United States Senate

BUDGET ENVIRONMENT AND PUBLIC WORKS FOREICN RELATIONS

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June 9, 2000

Jane Henney, Commissioner Food and Drug Administration 5600 Fishers Lane Rockville, Maryland 20857

Dear Dr. Henney:

I am writing to express my grave concerns about the Food and Drug Administration's (FDA) reported proposal to severely restrict the ability of women and doctors to have access to an approved prescription drug, mifepristone (RU-486).

According to news reports, the FDA is considering placing draconian restrictions on the accessibility of RU-486 as a condition of its approval. These barriers include a national registry of all doctors who prescribe the drug; allowing the drug to be prescribed only by doctors trained in surgical abortions; and requiring doctors who want to prescribe the drug to have admitting privileges at a hospital within an hour of their office.

It is my understanding that restrictions like these have been imposed only in rare cases, such as with thalidomide and narcotic pain killers. Furthermore, physicians in France, Great Britain and Sweden – countries that have allowed the use RU-486 for many years – are not required to be surgical abortion providers nor are they required to be ob/gyn specialists in order to prescribe RU-486.

In 1996, the FDA found RU-486 to be safe and effective. Therefore, it is a mystery to me why the FDA would even consider restricting access to it.

cancer, Cushing's disease, AIDS, endometriosis, infertility, and uterine fibroids), compromise the physical safety of women and physicians at reproductive health facilities, and threaten privacy.

I certainly trust that the press reports will prove erroneous. Please contact my health aide, Dana Lewis (224-1966), on this urgent matter.

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