NLWJC - Kagan

DPC - Box 001 - Folder 017

Abortion - RU - 486

Abortion - RU486

To: Elena

From: Cynthia Dailard

Date: October 1, 1998

Re: RU-486

Purpose

This memo describes where RU-486 is in the FDA approval process, explains the legislative status of the Agriculture Appropriations bill and the Coburn amendment preventing the approval of RU-486, and describes the implications of this amendment both within and beyond the abortion context.

Pharmaceutical Status

RU-486 (or mifepristone) is an effective non-surgical method of early abortion (often referred to as a "medical abortion") that has been in use in other countries since 1981. It is an antiprogesterone, one of a family of drugs that block the action of progesterone, a hormone needed to maintain pregnancy. The drug is administered within the first seven weeks following conception, and is followed three days later by misoprostol, a prostaglandin which causes uterine contractions.

RU-486 was approved for use in France, Great Britain, and Sweden following extensive clinical trials that demonstrated its safety and effectiveness. During the Bush Administration, the FDA issued an "import alert" which helped ensure that RU-486 would not be available in the United States for any purpose. A United States District Court that examined the "import alert" concluded, "[T]he decision to ban the drug was based not from any bona fide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."

When President Clinton took office in January 1993, he signed an Executive Order directing HHS to assess initiatives to promote the testing and licensing of RU-486. As the result of the Administration's efforts following this directive, the French drug company, Roussel Uclaf, donated the US patent rights to RU-486 to a non-profit research organization, the Population Council. The Council announced that it would conduct clinical trials in 17 sites across the country, and would work to locate a manufacturer to produce and distribute the product.

Population Council has completed its clinical trials, which show that RU-486 is 95% effective in terminating pregnancy. Women taking the drugs need to see a doctor three times. Its side effects can include painful uterine contractions, nausea, vomiting, diarrhea and headaches. A small number of the women in the trials had to be hospitalized or given transfusions because of bleeding, and 1.5% of participants in the US trial required a surgical abortion.

In 1996, shortly after the Population Council submitted its clinical trial data to the FDA, the Agency declared that clinical trials revealed the drug to be safe and effective for terminating an early pregnancy, when used under close medical supervision in combination with misoprostol. At that time, it issued an "approvable letter" for the use of mifepristone and misoprostol for early abortion, but said that it would withhold final approval until it received more information about the drug's manufacture and labeling. The Population Council has indicated that it has located a pharmaceutical company willing to manufacturer the drug, which could become available on the market sometime next year.

Legislative Status

Representative Coburn successfully offered an amendment to the House Agriculture Appropriations bill that would prohibit the expenditure of FDA funds for the testing, development, or approval of any drug for the "chemical" inducement of abortion. "Approval" was defined to include the approval of production, manufacturing or distribution. The Senate bill did not contain a similar provision.

The Coburn amendment and disaster relief are currently the only outstanding issues in conference. The Senate conferees voted 8-5 against receding to the House language on RU-486 (all the Democrats voted with us, as did Specter and Gorton. Chairman Stevens initially voted with us, which would have made the vote 9-4, but then switched his vote when he realized that it was not needed to prevent the language from being accepted by the Senate.)

If the House and Senate conferees continue to remain in disagreement, they could decide to approve the conference report with the RU-486 language "in disagreement", meaning that the conference report would return to both chambers, requiring an up or down vote on the Coburn amendment. The conference report would first go to the House, which would certainly approve the Coburn language once again. Then it would go to the Senate, which would probably (but not certainly) vote against the amendment. However, Lott is adamant about preventing the conference report from returning to the Senate, because procedural rules would allow the report to be opened up for any reason, and we could expect Daschle or Harkin to offer an amendment adding $7.5 billion for disaster relief. For this reason, Lott wants the issue to be resolved in conference.

Implications of the Coburn Amendment

This amendment has several far reaching implications both within and beyond the abortion context. First, this amendment represents the first time that Congress has attempted to override the FDA's authority in approving a drug. Americans rely on the FDA to appropriately evaluate drugs for safety and efficacy based on sound scientific principles. In attempting to legislate against RU-486's approval, Congress threatens the integrity of the FDA and its routine approval process.

Second, this amendment would deny women a major medical breakthrough which provides a safe non-invasive alternative to surgical abortion. Unlike a surgical abortion, RU-486 would be available in the privacy of a doctor's office -- rather than a clinic that may be subject to violence or protests -- and will be far more accessible to women who do not have abortion clinics conveniently located within their county or state. The amendment would also ban the approval of another promising drug named mexotrexate which is currently being testing in clinical trials for pregnancy termination. This drug has already been approved for chemotherapy and is being widely used for that purpose. Clearly, the Coburn amendment would block the FDA from approving its use for medical abortion, including efforts to provide labeling for this use.

Third, the amendment would freeze research on other drugs which could lead to important treatments for a host of diseases benefiting both women and men. For example, researchers believe that RU-486 has potential for use in treating breast cancer, endometriosis, Cushing's Syndrome, AIDS, diabetes, brain tumors and glaucoma. It has the potential to help treat a wide range of conditions related to reproductive health, including uterine fibroids. The amendment could also have dangerous implications for the development of drugs that are used for purposes other than terminating a pregnancy, but which may cause miscarriages. Many drugs, including chemotheraphy and anti-ulcer medications, have the side effect of inducing abortion. While the proponents of the amendment argue that their intent is only to ban those drugs that have the *primary purpose* of causing abortions, the research community believes that the broad scope of the amendment could stifle research in these other important areas.

Abortion - RU486

Jim R. Esquea
07/06/98 06:10:08 PM

Record Type: Record

To: Martha Foley/WHO/EOP
cc: See the distribution list at the bottom of this message
bcc:
Subject: Re: Senate Agriculture Approps SAP

Given your suggestion that we not specifically reference the House provision (Coburn amendment), I have made the Senate SAP draft language more general.

"The Administration would also strongly oppose language that would intervene in the drug safety practices of the Food and Drug Administration (FDA) and place restrictions on scientific research that can protect women's health and offer safe medical choices. We urge the Senate not to include language that would interfere with the FDA's continued use of rigorous testing and the highest scientific standards to protect the public health."

Martha Foley

Martha Foley
07/02/98 09:27:31 PM

Record Type: Record

To: Daniel N. Mendelson/OMB/EOP@EOP
cc: See the distribution list at the bottom of this message
Subject: Re: Senate Agriculture Approps SAP

I would not reference the House provision per se but talk more generically about how we would oppose an amendment related to, etc. etc.

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Charles E. Kieffer/OMB/EOP@EOP
Jennifer L. Klein/OPD/EOP@EOP
Christopher C. Jennings/OPD/EOP@EOP
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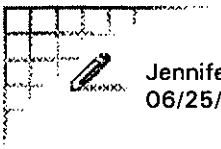
Jim R. Esquea/OMB/EOP@EOP

Message Copied To:

Abortion - RU486



Jennifer L. Klein
06/25/98 01:52:28 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:
Subject: Revised Talking Points on Coburn RU-486 Amendment

It is appalling that Congress would decide to intervene in the drug safety practices of the Food and Drug Administration. For years the FDA has used vigorous testing and the highest of scientific standards to protect public health. This unprecedented Congressional action substitutes political ideology for sound science. It would restrict scientific research that can protect women's lives and offer them safe medical choices. It shows the extremism of those whose real agenda is to deny completely the ability of women to make their own reproductive choices.

Message Sent To:

Elena Kagan/OPD/EOP
Ann F. Lewis/WHO/EOP
Maria Echaveste/WHO/EOP
Martha Foley/WHO/EOP
Joshua Gotbaum/OMB/EOP
Linda Ricci/OMB/EOP
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