# Tab B

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

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**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

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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.

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**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

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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

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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