, the President signed the five memorandums.]

Thank you very much.

President's Signature

Q. Mr. President, was it "William J." or "Bill"? The President. After a considered policy debate -- [laughter] -- we decided that I should sign my full name to all official documents of the government, and I'll continue to sign all my non -- my letters "Bill Clinton."

Zoe Baird

Q. Let me ask you: George was having a really hard time explaining to us what you knew about Zoe Baird's problem, when you knew it.

Press aid. Thank you.

Q. Can you please explain -- The President. No, I want to answer this.

Q. -- that to us, so that the American public would really know? The President. I think the American people are entitled to know that. If you go back to my statement, I acknowledged that there were errors in the evaluation process, for which I take full responsibility. What happened was this. She voluntarily disclosed that; it was not in any way picked up in the vetting. It was, as you know, we were trying to make a Christmas deadline, which was probably my error, again, on this.

So just before she was announced, but after I had discussed the appointment with her, I was told that this matter had come up. Nobody said anything to me about the taxes. And what I was told was what you heard, in a very cursory way, was that an error had been made in the hiring of an illegal alien; that it had been made after consulting a lawyer who was an expert in this area, so basically they had acted on counsel's advice, but they were wrong; that they moved immediately to try to correct it, and the status had been corrected in terms of the legality of the person; and that the bettor's conclusion was there would be no problem.

I have to tell you that during the course of these inquiries, I received other weightier warning, if you will, of things which had to be worked through with other potential nominees. In retrospect, what I should have done is to basically delay the whole thing for a couple of days and look into it in greater depth.

But that was -- I take full responsibility for that. This process is in no way a reflection on her. We would not have known any of this had she not disclosed it to us and to the United States Senate subsequently. So I will say again what I said this morning: I'm sorry about this. I still think she is an extraordinary person and a very able person who will have a rich and successful career, and I take full responsibility for what happened in the review process.

Thank you.

NOTE: The President spoke at 3:22 p.m. in the Roosevelt Room at the White House.

LANGUAGE: ENGLISH

LOAD-DATE: February 16, 1993

FDA's "Personal Use Policy" and RU-486

On January 22, 1993, President Clinton directed Secretary Shalala to assess initiatives to promote the testing, licensing, and manufacturing in the U.S. of mifepristone (RU-486). The President's executive order also directed the FDA to reassess whether RU-486 qualified for importation under FDA's personal use importation policy.

FDA concluded in July 1993 that RU-486 is not an appropriate candidate for FDA's personal use policy governing the importation of unapproved new drugs. In its reassessment, FDA determined that the distribution of mifepristone is very tightly controlled in those countries (the U.K., France, and Sweden) where it is approved. The strictly regulated administration of this drug in those countries suggests that it may not be able to be safely taken without careful medical supervision and controls.

In addition, Roussel-Uclaf (the French pharmaceutical firm) refuses to make its drug available for importation into the U.S. Therefore, any version of the drug that could be obtained elsewhere and brought into the U.S. would necessarily be a counterfeit copy of the original drug, and there would be no way to determine reliably the source and the chemical make-up of the drug. Because FDA has no knowledge of the purity, safety, or efficacy of the counterfeit version of RU-486, women using the drug would face potential harm from it.

Apart from any direct harm to the woman, there was also a concern that early misuse of this drug and the adverse consequences associated with such misuse could reduce the chances of the drug being properly tested or approved for use in the U.S.

Benten v. Kessler & The RU486 Import Ban

Benten was filed on July 7, 1992, just days after U.S. Customs officials seized a single dose of RU486 from Leona Benten at J.F.K. International airport. Benten intended to use the drug to terminate her pregnancy under the supervision of Dr. Louise Tyrer, a former vice president of Planned Parenthood Federation of America. On July 14, 1992, the district court issued a preliminary injunction ordering defendants (FDA Commissioner David Kessler and the chief of the Customs Bureau) to deliver the seized dose of RU486 to plaintiffs (Leona Benten and her physician), Benten v. Kessler, 799 F. Supp. 281 (E.D.N.Y. 1992), and orally denied a motion for a stay of its order. The district court carefully circumscribed its relief, stating that "[n]o broader decision from this Court is warranted at this time." 799 F. Supp. at 291; see also id. at 283 ("The broader preliminary relief sought by the plaintiffs is, at this juncture, denied.").

Despite the extremely urgent time constraints faced by Ms. Benten, defendants ignored and refused to comply with the district court's order for approximately five hours while they sought a stay pending appeal of from the United States Court of Appeals for the Second Circuit. At the conclusion of oral argument on July 14, 1992, on defendants' motion for a stay, the Court of Appeals issued a temporary stay pending its decision on defendants' motion for a stay pending appeal.

Recognizing that the time during which Ms. Benten could use the RU486 consistent with practices in the United Kingdom was running out, plaintiffs made an emergency application to Circuit Justice Clarence Thomas to vacate the stay issued by the Second Circuit.[1] On July 17, 1992, after Justice Thomas referred it to the full Court, the Court denied the application, In re Benten, 112 S. Ct. 2929 (1992),[2] and the time for Ms. Benten to use the RU486 expired.

Ms. Benten later obtained a surgical abortion, thereby rendering moot the narrow relief issued by the district court and stayed by the Court of Appeals pending appeal. Accordingly, the Court of Appeals, on the motion of defendants, dismissed defendants' appeal and vacated the July 14, 1992, decision of the district court as moot. Order dated Sept. 22, 1992 in Benten v. Kessler, No. 92-6170. The case was thus returned to the district court for further proceedings.[3]

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[1]On July 15, 1992, the Court of Appeals granted defendants' motion for a stay pending appeal. Because this conversion of the stay granted the day before occurred at about the same time as plaintiffs' application to the Supreme Court was filed, plaintiffs, by letter, asked the Supreme Court to construe their application to vacate the July 14, 1992 stay as an application to vacate the stay pending appeal.

[2]Copy attached.

[3]In addition to this motion by plaintiffs for summary judgment, a motion to dismiss filed by defendants was filed with the Court on October 8, 1992. By a series of stipulations filed with the Court, that motion has been adjourned to April 1, 1993, the same as the return date for this motion. Plaintiffs' response to the motion to dismiss is scheduled to be filed on February 26, 1993.

On October 8, 1992, the defendants filed a motion to dismiss the case in the district court based on three grounds: (1) the action is moot; (2) the challenged agency rule is immune from judicial review because it is within defendants' "enforcement discretion"; and (3) plaintiff is barred from seeking judicial relief because she has not exhausted her administrative remedies. On January 21, 1993, plaintiffs filed a cross-motion for summary judgment. Both motions were held in abeyance and suspended while the FDA decided whether to implement the President's order to re-evaluate the import ban. They were re-activated at a status conference before the district court on May 31, 1995, and are now pending before Chief Judge Sifton.

Plaintiffs' Constitutional Argument[4]

The import ban at issue in this case directs government agents to "[a]utomatically detain all shipments of unapproved abortifacient drugs." Import Alert 66-47. Because this directive has "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus," Planned Parenthood v. Casey, 112 S. Ct. 2791, 2821 (1992), and because it does not "further the health or safety of a woman seeking an abortion," id., it constitutes an "undue burden" and is invalid.

First, the purpose of the import ban was clearly to impose a substantial obstacle in the path of women seeking pre-viability abortions. In addition to the purely political basis for the ban as found by the district court -- a political basis comprising the anti-abortion views of certain members of Congress[5] -- the purpose of the ban is revealed by its language (and by the FDA's defense of it). It does not restrict its compass to RU486; nor is it directed at importation of RU486 for uses other than as an abortifacient. Instead, it is directed at "PRODUCT: Abortifacient Drugs (drug that induces abortion)." Import Alert 66-47. It instructs agents not only to detain all RU486, but "all shipments of unapproved abortifacient drugs." Id. On its face, the import ban's purpose is to block importation of any abortifacient drugs; this purpose, and therefore the ban itself, is illegitimate under Casey.[6]

Second, the effect of the ban is to place a substantial obstacle in the path of women seeking pre-viability abortions. "Legislation is measured for consistency with the Constitution by its impact on those whose conduct it affects." Casey, 112 S. Ct. at 2829. Thus it does not matter if only one woman (Leona Benten) or only a small number of women seek to import RU486 as an abortifacient, for "[t]he proper focus of constitutional inquiry is the group for whom the law is a restriction, not the group for whom the law is irrelevant." Id. For women

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[4]These arguments were not considered by the Supreme Court as a whole, only by Justice Stevens.

[5]The anti-choice opinions of congressmen such as "Robert K. Dornan, Henry Hyde and John LaFalce," prime sponsors of the import ban, are well-known.

[6]Thus, under Import Alert 66-47, if it were discovered that some common substance or drug not approved for the purpose of inducing an abortion -- say, Vitamin C or Cytotec -- could induce an abortion, it could be seized at the border regardless of any demonstrated safety risk.

like Ms. Benten, Import Alert 66-47 operates as an absolute ban on their chosen method of abortion, and such a ban is unconstitutional.

Leona Benten was completely barred from using the method of abortion of her choice to end her pre-viability pregnancy. As Justice Stevens wrote in his dissent to the U.S. Supreme Court's refusal to vacate the appellate court stay, there are two components of a woman's right to choose abortion "her decision to terminate the pregnancy and her decision concerning the method of doing so." Benten v. Kessler, 112 S. Ct. at 2930 (Stevens, J., dissenting); see also Planned Parenthood v. Danforth, 428 U.S. 52, 75-79 (1976) (prohibition on saline amniocentesis as a method of abortion after 12 weeks of pregnancy unconstitutional because it "fails as a reasonable regulation of maternal health"). Import Alert 66-47 is invalid because it imposes a substantial obstacle in the path of every woman seeking to obtain an abortion by use of RU486.[7]

Finally, the import ban is not justified by any real concern "about the health or safety of a woman seeking an abortion." Casey, 112 S. Ct. at 2821. The FDA must, under Casey, provide evidence of health or safety risks; they have not done so.[8]

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[7]In order to prove an undue burden, a litigant need not show that a restriction places a substantial obstacle in the path of every woman, but only that "in a large fraction of the cases in which [the restriction] is relevant, it will operate as a substantial obstacle . . . " Casey, 112 S. Ct. at 2830; see also Fargo Women's Health Org. v. Schafer, 113 S. Ct. 1668, 1669 (1993) (O'Connor, J., concurring).

[8]The FDA's entire safety argument appears to be based on the assumption that abortifacients are likely to be used without the supervision of a physician. This assumption was obviously false in plaintiff Benten's case. Indeed, the FDA's personal import rule, under which plaintiff Benten sought to import RU486, allows personal importation of unapproved drugs only when they will be used under the supervision of a physician; thus, no import alert was necessary to combat unsupervised use, because the general rule already deals with that problem.

cious, or cruel aggravating factor upon the rationale of *Smalley v. State*, 546 So.2d 720 (Fla.1989)." 589 So.2d 887, 894 (1991).

(1, 2) Our cases establish that, in a State where the sentencer weighs aggravating and mitigating circumstances, the weighing of an invalid aggravating circumstance violates the Eighth Amendment. See *Sochor v. Florida*, 504 U.S. ——, ——, 112 S.Ct. 2114, 2119, —— L.Ed.2d —— (1992); *Stringer v. Black*, 503 U.S. ——, ——, 112 S.Ct. 1130, 1140, 117 L.Ed.2d 367 (1992); *Parker v. Dugger*, 498 U.S. ——, ——, 111 S.Ct. 731, 738, 112 L.Ed.2d 812 (1991); *Clemons v. Mississippi*, 494 U.S. 738, 752, 110 S.Ct. 1441, 1450, 108 L.Ed.2d 725 (1990). Our cases further establish that an aggravating circumstance is invalid in this sense if its description is so vague as to leave the sentencer without sufficient guidance for determining the presence or absence of the factor. See *Stringer*, *supra*, 503 U.S., at ——, 112 S.Ct., at 1135. We have held instructions more specific and elaborate than the one given in the instant case unconstitutionally vague. See *Shell v. Mississippi*, 498 U.S. ——, 111 S.Ct. 313, 112 L.Ed.2d 1 (1990); *Maynard v. Cartwright*, 486 U.S. 356, 108 S.Ct. 1853, 100 L.Ed.2d 372 (1988); *Godfrey v. Georgia*, 446 U.S. 420, 100 S.Ct. 1759, 64 L.Ed.2d 398 (1980).

(3) The State here does not argue that the "especially wicked, evil, atrocious or cruel" instruction given in this case was any less vague than the instructions we found lacking in *Shell*, *Cartwright* or *Godfrey*. Instead, echoing the State Supreme Court's reasoning in *Smalley v. State*, 546 So.2d 720, 722 (Fla.1989), the State argues that there was no need to instruct the jury with the specificity our cases have required where the jury was the final sentencing authority, because, in the Florida scheme, the jury is not "the sentencer" for Eighth Amendment purposes. This is true, the State argues, because the trial court is not bound by the jury's sentencing recommendation; rather, the court must independently determine which aggravating and mitigating circumstances exist, and, after weighing the circumstances, enter a sentence "[n]otwithstanding the recommendation of a majority of the jury," Fla.Stat. § 921.141(3).

Our examination of Florida case law indicates, however, that a Florida trial court is required to pay deference to a jury's sentencing recommendation, in that the trial court must give "great weight" to the jury's recommendation, whether that recommendation be life, see *Tedder v. State*, 322 So.2d 908, 910 (Fla.1975), or death, see *Smith v. State*, 515 So.2d 182, 185 (Fla. 1987), cert. denied, 485 U.S. 971, 108 S.Ct. 1249, 99 L.Ed.2d 447 (1988); *Grossman v. State*, 525 So.2d 833, 839, n. 1 (Fla.1988), cert. denied, 489 U.S. 1071, 109 S.Ct. 1354, 103 L.Ed.2d 822 (1989). Thus, Florida has essentially split the weighing process in two. Initially, the jury weighs aggravating and mitigating circumstances, and the result of that weighing process is then in turn weighed within the trial court's process of weighing aggravating and mitigating circumstances.

It is true that, in this case, the trial court did not directly weigh any invalid aggravating circumstances. But, we must presume that the jury did so, see *Mills v. Maryland*, 486 U.S. 367, 376–377, 108 S.Ct. 1860, 1866–1867, 100 L.Ed.2d 384 (1988), just as we must further presume that the trial court followed Florida law, cf. *Walton v. Arizona*, 497 U.S. 639, 653, 110 S.Ct. 3047, ——, 111 L.Ed.2d 511 (1990), and gave "great weight" to the resultant recommendation. By giving "great weight" to the jury recommendation, the trial court indirectly weighed the invalid aggravating factor that we must presume the jury found. This kind of indirect weighing of an invalid aggravating factor creates the same potential for arbitrariness as the direct weighing of an invalid aggravating factor, cf. *Baldwin v. Alabama*, 472 U.S. 372, 382, 105 S.Ct. 2727, 2733, 86 L.Ed.2d 300 (1985), and the result, therefore, was error.

(4) We have often recognized that there are many constitutionally permissible ways in which States may choose to allocate capital-sentencing authority. See *id.*, at 889, 105 S.Ct., at 2736; *Spaziano v. Florida*, 468 U.S. 447, 464, 104 S.Ct. 3154, 3164, 82 L.Ed.2d 340 (1984). Today's decision in no way signals a retreat from that position. We merely hold that, if a weighing State decides to place capital-sentencing authority in two actors rather than one, neither actor must be permitted to weigh invalid aggravating circumstances.

The motion for leave to proceed *in forma pauperis* and the petition for a writ of certiorari are granted. The judgment of the Supreme Court of Florida is reversed. We remand for proceedings not inconsistent with this opinion.

So ordered.

THE CHIEF JUSTICE and Justice WHITE dissent and would grant certiorari and set the case down for oral argument.

Justice SCALIA, dissenting.

For the reasons given in my opinion in *Sochor v. Florida*, 504 U.S. ——, ——, 112 S.Ct. 2114, 2117, —— L.Ed.2d —— (1992), I dissent from the Court's summary reversal of Espinosa's death sentence. Since the Florida courts found several constitutionally sound aggravating factors in this case, Espinosa's death sentence unquestionably comports with the "narrowing" requirement of *Furman v. Georgia*, 408 U.S. 238, 92 S.Ct. 2726, 33 L.Ed.2d 346 (1972). Compliance with that requirement is the only special capital-sentencing procedure that the Eighth Amendment demands. See *Walton v. Arizona*, 497 U.S. 639, 669–673, 110 S.Ct. 3047, ——–——, 111 L.Ed.2d 511 (1990) (SCALIA, J., concurring in part and concurring in the judgment). I would deny the petition.

Leona BENTEN, et al.
v.
David KESSLER, Commissioner, Food and Drug Administration, et al.
No. A–40.
July 17, 1992.

Pregnant woman, who sought to import single dosage of French abortion pill RU–486, but whose supply of drug was confiscated at airport customs because not approved by the Food and Drug Administration, brought action, with others, in order to compel immediate return of drug. The United States District Court for the Eastern District of New York entered preliminary injunction in her favor, and appeal was taken. The United States Court of Appeals for the Second Circuit stayed the injunction pending the appeal. On petitioners' application to vacate stay, the Supreme Court held that: (1) petitioners failed to demonstrate substantial likelihood of success on claim that woman was entitled to return of drug because administrative document instructing enforcement officials to seize drug was promulgated without notice-and-comment procedures assertedly required under both Administrative Procedure Act and FDA regulations, and (2) court would express no view on merits of assertion that government's holding drug would constitute undue burden upon woman's constitutionally protected abortion rights, as claim was not addressed by District Court, Court of Appeals, or by petitioners in filings before Supreme Court.

Application denied.

Blackmun, J., dissented and would grant application to vacate stay.

Stevens, J., dissented and filed statement.

Drugs and Narcotics ⇐22

Pregnant woman, who sought to import single dosage of French abortion drug

RU-486 but whose supply of drug was seized from her at airport customs because not approved by Food and Drug Administration, failed to demonstrate substantial likelihood of success on claim that she was entitled to return of drug, on ground that administrative document instructing enforcement officials to seize drug was promulgated without notice-and-comment procedures assertedly required under both Administrative Procedure Act and FDA regulations, so as to be entitled to vacation of Second Circuit stay of preliminary injunction entered by federal district court in her favor on her claim for drug's return.

PER CURIAM.

Petitioner Leona Benten wants to use RU-486, a drug not approved by the Food and Drug Administration (FDA), in order to induce a nonsurgical abortion. She tried to import a single dosage of the drug for that purpose, but respondent federal officials confiscated her supply at airport customs. Petitioners filed suit in the District Court for the Eastern District of New York in order to compel the immediate return of the drug to Benten. The District Court entered a preliminary injunction granting this remedy. Respondents appealed, and the Court of Appeals for the Second Circuit stayed the injunction pending the appeal. Petitioners have filed an application to vacate the Court of Appeals' stay. We deny the application.

Petitioners contend that Benten is entitled to the return of her RU-486 because an administrative document instructing enforcement officials to seize that drug was promulgated without notice-and-comment procedures assertedly required under both the Administrative Procedure Act and FDA regulations. We conclude that petitioners have failed to demonstrate a substantial likelihood of success on the merits of these claims. Justice STEVENS contends that the Government's holding the drug would constitute an undue burden upon Benten's constitutionally protected abortion rights. See *post*, at 2930-2931. We express no view on the merits of this assertion. The claim under which Justice STEVENS would grant relief was addressed neither by the District Court nor by the Court of Appeals nor by petitioners' filings in this Court. Accordingly, we conclude that it is not properly before us.

Petitioners' application to vacate the Court of Appeals' July 15, 1932, stay pending respondents' appeal, presented to Justice THOMAS, and by him referred to the Court, is denied.

It is so ordered.

Justice BLACKMUN dissents and would grant the application to vacate the stay.

Justice STEVENS, dissenting.

Whether an undue burden has been imposed on the exercise of a constitutional right depends on the relative significance of the burden, on the one hand, and the governmental interest at stake, on the other.

In this case, the applicant's constitutionally protected interest in liberty has two components—her decision to terminate the pregnancy and her decision concerning the method of doing so. The Government does not assert any interest in, or right to, burden the former decision. The Government does, however, assert an interest in the latter by protecting the applicant from taking medication under the supervision of her doctor instead of undergoing an invasive surgical procedure. In view of the Government's "personal use exception" policy, expressed in the Federal Drug Administration's February 1, 1989, revision of its Regulatory Procedures Manual,* the only legit-

* The Regulatory Procedures Manual provides in pertinent part as follows:

"In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel should consider a more permissive policy in the following situations:

"when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk." Ch. 8-71-30(C).

imate governmental interest that is now relevant is the interest in avoiding any "significant health risk" associated with the use of this medication when prescribed by a competent physician. There is no evidence in this record that this applicant faces any such risk; indeed, on the specific facts of this case, the Government's purported interest actually supports the applicant's position. In all events, I am persuaded that the relevant legitimate federal interest is not sufficient to justify the burdensome consequence of this seizure.

Accordingly, I would grant the application.

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mifepristone (RU-486): Brief Overview

May 16, 1994

Contact: FDA Press Office
(301) 443-1130

On Jan. 22, 1993, in one of his first official acts, President Clinton issued a memorandum directing HHS Secretary Donna E. Shalala to assess initiatives to promote the testing and licensing of mifepristone (RU-486) in the United States.

During early 1993, Secretary Shalala and FDA Commissioner David Kessler communicated with senior Roussel Uclaf officials to begin efforts to pave the way for bringing RU-486 into the American marketplace.

In April 1993, representatives of FDA, Roussel Uclaf and the Population Council, a not-for-profit organization, met to discuss U.S. clinical trials and licensing of RU-486. Over the last year, the parties continued their negotiations, culminating in the donation announced today. Roussel Uclaf will transfer, without remuneration, its United States patent rights to mifepristone to the Population Council. In turn, the Population Council will take the necessary steps to bring RU-486 to the American market.

Mifepristone was developed by the French firm Roussel Uclaf. The drug has been marketed for use to non-surgically terminate pregnancy in France, the United Kingdom and Sweden. There are several investigative trials underway with FDA for other uses of the drug, including contraception, labor induction, Cushing's syndrome, endometriosis, meningioma and breast cancer.

It must be recognized that termination of a pregnancy is not a simple medical procedure, whether it is done surgically or through a medical regimen. In France, the United Kingdom and Sweden, where RU-486 has been administered to approximately 150,000 women, the procedure requires several visits to a medical facility, a precise dosing scheme using two different drugs, and close monitoring to care for women who may experience excessive bleeding or other complications. Any use of mifepristone in the United States would have to follow the same type of strict distribution and use conditions.

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FOR RELEASE UPON DELIVERY
MONDAY, MAY 16, 1994

*REMARKS BY

DONNA E. SHALALA

SECRETARY OF HEALTH AND HUMAN SERVICES

PRESS CONFERENCE
WASHINGTON, D.C.

*THIS TEXT IS THE BASIS OF SECRETARY SHALALA'S ORAL REMARKS. IT SHOULD BE USED WITH THE UNDERSTANDING THAT SOME MATERIAL MAY BE ADDED OR OMITTED DURING PRESENTATION.

I am here to announce that, with the encouragement of the Clinton Administration, the French pharmaceutical firm Roussel Uclaf is donating, without remuneration, its United States patent rights for the drug mifepristone (RU-486) to the Population Council, a not-for-profit organization.

This action is an important step toward providing the women of America access to non-surgical alternatives to pregnancy termination.

On January 22, 1993 -- President Clinton's third day in office -- he signed a Presidential Memorandum directing me to assess initiatives by which the Department of Health and Human Services could promote the testing and licensing of RU-486 in the United States.

This donation concludes months of complex negotiations, reflecting the Clinton Administration's repeated urging to bring the process to fruition. We commend Roussel Uclaf and the Population Council for their achievement on this very important issue.

We strongly believe that women in America should have access to the full range of safe and effective alternatives to surgical abortion. The donation announced today is a big step in that direction.

Although RU-486 has been used as an abortifacient in France, the United Kingdom and Sweden, I want to emphasize that mifespristone has not been approved for use in the United States.

In addition to conducting clinical trials, which will commence here in the United States in the near future, the Population Council will submit a new drug application for RU-486 to the Food and Drug Administration.

Let me make it clear: we will do all we can to evaluate quickly mifepristone. But I also want to make it clear that FDA's decision will be based solely on the scientific and medical evidence about the safety and efficacy of the product.

That is our responsibility to the women in America. Thank you.

Shalala commended Roussel Uclaf and the Population Council for coming to closure after months of complex negotiations amid repeated urging from the Clinton administration.

Shalala emphasized, however, that the donation does not mean RU-486 has been approved for use in the United States. The Population Council must conduct clinical trials, identify a manufacturer and submit a new drug application to the Food and Drug Administration.

"The FDA will do all it can to quickly evaluate mifepristone," said Shalala. "FDA's decision will be based solely on the scientific and medical evidence as to the safety and efficacy of the drug. That is our responsibility to the women of America."

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E X E C U T I V E O F F I C E O F T H E P R E S I D E

18-Jul-1996 12:00pm

TO: (See Below)

FROM: Lyndell Hogan
Domestic Policy Council

SUBJECT: Background on RU-486, talking points to come

Please see the following background information on President Clinton's record on Mifepristone, commonly referred to as RU-486. Several events in which Mifepristone will be discussed are scheduled for today and tomorrow. It is very likely that we will receive questions from media, advocacy groups, the public, etc.

On Friday, July 19, the FDA's Reproductive Health Drugs Advisory Committee will consider data submitted by the Population Council as part of a New Drug Application (NDA) for Mifepristone. FDA routinely refers NDAs to this Advisory Committee and asks the panel for a recommendation on the drug's safety and efficacy.

The Family Research Council and a number of pro-life groups held a news briefing at the National Press Club this morning to highlight what they view as the dangers of

Women's and reproductive health advocates are responding with their own press conference today at 1:00 p.m., also at the National Press Club.

Following is a history of President Clinton's record on Mifepristine.

On January 22, 1993, President Clinton directed Secretary Shalala to "determine whether the current import ban on the drug Mifepristone, commonly known as RU-486, is justified and to rescind the ban if there is no basis for it."

The President's executive order directed the FDA to reassess whether Mifepristone qualified for importation under FDA's personal use import policy. President Clinton further said that if the FDA concluded that meets the criteria for personal use importation exemption, Sec. Shalala should rescind the Import Alert 66-47. Finally, President Clinton ordered HHS to assess initiatives to promote the testing, licensing, and manufacturing in the U.S. of Mifepristone.

In July 1993, the FDA concluded that Mifepristone is not an appropriate candidate for the FDA's personal use policy governing the importation of unapproved new drugs. In its assessment, FDA determined that the distribution of Mifepristone is very tightly controlled in the UK, France, and Sweden, where it is approved. The strictly regulated administration of mifepristone in those countries suggests that it may not be able to be safely taken without careful medical supervision and controls.

Roussel Uclaf, a French subsidiary of the German company, held two United States patents for its product, Mifepristone. On May 16, 1994 Rousell Uclaf, at the encouragement of the Clinton Administration, donated its United States patent rights for Mifepristone to the U.S.-based Population Council, a not-for-profit organization, to allow the Population Council to begin the necessary steps to bring Mifepristone to market in this country.

U.S. clinical trials conducted by the Population Council were completed in September 1995.

On Friday, July 19, the FDA's Reproductive Health Drugs Advisory Committee will consider data submitted by the Population Council as part of a New Drug Application (NDA) for Mifepristone. FDA routinely refers NDAs to this Advisory Committee and asks the panel for a recommendation on the safety and effectiveness of the drug. There will not be a decision on Mifepristone in 1996.

(FYI--A specific scientific panel reviews reproductive drugs. There are rumors that two members on that panel were forced to resign because of pressure from right-to-life groups. This is a rumor and is inaccurate. Two members on the panel had conflicts of interest so were recused.)

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M E M O R A N D U M

To: Distribution
From: Lyn Hogan
Date: July 19, 1996
Re: Q&A For Mifepristone (RU-486) Hearing

Please refer questions about the FDA process to Jim O'Hara, 301-443-1130, at FDA Public Affairs.

Background

Today, Friday, July 19, the FDA's Reproductive Health Drugs Advisory Committee will consider data submitted by the Population Council as part of a New Drug Application (NDA) for Mifepristone. FDA routinely refers NDAs to this Advisory Committee and asks the panel for a recommendation on the drug's safety and efficacy.

Mifepristone, commonly referred to as RU-486, is an effective, non-surgical method of early abortion that has been in use since 1981. The drug was approved for use in France, Great Britain and Sweden following extensive clinical trials that demonstrated its safety and efficacy.

During the Bush Administration, the FDA issued an import alert which helped ensure that mifepristone would not be available in the United States for any purpose.

On January 22, 1993 the President issued an executive order that directed the FDA to reassess whether mifepristone qualified for importation.

1) What is expected to happen at today's FDA hearing?

Today, Friday, July 19, the FDA's Reproductive Health Drugs Advisory Committee will consider data submitted by the U.S.-based Population Council as part of a New Drug Application (NDA) for Mifepristone.

FDA routinely refers NDAs to this Advisory Committee and asks the panel for a *recommendation* on the safety and efficacy of the drug. Today's advisory committee is the usual next step in the review process of the marketing application.

There will not be a decision on Mifepristone in 1996.

2) What official action has the President taken to date regarding RU-486?

January 22, 1993 the President issued an executive order that:

- Directed the FDA to reassess whether Mifepristone qualified for importation under FDA's personal use import policy;
- Said that if the FDA concluded Mifepristone meets the criteria for personal use importation exemption, Sec. Shalala should rescind the Import Alert 66-47; and
- Ordered HHS to assess initiatives to promote the testing, licensing, and manufacturing in the U.S. of Mifepristone.

3) Prior to this hearing, what has the FDA concluded?

In July 1993, **the FDA concluded that Mifepristone is not an appropriate candidate for the FDA's personal use policy** governing the importation of unapproved new drugs.

In its assessment, FDA determined that the distribution of Mifepristone is very tightly controlled in the UK, France, and Sweden, where it is approved. The strictly regulated administration of mifepristone in those countries suggests that it may not be able to be safely taken without careful medical supervision and controls.

4) Since the FDA ruled that this drug is not safe for personal use, why are they continuing with regulatory hearings?

The FDA believes the drug can be taken safely with **careful medical supervision and controls**, and therefore, in routine fashion, has referred the New Drug Application to this Advisory Committee to ask the panel for a *recommendation* on the safety and efficacy of the drug.

5) How can we be sure the FDA process is a fair, objective process?

- The FDA advisory committee is a nonpartisan, objective committee comprised of scientists and doctors from outside the FDA.

- The process for approving New Drug Applications is based in science and medicine.

- The FDA is giving mifepristone a straightforward, honest review and will make their decision on the basis of whether this drug is safe for American women.

- The FDA follows well established procedures to assess independently all published studies and data, including those from other countries.

- Voting members of the FDA Advisory Committees are subject to conflict of interest laws and regulations governing federal employees and Advisory Committee members are required to have diverse professional education, training, and experience.

6) I understand that two members on the review panel were forced to resign because of pressure from right-to-life groups. Is this true?

This is a rumor and is inaccurate. Two members on the panel had conflicts of interest so were recused.

7) What are the pro-life groups and pro-choice groups saying about RU-486?

Pro-Life

On July 18, pro-life groups held a press conference on the FDA hearings.

The Family Research Council (FRC) lead by Gary Bauer issued a statement calling on the FDA not to approve RU-486 due to ethical considerations. In the statement, the FRC questioned the drug's safety and efficacy.

At the same time, the FRC accused the FDA of attempting to circumvent its own approval statutes that ensure safe and effective drugs for the sake of the lives and safety of women and children.

Other pro-life organizations claim RU-486 has long-term health risks for mothers and children.

Last summer a pro-life group, Americans United For Life, and other abortion opponents, submitted a Citizen's Petition to the FDA opposing approval of mifepristone. They did so before the clinical trials were over and before the extensive scientific data collected by the Population Council was submitted to the FDA.

Pro-Choice

Also on July 18, women's and reproductive health advocates held a press conference to call for approval of mifepristone. These groups called mifepristone a major medical advance for women and described its expected positive impact on the provision of women's health care services in this country.

The Feminist Majority is concerned that five Reproductive Health Advisory Committee members have demonstrated that they have a conflict of interest with the subject matter of the July 19 meeting concerning mifepristone, They expressed their concern in a July 10 letter to FDA Commissioner David Kessler.

8) Why does the Population Council hold the U.S. patent on mifepristone?

Roussel Uclaf, a French subsidiary of the German company, held two United States patents for its product, Mifepristone. On May 16, 1994 Rousell Uclaf, at the encouragement of the Clinton Administration, donated its United States patent rights for mifepristone to the U.S.-based Population Council, a not-for-profit organization, to allow the Population Council to begin the necessary steps to bring Mifepristone to market in this country. U.S. clinical trials conducted by the Population Council were completed in September 1995.

To: Betsy Myers
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From: Jeanne

FDA

TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
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FYI

T96-61
Sept. 18, 1996

Lawrence Bachorik
(301) 443-1130

Back to JSK

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, but 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.

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September 18, 1996

From: Jim O'Hara, FDA, 301-443-1130

Note to White House Press Office:

The FDA today issued an aprovable letter to the Population Council for mifepristone, when used with misoprostol, for the termination of early pregnancy. Approvable letters are issued when the Agency has determined the basic safety and efficacy of a drug, but other outstanding issues have to be resolved by the sponsor. An advisory committee of outside experts had recommended to the Agency in July that the benefits outweighed the risks for the mifepristone and misoprostol regimen. Under the law, FDA can only confirm that an approvable letter has been issued and confirm what a sponsor says about the approvable letter. There should be no speculation about when a final approval decision will be made.

Questions about the approvable letter should be referred to FDA's Office of Public Affairs: 301-443-1130.

Talking Points:

Election-year politics had nothing to do with either the substance or timing of this decision.

The advisory committee of outside experts said in July that the benefits outweighed the risk, and while the Agency is not bound by an advisory committee decision, it generally follows them. Because this drug is the first in its class, it is considered a priority drug; the FDA has a goal of acting on priority drugs within six months of an application being filed, and this application was filed in March 1996. This is not a final decision.

This decision is being made on the science and medicine.

This drug regimen has been in use for a number of years in other countries. Data from clinical trials in both France and the U.S. have been submitted to the Agency in support of this application and was reviewed by a committee of outside scientific and medical experts.

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017 Telephone: (212) 339-0500 Telex: 234722 POCO UR Facsimile: (212) 755-6052 Cable: POPCOUNCIL NEW YORK

News Release

For further information, contact:
Sandra Waldman, 212/339-0525

18 September 1996
FOR IMMEDIATE RELEASE

FDA Issues Approvable Letter for Mifepristone Medical Abortion

NEW YORK—The Population Council announced today (18 September 1996) that the U.S. Food and Drug Administration has issued an Approvable Letter for mifepristone, in combination with misoprostol, for early medical abortion. The FDA letter, which the Council received earlier today, states that the agency has determined that substantial clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under medical supervision.

An Approvable Letter is an action frequently used by the FDA to indicate that safety and efficacy data have passed agency review, but that additional information must be submitted before final approval for marketing is granted. The FDA Approvable Letter to the Council said that a few parts of the application, including those related to labeling and additional information about the manufacturing process, remain to be completed by the Council. An FDA Advisory Committee recommended on July 19 that the agency approve the regimen for early medical abortion. The Council's 164-volume New Drug Application was submitted in March 1996.

In a statement, the Population Council said, "This FDA action marks another major step in the long and complex process to make mifepristone available to American women as it is to women in other countries. We are delighted to have an Approvable Letter. We are sure we will be able to provide the FDA the outstanding information necessary for approval."

# # #

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

19-Jul-1996 06:27pm

TO: (See Below)

FROM: Lyndell Hogan
Domestic Policy Council

SUBJECT: FDA Advisory Committee Voted Yes On RU-486

As of 6:00 p.m. July 19, the FDA Advisory Committee had taken its votes on mifepristone (also known as RU-486). There are 8 voting people on the committee. Three votes were significant. A verbal report from Dept. of Health and Human Services indicates the following results:

Members voted: On the efficacy of mifepristone, 6 yes, 2 no
On the safety of mifepristone, 7 yes, 1 abstained
On approval of mifepristone, 6 yes, 2 abstained

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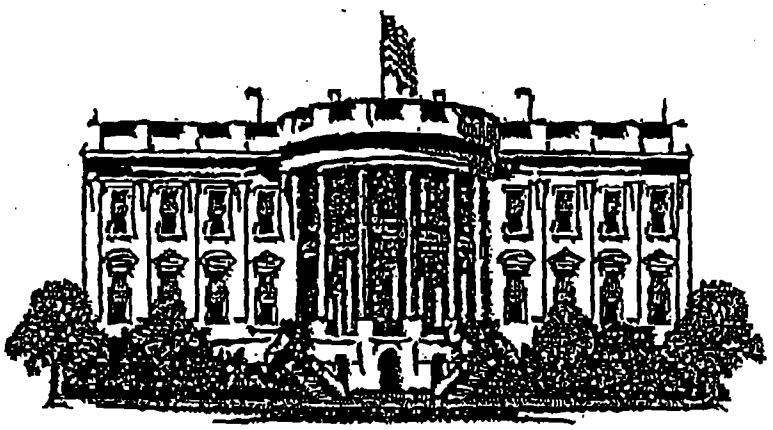

Christopher C. Jennings
Deputy Assistant to the President for Health Policy
216 Old Executive Office Building
Washington, DC 20502
phone: (202) 456-5560
fax: (202) 456-5557

Facsimile Transmission Cover Sheet

To: Jan Klein

Fax Number: 6-2878

Telephone Number: 6-6266

Pages (Including Cover): (2)

Comments:

DRAFT

October 14, 1998

The Honorable Don Nickles
Assistant Majority Leader
United States Senate
Washington, D.C. 20510

Dear Senator Nickles:

Thank you for meeting with me and Secretary Shalala concerning my nomination to be Commissioner of the Food and Drug Administration (FDA). I appreciate the time and consideration that you have given to my nomination.

I want to take this opportunity to restate that during my earlier service at FDA (1992-1994) I was not involved either in the solicitation or the review of the RU-486 application. As a general matter, I believe the Agency should exercise caution in soliciting product applications.

If I am confirmed as Commissioner, I do not intend to actively solicit a manufacturer for this product.

Thank you again for considering my nomination.

Sincerely,

Jane E. Henney, M.D.

LONG ALDRIDGE & NORMAN

ATTORNEYS AT LAW

FACSIMILE TRANSMITTAL

701 PENNSYLVANIA AVENUE, N.W.
SUITE 600
WASHINGTON, D.C. 20004
TELEPHONE: 202 624-1200
FACSIMILE: 202 624-1298

DATE: 6.27.97

TO: Ms. Jennifer Klein

COMPANY: OFFICE OF DOMESTIC POLICY

FACSIMILE NO.: 202.456.5557

FROM: Kyle Mitchell

COMMENTS:

THANKS

(Thanks for delivering to Jennifer Klein)

CLIENT NO.: 9999.021

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LONG ALDRIDGE & NORMAN
ATTORNEYS AT LAW

June 27, 1997

Via Facsimile

Ms. Jennifer Klein
Special Assistant to the President
Office of Domestic Policy
The White House
Washington, DC 20500

Dear Jennifer:

Thank you for calling me today to discuss the mifepristone matter currently under consideration in your office. Moreover, I appreciate your commitment to give this matter further thought.

Per our discussion, I am attaching to this letter background information on the status of our efforts to bring this drug to market. I would appreciate your keeping this information confidential. I want to reiterate that at this time, we are most interested in ensuring that Gedeon Richter understand the importance this Administration places on bringing mifepristone to market. If after being made aware of such importance, Gedeon still decides it will not manufacture the product for us, we will have done all we can do.

The member of the Administration in the best position to make these concerns known to Gedeon is Ambassador Donald Blinken. I have always maintained that it would be inappropriate for the Ambassador to insert himself in any of the particular business matters now pending between Gedeon and the investor group. However, in the interest of full knowledge and disclosure, I think it would be appropriate and advisable for him to inform Gedeon that bringing mifepristone to market in the United States is important to the President. To the extent that Gedeon can be of assistance in helping bring mifepristone to market in the United States, it would be helping our Administration. Having the Ambassador make these points to Gedeon would ensure that all parties in this dilemma would go forward fully informed of the others' priorities.

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202 624-1200 • FACSIMILE 202 624-1298

ATLANTA, GEORGIA OFFICE:
303 PEACHTREE STREET • SUITE 5300 • ATLANTA, GEORGIA 30308

I want to also reiterate that Gedeon is 38.5% owned by the Hungarian government. The government owns the controlling interest. Such government ownership changes in some ways the contour of the discussions between the Ambassador and Gedeon. This is more of a government to government communication.

Again, thank you for your time and consideration. I am available to provide any information or assistance you may need on this matter.

Sincerely,

Kyle Michel

attachment

~~CONFIDENTIAL~~ **BACKGROUNDER**
June, 1997

Overview

When President Clinton took office in 1993, one of the first acts of his Presidency was to reverse the ban President Bush had imposed on the importation into the United States of mifepristone, the drug commonly known as RU 486. On January 22, 1993, the President sent a memorandum to the Secretary of Health and Human Services directing her to "assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU 486 or other antiprogestines." In response to this directive, Secretary Shalala undertook initiatives that resulted in the manufacturer of the drug, Roussel-Uclaf, transferring the U.S. rights to the drug to the Population Council. Secretary Shalala was personally involved in the transferral process.

The Population Council conducted a search for business interests that would bring the drug to market in the United States, including taking responsibility for financing the venture, acquiring FDA approval for the drug, selecting and contracting with a manufacturer, designing and implementing a distribution network and taking all other steps necessary to make mifepristone available in the U.S. After determining that no existing drug company was willing to manufacture and distribute mifepristone, the Council turned to private investors.

During 1995 and 1996, an investor group was formed to bring the drug to market. This group was led by a general partner who took some meaningful steps to advance the project, but neglected to develop key aspects of the venture. Ultimately, in early 1997, this general partner withdrew from the project. He was replaced by the current general partner who is endeavoring to bring the project to fruition.

In early 1997, the investor group projected that the drug would be available in the United States in December, 1997. This goal was imperiled in late February when the contracted manufacturer, Gedeon-Richter, informed the investor group that it was terminating its manufacturing contract. Settlement negotiations to achieve some type of manufacturing arrangement began immediately. On May 7, 1997, the investor group filed suit against Gedeon for breach of contract. The suit is going forward, though the investor group would prefer to reach a negotiated settlement with Gedeon to provide enough drug product to go to market as scheduled, and meet minimum demands until a new manufacturing facility can be brought on line.

The general partner of the investor group is in the process of building relationships with the Choice community in Washington, DC, New York, and across the country. These relationships were largely neglected under the former general partner. As a result, there are many issues surrounding mifepristone on which the Choice community is not educated. This paper is written to address those issues and provide general background on the subject.

Manufacturing

Mifepristone is a steroid drug, the production of which requires a series of intricate molecule-building procedures. The only licensed manufacturer of mifepristone in the world at the time the investor group acquired the rights to produce and market the drug was Roussel-Uclaf. Roussel has since been acquired by Hoechst Corporation. Hoechst has decided to cease all manufacturing of mifepristone. The company is currently fulfilling a small, two year contract for production of the drug for Mr. Edouard Sakiz. Mr. Sakiz, a resident and citizen of France, is the inventor of the drug, a former Roussel executive, and the current holder of the rights to market the drug in France, England and Sweden. Other than fulfilling the agreement with Mr. Sakiz, Hoechst has refused to consider manufacturing additional mifepristone, despite repeated inquiries and requests by the investor group.

After the Population Council licensed the drug to the investor group, the group began a search for a manufacturer. Because of the sensitive political nature of mifepristone, no U.S. manufacturer was interested in producing the drug. The investor group approached Roussel, later Hoechst, about producing the drug, but was told the company was not changing plans to cease producing mifepristone. Finally, the group located Gedeon-Richter, a Hungarian pharmaceutical company with a history of producing FDA-approved drugs for use in the United States.

Gedeon contracted to produce the drug for the investor group and Roussel agreed to transfer technology to Gedeon to enable it to do so more rapidly. After much work, Gedeon achieved successful production of the drug and, now, has attained all but final approvals from the FDA. In May, 1996, Gedeon signed a contract with the investor group to produce two years' full supply of mifepristone for the investor group beginning in the fall of 1997. The investor group paid Gedeon a down payment in contemplation of the continuing manufacturing relationship between the two parties.

Current Impasse

In February of 1997, Gedeon informed the investor group that it was terminating the contract to produce mifepristone. Gedeon did not give a full and adequate explanation for its actions. Subsequently, representatives from Gedeon and the investor group met in New York and Hungary to try to work out a settlement. When these negotiations broke down, the investor group filed suit against Gedeon in New York for breach of contract. The lawsuit is going forward; however, the investor group is still interested in finding a way to reach an agreement with Gedeon for manufacture of the product so it can be brought to market in the United States.

The cancellation of the manufacturing contract by Gedeon will cause at least a three to five year delay in bringing the drug to market, even assuming a new manufacturer is located immediately. Any new manufacturer will have to successfully master the technology transfer and manufacturing procedures required to produce mifepristone, and additional FDA approvals will be required. There are no known FDA-approved manufacturers that can currently produce the drug. Because Gedeon is a leader in steroid drug technology and because it now has the technology to produce this drug, it is the only manufacturer capable of producing mifepristone in the short term.

The investor group's goal remains unchanged - to bring mifepristone to market in the United States as soon as possible. To this end, the investors would like to work out an agreement with Gedeon that Gedeon produce a reduced, set amount of mifepristone for a two to three year period. This would give the investor group time to either locate another manufacturer, or build its own production facility. During the negotiations, before the lawsuit was filed, there were discussions of such an agreement, but Gedeon was reluctant to agree to any manufacturing arrangement. Revisiting these discussions is the most promising path to achieving the investor group's goal.

Gedeon is 38.5% owned by the Hungarian government. The Managing Director, Erik Bogsch, has been surprised at the investor group's strong reaction to Gedeon's cancellation of the contract. He is also concerned that the cancellation not create political problems for the company or the Hungarian government. The government is in the process of selling off 13.5% of the company in a private sale in London and New York. Mr. Bogsch has asked for a meeting with US Ambassador to Hungary, Donald Blinken. Ambassador Blinken is currently considering whether to meet with Mr. Bogsch. He is awaiting word from the Administration in Washington giving him instruction on this matter.

It is important that the proponents of mifepristone get a message to Ambassador Blinken encouraging him to meet with Mr. Bogsch. We do not need the Ambassador to help us settle a lawsuit between two business interests. We need the Ambassador to stress to Mr. Bogsch the importance of this product to the current Administration and encourage Gedeon to work with the investor group to work out an interim arrangement whereby the investor group can bring the drug to market on schedule. The Ambassador should inform Mr. Bogsch that Gedeon is the only manufacturer that can assist the Administration in achieving this goal. Again, the Ambassador does not need to go into the details of the lawsuit, or even into the details of an interim arrangement. He needs to underscore to the importance of this matter to the U.S. government and the Clinton Administration and encourage him to work with us to reach an agreement for production of mifepristone.

LONG ALDRIDGE & NORMAN

ATTORNEYS AT LAW

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TELEPHONE: 202 624-1200
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DATE: 6.27.97

TO: Ms. Jennifer Klein

COMPANY: OFFICE OF DOMESTIC POLICY

FACSIMILE NO.: 202.456.5557

FROM: Kyle Michel

COMMENTS:

THANKS

(Thanks for delivering to Jennifer Klein)

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attachment

~~CONFIDENTIAL~~ **BACKGROUNDER**
June, 1997

DETERMINED TO BE AN ADMINISTRATIVE MARKING
INITIALS: MA DATE: 4-29-14

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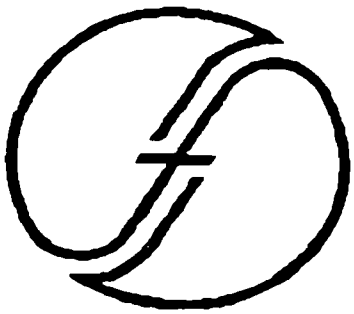

Future View, Inc.

1250 Taylor St., N.W.
Washington, DC 20011

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To: Jennifer
Company: AMEX
Phone:
Fax: (202) 456-5552 OR 5557 (?)

From: Gregg Johnson
Company: Future View, Inc.
Phone: 202-882-7400
Fax: 202-882-7450

pgr (202) 4249524 ↑ Five!

Total pages: (1)

Comments: Jennifer.

Vehicle # D.C. tags. 802-497

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Paul Kesari
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Derrick Peart
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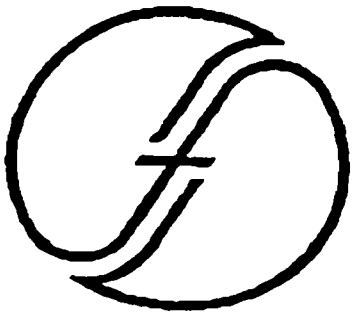

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pgr (202) 424 9524 ↑ Five!

Total pages: (1)

Comments: Jennifer.

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D.O.B. 08/04/69
SS# 579742866

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