A Judicial Watch Special Report:

The Clinton RU-486 Files

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The Clinton Administration's Radical Drive to Force an Abortion Drug on America

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Introduction

This Judicial Watch Special Report analyzes newly uncovered documents from the National Archives at the Clinton Presidential Library in Little Rock, Arkansas, describing the Clinton administration's radical drive to introduce the abortion drug RU-486 (mifepristone) into the American marketplace.

The records include the Clinton administration's legal, political and press strategies for rushing RU-486 through the Food and Drug Administration (FDA) processes, despite the manufacturer's historical refusal to permit marketing the drug here. The legal, political and press memos articulate the Clinton administration's views regarding various players in the drug approval and marketing process -- women's groups, members of Congress, public interest groups and the media.

Judicial Watch has engaged in a five-year legal battle with the FDA for release of records under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. §552, concerning RU-486. We uncovered over 9,300 pages of documents and 840 Adverse Event Reports pertaining to the abortion drug. To date, the deaths of at least six women have been attributed to RU-486. The FDA scheduled a scientific conference for May 11, 2006 in order to study the controversial abortion drug and the circumstances leading to the deaths.

Judicial Watch promotes transparency, integrity and accountability in government, politics and the law. We make aggressive use of open records and open meetings laws as a means to obtain documents with which to educate the American public on the operations of their government and to hold public officials accountable. Judicial Watch also provides technical, research and litigation assistance to public interest groups interested in obtaining information about government activity which may not have the necessary resources or experience to pursue information on their own as part of the Judicial Watch Open Records Project.

Thomas Fitton
President
Judicial Watch, Inc.

April 26, 2006

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Executive Summary

During a February 2006 research trip to the National Archives at the Clinton Presidential Library, Judicial Watch uncovered new records detailing the Clinton administration's rush to market the abortion drug RU-486 (mifepristone) to American women. The documents include political, legal and press strategy memoranda from Health and Human Services (HHS) Secretary Donna Shalala, FDA Commissioner, Dr. David Kessler, and HHS Chief of Staff Kevin Thurm. Some of the memoranda are addressed to the White House -- in particular, Carol Rasco, the Clinton administration Director of Domestic Policy.

Analysis of the records shows:

- President Clinton ordered HHS and FDA to coordinate and promote the marketing of RU-486 as his first official act in office.
- Within one month, the FDA Commissioner had met with the RU-486 manufacturer and their parent company.
- Official U.S. Government political, economic and diplomatic pressure was brought to bear to strong-arm the companies into changing their policies in order to make the drug available in the United States.
- The FDA was compromised in its role as objective reviewers of the safety and efficacy of the drug.
- The five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.
- Radical, pro-abortion extremists dominated the Clinton administration's "women's health care" agenda and their reckless drive to bring RU-486 to America ultimately cost at least six women their lives and the lives of over 560,000 unborn children.

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* * *

"Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both Dr. Kessler [FDA Commissioner] *and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position."*

Donna Shalala
Health & Human Services Secretary
Clinton Administration
November 15, 1993
Confidential Memo to White House

* * *

In February 2006, Judicial Watch uncovered previously confidential files and working papers from the holdings of the National Archives at the Clinton Presidential Library in Little Rock, Arkansas that provide remarkable insight into the Clinton administration's relentless drive to market RU-486 (mifepristone), a drug used to cause abortion, to American women. The documents offer a window into the political strategy, legal theories and media "spin" on the Clinton administration's abortion program.

RU-486 was first developed in France in 1981. It is a manmade steroid designed to work against the hormone progesterone, which is required to promote a baby's proper growth and development. RU-486 works to chemically destroy the unborn child's environment, cutting off nourishment and starving the baby to death in the mother's womb. A second chemical, misoprostol, is then used to create cramping and contractions to expel the dead baby from the mother's womb. The "procedure" must begin within 49 days of conception. The Clinton administration considered this method of abortion part of "women's health care." President Clinton thanked the maker of RU-486 in writing, "On behalf of the government of the United States and for the women of America. . ."[i]

On January 22, 1993, in his first official act, President Clinton issued a memorandum directing HHS Secretary Donna Shalala to promote the testing and licensing of RU-486 in the United States. (See Tab A)

Abortion was a key domestic policy item for President Clinton. RU-486 was just one part of the overall strategy for his administration's agenda. For example, in a

National Archives document entitled, "President William J. Clinton -- Eight Years of Peace, Prosperity and Progress," the first "accomplishment" listed reads:

> **Abolished Restrictions on Medical Research and the Right to Choose** As his first executive actions, President Clinton revoked the Gag Rule, which prohibited abortion counseling in clinics that receive federal funding to serve low-income patients. He also revoked restrictions on a woman's legal right to privately funded abortion services in military hospitals, restrictions on the import of RU-486, and restrictions on the award of international family planning grants (the "Mexico City Policy"). The President also lifted the moratorium on federal funding for research involving fetal tissue, allowing progress on research into treatments for Parkinson's disease, Alzheimer's, diabetes and leukemia. (Executive Memoranda, 1/22/93)[ii]

The tone was set for the Clinton administration's drive towards promoting abortion as "health care." Shalala and FDA Commissioner, Dr. David Kessler, engaged in a political, legal and economic campaign to force the French pharmaceutical firm, Roussel Uclaf, and their German parent corporation, Hoechst, A.G., to file a "new drug application" (NDA) with the FDA, and begin marketing RU-486 to American women.[iii]

In April 1993, the FDA brokered a meeting between Roussel Uclaf and the Clinton administration's anointed abortion proponent, the Population Council, a non-profit organization that conducts research on so-called "reproductive health issues." Roussel Uclaf and the Population Council already had an existing contractual relationship concerning provision of abortifacients (substances that induce abortion) for various clinical trials.[iv] It is difficult to understand the FDA's role in bringing the parties together, other than to continue to bring official U.S. government pressure on Roussel Uclaf and to designate the Population Council as the Clinton administration's abortion drug development and marketing proxy.

The Population Council claims to be " . . . an international, nonprofit, nongovernmental organization, seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources."[v] The organization was founded by John D. Rockefeller III in 1952. In 2005, they projected spending over $71 million in 70 countries around the world. Their work is funded by governments, foundations, individuals and "multilateral organizations."[vi]

According to the Clinton RU-486 files, Roussel Uclaf made the decision to use the Population Council as the administration's surrogate for forcing RU-486 on America.

There is no mention in the memoranda of Planned Parenthood or the National Abortion and Reproductive Rights Action League (NARAL). There is no mention of public disclosure, discussion, competition or bidding. One might imagine a selection process or staff discussion of the relative pros and cons for selection of another abortion group, but there is no evidence of any such discussion or consideration. In a memo by HHS Chief of Staff Kevin Thurm (discussed in detail below), the Clinton administration seems to have been predisposed to using the Population Council to carry out their abortion plans based on an existing relationship of the abortion non-profit with the maker of RU-486.

Roussel Uclaf repeatedly sought total U.S. government-sponsored indemnification from any damages it might incur by bringing RU-486 to the U.S. marketplace. Roussel Uclaf President, Dr. Edouard Sakiz, specifically expressed concerns over liability actions against his firm "if a woman had an incomplete abortion and delivered a deformed fetus." Dr. Sakiz was also particularly concerned about "consequential damages," such as the economic costs from boycotts. The Clinton administration's fervent commitment to making RU-486 part of the American abortion industry is demonstrated through Dr. Sakiz's reservations concerning legal and economic exposure. The Clinton administration's near-obsession with introducing a "safe and effective" abortion drug is revealed in Shalala's confidential memo to the White House of November 15, 1993:

> "Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request."

(See Tab B)

Dr. Sakiz was saying, in other words, "If <u>you</u> want it so badly, <u>you</u> pay the consequences." The Clinton administration was attempting to trump a business decision of the pharmaceutical company while exposing the corporation to risk for abiding by a U.S. government request.

Even Clinton FDA Commissioner Kessler understood and memorialized the controversy over the administration's aggressive efforts to introduce RU-486 when he wrote in a September 30, 1993 memorandum to Shalala:

> " . . . other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Ucalf with evidence that the U.S. population

lacks cohesiveness on this issue and that the abortion debate continues."

(See Tab C)

The Clinton administration realized that attempting to enact blanket indemnification by the U.S government of a foreign corporation for an abortion drug was politically and practically impossible. According to the Clinton RU-486 files, Dr. Sakiz still went ahead and committed to negotiating with the Clinton administration surrogates – the Population Council – agreeing:

- To license RU-486 to the Population Council which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug application;

- The Population Council would ultimately submit an NDA to the FDA based on the results of the clinical trial and on other studies conducted by Roussel Uclaf; and

- The Population Council, with the concurrence of Roussel Uclaf, would chose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf did not want to manufacture the drug for sale in this country. [Emphasis added.]

(See Tab B)

According to the Clinton RU-486 files, over the next few months Roussel Uclaf reiterated its desire for protective federal legislation providing blanket indemnification from the use of RU-486. Roussel Uclaf did not anticipate any profit from selling RU-486 in the United States; and was only entering the American market at the insistence of the Clinton administration. FDA representatives told Roussel Uclaf that such protection was extremely unlikely.

In a September 30, 1993 memorandum to Shalala, FDA Commissioner Kessler recounts a conversation he had with Jim Boynton, legal counsel for the Population Council, concerning the Roussel Uclaf indemnification legislation. Kessler pointed out the recent passage of the Hyde Amendment (restricting federal funds for abortion), and that with one exception (swine flu event), the United States had never agreed to indemnify any drug manufacturer. Apparently sensing that it might be perceived as inappropriate for the FDA commissioner to be discussing indemnification with a drug company representative for a supposedly safe drug, Kessler tried to cover his tracks. Kessler wrote that he, ". . . further explained that it would go far beyond FDA'S

appropriate role to seek such protection for a drug company." [Emphasis added.] Nonetheless, the FDA offered to advance the idea within HHS.

Not satisfied with the denials of indemnification from the FDA and HHS, in September 1993 Roussel Uclaf hired legal counsel (reportedly, Lester Hyman and John Hoff of the firm Swidler & Berlin) to lobby the federal government for indemnification "at levels higher than the FDA" – presumably from President Clinton and other pro-abortion advocates in the Congress, such as Rep. Ron Wyden and Rep. Henry Waxman. Concerned with these moves, HHS Chief of Staff Kevin Thurm and HHS General Counsel Harriet Rabb initiated a meeting with attorneys from Swidler & Berlin. During that meeting Roussel Uclaf's lawyer suggested that the United States could exercise its statutory powers of eminent domain and seize the patent for RU-486 for the abortifacient uses of the drug.[vii]

Meanwhile, the Population Council and Roussel Uclaf pressed forward with licensing details, and simultaneously made plans to sway the leadership of Hoechst to allow their subsidiary to enter into an agreement with the Population Council. Shalala's confidential memo to the White House warns, ". . . we do not think the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst."[viii]

Shalala suggested the Clinton administration bring the force of the United States Government to bear on the Hoechst and Roussel Uclaf corporations. She also went on to suggest that the United States exercise its international diplomatic and economic pressure on the German and French governments, as a means of further "influence" against the corporations. In a November 15 confidential memo to the White House, Shalala wrote: "The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government."

While the Clinton administration pondered exercising the full economic and diplomatic weight of the United States Government to advance its abortion agenda, it is important to note that Roussel Uclaf was willing to give a royalty-free license to any major U.S. pharmaceutical company – but no U.S. company would take the license.

The Clinton RU-486 files show specualtion among administration officials concerning delays in the negotiations between Roussel Uclaf and the Population Council. The pending retirement of the chief executive officer of Hoechst, Professor Wolfgang Hilger, was discussed in Kessler's September memo, noting that Prof. Hilger was "very staunchly Catholic." There was also a discussion of the likelihood of an international foundation being created by the drug's inventor, Dr. Etiene Balieu, for broader marketing opportunities. Apparently the Clinton administration was concerned about competition from an abortion drug "insider."[ix]

Just as the name of the Population Council "appeared" in the Clinton administration's confidential memos without a trace of how it became the administration's surrogate, so too does the recommendation for Felix Rohatyn to serve as an "expert advisor."[x]

After a review of the economic, political and diplomatic issues involved in strong-arming Hoechst and Roussel Uclaf, Dr. Kessler advanced Mr. Rohatyn's name by concluding with a political point: "We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market." Again, there is no discussion, alternatives or explanation offered for this appointment. The question of appointment of an "expert advisor" for the U.S. government is raised and answered in the space of one paragraph.

In a remarkable admission that the FDA had been thoroughly politicized in the Clinton administration's radical drive for RU-486, the agency's commissioner, Dr. Kessler, wrote in his September memo, " . . . the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug."

The Clinton RU-486 file offering the most comprehensive treatment of the administration's strategic campaign to introduce RU-486 to the American market is a memorandum dated May 11, 1994 from HHS Chief of Staff Kevin Thurm to the White House – in particular, Carol Rasco, Director of the Clinton administration Domestic Policy Council. (See Tab D)

Thurm's memo details three issues submitted for decision by the President:

- Whether the President is willing to write a letter to the maker of RU-486, asking that the U.S. patents for the drug be assigned to a non-profit entity in this country [Population Council].

- If the negotiations between Roussel Uclaf and the Population Council fail, and the "only" available option is the "gift offer," is the U.S. Government willing to accept the RU-486 patent rights, and under what conditions?

- If the government is not willing to accept the patent rights, what will be the basis for that decision, and how will it be communicated to the American public?

Thurm develops and discusses each of the factors bearing on the subject in a series of tabs and exhibits to his memo. He provides a history and background tab recounting the Clinton administration's position on RU-486; a tab discussing legal issues;

a brief marketing study addressing timing, administration, and abortion proxies; political considerations; and finally, a discussion of press strategies and concerns.

Thurm explains that on April 26, 1994, the Board of Roussel Uclaf passed a resolution authorizing the assignment of RU-486 patent rights to either the U.S. Government or to a non-profit organization. If the rights were to go to a non-profit organization [Population Council], then Roussel Uclaf demanded a letter from the President of the United States requesting RU-486 on behalf of the women of the United States. President Clinton signed exactly such a letter on May 16, 1994. (See Tab E)

President Clinton's extraordinary letter is direct documentary evidence of his personal intervention as a politician, and clear evidence that the RU-486 patent rights would never have been assigned to the Population Council without his compliance with Roussel Uclaf's demands.

President Clinton's RU-486 request letter to Dr. Edouard Sakiz of Roussel Uclaf claims that it is important for the women of the United States to have "safe and effective medical treatments." Under that rubric, President Clinton writes that he "understands" Roussel Uclaf has been in negotiations with the Population Council. Of course, the Population Council had been serving as a Clinton administration abortion "front" for several months. President Clinton closes his RU-486 request letter by stating: "On behalf of the government of the United States and for the women of America, I thank you for your work."

Thurm's memo specifically addresses the requirements for RU-486 clinical trials and the Population Council's requirements for marketing application for the FDA. The significance of speedy approval and abbreviation of various timelines is a theme throughout his analysis. Not surprisingly, the Clinton administration's radical drive to bring RU-486 to the American market manifested itself in other ways, once the patent rights were obtained by the Population Council. For example, the five standard requirements for certifying a drug "safe and effective" were circumvented to rush RU-486 to market.[xi] Probably the most reckless act by the FDA was the waiver of the normal requirement for random, double-blind, control tests for new drugs. The FDA's expedition in this process was justified with language reserved for drugs developed to cure life-threatening conditions. Certainly, pregnancy is not a disease, nor is it likely to be life threatening – so how could they have twisted the rules so dramatically? What political pressure was brought to bear?

The "political issue discussion" tab to Thurm's memo offers a glimpse into the Clinton administration's abortion politics techniques. The Clinton administration steadfastly continues the manipulation of language that seeks to forever separate the words "kill," "baby" and "abortion." Thurm states: "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 ["pro-choice" and women's groups] groups."

The Clinton administration wanted a quick victory on RU-486 and was deeply concerned that RU-486 might remain a "front burner" issue through the 1996 presidential election. They were particularly sensitive to the prospect of prolonged, intense, public attention and debate on RU-486. Thurm advised political caution concerning unintended consequences, allowing " . . . Republicans and others opposed to the administration to focus attention on this decision and its aftermath."

The Clinton press strategy documents discuss the ramifications of accepting or rejecting the gift of the RU-486 patents. Acceptance of the patent gifts was relegated to Secretary Shalala "on behalf of American women," but specifically as a means of "insulating the White House." While seeking insulation, the press memo stresses the need to credit President Clinton for keeping his campaign promises and giving a major "reproductive rights victory" to American women. The memo also contains a disturbing directive:

> " . . . there should also be a concerted effort on the part of HHS Public affairs team to place stories that outline the hurdles that must be overcome to shield the Administration against fallout from our allies in the event efforts to get RU-486 to the market become stalled in bureaucratic process, in Congress or for other reasons."[xii]

If the Clinton administration's RU-486 strategy failed all together, it appears the press response included a calculated scenario for resorting to lying to the American public. Working through the various scenarios, the author of the memo offers an "alternative":

> " . . . 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."[xiii]

Still worried about potential fallout and damage with abortion proponents and allied political groups, the press memo ends stating:

> "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."[xiv]

Beyond the Clinton Files -- RU-486 in 2006

As Judicial Watch reviewed the Clinton RU-486 files, documenting the extraordinary lengths the administration went to rush the abortion drug to U.S. markets, the earliest correspondence on file at the Archives caught our attention and, in hindsight, provided some perspective for examining RU-486 matters in 2006. (See Tab F)

The file contained a handwritten letterhead note from Betsey Wright, President Clinton's former Chief of Staff, and the White House staff member charged with covering-up "bimbo eruptions." The note reads: "To Carol Rasco. This just got forwarded to me. Please handle. BW 3/9/93." There is an additional notation that reads: "cc for Shalala on Tues. MK," with the name Shalala circled and a line drawn to the words "To handle."[xv]

Betsey Wright's note was attached to a letter dated January 6, 1992, from Ron Weddington, an attorney that served as co-counsel in the infamous *Roe v. Wade* lawsuit. Weddington attached an "open letter" to President-elect Clinton. Weddington's letter recommends that the new president should, " . . . start immediately to eliminate the barely educated, unhealthy and poor segment of the country . . ." and that the " . . . government is going to have to provide vasectomies, tubal ligations and abortions . . . RU-486 and conventional abortions."[xvi]

Weddington states: "Condoms won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars."

The full text of Weddington's letter is a breathtakingly arrogant exegesis on the abortion lobby's culture of death. As disturbing as the Weddington letter is to read, what is more disturbing is the fact that Betsey Wright, one of President Clinton's closest confidantes, tasked Donna Shalala to "handle" it along with the Director of the White House Domestic Policy Council, Carol Rasco. Weddington's ravings were not relegated to a file for unsolicited constituent correspondence. On the contrary, the Weddington letter is, chronologically and philosophically, the foundation document for the Clinton RU-486 files.

Today we are faced with the horrible results of the political and "health care" campaign to put RU-486 on the market. Since RU-486 was approved for use in the United States in September 2000, at least six women have died after taking the abortion drug. Only after the death of 18 year old Holly Patterson, on September 17, 2003, did the media and the FDA begin to pay attention to the dangers of RU-486.

In November 2004, following the third woman's death, the FDA elected to "strengthen the warning notice," a step that may have provided some sort of "informational" or disclaimer insulation for the FDA, but a tactic that certainly did not make RU-486 any safer for women.

Planned Parenthood, which had ignored the FDA's warnings concerning how to administer the drug regimen, played a role in the deaths of four women as the "procedure" provider. The FDA has determined that the four California women who died after taking RU-486 all suffered from a highly lethal bacterial infection -- Clostridium sordellii. The bacterium flourishes in the uterus and then enters the bloodstream, eventually leading to toxic shock.

It is quite likely that more women have died from RU-486 and their deaths have gone unreported because doctors, medical examiners and coroners are not obligated to forward reports dealing with RU-486 side effects to the FDA. This is particularly true in cases where local health officials may not associate a death with an RU-486 abortion, especially if the woman's death occurs several days or even weeks later.

Even abortion providers now have low regard for the safety of RU-486. Dr. Warren Hern, an abortionist in Denver, Colorado has stated: "I think surgery should be the procedure of choice." Pills, he said, "are a lousy way to perform an abortion." He is not alone. Dr. Damon Stutes, an abortionist from Reno, Nevada reluctantly agrees with Pro-Life critics of RU-486, stating, "the truth is the truth," and that, "The complications from RU-486 far exceed the complications of surgical abortion." [xvii]

It seems that the federal government has finally come to grips with the growing number of deaths attributed to the use of RU-486 and is prepared to take some action, however late. The government will convene a scientific conference at the Center for Disease Control in Atlanta, Georgia on May 11, 2006. More than two dozen scientists and doctors will make presentations concerning the deadly bacterial infections that killed the California women mentioned above.

Conclusion

Judicial Watch hopes that this special report on the Clinton RU-486 files has provided the reader with sufficient documentary evidence from primary sources to illuminate the Clinton administration's rush to achieve part of its abortion agenda through bringing RU-486 to America. Armed with the long-delayed facts from Clinton insider memoranda, the reader is now equipped to evaluate policy and hold public officials accountable.

On September 28, 2000, the day RU-486 was approved for U.S. markets, the FDA Commissioner, Dr. Jane E. Henney, said in an interview, "Politics had no role in this

decision."[xviii] The public now has copies of the the Clinton RU-486 files that unequivocally say otherwise.

Endnotes

[i] See Tab E: Letter from President William J. Clinton to Dr. Edouard Sakiz, Chaiman of Roussel Uclaf, dated May 16, 1994.

[ii] See: http://clinton5.nara.gov/media/pdf/eightyears.pdf

[iii] Hoechst had a historical reason for wanting to keep a low profile concerning RU-486. Hoechst was part of a cartel connected to the infamous I.G. Farben Chemical Company, the makers of Zyklon-B -- the cyanide gas used in Nazi death camps. In 1999, Hoechst merged with another European pharmaceutical company to form Aventis.

[iv] Copies of the Roussel Uclaf – Population Council contract were not available from the Archives.

[v] See: http://www.popcouncil.org/about/index.html

[vi] See: http://www.popcouncil.org/mediacenter/PC_Key_Facts.html

[vii] See Tab C: FDA Commissioner Kessler's Memorandum to HHS Secretary Shalala, dated September 30, 1993.

[viii] See Tab B: HHS Secretary Shalala's Confidential Memorandum to White House Director of Domestic Policy Carol Rasco, dated November 15, 1993.

[ix] See Tab C, pages 4-5.

[x] Felix Rohatyn is a Wall Street investment banker and served as President Clinton's Ambassador to France from 1997 to 2000.

[xi] Donna J. Harrison, M.D., "Dangerous Medicine," *The New York Times*, November 19, 2004.

[xii] See Tab D: HHS Chief of Staff Kevin Thurm's Memorandum to White House Director of Domestic Policy Carol Rasco, Subject: RU-486, dated May 11, 1994; Tab 5: Press Strategies and Concerns.

[xiii] *Ibid.*

[xiv] *Ibid.*

[xv] See Tab F: Clinton Transition Team Director of Public Outreach Betsey Wright's correspondence file Re: RU-486 from Mr. Ron Weddington, dated 3/9/93.

[xvi] *Ibid.*

[xvii] Gardiner Harris, "Some Doctors Voice Worry Over Abortion Pill's Safety," *The New York Times*, April 1, 2006.

[xviii] Gina Kolata, "U.S. Approves Abortion Pill; Drug Offers More Privacy, and Could Reshape Debate, *The New York Times*, September 29, 2000.

Tab A

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

Tab B

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 15 1993

~~CONFIDENTIAL~~

file

MEMORANDUM FOR CAROL RASCO

The purposes of this memorandum are: (1) to inform you of the Department's progress in implementing the President's directive of January 22, 1993, 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 antiprogestins;" and (2) to outline the necessary next steps to accomplish the President's directive.

Background: You may recall that RU-486 is manufactured by the French firm Roussel Uclaf and is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG, a German firm. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States.

Both Dr. Kessler and I have taken steps to persuade Roussel Uclaf and Hoechst to change their position. In February Dr. Kessler met with Dr. Edouard Sakiz, the President of Roussel Uclaf, to discuss the availability of RU-486 in the United States for research and marketing. In March I wrote to Professor Wolfgang Hilger, President of the Board of Hoechst, to ask him to permit Roussel Uclaf to begin any necessary testing of RU-486 in the United States in preparation for filing a new drug application with the FDA. Later in March there were press reports that Roussel Uclaf would respond to the requests of the Clinton Administration to make RU-486 available in this country and that testing of the drug would begin approximately two months later (i.e., in May).

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council, a non-profit corporation that conducts research on reproductive health issues. The meeting's purpose was to facilitate an agreement between those parties to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because of an existing contract between these two parties that required Roussel Uclaf to give the Population Council sufficient amounts of the drug for the Population Council to conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf were unwilling to sell the drug in the United States.

At the April meeting, Dr. Edouard Sakiz, President of Roussel Uclaf, raised the issue of federal legislation to indemnify

Roussel Uclaf from any damages it might incur by permitting RU-486 to be marketed in the United States. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and delivered a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of other Roussel Uclaf or Hoechst products, or bombings of Roussel Uclaf/Hoechst facilities by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 to be marketed in the United States, it should compensate Roussel Uclaf for any damages that the company might suffer from complying with the United States Government's request.

Dr. Sakiz was clearly informed at the April meeting that such legislation would never be enacted and that the FDA would not support Roussel Uclaf in seeking it.

Despite being told that there was no possibility of obtaining federal legislation to protect Roussel Uclaf from consequential damages or product liability suits, Dr. Sakiz committed Roussel Uclaf to negotiate with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit a new drug application (NDA) to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population Council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. A tentative goal of September 15 was established for concluding the contract negotiations. As of late July 1993, the Population Council thought that the negotiations were proceeding smoothly, though slowly.

CURRENT STATUS

On August 2, 1993, the Population Council's lawyer notified FDA that **Roussel Uclaf had recently reasserted its demand for protective federal legislation.** Roussel Uclaf insisted that the Population Council obtain a commitment from the United States Government that: 1) legislation would be enacted making it a crime for any person to hurt or harass any doctor administering RU-486, their patients, or the drug's manufacturers, distributors, and salespersons; 2) the Department of Justice publicly commit to enforce this law, if enacted; 3) legislation would be enacted indemnifying Roussel Uclaf for any product liability exposure resulting from the use of RU-486 in this country, or, as an alternative, a prohibition of any product liability actions against Roussel Uclaf for RU-486; 4) as part of any legislation, indemnification for consequential damages.

In exchange Roussel Uclaf would give the Population Council a royalty-free license because it has decided to forego any profit from entering the United States market. **In short, Roussel Uclaf's position is that it should not incur any liability exposure as a result of making RU-486 available in this country** as an abortifacient because it does not anticipate any profit from selling RU-486 for that use in the United States and is entering the American market only at the request of the United States Government. Roussel Uclaf remains willing to exploit its patent for non-abortifacient uses of RU-486, should any other use be found to be safe and effective.

FDA advised the Population Council's lawyer that it could not make a commitment to seek such legislation and that its enactment was extremely unlikely, both for political reasons and because the United States had never agreed to indemnify any drug manufacturer, with the exception of the swine flu precedent. The FDA also communicated that seeking such protection for a drug company far exceeded FDA's appropriate role, but that the agency would discuss the situation with the Department.

In mid-September Roussel Uclaf hired legal counsel, Swidler and Berlin, to lobby the federal government at levels above FDA to obtain the legislation described above. On October 5, Kevin Thurm, the Department's Chief of Staff, and Harriet Rabb, the Department's General Counsel, met with lawyers from Swidler and Berlin to discuss the situation. The Department initiated the meeting to assess how the United States Government might facilitate successful completion of the negotiations between Roussel Uclaf and the Population Council. At that meeting, the company reiterated its concerns about obtaining indemnification for potential losses and was again told emphatically that the Department would not support its efforts to obtain federal legislation. Roussel Uclaf's lawyer then suggested that the

United States could exercise its statutory powers of eminent domain and take over the patent for RU-486 insofar as it covers abortifacient uses of the drug.

The Population Council appears to be attempting to meet those demands of Roussel Uclaf that do not require the enactment of federal legislation. We have been advised by the Population Council that they sent a proposed licensing agreement to Roussel Uclaf on October 11, although we do not know whether Roussel Uclaf and Hoechst will find this proposal acceptable. In addition, the Population Council's President recently met with the President of Roussel Uclaf, and is planning to send a delegation to Germany during the first few weeks of November in the hope that if Hoechst understands that the Population Council is a serious, credible organization, Hoechst will withdraw its objections and permit Roussel Uclaf to enter into an agreement with the Population Council. Despite these moderately positive developments, we do not think that the negotiations will be successfully concluded without pressure on Roussel Uclaf/Hoechst.

Moreover, we have learned that Hoechst is interested in using an American venture capitalist group as a partner for the Population Council; this group is thought to be able to secure funds sufficient to indemnify Hoechst at the level it desires. However, it is our understanding that the Population Council appears unwilling to work with this group. This issue has further complicated the negotiations.

AVAILABLE OPTIONS TO MOVE FORWARD NEGOTIATIONS

The negotiations between Roussel Uclaf and the Population Council have not been successfully concluded because of the insistence of Roussel Uclaf and Hoechst that they be protected from all economic harm if they permit RU-486 to be marketed in this country. There are two options for moving forward the stalled negotiations:

One option is to enlist the aid of Felix Rohatyn, or someone of comparable stature, to negotiate with Roussel Uclaf and Hoechst on behalf of the United States Government. The negotiations require a person with extensive experience in the international business community, especially France and Germany. In addition the person must understand the pharmaceutical industry and have the standing to participate in high-level discussions that might involve appropriate ambassadors, as well as the Health Ministers in France and Germany.

A second option is for the United States to exercise its statutory powers of eminent domain and take over the patent for RU-486, insofar as it covers the abortifacient use of the drug. The Government could then contract with a company to manufacture

and distribute the drug. As noted above, this option was suggested by Roussel Uclaf's lawyers in their October 5 meeting with the Department's Chief of Staff and is clearly the company's preferred approach. While the United States government has the legal authority to take over the patent, such an approach is rare and in this case is politically complex. Although legal, there are particular concerns about the political viability of this approach and the willingness of Congress to permit such an action to stand. We note that Roussel Uclaf did not demand that the governments of France, England, or Sweden take such steps.

NEXT STEPS

Unless you object, the Department plans to engage the services of Felix Rohatyn or someone comparable as a negotiator. This negotiator would require the State Department's support in making appropriate diplomatic contacts, both with the United States Ambassadors to France and Germany, the French and German Ambassadors to this country, and other high-level officials in France and Germany, such as the respective Health Ministers. The purpose of such contacts would be to assess the situation and determine what measures the United States could take to persuade Roussel Uclaf and Hoechst to make RU-486 available in the United States. The French and German governments might be displeased to learn that their companies are not accommodating a request made by the United States Government. In addition, a negotiator of Felix Rohatyn's caliber might identify means other than federal legislation to satisfy Roussel Uclaf's and Hoechst's concerns.

In order for the negotiator to succeed, the Department and the Administration must be unequivocal in the position that taking over the patent for RU-486 is not an option. To avoid any ambiguity on this point, the negotiator should have a letter signed by the Secretary of Health and Human Services making clear on behalf of herself and the Administration that the United States government will not take over the patent. In addition the letter should request on behalf of the Administration that Hoechst and Roussel Uclaf conclude negotiations for the entry of RU-486 onto the U.S. market expeditiously. Roussel Uclaf will have every incentive to delay the negotiations if it thinks that the United States will ultimately take over the patent. It is the Department's position that this option should be unambiguously rejected, not only because it is controversial, but because its continued existence will make it impossible for the negotiator to obtain any other agreement.

Donna E. Shalala

Tab C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 30, 1993

NOTE TO: The Secretary

FROM: The Commissioner of Food and Drugs

SUBJECT: RU-486

On January 22, 1993, President Clinton issued a memorandum directing you to assess initiatives to promote the testing, licensing, and manufacturing in the United States of RU-486 (mifepristone).[1] The Agency has had ongoing dialogue with Roussel Uclaf to get a marketing application submitted to FDA for the drug. Both you and the FDA are on record as stating that if RU-486 is a safe and effective alternative to surgical abortion, then women in the U.S. should have access to that drug. The President also directed you to reassess whether RU-486 qualifies for importation under FDA's personal use importation policy.[2]

I. Current Marketing of the Drug

RU-486 is manufactured by the French firm Roussel Uclaf and it is approved to induce abortions in France, the United Kingdom, and Sweden. Roussel Uclaf has stated that it can act in the United States only with the approval of its parent company, Hoechst AG. Hoechst has historically refused to permit Roussel Uclaf to seek marketing approval for RU-486 as an abortifacient in the United States. Both you and I have asked Hoechst to permit Roussel Uclaf to file a new drug application (NDA) for the drug. Hoechst remains adamant in its refusal. While some members of Congress have written to Hoechst urging the company to

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[1] Although there are several investigational new drug applications (INDs) on file with FDA for RU-486 for other uses, including Cushing's syndrome, diabetes, meningioma, and breast cancer, Roussel Uclaf will not pursue marketing applications for these indications until the abortion issue is resolved. FDA representatives have met with representatives from the National Institutes of Health (NIH) to discuss initiatives to promote the testing in the United States of RU-486 and other antiprogestins. NIH is limited in what it can do by the restrictions placed on its appropriation by the Hyde Amendment.

[2] In accordance with the President's January 22 memorandum, FDA has reassessed whether RU-486 might qualify for importation under FDA's personal use importation policy and whether the import alert should be rescinded. There are significant public health implications associated with rescinding the import alert, especially related to whether the drug could be safely used under these circumstances; the availability of counterfeit RU-486 on the world market for which the Agency cannot attest to purity, quality, or safety; and the fact that Roussel Uclaf's RU-486 is so tightly controlled as to be unavailable for personal importation even if the import alert were to be rescinded. The Agency submitted its recommendation on this issue to PHS on July 14, 1993. Because the import alert has been challenged by a woman who attempted to bring a small quantity of RU-486 into the country, the Agency is working with the Department on an appropriate response to this ongoing litigation.

submit a marketing application for RU-486, other Congressional members have written to Hoechst expressing their strong opposition to the marketing of RU-486 in this country. This, and the well-publicized activities of anti-abortion groups, have provided Hoechst and Roussel Uclaf with evidence that the U.S. population lacks cohesiveness on this issue and that the abortion debate continues.

II. Summary of Discussions with Roussel Uclaf Regarding Testing of the Drug

In April 1993, FDA arranged a meeting between Roussel Uclaf and the Population Council to attempt to get those parties to agree to work together to test RU-486 and file a new drug application for the drug. The Population Council was identified as the most likely group to work with Roussel Uclaf because the Population Council had a contract with Roussel Uclaf which required Roussel Uclaf to give the Population Council sufficient amounts of the drug so that the Population Council could conduct clinical trials. The contract also appeared to require Roussel Uclaf to license the drug to the Population Council if Roussel Uclaf was unwilling to sell the drug in the United States. A copy of that contract, which must remain confidential, is attached.

At the April meeting, Dr. Edouard Sakiz, president of Roussel Uclaf, raised the issue of federal legislation to indemnify Roussel Uclaf from any damages it might suffer from permitting RU-486 to go onto the United States market. Dr. Sakiz was worried about product liability actions against Roussel Uclaf if a woman had an incomplete abortion and a deformed fetus. Dr. Sakiz was also concerned about consequential damages, such as the economic costs from boycotts of Roussel Uclaf (or Hoechst) products, bombings of Roussel Uclaf/Hoechst facilities, etc. by right-to-life groups. Dr. Sakiz's view was that if the United States Government wanted RU-486 on the U.S. market, then the United States Government should make Roussel Uclaf whole for any damages Roussel Uclaf might suffer because it had agreed to the United States Government's request.

Dr. Sakiz was told quite clearly at the April meeting that such legislation would never be enacted and the FDA would not support Roussel Uclaf in its advancement of that idea.

Despite being told that there was no possibility of obtaining favorable legislation, Dr. Sakiz committed Roussel Uclaf to go forward with the Population Council to bring RU-486 onto the United States market. Specifically, at the April meeting Roussel Uclaf and the Population Council agreed:

- That Roussel Uclaf would license RU-486 to the Population Council, which would conduct a clinical trial involving 2000 women pursuant to an investigational new drug (IND) application;

- That the Population Council would ultimately submit an NDA to FDA, based on the results of the clinical trial and on other studies that have been conducted by Roussel Uclaf; and

- That the Population council, with the concurrence of Roussel Uclaf, would choose a new manufacturer for the drug, and that Roussel Uclaf would transfer its technology for making the drug to that manufacturer, because Roussel Uclaf does not want to manufacture the drug for sale in this country.

It was then left for the Population Council and Roussel Uclaf to revise the terms of their contract, while Roussel Uclaf began sending scientific information to FDA and the Population Council. The contract negotiations continued from sometime after the April meeting until recently. As of late July 1993, the Population Council thought the contract negotiations were proceeding smoothly, though slowly. In those negotiations the Population Council was represented by Jim Boynton of Christy and Viener and Roussel Uclaf was represented by Joe Orsini, its corporate council in Paris.

On August 2, 1993, Jim Boynton, the Population Council's lawyer, notified FDA that Roussel Uclaf had recently demanded that the Population Council obtain a commitment from the U.S. Government that the U.S. would enact legislation that would protect all persons who had anything to do with RU-486. This was described as similar to "right-to-access" legislation that would make it a crime for any person to hurt or harass any doctor administering RU-486, their patients, and the manufacturers, distributors, and salespersons for the drug. Roussel Uclaf also demanded that the Department of Justice promise to expend its resources to enforce this law, if enacted. Roussel Uclaf also asked for legislation that would indemnify Roussel Uclaf against any product liability exposure as a result of the use of RU-486 in this country or, as an alternative, that would ban any product liability actions against Roussel Uclaf for RU-486. Finally, Roussel Uclaf asked for legislation that would indemnify Roussel Uclaf against consequential damages. Roussel Uclaf's principal assertion is that it is willing to give the Population Council a royalty-free license, because it has decided (given a push by Hoechst), that it will forego any monetary gain from entering the U.S. market. In short, because Roussel Uclaf does not expect to make any money off of RU-486 in the U.S. market, and sees itself as permitting RU-486 to enter the U.S. market only because asked to do so by the United States Government, then it should not incur any liability exposure on account of the drug.

FDA advised Mr. Boynton that the FDA could not make a commitment to seek such legislation, pointing out that Congress had recently reenacted the Hyde Amendment and that other than the swine flu situation, the United States had never agreed to indemnify any drug manufacturer. The FDA further explained that it would go far beyond FDA's appropriate role to seek such protection for a drug company. The FDA offered to advance the idea within the Department, but was advised by Mr. Boynton that the answer given was sufficient.

In mid-September, Roussel Uclaf hired legal counsel (allegedly, Lester Hyman and John Hoff of Swindler and Berlin) to lobby the federal government at levels above FDA to obtain legislation protecting the company from potential losses, as described above.

III. Analysis

The FDA's principle objection to Roussel Uclaf's request for indemnification and related relief has been pragmatic--we did not (and do not) think Congress would ever pass such legislation. Having said that, we also think that there are other policy reasons for refusing to seek indemnification of a drug manufacturer, for example:

- It would create an unacceptable precedent for any manufacturer of a significant vaccine or drug to seek indemnification as a condition for bringing the product to market. There is little basis to distinguish RU-486 from a breakthrough AIDS drug or unique vaccine. The swine flu indemnification plan proved very problematic for the United States Government.

- If public health problems were to occur post-approval, the interest of the United States as an indemnifying party would be to disprove that problems had occurred, while FDA's obligation would be to objectively investigate and take appropriate actions to protect the public health. This would be an untenable conflict for the United States Government.

Roussel Uclaf's liability and boycott concerns should not be underestimated. Because Roussel Uclaf is willing to give the Population Council a royalty-free license, it wants to eliminate any potential for expenses due to the drug's introduction into the United States market. Roussel Uclaf has also expressed its willingness to give a royalty-free license to any other major U.S. pharmaceutical company, but has found no company willing to take the license. Roussel Uclaf could, possibly, sell the drug to the Population Council (or to others) but it appears unwilling to do so, perhaps because the drug may have important other therapeutic benefits in the future, and it may want to maintain the right to sell to those markets. However, Hoechst may be willing to simply abandon the patent or give it to the United States.

There are some that suggest that Roussel Uclaf is simply playing a delaying game--waiting until the very staunchly Catholic Hoechst CEO (Prof. Wolfgang Hilger) retires in April 1994--so that then Roussel Uclaf would be free to exploit the drug in the United States and elsewhere for all uses. Others suggest that Roussel Uclaf does not want to reach agreement with the Population Council, but is merely stalling until an international foundation is created by Dr. Etienne Balieu, the inventor of the drug and a former Roussel Uclaf employee, to which Roussel Uclaf could then sell the rights to the drug.

The speculation is fueled by the essentially unanswered question--as to why Roussel Uclaf is willing to manufacture and sell RU-486 to some markets (England, France, and Sweden) but not to others (e.g., the United States). The common thinking is that Hoechst is only willing to permit Roussel Uclaf to sell RU-486 in a country when Hoechst is forced to do so politically, and, therefore, the only way to get RU-486 onto the U.S. market is to exercise political pressure on Roussel Uclaf and on Hoechst.

This thinking appears borne out by the circumstances here--Roussel Uclaf was willing to come to the table (at FDA) when it had received pressure from President Clinton (the January 23, 1993, Executive Order), you (your March 12, 1993, letter to Prof. Hilger at Hoechst), and FDA, but that since that pressure has waned the incentive to come to an agreement has also waned.

Another possibility is that the Population Council is simply attempting to reach an agreement that leaves Roussel Uclaf with too little, and that if the Population Council were willing to settle for less (e.g., the ability to study, but not to market the drug or to indemnify Roussel Uclaf) then a deal could be reached.

IV. Recommendation for Expert Advisor

This situation calls for someone of Felix Rohatyan's caliber for several reasons. At the outset, we must make it clear that the FDA cannot take this issue too far without compromising its role as objective reviewers of the safety and efficacy of the drug. But equally as important is the fact that this is an issue where business and politics intersect quite dramatically. Because of the abortion debate, Roussel Uclaf is left alone to promote its drug. Other major U.S. drug manufacturers have, to date, refused to join forces with Roussel Uclaf--either by agreeing to go forward with their own abortifacient drug products, or by agreeing to be the manufacturer or distributor of RU-486. Therefore, Roussel Uclaf feels isolated (and vulnerable) by the U.S. demands. It will take an experienced person, familiar with the drug industry, to sort out these issues.

Second, there are pragmatic, economic concerns to be faced. Roussel Uclaf's concerns about indemnification are realistic concerns that need to be satisfied. Someone with extensive experience in the business community (in France and Germany as well as in the United States) will have a better understanding of the various ways this concern can be overcome.

Finally, there are diplomatic issues that may need to be addressed. It may be that France and Germany would be unhappy to learn that their companies were not accommodating a request made by the United States Government. The U.S. Ambassadors to France and Germany will

need to be consulted on these issues, and your counterparts in France and Germany may also need to be involved. We think that someone familiar to these circles would advance the Administration's goal to bring a safe and effective abortifacient to the U.S. market.

Mary Pendergast
for David A. Kessler, M.D.

Attachment: Contract

cc: Dr. Philip Lee
Mr. Kevin Thurm

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

Tab D

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 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.

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 & CBO

cc. Dr. KESSLER

35, Boulevard des Invalides 75323 Paris Cedex 07
[illegible]

ROUSSEL UCLAF

DRAFT

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

35, Boulevard des Invalides 75323 Paris Cedex 07

PROJET 09.05.94

ROUSSEL UCLAF
Société anonyme à Directoire et Conseil de Surveillance
au capital de 544.749.300 F.
Siège social : 35, Boulevard des Invalides 75007 PARIS
R.C.S. Paris B 542 000 021

Extrait du Projet de Procès-Verbal
de la séance du Conseil de Surveillance du 4 Mai 1994
à 17 h 30

Présents :

Membres du Conseil de Surveillance :

Dr. E. SAKIZ, Président,
Dr. M. FRUEHAUF, Vice-Président,
MM. F. BOISSON, C. de CROISSET, le Pr. J. DAUSSET, E. ERAMBERT,
le Pr. G. MILHAUD, H. MONOD, E. de ROYERE, le Dr. K.G. SEIFERT.

Sans voix délibérative :

Pr. R.G. APTING, Président du Directoire,
M. G. JACQUINSON, Directeur Général, Membre du Directoire,
M. D. CAMUS, Membre du Directoire,
M. B. WINICKI, Membre du Directoire.

M. J.F. CHAVANCE et Mme D. PIERRON, Délégués du Comité Central d'Entreprise.

M. F. DESCOURS, Secrétaire du Conseil.

Absents excusés :

M. le Dr. G. METZ, Membre du Conseil de Surveillance,
M. J. MISCHE, Membre du Conseil de Surveillance.
MM. F. BRECHARD et D. GAILLET, Délégués du Comité Central d'Entreprise.

.....

.../...

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]

Tab E

THE WHITE HOUSE

WASHINGTON

May 16, 1994

Dr. Edouard Sakiz
Chairman, Supervisory Board
Roussel Uclaf
35, boulevard des Invalides
75323 Paris Cedex 07
FRANCE

file

Dear Dr. Sakiz:

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.

I understand that since at least that time, your company has been in negotiations with The Population Council, Inc., a nonprofit organization with whom you have had dealings on mifepristone since early in the last decade. Those discussions, I understand, have been directed toward the purpose on which I charged the Secretary. I am grateful for the effort those negotiations represent.

In order to permit the appropriate testing, development, and distribution of your product, I urge, at the conclusion of your negotiations, that you bring your plans to fruition. I understand that your company will assign without remuneration your United States patent rights on mifepristone to The Population Council, Inc. which has been studying this product since 1982 and which would take all necessary steps to file a new drug application with the Food and Drug Administration, so that the agency can determine whether the drug is safe and effective for use in the United States.

On behalf of the government of the United States and for the women in America, I thank you for your work.

Sincerely,

Bill Clinton

Tab F

BETSEY WRIGHT

cc for Shalala on Tues

To Randa

TO Carol Rasco

This just got forwarded to me please handle

BW 3/9/93

Jeffrey M. Friedman
James R. (Ron) Weddington

Shari L. Nichols
Kirk W. Tate

F&W

Friedman & Weddington, Attorneys, L.L.P.

502 W. 13th Street
Austin, Texas 78701
(512) 477-9641
Fax: (512) 320-8312

file

January 6, 1992

Betsey Wright
Director for Public Outreach
Transition Team
P. O. Box 615
Little Rock, AR 72203

Dear Betsey,

Enclosed is a "letter" to your boss, which I am going to try to get published. If I am unsuccessful; I may try to raise the money to print it as an ad in The N. Y. Times and other places.

Sarah and I have been discussing the notion of our setting up a non-profit corporation to license and distribute R U 486. Being non-profit would eliminate the need for products liability insurance, which is a major hang-up for a company thinking about marketing a new drug.

It's possible that such an endeavor could be the vehicle for a number of birth control efforts. Something's got to be done very quickly. 26 million food stamp recipients is more than the economy can stand.

Congratulations on your work for Clinton. It's good to see a UTYD doing good. I hope the new President can find the time to deal with the issues I raise in my letter. Please give it to him if you get a chance.

Sincerely,

Ron

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Dear President-To-Be Clinton,

Some years ago another Southern Governor, when asked about the possibilities for prison reform, supposedly said something to the effect of, "Well, I don't think we're going to get very far until we get a better class of prisoner."

Well, I don't think you are going to get very far in reforming the country until we have a better educated, healthier, wealthier population.

Face it, you know that anything that even resembles the programs of Democratic Presidents in the past is going to make you a one term President. Reagan spent all our money on bombs and even if there were money for programs such as pre-natal health care, job training and day care centers it would be years before we would see any dramatic results. And, as anyone who follows education can see, more money doesn't necessarily translate into better educated kids.

But you can start immediately to eliminate the barely educated, unhealthy and poor segment of our country. No, I'm not advocating some sort of mass extinction of these unfortunate people. Crime, drugs and disease are already doing that. The problem is that their numbers are not only replaced but increased by the birth of millions of babies to people who can't afford to have babies.

There, I've said it. It's what we all know is true, but we only whisper it, because as liberals who believe in individual rights, we view any program which might treat the disadvantaged differently as discriminatory, mean-spirited and...well...so Republican.

In 1989, 27 percent of all births were to unmarried mothers, a huge percentage of whom were teenagers. If current trends continue, soon a majority of the babies born will be born into poverty and one half of the country cannot support the other half, no matter how good our intentions.

I am not proposing that you send federal agents armed with Depo-Provera dart guns to the ghetto. You should use persuasion rather than coercion. You and Hillary are a perfect example. Could either of you have gone to law school and achieved anything close to what you have if you had three or four or more children before you were 20? No! You waited until you were established and in your 30's to have one child. That is what sensible people do. For every Jesse Jackson who has fought his way out of the poverty of a large family there are millions mired in poverty, drugs and crime.

If Ronald Reagan could use the media to convince the American public that a trillion dollars of borrowed money needed to be spent to combat the "Evil Empire," then you ought to be able to persuade people to only have children when they are able to afford them. Point out that only people like George Bush who inherit money can pay for more than one or two kids in today's economy. (And even then, some of the kids grow up to do embarassing things like loot savings and loans.)

You made a good start when you appointed Dr. Elders, but she will need a lot of help. You will have to enlist the aid of sports and entertainment stars to counteract the propaganda spread by church officials seeking parishioners, generals seeking cannon fodder and businessmen seeking cheap labor that, throughout the ages, has convinced the poor that children are necessary to fulfillment as a person.

It wouldn't hurt to point out that while only 11.1 percent of three person families are below the poverty level, 20.2 percent of six person families and 28.6 percent of families of seven or more are poor. (1992 Statistical Abstract of the United States, p. 459)

And, having convinced the poor that they can't get out of poverty when they have all those extra mouths to feed, you will have to provide the means to prevent the extra mouths, because abstinence doesn't work. The religious right has had 12 years to preach their message. It's time to officially recognize that people are going to have sex and what we need to do as a nation is prevent as much disease and as many poor babies as possible.

Condoms alone won't do it. Depo-Provera, Norplant and the new birth control injection being developed in India are not a complete answer, although the savings that could be effected by widespread government distribution and encouragement of birth control would amount to billions of dollars.

No, government is also going to have to provide vasectomies, tubal ligations and abortions...RU 486 and conventional abortions. Even if we make birth control as ubiquitous as sneakers and junk food, there will still be unplanned pregnancies. There have been about 30 million abortions in this country since Roe v. Wade. Think of all the poverty, crime and misery ...and then add 30 million unwanted babies to the scenario. We lost a lot of ground during the Reagan-Bush religious orgy. We don't have a lot of time left.

You could do it, Mr. President-To-Be. You are articulate and you've already alienated the religious right with your positions on abortion and homosexuals. The middle-class taxpayer will go along with this plan because it will mean fewer dollars for welfare. The retirees will also go along because because poor people contribute very little to Social Security.

And the poor? Well, maybe if we didn't have to spend so much on problems like low birth weight babies and trying to educate children who come to school hungry, we might have some money to help lift the ones already born, out of their plight.

The biblical exhortation to "Be fruitful and multiply," was directed toward a small tribe, surrounded by enemies. We are long past that. Our survival depends upon our developing a population where everyone contributes. We don't need more cannon fodder. We don't need more parishioners. We don't need more cheap labor. We don't need more poor babies

Very truly yours,

Ron Weddington

P.S. I was co-counsel in Roe V. Wade, have sired zero children and one fetus, the abortion of which was recently recounted by my ex-wife in her book, A Question Of Choice. (Grosset/Putnam, 1992) I had a vasectomy in 1969 and have never had one moment of regret.