THE WHITE HOUSE

WASHINGTON

September 29, 2000

MEMORANDUM FOR HILLARY RODHAM CLINTON

FROM: **HEATHER HOWARD** HLT

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

SUBJECT: **RU-486**

Attached please find guidance from the FDA and HHS on yesterday's RU-486 (mifepristone) decision. You asked whether the restrictions imposed by the FDA were comparable to those women face in Europe. Although the restrictions vary by country and health care system, I am told by advocates that they are comparable. For example, like the FDA plan, many countries require three visits to the physician's office.

Medicaid Coverage

Medicaid coverage of mifepristone should be similar to Medicaid coverage of surgical abortions. Thus, in the 16 states that cover abortion with their own state Medicaid funds (California, Connecticut, Hawaii, Idaho, Illinois, Maryland, Massachusetts, Minnesota, Montana, New Jersey, New Mexico, New York, Oregon, Vermont, Washington, and West Virginia), mifepristone should be covered, but in the other states, Medicaid would only cover under Hyde amendment situations: in case of rape or incest or life endangerment. HHS is currently in the process of determining whether to classify mifepristone a physician service or a drug.

Legal and Legislative Responses to the Decision

Opponents of mifepristone will respond in two ways to the decision. First, they have suggested they will sue the FDA, arguing that the approval process was flawed and political. If there is a more sympathetic FDA commissioner, they may also wait until women have been using the drug and sue on behalf of women who claim they were injured by it, and ask the FDA to reconsider the safety and efficacy.

Second, opponents are already contemplating a legislative response. Rep. Tom Coburn, who for the last three years has led the unsuccessful fight to prevent the FDA from approving mifepristone through Agriculture Appropriations riders, is planning to introduce legislation that would sharply curtail access to the drug. His proposed legislation would impose the following "patient protections:"

1) Only licensed physicians could distribute mifepristone. (Under the FDA plan, mid-level providers such as nurse-practitioners could dispense mifepristone under physician supervision, as allowed by state law.)

2) The physician must be trained and authorized by law to provide surgical abortions. This is clearly intended to limit the pool of providers.
3) The physician must be certified to provide ultrasound. Again, this would limit the pool of possible providers.
4) Distributing physicians must be certified to provide mifepristone through a curriculum approved by the FDA. This would require physicians to go through an FDA training program– creating hurdles for doctors and probably discouraging them from providing mifepristone.

Rep. Coburn, who is retiring this year, may try to attach these restrictions to an appropriations bill before the end of the session. The Republican leadership may prevent him, however, in order to keep the appropriations bills moving.