A.F. [redacted] FILE

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Date: May 13, 1993

To: [redacted] Division of Drug Labeling Compliance, HFD-310

From: [redacted] Regulatory Review Officer, Division of Drug Marketing, Advertising, and Communications, HFD-240

Through: /S/ 5/13/93 [redacted] Division of Drug Marketing, Advertising, and Communications, HFD-240

Subject: Flyer Regarding RU486

The enclosed flyer was found in a News Bulletin, a daily newsletter, about convention activities at the Annual Clinical Meeting of the American College of Obstetricians and Gynecologists. This meeting was held in Washington D.C. May 1 - 6, 1993.

One cannot determine how the flyer was placed in the newsletter(s) or if there was any kind of general effort in this regard.

[redacted]

Please contact me if you require any further information.

Thank you for your attention to this matter.

/S/

ATTACHMENT

cc: HFD-240
HFD-~~240~~/ [redacted] 5/13/93 (With attachment)
Concurrence: [redacted] 5/13/93

HFA-224

MFL

MIF 006001

NOW AVAILABLE TO THE WOMEN OF AMERICA

The Abortion Pill RU486 is now available for your use

- **End unwanted pregnancy**
- **No surgery/No emotional stress**
- **The White House and the FDA have invited the French mfg. of RU486 to apply to sell in America**

The first source is Woman's Information Service. WIS (no medical affiliations). WIS will inform you as to the quickest, easiest, most comfortable and least expensive way for you to get to RU486. For privacy, include address of the main Post Office nearest you. Pick up our reply at General Delivery, under your name.

For Fast Response include your phone number. We can only service a limited amount of requests per week, so time is precious, don't waste any, always take care of your health.

WRITE TO WIS:
P.O. Box 500
Hollywood, Florida 33022

WIS IS THE INFORMATION SERVICE TO GET YOU TO RU486
THE FAMOUS ABORTION PILL
Fax: 1-305-963-0025

bml
Drafted: [redacted]:HF-43:5/6/93
Cleared: [redacted]:5/10/93

ROUTING AND TRANSMITTAL SLIP Date 5/5/93

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. [redacted]		
2.		
3.		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate	X	For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

5/6/93 Talked w/ [redacted]; used other channels to obtain the drug; has it — no further action needed.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
[redacted]	Phone No.

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

☆ U.S.G.P.O. 1992 312-070/60006

MIF 006003

HOUSE OF REPRESENTATIVES, U.S.
WASHINGTON, D.C.

March 22, 1993

Kay Hocombe, Acting Associate
Commissioner for Leg. Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

The attached communication is submitted for your consideration, and to ask that the request made therein be complied with, if possible.

If you will advise me of your action in this matter and have the letter returned to me with your reply, I will appreciate it.

RECEIVED
MAR 29 11 02 AM '93
OFFICE OF
LEGISLATIVE AFFAIRS

Very Truly yours,

Jack Brooks/J.E.
M.C.

Ninth Texas District.

#12981

A.F. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 15 1993

The Honorable Jack Brooks
House of Representatives
Washington, D.C. 20515-4309

Dear Mr. Brooks:

This is in response to your inquiry of March 22, 1993, on behalf of _____ concerning the unapproved new drug, RU-486.

The Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to FDA. After a comprehensive review by the FDA the NDA is either approved or not approved; upon approval the drug may be marketed.

We are enclosing a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

Please assure Ms. Webb that all important new drug submissions to FDA are given prompt attention, so that the public can benefit from new products as soon as possible.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-18		4/13/93						

MIF 006005

We hope these comments are helpful. If we can be of any further assistance, please let us know.

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

2 Enclosures
Constituent's letter
New Drug Development in
the United States

cc: HFW-10(2)
F/D: 4/9/93
F/T: 4/12/93
Cong-11007 and No. 12981 \DRUGLTR\NEWRU.MDG)

January 23, 1993

Mr. Jack Brooks
Capital Hill Office
2449 RHOB
Washington, D.C. 20515

Dear Mr. Brooks:

I would like to know how you feel about allowing the controversial drug RU486 into the United States to be tested for FDA approval. I believe that it is ridiculous to ban RU486 from our country when it could possibly save lives just because it can be used to terminate a pregnancy. I am in favor of testing this drug for its safety in treating cancer as well as terminating unwanted pregnancies. I would like to know if you are doing anything about this and if there is anything I can do to allow this drug a chance to be FDA approved.

Sincerely,

/S1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

April 13, 1993

The Honorable Sharon Sayles Belton
President, Minneapolis City Council
350 5th Street South, Room 307
Minneapolis, Minnesota 55415-1383

Dear Ms. Belton:

Thank you for writing to Secretary Shalala expressing your support for the Administration's policy on RU-486 (mifepristone).

Since your February 11 letter, senior representatives of the Food and Drug Administration (FDA) and Roussel-Uclaf, the manufacturer of RU-486, met to discuss clinical and manufacturing data on the drug that FDA would need in considering a new drug application for an abortifacient indication. At that February 24 meeting, FDA received a strong commitment from Roussel-Uclaf to continue to make the drug available for research on other potential uses. In March, the Secretary wrote to the president of Hoechst, the parent company of Roussel-Uclaf, and urged him to eliminate corporate barriers to the introduction of RU-486 into the United States. Recently, Roussel-Uclaf has announced that a clinical trial on RU-486 as an abortifacient may begin in the U.S. in the next few months.

Thus, at present we believe that our efforts, in combination with the President's strong continuing commitment to promote, enhance, and protect reproductive choices for women, will stimulate sufficient research and approval activities on RU-486 to obviate the need for federal legislation.

Thank you again for writing expressing your support for effective reproductive choices for all Americans.

Sincerely yours,

/S/

Senior Advisor to the Commissioner

APPEARS THIS WAY
ON ORIGINAL

9300928

bcc list:
HF-1
HF-20
HF-22
HF-24
HF-28
HF-32
Chron
HF-1
HF-40
HF-40
HF-40

OFFICE OF CITY COUNCIL
350 5TH STREET SOUTH - ROOM 307
MINNEAPOLIS, MINNESOTA 55415-1383

(612) 673-2208

SHARON SAYLES BELTON
COUNCIL MEMBER, EIGHTH WARD

minneapolis
city of lakes

Donna Shalala
Department of Health and Human Services
200 Independence Ave. S.W.
Washington, D.C. 20201

February 11, 1993

I am writing to you to express my support for the Senate Bill S. 222 introduced by Senator Paul Wellstone. S. 222 is a Bill which would require that the FDA collect the same information on the drug RU-486 that is required to be submitted by a manufacturer with a new drug application under the Federal Food, Drug, and Cosmetic Act. RU-486, as you know, is a drug which seems to be a very effective and safe choice to surgical abortions and may have many other potential uses for treatment of diseases.

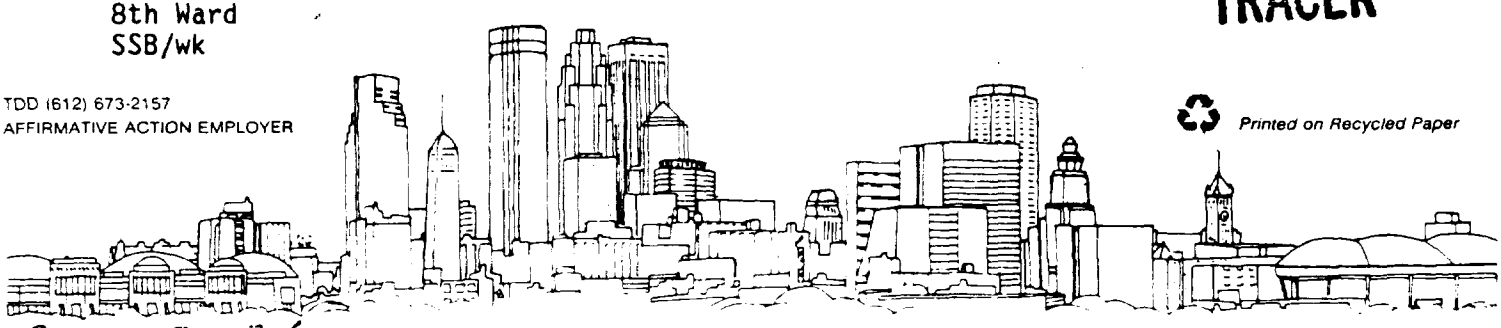
Senator Wellstone believes that a supportive Clinton Administration would encourage the marketing of RU-486 by its manufacturers. The Clinton administration has, thus far, been supportive of a manufacturer application seeking approval to market RU-486; but the manufacturer continues to show reluctance to market the product.

I want to express my support for the Clinton Administration's policy on RU486 and for Senate Bill S. 222. I believe that RU-486 will be a significant addition to the effective family planning choices available to all Americans.

Sincerely,

Sharon Sayles Belton, President
Minneapolis City Council
8th Ward
SSB/wk

T5412
TRACER



9211226.26

Memorandum

March 24, 1993

Ms. Jennifer McCarthy
Director
Office of Agency Liaison
Room 91, OEOB
The White House
Washington, DC 20500

Dear Ms. McCarthy:

Per your instructions, I am enclosing a copy of the response to _____ who requested a single patient-use investigational new drug application for RU-486 to treat her daughter who is suffering from Cushings Disease.

Sincerely,

/S/

_____

Superivsory Policy Monitor

Enclosure

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 24, 1993

FILE

[redacted]

Your letter to President Clinton has been referred to the Food and Drug Administration (FDA) for response. We are sorry to hear that your daughter is suffering from Cushings Disease.

As you may know, the President has directed the Secretary of Health and Human Services to assess initiatives to promote the testing of RU-486 (mifepristone) and other antiprogestins in the United States. FDA is an active participant in this ongoing evaluation. Please be assured that we are prepared to review a marketing application for RU-486, if one is submitted, based on established legal and scientific criteria. On February 24, senior representatives of the FDA and Roussel-Uclaf, the manufacturer of RU-486, met to discuss clinical and manufacturing data on the drug that FDA would need in considering a new drug application for an abortifacient indication. At that meeting, FDA received a strong commitment from Roussel-Uclaf to continue to make the drug available for research on other potential uses, including Cushings Disease.

In order for your daughter to receive RU-486 for Cushings Disease, her physician would need to contact Roussel-Uclaf to receive the company's commitment to supply the drug for her treatment. We understand that the firm requires a brief, written, medical history in order to justify the request. Once your daughter's physician has received this commitment from the company, he or she should contact FDA's Division of Metabolism and Endocrine Drug Products. Generally, FDA may be expected to grant a single patient-use investigational new drug application if the company agrees to supply the drug.

The individual to contact at Roussel-Uclaf is:

André Ullman, M.D., Ph.D.
Head of Clinical Research
Roussel-Uclaf
102, Route de Noisy
93230 Romainville, France
Telephone: 33-1-49914821
Fax: 33-1-49915505

93 01340

MIF 006014

The individuals to contact in FDA's Division of Metabolism and Endocrine Drug Products are:

FDA, HFD-510
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: 301-443-3520
Fax: 301-443-9282

I hope that this information is helpful to you and to your daughter.

Sincerely yours,

/S/

Office of the Executive Secretariat

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. _____ FI

MAR 16 1993

The Honorable Connie Mack
United States Senator
1342 Colonial Boulevard, Suite 27
Fort Myers, Florida 33907

Dear Senator Mack:

This is in response to your inquiry of February 17, 1993, on behalf of _____ regarding RU-486 for his daughter's treatment.

As we stated in our December 30, 1992, letter to you, it is the manufacturer who must agree to supply the drug for her treatment. The Food and Drug Administration cannot compel a manufacturer to provide an experimental drug for any particular patient.

Again, we were very sorry to hear of her illness and regret that we cannot be of more help in this matter.

Sincerely yours,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: _____ :3/11/93
R/T: _____ :3/11/93
F/T: var:3/16/93
re/t:var:3/18/93
(S: _____ \RU-486.IND)
CONG-10703 and NO. 12658

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	3/16/93						

/S/ 3/19

MIF 006016

January 25, 1993

FORT MYERS

FEB 17 1993

Honorable Connie Mack
United States Senator, Florida
Senate Office Building
Washington, D.C. 20510-0904

Dear Senator Mack:

Thank you very much for your assistance in the attempt to obtain the RU-486 medication for my Daughter, _____ who has a meningioma tumor.

Aside from the fact that she has this tumor which is affecting her eyesight since it is in close proximity of her right optic nerve, it is also in or around the right carotid artery and cannot be further surgically removed. She has undergone surgery twice, has had the maximum dose of radiation she can take and cannot take further radiation. The RU-486 is the only other alternative.

She has no Medical Insurance since her husband allowed the insurance to lapse when he lost his business due to the economy. She has three children, no job, no insurance and their home was foreclosed upon.

Since this is my Daughter, I am obviously greatly concerned that she obtain this medication as quickly as possible. The tumor was seen to have commenced growing again in the latest MRI taken.

Again, I want to express my appreciation to you for your assistance in trying to obtain the medication from Roussel-UCLAF, the French Drug Company in Paris, France.

Since I know that there are several individuals in this Country using ~~this~~ drug in the treatment of their tumors, I am determined to continue the attempt to obtain this medication for her. I do know that the FDA has given an IND number to others who are not participating in the controlled study, and that they have obtained the Drug for use in the treatment of their tumors. It is very frustrating for her to talk, personally, to some who are taking the drug for their tumors, and she can't get it.

However, as I said before I will continue to try to obtain this medication, legally if possible.

Very truly yours

/s/

_____

MIF 006017

CONNIE MACK
FLORIDA

United States Senate

WASHINGTON, DC 20510-0904

February 17, 1993

Associate Commissioner Hugh C. Cannon
Food and Drug Administration
Congressional Liaison Office
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Associate Commissioner Cannon:

Enclosed please find correspondence from [redacted]

I would appreciate your advising me of your action in this matter and returning the letter with your reply. Please respond to my Fort Myers Regional Office, located at 1342 Colonial Blvd, Suite 27, Fort Myers, Florida 33907, (813) 275-6252.

Thank you for your prompt attention.

Sincerely,

Connie Mack

Connie Mack
U.S. Senate

CM/ihg
Enclosure

APPEARS THIS WAY
ON ORIGINAL

FF12658

A.F. 4-2-5 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 17 1993

The Honorable Dennis DeConcini
United States Senator
40 North Center, Suite 110
Mesa, Arizona 85201

Dear Senator DeConcini:

This is in response to your inquiry of February 17, 1993, on behalf of [redacted] regarding the availability of RU-486 for the treatment of her breast cancer.

In order for her to be treated with RU-486, her physician should contact the manufacturer, Roussel Uclaf, directly regarding the possibility of receiving a supply of the drug. The address is 35, Blvd, Des Invalides, F-75323 Paris, CEDEX-07 France. If there is an agreement relative to the supply of the drug, her physician should contact [redacted] Division of Oncology and Pulmonary Drug Products at [redacted] to receive guidance on submitting the Investigational New Drug Application.

If we can be of any further assistance, please let us know.

Sincerely yours,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D; [redacted] :3/11/93
F/T: [redacted] :3/12/93

CONG-10690 and NO. 12645
(P: [redacted] DRUGLTRS\RUIND.AVL)

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	3/17/93						

MIF 006019

DENNIS DeCONCINI
ARIZONA

COMMITTEES
APPROPRIATIONS
JUDICIARY
VETERANS' AFFAIRS
INDIAN AFFAIRS
RULES AND ADMINISTRATION
INTELLIGENCE

COMMISSION ON
SECURITY AND COOPERATION
IN EUROPE/CHAIRMAN

PLEASE DIRECT YOUR RESPONSE
TO THE ____ OFFICE

United States Senate

WASHINGTON, DC 20510-0302

WASHINGTON OFFICE
328 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-0302
(202) 224-4521

PHOENIX OFFICE
323 WEST ROOSEVELT, SUITE C-100
PHOENIX, AZ 85003-1366
(602) 379-6756

SOUTHERN ARIZONA OFFICE
2730 EAST BROADWAY, SUITE 160
TUCSON, AZ 85716-5340
(602) 670-6831

EAST VALLEY OFFICE
40 NORTH CENTER STREET, SUITE 110
MESA, AZ 85201
(602) 379-4998

February 17, 1993

U.S. Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir or Madam:

Senator DeConcini has been contacted by his constituent, _____ regarding RU-486 and her why it has not been allowed in this country at this time.

Enclosed, please find a letter from _____ as well as her doctor, _____

It would be greatly appreciated if you would look into this matter and respond to the concerns raised by this constituent.

Thank you for your assistance to Senator DeConcini.

Sincerely,

PAMELA K. NOLAN
Assistant to the Senator
Office of Dennis DeConcini
40 North Center, Suite 110
Mesa, Arizona 85201
(602) 379-4998

PN/g
Enclosure

RECEIVED
FEB 1 48 PM '93
OFFICE OF
LEGISLATIVE AFFAIRS

APPEARS THIS WAY
ON ORIGINAL

FF12645

February 18, 1993

NOTE TO: [redacted]

Attached documents are "heads-up" in the event you are not already aware. We have received at least one inquiry [redacted] copy attached) who believes that the President has issued an Executive Order providing for the personal importation of RU-486. We do not believe that is the case, but rather the inquirer is confused about the President's memo of January 22 (attached).

[redacted]

/s/

for [redacted]

Attachment

APPEARS THIS WAY
ON ORIGINAL

Rec'd - 2/16/93

[redacted]

February 4, 1993

Ms. Jean White
FDA Division of Import Policy
Washington, D.C.

RE: Personal Use Importation of RU 486

Dear Ms. White,

As per our conversations, the purpose this transmittal is for clarification by the FDA as to the exact mechanism required for an individual to import RU 486 for personal use and under the care of a licensed physician.

Currently Import Alert 66-47 forbids importation. The Executive Order recently issued by the President, however, authorizes the personal use importation of RU 486 as an exemption to the Import Alert.

My basic questions concern the mechanisms and documentation required by the individual for the importation.

In the simplest scenario the import procedure of RU 486 should treated be no differently than current import procedures already established for regulating personal importation use of any other medication/drug, administered under the care of a doctor.

The manufacturer receives a request from an individual in the U.S. for a personal use purchase of the medical/drug product made by that manufacturer. Attached to the request is:

(1) A prescription and authorization to administer form signed by the doctor

(2) A signed Declaration form the stating that the medication/drug is:

a. For personal use by the Individual
b. Not for resale
c. Prescribed by a licensed physician

930123

With receipt of the Request the manufacturer will package the product including the prescription and the declaration and mail it to the doctor administering the medication. Given no reason to suspect any illegality, the package will simply go through customs and into the mail for delivery to the doctor.

Since the above basic scenario is the procedure already established between the FDA and U.S. Customs then the fact that the product imported is RU 486 should not deter the basic simplicity of the process as set forth above.

Given the approval by the FDA of the above procedure, I believe that thousands of requests for importation as set forth above will be made within the next few weeks.

Do we need a test importation by an individual? It is done.

Are there other procedures or other documentation to be required by you (i.e. the doctor needing to register qualification with you or sending documentation of the results back to you)? It can be arranged.

Please fax me your comments at the earliest.

Presidential Documents

Memorandum of January 22, 1993

Importation of RU–486

Memorandum for the Secretary of Health and Human Services

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

THE WHITE HOUSE,
Washington, January 22, 1993.

[FR Doc. 93–2975 —
Filed 2–3–93; 1:20 pm]
Billing code 3195–01–M

Editorial note: The Secretary of Health and Human Services is publishing a document relating to this memorandum in Part V of this issue. For the President's remarks on signing this memorandum, see p. 88 of the *Weekly Compilation of Presidential Documents.*

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Actions Regarding Family Planning Service Projects, Transplantation of Human Fetal Tissue, and Importation of the Drug Mifepristine

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In accordance with directives of President Clinton dated January 22, 1993, I have today ordered that the following actions be taken:

(1) The Standard of Compliance for Abortion-Related Services in Family Planning Service Projects (the "Gag Rule") is to be suspended, pending the publication of regulations to formally rescind the rule.

(2) The temporary moratorium imposed March 22, 1988, by the Assistant Secretary for Health and continued by the previous Secretary on November 2, 1988, prohibiting Federal funding of research involving transplantation of human fetal tissue from induced abortions, is to be rescinded.

(3) Food and Drug Administration Import Alert 66-47, importation of the drug Mifepristine ("RU-486") is to be immediately and thoroughly reviewed regarding the health and safety implications of potential import of the drug for personal use.

FOR FURTHER INFORMATION CONTACT: Audrey Manley, M.D., M.P.H., Acting Assistant Secretary for Health, Public Health, Public Health Service (202) 690-7694.

SUPPLEMENTARY INFORMATION: *The Standard of Compliance for Abortion-Related Services in Family Planning Service Projects (the "Gag Rule")*—In documents printed elsewhere in this issue of the Federal Register, the amendments to 42 CFR part 59, subpart A, published on February 2, 1988 (53 FR 2922)—commonly referred to as the "Gag Rule"—are suspended and new regulations are proposed to govern the Family Planning program established under Title X of the Public Health Service Act.

Federal Funding of Fetal Tissue Transplantation Research—This notice advises the public that the PHS is directed to rescind the moratorium imposed on March 23, 1988 which prohibits Federal funding of research involving transplantation of human fetal tissue from induced abortions. Such funding may be provided, subject to the procedures and protections which govern Federal support of biomedical research, and subject to guidelines as recommended by a National Institutes Health advisory committee. Interim guidelines are to be prepared immediately by the Director of the National Institutes of Health, as recommended by the committee, to assure that Federal support of such research does not encourage the choice of induced abortion.

FDA Alert 66-47 Excluding Importation of the Drug Mifepristine ("RU-486")—The FDA has been directed to initiate immediate and thorough review, directed at the health and safety implications of potential import of the drug for personal use. Findings of the review are to be reported promptly to the Secretary. If sufficient evidence does not exist to warrant exclusion of the RU-486 from the list of drugs that qualify for the personal use importation exemption, this import alert shall be rescinded. At the same time, FDA is directed to promptly assess initiatives to promote testing of RU-486 or other antiprogestins in the United States, and, as appropriate, licensing and manufacturing in this country, and report on options to the Assistant Secretary for Health and the Secretary.

The President's memoranda are published in Part IV of this Federal Register issue.

Donna E. Shalala,

Secretary.

[FR Doc. 93-2738 Filed 2-3-93; 1:18 pm]

BILLING CODE 4160-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES Revised 11/6/93

MAR 01 1993

The Honorable Christopher H. Smith
House of Representatives
Washington, D.C. 20515

Dear Mr. Smith:

This is in further response to your letter of January 12, 1993, addressed to Dr. Kessler, in which you asked several questions relative to the unapproved new drug RU-486. The following responds to these questions.

QUESTION 1.

Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU-486? If so, how many of those applications were approved? How many were denied?

ANSWER.

In general, FDA is precluded by law from publicly discussing, or even acknowledging the existence of a study under clinical investigation, unless the sponsor of the study has made public the existence of the study. We are, therefore, unable to respond fully to your specific question.

However, we can confirm that the FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drug applications (INDs). Specifically, the National Institutes of Health, whose studies are public information, are using RU-486 in biochemical research and investigating its potential for the treatment of various conditions, including Cushing's syndrome. In addition, the Population Council of New York has publicly acknowledged its sponsorship of clinical trials with RU-486. The following INDs have been publicly acknowledged:

IND ———	Population Council	Contraception
IND 26, 240	Lynette Nieman, M.D.	Effects on biochemical parameters
IND 26, 241	Lynette Nieman, M.D.	Cushing's syndrome
IND 28, 831	Philip Gold, M.D.	Effect on neuroendocrine functions

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-12	———	2/26/93						
HFD-2	———	2/26/93						

311

MIF 006026

The FDA has approved all of the INDs that have been submitted to the Agency on RU-486, except for those which did not provide manufacturing information because they did not have a source of drug supply.

QUESTION 2.

Is there now or has there ever been any legal or administrative barrier to the research and testing of RU-486 by private drug companies?

ANSWER.

No.

QUESTION 3.

Is the following statement accurate?

> "RU-486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU-486 prevent the introduction into this country for research purposes? What is prohibited under the import alert?

ANSWER.

The statement quoted in your question is not accurate. The FDA has not placed any barriers in the way of research with RU-486, and has not withheld the drug from any research with an approved IND. Importation of RU-486 for research for therapeutic uses can and does occur when an approved IND exists. The import alert applies only to the importation of RU-486 by individuals for their own personal use; it does not apply to the importation of the drug for research under an approved IND.

QUESTION 4.

Is there a firm FDA policy on accepting non-US trial data in the approval of new drugs?

ANSWER.

Yes. FDA accepts data from foreign clinical studies provided they are well designed, well conducted, and conducted in accordance with ethical principles acceptable to the world community. Parts 312.120 and 314.106 of Title 21 of the Code of Federal Regulations describe the criteria for acceptance of foreign clinical data. Copies are enclosed for your information.

Thank you for your interest in this issue. If we can be of any further assistance, please let us know. A similar letter has been sent to the other co-signers of your letter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for legislative Affairs

2 Enclosures
CFR Part 312.120
CFR Part 314.106
cc: HFW-10(2)

R/D: [redacted] :1/15/93
R/T: [redacted] :1/15/93
Revise: [redacted] 1/15/93
Edit: [redacted] :1/15/93
Init: [redacted] 1/19/93
Revise: [redacted] :1/28/93
ReT: [redacted] 1/28/93
Init: [redacted] GCF-1:2/4/93
Edit: [redacted] :2/9/93
Edit: [redacted] :2/11/93
ReT: [redacted] 2/11/93
Edit: [redacted] 2/19/93
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Edit: [redacted] to include list of disclosable INDs):2/24/93
re/t: [redacted] :2/25/93
Edit: [redacted] :2/25/93
F/T: [redacted] 2/25/93
(S:\WP\ [redacted] RU-486.Q'S)
Cong-10366 and No. 12291

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Hnorable Harold L. Volkmer
House of Representatives
Washington, D.C. 20515

Dear Mr. Volkmer:

This is in further response to your letter of January 12, 1993, addressed to Dr. Kessler, in which you asked several questions relative to the unapproved new drug RU-486. The following responds to these questions.

QUESTION 1.

Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU-486? If so, how many of those applications were approved? How many were denied?

ANSWER.

In general, FDA is precluded by law from publicly discussing, or even acknowledging the existence of a study under clinical investigation, unless the sponsor of the study has made public the existence of the study. We are, therefore, unable to respond fully to your specific question.

However, we can confirm that the FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drug applications (INDs). Specifically, the National Institutes of Health, whose studies are public information, are using RU-486 in biochemical research and investigating its potential for the treatment of various conditions, including Cushing's syndrome. In addition, the Population Council of New York has publicly acknowledged its sponsorship of clinical trials with RU-486. The following INDs have been publicly acknowledged:

IND ———	Population Council	Contraception
IND 26, 240	Lynette Nieman, M.D.	Effects on biochemical parameters
IND 26, 241	Lynette Nieman, M.D.	Cushing's syndrome
IND 28, 831	Philip Gold, M.D.	Effect on neuroendocrine functions

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

The FDA has approved all of the INDs that have been submitted to the Agency on RU-486, except for those which did not provide manufacturing information because they did not have a source of drug supply.

QUESTION 2.

Is there now or has there ever been any legal or administrative barrier to the research and testing of RU-486 by private drug companies?

ANSWER.

No.

QUESTION 3.

Is the following statement accurate?

> "RU-486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU-486 prevent the introduction into this country for research purposes? What is prohibited under the import alert?

ANSWER.

The statement quoted in your question is not accurate. The FDA has not placed any barriers in the way of research with RU-486, and has not withheld the drug from any research with an approved IND. Importation of RU-486 for research for therapeutic uses can and does occur when an approved IND exists. The import alert applies only to the importation of RU-486 by individuals for their own personal use; it does not apply to the importation of the drug for research under an approved IND.

QUESTION 4.

Is there a firm FDA policy on accepting non-US trial data in the approval of new drugs?

ANSWER.

Yes. FDA accepts data from foreign clinical studies provided they are well designed, well conducted, and conducted in accordance with ethical principles acceptable to the world community. Parts 312.120 and 314.106 of Title 21 of the Code of Federal Regulations describe the criteria for acceptance of foreign clinical data. Copies are enclosed for your information.

Thank you for your interest in this issue. If we can be of any further assistance, please let us know. A similar letter has been sent to the other co-signers of your letter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for legislative Affairs

2 Enclosures
CFR Part 312.120
CFR Part 314.106

cc: HFW-10(2)

R/D: [redacted] 1/15/93
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Revise: [redacted] 1/15/93
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re/t: [redacted] 2/25/93
Edit: [redacted] :2/25/93
F/T: [redacted] 2/25/93
(S:\WP\ [redacted] \RU-486.Q'S)
Cong-10366 and No. 12291

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Bill Emerson
House of Representatives
Washington, D.C. 20515

Dear Mr. Emerson:

This is in further response to your letter of January 12, 1993, addressed to Dr. Kessler, in which you asked several questions relative to the unapproved new drug RU-486. The following responds to these questions.

QUESTION 1.

Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU-486? If so, how many of those applications were approved? How many were denied?

ANSWER.

In general, FDA is precluded by law from publicly discussing, or even acknowledging the existence of a study under clinical investigation, unless the sponsor of the study has made public the existence of the study. We are, therefore, unable to respond fully to your specific question.

However, we can confirm that the FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drug applications (INDs). Specifically, the National Institutes of Health, whose studies are public information, are using RU-486 in biochemical research and investigating its potential for the treatment of various conditions, including Cushing's syndrome. In addition, the Population Council of New York has publicly acknowledged its sponsorship of clinical trials with RU-486. The following INDs have been publicly acknowledged:

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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

MIF 006032

The FDA has approved all of the INDs that have been submitted to the Agency on RU-486, except for those which did not provide manufacturing information because they did not have a source of drug supply.

QUESTION 2.

Is there now or has there ever been any legal or administrative barrier to the research and testing of RU-486 by private drug companies?

ANSWER.

No.

QUESTION 3.

Is the following statement accurate?

> "RU-486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU-486 prevent the introduction into this country for research purposes? What is prohibited under the import alert?

ANSWER.

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QUESTION 4.

Is there a firm FDA policy on accepting non-US trial data in the approval of new drugs?

ANSWER.

Yes. FDA accepts data from foreign clinical studies provided they are well designed, well conducted, and conducted in accordance with ethical principles acceptable to the world community. Parts 312.120 and 314.106 of Title 21 of the Code of Federal Regulations describe the criteria for acceptance of foreign clinical data. Copies are enclosed for your information.

Thank you for your interest in this issue. If we can be of any further assistance, please let us know. A similar letter has been sent to the other co-signers of your letter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for legislative Affairs

2 Enclosures
CFR Part 312.120
CFR Part 314.106

cc: HFW-10(2)

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re/t: :2/25/93
Edit: 2/25/93
F/T: :2/25/93
(S:\WP\ \RU-486.Q'S)
Cong-10366 and No. 12291

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Robert K. Dornan
House of Representatives
Washington, D.C. 20515

Dear Mr. Dornan:

This is in further response to your letter of January 12, 1993, addressed to Dr. Kessler, in which you asked several questions relative to the unapproved new drug RU-486. The following responds to these questions.

QUESTION 1.

Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU-486? If so, how many of those applications were approved? How many were denied?

ANSWER.

In general, FDA is precluded by law from publicly discussing, or even acknowledging the existence of a study under clinical investigation, unless the sponsor of the study has made public the existence of the study. We are, therefore, unable to respond fully to your specific question.

However, we can confirm that the FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drug applications (INDs). Specifically, the National Institutes of Health, whose studies are public information, are using RU-486 in biochemical research and investigating its potential for the treatment of various conditions, including Cushing's syndrome. In addition, the Population Council of New York has publicly acknowledged its sponsorship of clinical trials with RU-486. The following INDs have been publicly acknowledged:

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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

The FDA has approved all of the INDs that have been submitted to the Agency on RU-486, except for those which did not provide manufacturing information because they did not have a source of drug supply.

QUESTION 2.

Is there now or has there ever been any legal or administrative barrier to the research and testing of RU-486 by private drug companies?

ANSWER.

No.

QUESTION 3.

Is the following statement accurate?

> "RU-486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU-486 prevent the introduction into this country for research purposes? What is prohibited under the import alert?

ANSWER.

The statement quoted in your question is not accurate. The FDA has not placed any barriers in the way of research with RU-486, and has not withheld the drug from any research with an approved IND. Importation of RU-486 for research for therapeutic uses can and does occur when an approved IND exists. The import alert applies only to the importation of RU-486 by individuals for their own personal use; it does not apply to the importation of the drug for research under an approved IND.

QUESTION 4.

Is there a firm FDA policy on accepting non-US trial data in the approval of new drugs?

ANSWER.

Yes. FDA accepts data from foreign clinical studies provided they are well designed, well conducted, and conducted in accordance with ethical principles acceptable to the world community. Parts 312.120 and 314.106 of Title 21 of the Code of Federal Regulations describe the criteria for acceptance of foreign clinical data. Copies are enclosed for your information.

Thank you for your interest in this issue. If we can be of any further assistance, please let us know. A similar letter has been sent to the other co-signers of your letter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for legislative Affairs

2 Enclosures
CFR Part 312.120
CFR Part 314.106

cc: HFW-10(2)

R/D: [redacted] 1/15/93
R/T: [redacted] 1/15/93
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Revise: [redacted] :1/28/93
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F/T: [redacted] :2/25/93
(S:\WP\ [redacted] \RU-486.Q'S)
Cong-10366 and [redacted] No. 12291

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable John J. LaFalce
House of Representatives
Washington, D.C. 20515

Dear Mr. Lafalce:

This is in further response to your letter of January 12, 1993, addressed to Dr. Kessler, in which you asked several questions relative to the unapproved new drug RU-486. The following responds to these questions.

QUESTION 1.

Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU-486? If so, how many of those applications were approved? How many were denied?

ANSWER.

In general, FDA is precluded by law from publicly discussing, or even acknowledging the existence of a study under clinical investigation, unless the sponsor of the study has made public the existence of the study. We are, therefore, unable to respond fully to your specific question.

However, we can confirm that the FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drug applications (INDs). Specifically, the National Institutes of Health, whose studies are public information, are using RU-486 in biochemical research and investigating its potential for the treatment of various conditions, including Cushing's syndrome. In addition, the Population Council of New York has publicly acknowledged its sponsorship of clinical trials with RU-486. The following INDs have been publicly acknowledged:

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FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

MIF 006038

The FDA has approved all of the INDs that have been submitted to the Agency on RU-486, except for those which did not provide manufacturing information because they did not have a source of drug supply.

QUESTION 2.

Is there now or has there ever been any legal or administrative barrier to the research and testing of RU-486 by private drug companies?

ANSWER.

No.

QUESTION 3.

Is the following statement accurate?

> "RU-486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU-486 prevent the introduction into this country for research purposes? What is prohibited under the import alert?

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Thank you for your interest in this issue. If we can be of any further assistance, please let us know. A similar letter has been sent to the other co-signers of your letter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for legislative Affairs

2 Enclosures
CFR Part 312.120
CFR Part 314.106

cc: HFW-10(2)

R/D: [redacted] :1/15/93
R/T: [redacted] 1/15/93
Revise: [redacted] :1/15/93
Edit: [redacted] :1/15/93
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Revise: [redacted] 1/28/93
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re/t: [redacted] :2/25/93
Edit: [redacted] :2/25/93
F/T: [redacted] :2/25/93
(S:\WP\[redacted] RU-486.Q'S)
Cong-10366 and No. 12291

Congress of the United States

House of Representatives

Washington, DC 20515

January 12, 1993

Dr. David A. Kessler
Commissioner
U.S. Food and Drug Administration
Room 14-71
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

Very shortly the House will consider legislation affecting Federal policy with regard to the drug RU 486. The Food and Drug Administration's response to the following questions will be important in ensuring that the House and Senate act with full knowledge of the current situation.

(1) Has the Food and Drug Administration ever received any formal applications from companies to initiate the research or testing of RU 486? If so, how many of those applications were approved? How many were denied?

(2) Is there now or has there ever been any legal or administrative barrier to the research and testing of RU 486 by private drug companies?

(3) Is the following statement accurate?

> "RU 486 has been withheld from researchers in the United States through the Food and Drug Administration's import alert policy."

Does the FDA's import alert concerning RU 486 prevent the introduction of the drug into this country for research purposes? What is prohibited under the import alert?

(4) In her letter of December 15, 1992 to Rep. Ron Wyden, Ms. Carol Scheman, Deputy Commissioner for External Affairs at FDA, indicated that certain safety testing and clinical trials would probably not be required by a company wishing to market RU 486 in the United States because of the research and clinical results available from France and Great Britain.

#1229/

Was Ms. Scheman speaking hypothetically in offering this opinion or was she describing a firm FDA policy? Is there a firm FDA policy on accepting non-US trial data in the approval of new drugs? If so, please describe this policy. If not, who decides whether non-US data will be used and what criteria is used for making this decision?

Noting your office's rapid response to our colleague, Rep. Ron Wyden's request, we would appreciate receiving answers to the above questions (as well as a copy of the RU 486 import alert) by Tuesday, January 19, 1993. We recognize that some information provided to answer these questions may be privileged. Please indicate whether any particulars in your response may not be made available to the public.

Thank you very much for your assistance in providing this information.

Sincerely,

CHRISTOPHER H. SMITH, M.C.

ROBERT K. DORNAN, M.C.

BILL EMERSON, M.C.

HAROLD L. VOLKMER, M.C.

JOHN J. LaFALCE, M.C.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

The Honorable Peter T. King
House of Representatives
Washington, D.C. 20515-3203

JUN 21 1994

Dear Mr. King:

This is in response to your inquiry of April 6, 1994, on behalf of _____ regarding the unapproved new drug, RU-486.

To provide you with background information, the Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to the FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

Please assure your constituent that FDA is committed to an expeditious review of the data once a new drug application for RU-486 is submitted to the FDA, so that American women may have access to this alternative to surgical abortion as quickly as possible, if the data show that RU-486 is safe and effective.

We hope this information is helpful. If we can be of further assistance, please let us know.

Sincerely yours,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	_____	6/21/94						

*U.S. GPO: 1988-216-488

MIF 006043

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

JUN 21 1994

The Honorable John Breaux
United States Senate
Washington, D.C. 20510-1803

Dear Senator Breaux:

This is in response to your inquiry of February 10, 1994, on behalf of _____ regarding the unapproved new drug, RU-486 and the resumption of the use of fetal tissue in research. We apologize for the delay in responding.

To provide you with background information, the Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of an unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to the FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

It is also important to point out that FDA does not actually do the clinical testing of drugs before they are marketed. Pharmaceutical manufacturers, the National Institutes of Health, and other research institutions across the country carry out programs to identify, develop and test drugs. It is FDA's responsibility to review and analyze the results of the testing to determine if a drug is safe and effective for widespread marketing for use by the general public.

We are enclosing a publication, "New Drug Development in the United States," that describes in more detail the requirements for new drug clearance in the United States.

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	TST	6/21/94						

*U.S. GPO: 1988-216-488

MIF 006044

We appreciate the concerns expressed by [redacted] and respect his personal opinion on this issue. Please assure him that approval of this, or any product, will only be granted if the safety and efficacy requirements mandated by law are satisfied.

With regard to fetal tissue research, FDA has not been involved in this matter. Government research is conducted at the National Institutes of Health.

We hope this information is helpful. If we can be of further assistance, please let us know.

Sincerely yours,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

2 Enclosures
Constituent's letter
As stated above

cc: HFW-10(2)
ES/PHS(2) T65942
CCU 02189400017
R/D: [redacted] :6/20/94
R/T:mm:2/25/94:(s:\wp\ [redacted] \RU-486#2.bre)
Revise: [redacted] :3/23/94
F/T:tdt:6/21/94

No. 94-1701

APPEARS THIS WAY
ON ORIGINAL

JOHN BREAUX
LOUISIANA

MAJORITY
CHIEF DEPUTY WHIP

COMMITTEES:

COMMERCE, SCIENCE, AND TRANSPORTATION

FINANCE

SPECIAL COMMITTEE ON AGING

WASHINGTON OFFICE:
(202) 224-4623

United States Senate

WASHINGTON, DC 20510

STATE OFFICES:

ONE AMERICAN PLACE, SUITE 2030
BATON ROUGE, LA 70825
(504) 382-2050

THE FEDERAL BUILDING
705 JEFFERSON STREET, ROOM 103
LAFAYETTE, LA 70501
(318) 262-6871

WASHINGTON SQUARE ANNEX BUILDING
211 NORTH 3RD STREET, ROOM 102A
MONROE, LA 71201
(318) 325-3320

HALE BOGGS FEDERAL BUILDING
501 MAGAZINE STREET, SUITE 1005
NEW ORLEANS, LA 70130
(504) 589-2531

CENTRAL LOUISIANA:
(318) 487-8445

February 10, 1994

Mr. Gerry D. Klepner
Assistant Secretary for Legislation
U.S. Department of Health and Human Services
HHH Building, Room 416G
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Klepner:

I have been contacted by _____ _____ concerning the resumption of the use of fetal tissue in scientific research and the authorization of RU-486 for medical study in the United States.

Please investigate the enclosed information sent to me and provide me with a report which responds to _____ concerns. Your reply may be forwarded to the attention of Denise G. Riemer.

Thank you for your attention and assistance.

Sincerely,

John

JOHN BREAUX
United States Senator

JB:dgr~~/gcs~~
Enclosure

APPEARS THIS WAY
ON ORIGINAL

T65942
TRACER

94-1701

MIF 006046

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE

May 31, 1994

NOTE TO:

Presidential Letters
Office of Correspondence

SUBJECt: RU-486 Letter

FROM:

Executive Secretariat
FDA (301)443-3900

This is in response to your May 17, 1994, request for approval of text for your general reply letter to people writing about RU-486. We have updated it to reflect current developments and will forward the rewrite of the dietary supplement letter as soon as it is completed and cleared.

Please let me know if we can help further.

Attachment

APPEARS THIS WAY
ON ORIGINAL

Thank you for sharing your views with me regarding RU-486 (mifepristone).

On taking office, I directed the Secretary of Health and Human Services to assess initiatives to promote the testing and licensing of mifepristone in the United States. I took this action because I believe that women should have access to all safe, medically appropriate, and legal options when making difficult and intensely personal decisions.

On May 16, 1994, Secretary Shalala announced that Roussel Uclaf, the French manufacturer of mifepristone, will donate its U.S. patent rights to mifepristone to the Population Council, a not-for-profit organization, and that the Population Council will take the necessary steps to bring mifepristone to the American market.

I want to emphasize that this donation does not mean that mifepristone is approved for use in this country. The Population Council must conduct clinical trials, identify a manufacturer and submit a new drug application to the FDA. FDA's decision will be based solely on the scientific and medical evidence as to the safety and efficacy of the drug.

At the same time, I believe we must do more to reduce the number of abortions and unwanted pregnancies. While I am firmly pro-choice, I am not pro-abortion.

Though we may differ on these issues, I hope that our common concerns for the future of America will unite us. I appreciate your sincerity and your candor.

APPEARS THIS WAY
ON ORIGINAL

CHRISTY & VIENER
620 FIFTH AVENUE
NEW YORK, NEW YORK 10020-2402
(212) 632-5500

FACSIMILE
(212) 632-5555

DIRECT DIAL NUMBER
(212) 632- 5517

April 11, 1994

BY FACSIMILE

Lester S. Hyman, Esq.

Swidler & Berlin, Chartered
3000 K Street, N.W.
Suite 300
Washington, D.C. 20007-5116

Re: Revised Distribution Requirements

Dear Lester and John:

There follows a revised draft of the proposed Distribution, Dispensation and Use Requirements with respect to mifepristone, which incorporates in Sections (c) (i) and (ii) the changes we discussed at our meeting last Thursday. I would appreciate your forwarding a copy to ——— as I have been unsuccessful at reaching him this morning.

At the request of ——— and as Lester and Jim Boynton discussed, by copy of this letter I am also sending this draft to ——— to advise the FDA of the current status of these requirements.

Of course, the requirements remain subject to further comment based on our clients' discussions tomorrow. Please do not hesitate to call me if you have any questions.

Sincerely yours,

cc: ———

10118765

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

April 22, 1994

James S. Boynton, Esq.
Christy & Viener
620 Fifth Avenue
New York New York 10020-2402

Lester S. Hyman, Esq.
Swidler & Berlin, Chartered
3000 K Street, N.W., Suite 300
Washington, D.C. 20007-5116

Dear Mr. Boynton and Mr. Hyman:

As you requested, enclosed are the Agency's preliminary comments on the April 11, 1994, proposed distribution scheme for mifepristone in the United States. As I have mentioned to you, the question as to whether any residency requirement can be imposed needs further examination. Moreover, any final comments on the distribution scheme must follow the Food and Drug Administration's review of the scientific, medical, and other data and information contained in a new drug application for the drug.

We are heartened by the fact that you, Roussel Uclaf, and Hoechst AG are close to agreeing on a distribution plan. As the Secretary noted, however, we expect all issues, not just the distribution issue, to be concluded by May 15, 1994.

As Commissioner Kessler promised in our recent meeting, the Food and Drug Administration stands ready to assist all parties in any scientific, medical, or labeling issues that may arise.

Sincerely yours,

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

APR 05 1994

The Honorable Paul Simon
United States Senator
250 West Cherry Street
Carbondale, Illinois 62901

Dear Senator Simon:

This is in response to your letter of December 15, 1994, on behalf of _____, regarding RU-486 for her husband's treatment.

An official in our Division of Oncology has discussed treatment of this patient with RU-486 with _____ where _____ was evaluated for inclusion in the ongoing study with RU-486. _____ is also exploring other options with the patient and his family.

If we can be of any further assistance, please contact us.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure:
Constituent's ltr

cc: ES/PHS (2) (#T64371)
OS/CCU (#12239300014)
HFW-10 (2)

R/D: _____ (per info. from _____ :4/4/94
R/T:mjp:4/4/94 (S:\wp\ _____ .RU4)
Cong. # 94-171

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-2	[illegible]	4/5/94						

*U.S. GPO: 1988-216-488

MIF 006051

DEC 13 1993

December 9, 1993

Honorable Paul Simon
United States Senate
250 W. Cherry
Carbondale, Il. 62901

Dear Senator Simon:

Please find enclosed a copy of a letter I have submitted to the Federal Food and Drug Administration.

Once more I am asking for your help. You have been such an advocate of the people and for me and my husband. Without you we would have lost our home and all we had worked for. You helped me about 3 years ago get my husband on disability.

Now I am asking something even more important.

If you would follow up on this letter to the director of The Food and Drug Administration, I'm sure your distinguished voice would have great influence on the possibility of saving my husband's life.

Once again I thank you for any help you can give me in this matter.

Sincerely,

/s/

MIF 006052

December 9, 1993

Mr. David Kestler
Director
Federal Food and Drug Administration
5600 Fischers Lane
Rockville, Maryland 20857

Dear Sir:

I have been instructed by my husband's physician to write to you concerning the benefits of the abortion drug RU-84 in the treatment of meningioma brain tumors.

My husband has been ill with recurrent meningiomas for the last 8 years and is in very poor condition at this time. The meningioma has completely closed off the main artery in the falx in the saggital sinus area of his brain. His prognosis is dismal as he cannot have surgery at this time due to the fact he does not have enough blood flow or oxygen to that portion of the brain. He has had radiation twice and his doctors are reluctant to try that again as well as four craniotomies. They have advised us that research has shown that the french abortion drug RU-84 has proven very beneficial in the stoppage of growth in some meningiomas.

We realize the importance of testing and research in the use of all new drugs, however when one is considered terminal, we believe that person should be allowed to explore every drug for treatment of his condition.

I ask you, is it more ethical to deny a dying man the drug that might save his life, than to kill a fetus with it?

My husband is a Vietnam Veteran and we have struggled with this problem for most of our married life. I feel the government owes him this opportunity, as the cause of his illness may very well be Agent Orange related, even though the Veteran's Administration denies it

We would ask that you find it in your heart to take our request under advisement and to grant us this opportunity to save my husband's life.

It is critical that a decision be made on the use of this drug for many people suffer from this type of brain tumor, and are maimed and dying from this illness every day.

If you wish to contact his neurosurgeon we would be happy to provide you with that information.

Please provide us with a determination as swiftly as possible. At this point it seems to be our last hope.

Sincerely,

cc: Honorable Paul Simon
United States Senate
Washington, D.C.

PAUL SIMON
ILLINOIS

COMMITTEES
LABOR AND HUMAN RESOURCES
JUDICIARY
FOREIGN RELATIONS
BUDGET
INDIAN AFFAIRS

United States Senate

WASHINGTON, DC 20510-1302

December 15, 1993

Congressional Liaison
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: [redacted]

Dear friend:

The attached communication is sent for your consideration.

Please investigate the statements contained therein and forward me the necessary information for reply.

Thanks for the help in this matter.

Cordially,

Paul Simon, U. S. Senator
250 West Cherry Street
Carbondale, IL 62901

PS:de

APPEARS THIS WAY
ON ORIGINAL

164371
TRACER

MIF 006055

462 DIRKSEN BUILDING
WASHINGTON, DC 20510-1302
202/224-2152
TDD: 202/224-5469

230 S. DEARBORN
KLUCZYNSKI BLDG., 38TH FLOOR
CHICAGO, IL 60604
312/353-4952
TDD: 312/786-0308

3 WEST OLD CAPITOL PLAZA
SUITE 1
SPRINGFIELD, IL 62701
217/492-4960
TDD: 217/544-7524

250 WEST CHERRY
ROOM 115-B
CARBONDALE, IL 62901
618/457-3653

#93-171

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

APR 01 1994

The Honorable Peter T. King
House of Representatives
Washington, D.C. 20515-3203

Dear Mr. King:

This is in response to your inquiry of January 12, 1994, on behalf of several of your constituents regarding the unapproved new drug, RU-486.

To provide you with background information, the Federal Food, Drug, and Cosmetic Act, which the Food and Drug Administration (FDA) administers, defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug application (NDA) containing substantial scientific evidence of safety and effectiveness for use of the drug as labeled.

An investigational new drug (IND) application acceptable to the FDA is required of a sponsor (e.g., a drug manufacturer or a clinical investigator) to study the safety and effectiveness of and unapproved new drug. When the sponsor determines that adequate and well-controlled studies have been performed, which reflect favorably on a new drug's safety and effectiveness, the sponsor then submits that information, together with adequate information on manufacturing procedures and controls, in a new drug application to the FDA. After a comprehensive review by the FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

Please assure your constituents that FDA is committed to an expeditious review of the data once a new drug application for RU-486 is submitted to the FDA, so that American women may have access to this alternative to surgical abortion as quickly as possible, if the data show that RU-486 is safe and effective.

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	4/1/94						

*U.S. GPO: 1988-216-488

MIF 006056

We hope this information is helpful. If we can be of further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: ———— 2/23/94
R/T:mm:2/25/94:(s:\wp\ ——— \RU-486#2)
Revise: ———— 3/23/94
F/T:as:3/31/94

No. 94-621

APPEARS THIS WAY
ON ORIGINAL

Congress of the United States

House of Representatives

Washington, D.C.

January 12, 1994

Sir/Madam:

The attached communication is sent for your consideration. Please investigate the statements contained therein and forward me the necessary information for reply, returning the enclosed correspondence with your letter.

Yours truly,

Peter T. King M.C.

NY-3

94-6 21

EC 8 1993

December 6, 1993

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2 DEC

in regard to the abortion pill. I ortion is unique in that I am not an owever, I feel the morning after pill ogical advancement that cannot, nor ne issue is not pro-abortion or co-responsibility of life and the coming umanity.

ed, the issue is not abortion per say. after pill is synonymous with abortion. ion is pre-coital. I believe the ing after pill is in that it is . Therefore, it is immediately equated e understood that the pill is separate s a contraceptive that prevents tion is a termination of a pregnancy. e the similarities in the morning pill What is the difference between and post-coital birth control where and the latter is taken within either prevent fertilization or affect int where insemination will not occur. t morning after pill "kills" an already not the case. Ru-486 does not and living being, it is a antipregnancy s in the uterus for the horomone h the uterus cannot begin or maintain ul responsibility of every individual aware of these facts before they ll.

Jan Hoffman in the New York Times coming pregnant on a woman's most the day is at most 25 percent. She states that "the morning-after reduces that likelihood to somewhere between 0 and 8 percent, depending on when the woman had intercourse and took the pills". In fact, about 1.6 million abortions are performed each year partially because 3.5 million American women become pregnant either because a contraceptive method failed or they failed to use anything at all. The availability of

the morning-after pill would reduce unintended pregnancies by 1.7 million annually and prevent 800 thousand abortions.

Like Dr. Felicia H. Stewart comments "it is not a question of contraception or abortion, it's a grey area-so we call it interception". It takes a stand on sexual behavior, hence responsibility. It is society's attitude towards the pill which discourages the availability of this resolution. So what I ask of you is to pass legislation on the morning-after pill which would put an end to using abortion as an alternative.

Truly yours,

DEC 14 1993

December 2, 1993

The Honorable Peter T. King
1003 Park Blvd.
Massapequa Park, New York 11762

Dear The Honorable Peter T. King:

I am writing in concern to the french abortion pill RU-486. The pill was discovered by French physician and biochemist Etienne-Emile Baulieu. The pill was designed to abort the fetus in a more comfortable fashion. I feel this pill would be beneficial to the women citizens of the United States. An abortion is up to a women's discretion, not the government's. The government has no right to interfere in the personal lives of it's citizens. The pill should be permitted in the United States and offered to all that choose to use it.

More than one third of France's abortions are now done with the RU-486. The abortion can be administered in a physician's office, and the procedure is a private decision between the woman and her doctor. The pill can be used safely and effectively. This drug has been approved by several European and Asian countries, some including France, the United Kingdom, Sweden, and China. Official statistics show that in the four years that the pill has been available in France, the annual number of abortions has remained the same, while the demand for contraceptives has increased. In fact people are not using the pill as an escape to their sexual mistakes, instead they are preventing them by using a simple condom. A French doctor noted that, " a woman wants the right to decide an abortion on their own, and that public authorities will not influence the woman's decision." The pill may prove to have far wider medical applications, that would benefit the welfare of the United States citizens. The Ragan Bush administration banned this pill in the United states. Being pro-life activists they felt the pill was not necessary in the doctor's offices today. They felt that the pill would encourage abortions because of its easy procedure, when in fact it does not, according to a young lady " If an abortion is necessary it will be done, the pain does not matter it is the remembrance of the procedure that hurts."
According to the information given it is evident that women would not use this pill as an escape to her sexual mistakes.

I am writing asking the government to make actions to pass the Clinton Administration allowing the pill to be used in the proper Doctor's offices today. As a citizen of the United States I feel the government is depriving women the right to this pill and wish to see the proper actions taken to allow the pill to our use. The United States is the land of freedom

and opportunity, please take all the proper actions to ensure my freedom as a woman in the United States.

Thank You.

Yours Truly,

L 1993

DEC 1993

Dec. 6, 1993

The Honorable Peter T. King
1003 Park Blvd.
Massapequa Park, N.Y., 11762

Dear Mr. King:

I am writing to you in concern of the RU-486 French abortion pill. I am in favor of the legislation.

I am not pro-abortion, but I believe that the RU-486 could be an ideal drug to bring in to the United States. Many scientists that have tested the drug have said that RU-486 not only stops a fertilized egg from living in the womb, but also has been known to treat life threatening diseases. The RU-486 has been shown to stop the growth of tumors, particularly in breast cancer. The drug has also shown effectiveness in treating other diseases such as brain cancer, endometriosis, and cushing syndrome. Some scientists also think that it could cure obesity.

21575

There are many major supporters of the RU-486. This includes many politicians, the American Medical Association, The American Public Health Association, The American College of Obstetricians and Gynecologists, and The American Association for the Advancement of Science. But as of now the main reason the RU-486 hasn't been more publicized by these organizations, is because there is too much controversy.

This new pill is 97% effective according to the Los Angles Times. The side effects of the RU-486 when used as a "morning after pill" are considerably less painful, and less harmful compared to other pills used for the same purpose. There is no recorded failure with the RU-486, and the method is much more simple, because only one dose is needed. Many doctors have expressed their support for the RU-486 because of it's safety factor. It is much less harmful than the traditional abortion.

I have read that the President plans to lift the Bush administration's ban on the RU-486, and I strongly express my support for it. I honestly believe that the drug would be an asset to the people of the United States. A major set back to the RU-486 is it's expense. One of the main idea's of the development of RU-486 is that it will be much safer than the "back ally abortion." But the drug is very expensive, and the women of the United States that have a lower income will not be able to afford it. So I ask you to look into a way that the drug could be made affordable to everyone.

Thank you very much for your time.

Sincerely.

151

DEC 8 1993 DEC 10 1993

November 29, 1993

The Honorable Peter T. King
1003 Park Blvd.
Massapequa Park, N.Y. 11762

Dear Mr. King,

I am writing to you about the possible legalization of the French abortion pill RU-486. In a country that supports freedom and the right to choose, banning this pill would be un-American.

The pill is most effective if used within seven weeks of conception. It prevents the hormone progesterone from being The pill is ninety-five percent effective. In 1988, France and China approved the use of the pill and seventy-three percent of all Americans support its legalization and use. This past June the American Medical Association passed a resolution supporting the "legal availability of RU-486 for appropriate research, and if indicated, clinical practice." In a time when teenage pregnancies and illegitimate pregnancies are on the rise, the threat of harmful and unsafe abortions is also on the rise. The pill rules out the danger of unqualified doctors used because of the high cost of abortions. Too many women are suffering from botched abortions. The pill has already been used by an estimated 55,000 women in fifteen countries. This drug marks a great advancement over other pregnancy ending techniques, solely based on its efficiency and its safety. The pill has also been linked to possible cures for AIDS, breast cancer, brain tumors, Cushings syndrome, and infertility. All in all, this pill is a highly positive advancement. Not permitting this pill to be available in t he United States contradicts the Roe v. Wade case of a woman's right to choose. It is the freedom of choice that makes this country special and unique. This country was formed on freedom and continues to thrive on that gift.

3/573

The abortion pill RU-486 is a necessary discovery in today's society. It is the safest approach to abortions these days. There have been too many instances where women have died as a result of unsafe abortions. This country is based on free choice.

Yours Truly,

/S1

MIF 006064

Congress of the United States

House of Representatives

Washington, D.C.

EC 8 1993

December 6, 1993

January 12, 1994

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in regard to the abortion pill. I
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The attached communication is sent for
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Yours truly,

Peter T. King M.C.

NY-3

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94-621

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fertile day is at most 25 percent. She states that "the
morning-after reduces that likelihood to somewhere between 0
and 8 percent, depending on when the woman had intercourse and
took the pills". In fact, about 1.6 million abortions are
performed each year partially because 3.5 million American women
become pregnant either because a contraceptive method failed
or they failed to use anything at all. The availability of

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAR 02 1994

The Honorable Michael R. McNulty
Member, United States
House of Representatives
Leo O'Brien Federal Building
Albany, New York 12207

Dear Mr. McNulty:

This is in response to your letter of December 23, 1993, on behalf of _____ who wrote to you on behalf of his brother, _____ regarding the compassionate release of RU-486 for the treatment of malignant meningioma.

The Treatment Investigational New Drug (IND) Application that _____ submitted to the FDA has been approved.

If we can be of further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D: _____ (per discussion _____ 1/14/94)
F/T:as:2/28/94(s:\wp\ _____ \RU-486.MCN)

No. 94-470

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-10	/S/	3/1/94						

*U.S. GPO: 1988-216-466

MIF 006066

WAYS AND MEANS COMMITTEE
SUBCOMMITTEES:
TRADE
SELECT REVENUE MEASURES

MAJORITY WHIP AT-LARGE

D.S.G. EXECUTIVE COMMITTEE

WASHINGTON OFFICE:
217 CANNON BUILDING
WASHINGTON, DC 20515-3221
(202) 225-5076

MICHAEL R. McNULTY

CONGRESS OF THE UNITED STATES
21ST DISTRICT, NEW YORK

DISTRICT OFFICES
ROOM 827
LEO W. O'BRIEN
FEDERAL BUILDING
ALBANY, NY 12207
(518) 465-0700

U.S. POST OFFICE
SCHENECTADY, NY 12305
(518) 374-4547

33 2ND STREET
TROY, NY 12180
(518) 271-0822

9 MARKET STREET
AMSTERDAM, NY 12010
(518) 843-3400

December 23, 1993

Dr. David I. Kessler, M.D.
Commissioner
Food and Drug Administration
Parklawn Building
Room 14-71
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

The attached communication from [redacted] on behalf of, [redacted] is sent for your review.

I would appreciate it if you would investigate the enclosed statements and forward me the necessary information for reply.

Please send your reply to my Albany office, Leo O'Brien Federal Building, Albany, New York 12207.

Thank you for your consideration in this matter.

Sincerely,

Michael R. Mc Nulty
Member of Congress

MRM/mjs
Enclosure

APPEARS THIS WAY
ON ORIGINAL

94-470

PRINTED ON RECYCLED PAPER

MIF 006067

A.F. FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 8 1994

The Honorable Ron Wyden
Chairman, Committee on Small Business
Subcommittee on Regulation, Business
Opportunities, and Technology
House of Representatives
Washington, D.C. 20515-6318

Dear Mr. Chairman:

Thank you for your letter regarding the progress in the negotiations between Roussel of France, Hoeschst AG Germany, and the Population Council, for licensing the drug mifepristone (RU-486). We share your concern that continued delays in negotiations delay submission to the Food and Drug Administration (FDA) of an application for marketing approval and the product's availability to American women, assuming it is found to be safe and effective.

As you know, HHS has been working actively with several individuals and organizations in an effort to facilitate the study and potential availability of RU-486 and other antiprogestins in the United States. As you mentioned, the drug is being studied for various possible uses, in addition to abortifacient use.

Our assessment of the current licensing negotiations is that progress is being made. Please be assured that we are following these negotiations closely. We are committed to an expeditious review of the data once a new drug application for RU-486 is submitted to the FDA, so that American women may have access to this alternative to surgical abortion as quickly as possible, if the data show that RU-486 is safe and effective.

Again, thank you for writing on this important public health issue.

Sincerely,

Donna

Donna E. Shalala

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

MIF 006068

103d Congress

United States House of Representatives
Committee on Small Business
Subcommittee on Regulation, Business Opportunities, and Technology
B-363 Rayburn House Office Building
Washington, DC 20515-6318

December 22, 1993

The Honorable Donna E. Shalala
Secretary
U.S. Department of Health and
Human Services
Room 615F
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I know we share an interest in improving both the health and healthcare choices of American women. I strongly endorse the significant initiatives you have launched in this regard. We will work hard to ensure your proposals get the attention and support they deserve during the remainder of the 103rd Congress.

I write to you, today, to urge your action on one element of the evolving healthcare agenda...the U.S. approval and distribution of the French drug RU 486. There have been substantial delays in the still-uncompleted licensing negotiations between the French manufacturer of this important drug, and the U.S.-based Population Council. This, in turn, defers the initiation of clinical trials needed for Food and Drug Administration approval and, ultimately, the drug's availability to American women.

> A clear, personal admonition from you to the negotiating parties at this point, I believe, could do much to overcome final roadblocks to the completion of the licensing agreement.
>
> I strongly urge you to contact executives of the drug manufacturing companies -- Roussel Uclaf of France, and Hoerchst AG Germany -- and request their cooperation.

As you know, RU 486 offers unique properties as an abortifacient and as a verifiable safe alternative to surgical pregnancy termination. And in testimony before this subcommittee, a number of medical researchers have testified that this anti-progestin also may be valuable in treating a number of other conditions and illnesses including endometriosis, Cushing's syndrome, meningioma and perhaps even Alzheimer's disease.

T64254

As one who has fought hard for nearly four years too get a fair and rapid assessment of this drug in the United States, I believe that our government should do all within its power to bring the current negotiations between the manufacturer and the Population Council to a swift and positive conclusion.

The potential benefits of this pharmaceutical...one which we could in the alternative replicate ourselves...are just too promising to ignore, or to be held hostage to the whims of a foreign manufacturer.

Thank you for your attention to this important matter, and for your continuing concern regarding women's health issues. Should you have any questions regarding this request, please don't hesitate to contact me, or Steve Jenning of the subcommittee staff at (202) 225-7797.

Sincerely,

RON WYDEN
Chairman

APPEARS THIS WAY
ON ORIGINAL

9312280007

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 08 1994

The Honorable Daniel P. Moynihan
405 Lexington Avenue
41st Floor
New York, New York 10174

Dear Senator Moynihan:

RU-486

This is in further response to your inquiries of June 29, and August 23, 1993, on behalf of _____ concerning the possible relationship between abortion and breast cancer. _____ refers to the Food and Drug Administration's (FDA's) response to _____ on this subject and asked for a more definite response.

_____ suggested in his letter of January 27, 1993, that (1) the Agency is being asked to "short-circuit" the approval process established for new drug applications when considering abortifacient products and (2) the induction of abortion, spontaneous or otherwise, increases a woman's lifetime risk of breast cancer.

The FDA is charged with the responsibility of safeguarding the public health by approving for sale and distribution only those drug products that have been demonstrated to be both safe and effective. The approval of any pharmacologically induced method of abortion would be based on the criteria set forth for all new drugs in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations (Title 21 of the Code of Federal Regulations). Those regulations explicitly require that approval be based on scientific evidence that supports the drug's safety and efficacy. The Agency will not deviate from the laws and regulations that govern the drug review and approval process.

All new drug applications are required by the Agency's regulations to contain an integrated summary and statistical analysis of all available information about the safety of the drug product, including pertinent animal data, demonstrated or potential adverse effects of the drug, clinically significant drug/drug interactions, and other safety considerations, such as data from epidemiological studies of related drugs. In addition, the applicant is required to provide an integrated summary of the benefits and risks of the drug, including a

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD12	/S/	2/8/94						

*U.S. GPO: 1988-216-488

MIF 006071

discussion of how the benefits exceed the risks under the conditions stated in the labeling. Therefore, the possible relationship between abortion and breast cancer suggested by ——— would be evaluated as part of the benefit/risk assessment for any abortifacient product, provided there is substantive, reliable information available.

We hope this information adequately addresses your constituent's concerns.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc:HFW-10(2)
HFD-510/UTERINE ACTING AGENTS(+control HFD-8-9-12C) +
incoming
HFD-8/ ——— (+ control HFD-8-9-12C)
HFD-500/ ——— + control HFD-8-9-12C)
HFD-510/ ——— / (+ control HFD-8-9-12C)
HFD-511/ ——— + attachments)/9/30/93/ .001
concurrences: ——— 10/22/93
edited: ——— 11/8/93

Initialed: ———:11/22/93
———:1/14/94
Edit:HFD-500 ———:1/12/94
Edit: ——— GCF-1:2/4/94
Init: ——— 2/7/94
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F/D: ——— 2/7/94
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No. 14-134
14-848
93-7334
HFD-8-9-12C

APPEARS THIS WAY
ON ORIGINAL

Senator Patrick Moynihan
405 Lexington Ave
NY NY 10174

June 24, 1993

Attached: [redacted]'s January 27th letter to FDA Commissioner David Kessler

Subject: Abortion breast cancer link

Dear Senator

I spoke today with [redacted] office - phone number last page of attached letter. The answer to his letter from the FDA office was a polite 'we received your letter'

I think that this cavalier attitude of the FDA is almost criminal. Long Island has the highest breast cancer rate in the country. We also have the highest abortion rate. Is there a link as indicated by Dr Joel Brind?

Do Long Island women have the right to know? Is this a medically incorrect question to ask?

I have three daughters and two grand daughters.

Please contact the FDA Commissioner and request that he answer this letter in a defenative manner.

May I hear from you? Please advise answer from FDA.

Very truly [redacted]

MIF 006073

DANIEL P. MOYNIHAN
NEW YORK

405 LEXINGTON AVENUE
SUITE 4101
NEW YORK, NY 10174-4101

United States Senate

WASHINGTON, DC 20510-3201

August 23, 1993

Mr. Marc J. Scheineson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Department of Health and Human Services
Room 14-71, PKLN
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Scheineson:

The enclosed inquiry is from a constituent of mine,

I would appreciate your careful consideration of these remarks, and your thoughts on what remedies there may be for this situation.

Please send me your written response in duplicate along with the letter from my constituent to:

Senator Daniel P. Moynihan
405 Lexington Avenue
41st Floor
New York, New York 10174
ATTN: Deborah A. Famighette

Sincerely,

Daniel Patrick Moynihan

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
SEP 8 11 38 AM '93
OFFICE OF
LEGISLATIVE AFFAIRS

14848

MIF 006074

DANIEL P. MOYNIHAN
NEW YORK

405 LEXINGTON AVENUE
NEW YORK, NY 10174

United States Senate

WASHINGTON, DC

June 29, 1993

Mr. Marc J. Scheineson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Department of Health and Human Services
Room 14-71, PKLN
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Mr. Scheineson:

The enclosed inquiry is from a constituent of mine,

I would appreciate your careful consideration of these remarks, and your thoughts on what remedies there may be for this situation.

Please send me your written response in duplicate along with the letter from my constituent to:

Senator Daniel P. Moynihan
405 Lexington Avenue
41st Floor
New York, New York 10174
ATTN: Deborah A. Famighette

Sincerely,

Daniel Patrick Moynihan

APPEARS THIS WAY
ON ORIGINAL

#14134

A.F. _____ FILE
Jaussel Mack

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 04 1994

The Honorable Connie Mack
United States Senator
1342 Colonial Boulevard, Suite 27
Fort Myers, Florida 33907

Dear Senator Mack:

This is in response to your letter of July 9, 1993, on behalf of [redacted], regarding RU-486 for his daughter's treatment. We apologize for the delay in responding.

[redacted] daughter's physician, [redacted], has had several discussions with an official in our Division of Oncology and Pulmonary Drug Products about receiving RU-486, most recently on December 10, 1993. He will be providing the necessary information so that she will be able to receive the drug.

If we can be of any further assistance, please contact us.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D: [redacted] (perdiscussion [redacted]):1/18/94
R/T:jln:2/1/94 ([redacted]\RU-486)
F/D: [redacted]:2/2/94
F/T:jln:2/2/94 ([redacted]\RU-486)
Control Cong #12180 and #14233

APPEARS THIS WAY
ON ORIGINAL

5391

4/5/94

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	2/3/94						

*U.S. GPO: 1988-216-488

MIF 006076

CONNIE MACK
FLORIDA

United States Senate

WASHINGTON, DC 20510-0904

July 9, 1993

Associate Commissioner Hugh C. Cannon
Food and Drug Administration
Congressional Liaison Office
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Associate Commissioner Cannon:

In further regard, enclosed please find correspondence from my constituent.

I would appreciate your advising me of your action in this matter and returning the letter with your reply. Please respond to my Fort Myers Regional Office, located at 1342 Colonial Boulevard, Suite 27, Fort Myers, Florida 33907.

Thank you for your prompt attention.

Sincerely,

Connie Mack

Connie Mack
U.S. Senate

CM/ihg
Enclosure

APPEARS THIS WAY
ON ORIGINAL

14233

MIF 006077

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

KEATING C
333 W 86TH ST 1102A
NEW YORK, NY 10024

10/27/94

In reply refer to:
94042285

Dear Requester:

This is in response to your request for information from the Food and Drug Administration pursuant to the Freedom of Information Act regarding:

RU-486 - RESEARCH, APRVD, COST, ETC

Because the information you requested is not governed by the Freedom of Information Act, your request has been referred for direct response to:

CENTER FOR DRUG EVALUATION
AND RESEARCH (HFD-8)
EXECUTIVE SECRETARIAT STAFF
5600 FISHERS LANE
ROCKVILLE, MD 20857

Communications concerning the status of this request should be addressed to the office listed above. Communications concerning the processing of this request by the Freedom of Information Staff should be identified with the reference number above and addressed as follows:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, MD 20857

Sincerely yours,

/S/

Enclosures:
if indicated

APPEARS THIS WAY
ON ORIGINAL

October 20, 1994

RU486 + DepoProvera + Norplant + pills

Dear Freedom of Information Committee:

Please send answers to these questions to the following address:
(If you do not have the answers, please direct them to someone who does.

PPI

PPI

1. What is RU-486 ? Is it similar to "the morning after pill" ?
2. How does it work?
3. What type of research has been done on this substance?
4. How much data are available?
5. When will it be FDA Approved?
6. What is holding up this process?
7. In what countries is it available, (Besides France, is it in Canada)?
8. How much does it cost?
9. How much will it cost here?
10. How does one get a list of doctors from abroad?
11. What research is being done on male birth control?
12. What is the male pill and how does it work?
13. What types of shots are available and how often does one have to get them?
14. What is Depro-Provera?
15. What research has been done on this substance?
16. What are its side effects?
17. How many women have used this as a means of birth control?
18. What is norplant?
19. Please extrapolate by answering questions 13, 14, 15 on norplant.
20. How reliable are any of these methods? In the practical, scientific and statistical senses?
21. Why is it that the prevention of pregnancy is not supported by most (if not all) health plans?
22. When will this change?
23. What other methods of birth control are there that are not known to the general public?

306-007-C2

Please send the answers to these questions along with articles and any other pertinent information to : Ms. Colleen Keating
333 West 86th Street, 1102A
New York, NY 10024

94-42285

HFI-GC

Thank you,
Sincerely,
Colleen Keating

FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NF 43-253
Roussel-UCLAF

OCT 21 1994

The Honorable Daniel Patrick Moynihan
United States Senate
Washington, D.C. 20510-3201

Dear Senator Moynihan:

This is in response to your request of September 14, 1994, on behalf of [redacted] concerning the availability of the drug mifepristone (RU 486) for the treatment of endometriosis. We are sorry to hear of their daughter's diagnosis.

As you know, the Food and Drug Administration (FDA) regulates the manufacture, sale, and distribution of drugs in the United States under the authority of the Federal Food, Drug, and Cosmetic (FDC) Act. That law defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed in interstate commerce (except for clinical study) until a sponsor, usually the drug's manufacturer, has submitted and FDA has approved a New Drug Application (NDA) for it. For approval, the NDA must contain substantial scientific evidence of safety and effectiveness for the drug's use as labeled. FDA has authority under the FDC Act to approve drugs only after they have been shown to be safe and effective.

In order to study the safety and effectiveness of a new drug, the sponsor (a pharmaceutical company, private, academic or other organization, or an individual) is required to file an Investigational New Drug application (IND) with FDA. Once accepted, the IND allows the sponsor to ship the drug in interstate commerce for research purposes only. The responsibility for the clinical trials and distribution of the drug falls upon the holder of the IND.

When the sponsor determines that adequate and well-controlled studies showing the drug is safe and effective have been carried out, that information, coupled with information on the manufacturing procedures and controls used in producing the drug, is submitted to FDA in the form of an NDA. After comprehensive review by FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

Patient access to drugs in investigational status is a complex issue. When a disease has no good therapy and is severe, there is tremendous desire and pressure to use the drug primarily as

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	10/20						

*U.S. GPO: 1988-216-488

MIF 006081

a treatment before it is approved. For many years, FDA has allowed such use under certain circumstances and in 1987 FDA published regulations that formally recognized the treatment IND and clarified the conditions under which a treatment IND is appropriate. Where the available data are not sufficient to support a treatment IND, such as when controlled clinical trials have not been completed, sponsors may conduct an open-label safety protocol where all patients receive active drug and the safety of the drug is studied.

A physician may wish to explore the use of an individual investigator IND with the sponsor. However, this process is dependent upon the sponsor supplying the drug for this purpose. We can, and do, encourage sponsors to provide access to promising agents when there is potential benefit to patients, but, as a regulatory Agency, we do not have the authority to require that a sponsor do so.

If your constituent's daughter's physician believes RU-486 may be of value in treating his/her patient, the physician should contact the sponsor to determine if a supply of the drug is available for such a study. If the physician can obtain a supply of the drug, he/she should contact a medical officer in FDA's Division of Metabolism and Endocrine Drug Products at _____ for further information.

We hope this information is helpful. If we can be of further service, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10 (2)
R/D: _____:10/6/94
F/T:mts:10/10/94 _____ 948533.moy)
Control 94-8533

APPEARS THIS WAY
ON ORIGINAL

The Honorable Daniel Patrick Moynihan
Senator
(NY) U.S. Senate
464 Russell SB
Washington, DC 20510

Dear Senator Moynihan:

I am writing to you concerning the drug, Mifepristone, better known as RU-486. Studies in Europe have shown that it has been able to successfully treat some women who have endometriosis.

This disease can cause infertility in women. My daughter has this disease. Not only does it cause her daily physical pain, but she and her husband have tried unsuccessfully for nearly five years to have a baby. She has undergone two diagnostic laparoscopies, taken fertility pills two different time frames, and taken Lupron Depot (medication given in the form of a shot).

Since none of these operations or treatments have been effective, I know she would welcome the opportunity to participate in a study of RU-486 to see if it could successfully treat her endometriosis. This drug could be helpful to her and the five million other women in the U.S. that suffer the pain and infertility of this awful disease.

Any help that you could offer me on her behalf would be very appreciated.

Sincerely yours, 6/9/94

The Honorable Daniel Patrick Moynihan
Senator
(NY) U.S. Senate
464 Russell SB
Washington, DC 20510

Dear Senator Moynihan:

I am writing to you concerning the drug, Mifepristone, better known as RU-486. Studies in Europe have shown that it has been able to successfully treat some women who have endometriosis.

This disease can cause infertility in women. My daughter has this disease. Not only does it cause her daily physical pain, but she and her husband have tried unsuccessfully for nearly five years to have a baby. She has undergone two diagnostic laparoscopies, taken fertility pills two different time frames, and taken Lupron Depot (medication given in the form of a shot).

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Any help that you could offer me on her behalf would be very appreciated.

Sincerely yours,

/s/

Eva D. Seeber

UNITED STATES SENATE

Date: 9-14-94

Respectfully referred to:

F D A

for such consideration as the enclosed may warrant. Please send me your written response in duplicate along with the letter from my constituent.

Sincerely,

United States Senate

Mark to the attention of: M. Marinello

APPEARS THIS WAY
ON ORIGINAL

94-8533

MIF 006085

AF 43-253
Roussel-UCLAF

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

OCT 03 1994

The Honorable David A. Levy
House of Representatives
Washington, D.C. 20515-3204

Dear Mr. Levy:

This is in response to your letter of August 5, 1994, on behalf of [redacted] concerning the availability of the drug RU 486 for the treatment of meningioma. We are sorry to hear of his diagnosis.

As you know, the Food and Drug Administration (FDA) regulates the manufacture, sale, and distribution of drugs in the United States under the authority of the Federal Food, Drug, and Cosmetic (FDC) Act. That law defines a new drug as one not generally recognized by qualified experts as safe and effective for the recommended uses. A new drug may not be distributed in interstate commerce (except for clinical study) until a sponsor, usually the drug's manufacturer, has submitted and FDA has approved a New Drug Application (NDA) for it. For approval, the NDA must contain substantial scientific evidence of safety and effectiveness for the drug's use as labeled. FDA has authority under the FDC Act to approve drugs only after they have been shown to be safe and effective.

In order to study the safety and effectiveness of a new drug, the sponsor (a pharmaceutical company, private, academic or other organization, or an individual) is required to file an Investigational New Drug application (IND) with FDA. Once accepted, the IND allows the sponsor to ship the drug in interstate commerce for research purposes only. The responsibility for the clinical trials and distribution of the drug falls upon the holder of the IND.

When the sponsor determines that adequate and well-controlled studies showing the drug is safe and effective have been carried out, that information, coupled with information on the manufacturing procedures and controls used in producing the drug, is submitted to FDA in the form of an NDA. After comprehensive review by FDA, the NDA is either approved or not approved; upon approval the drug may be marketed.

Patient access to drugs in investigational status is a complex issue. When a disease has no good therapy and is severe, there is tremendous desire and pressure to use the drug primarily as a treatment before it is approved. For many years, FDA has

5094.51

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	[illegible]	10/3						

*U.S. GPO: 1988-216-488

MIF 006086

allowed such use under certain circumstances and in 1987 FDA published regulations that formally recognized the treatment IND and clarified the conditions under which a treatment IND is appropriate. Where the available data are not sufficient to support a treatment IND, such as when controlled clinical trials have not been completed, sponsors may conduct an open-label safety protocol where all patients receive active drug and the safety of the drug is studied.

A physician may wish to explore the use of an individual investigator IND with the sponsor. However, this process is dependent upon the sponsor supplying the drug for this purpose. We can, and do, encourage sponsors to provide access to promising agents when there is potential benefit to patients, but, as a regulatory Agency, we do not have the authority to require that a sponsor do so.

If your constituent's physician believes RU-486 may be of value in treating his patient, the physician should contact a medical officer in FDA's Division of Oncology and Pulmonary Drug Products at [redacted] for further information.

We hope this information is helpful. If we can be of further service, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-10 (2)
R/D: [redacted] :9/28/94
R/T: [redacted] 9/28/94
Edit: [redacted] :9/29/94
F/T: [redacted] :9/30/94 ([redacted] 947341.
Control 94-7341

APPEARS THIS WAY
ON ORIGINAL

DAVID A. LEVY
4TH DISTRICT, NEW YORK
COMMITTEES:
FOREIGN AFFAIRS
PUBLIC WORKS AND
TRANSPORTATION

Congress of the United States

House of Representatives

Washington, DC 20515-3204

116 CANNON HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3204
(202) 225-5516

203 ROCKAWAY AVENUE
VALLEY STREAM, NY 11580-5837
(516) 872-9550

August 5, 1994

Ms. Kay Holcombe
Acting Associate Commissioner for
Legislative Affairs
Food and Drug Administration
Room 1555, 5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Holcombe:

The enclosed letter from my constituent, ———— is forwarded for your consideration and assistance.

I would appreciate your review of this matter. As you can see, ———— would like to have use of RU486 under the Compassionate Use program. Please let me know the steps that must be taken to make him eligible for this program.

Thank you for your anticipated cooperation. I look forward to hearing from you very soon. **When responding to this inquiry, please refer to the constituent's name listed above.**

Sincerely,

DAVID A. LEVY
Member of Congress

DAL/ko

APPEARS THIS WAY
ON ORIGINAL

94-7341

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE 4:

September 14, 1994

Dr. Andre Ullman
~~Roussel Uclaf~~
102, route de Noisy
93235 Romainville Cedex
FRANCE

Dear Dr. Ullman:

The Food and Drug Administration asks that Roussel Uclaf provide The Population Council access to, and the ability to copy and submit to the United States Food and Drug Administration, any information relevant to the use of mifepristone (RU-486) for the termination of early pregnancy. This request includes case report forms, electronic data bases, synthesis and manufacturing information, and any other information required by United States laws and regulations to be included in a New Drug Application for mifepristone.

We would appreciate your prompt consideration of this request.

Sincerely yours,

/S/

- APPEARS THIS WAY
ON ORIGINAL

94-8442

MIF 006089

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 14, 1994

FILE 43-22

Note to: Secretary Donna Shalala

We thought you would be interested in the status of RU-486. We have been told by the Population Council that its pilot studies on mifepristone (RU-486) will begin this week in Texas and California. The larger studies (involving 2,100 women) will begin in 12 to 16 clinics after the investigators from those clinics meet at the Population Council on October 3-4, 1994, to review the protocol, informed consent procedures, and other study issues.

The Population Council's efforts to obtain information from Roussel Uclaf and to manufacture mifepristone are somewhat more problematic. I have asked Roussel Uclaf to provide the necessary safety, effectiveness, and manufacturing data to the Population Council. We have also let the Population Council know the importance of resolving the chemistry and manufacturing issues early. We will continue working with Roussel Uclaf and the Population Council in an effort to resolve these outstanding concerns.

/S/

cc:

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

CHARLES S. ROBB
VIRGINIA

STATE OFFICE:
Old City Hall
1001 East Broad Street
Richmond, VA 23219
(804) 771-2221

United States Senate

WASHINGTON, DC 20510-4603

COMMITTEES:
ARMED SERVICES
COMMERCE, SCIENCE, AND TRANSPORTATION
FOREIGN RELATIONS
Chairman, East Asian and Pacific Affairs Subcommittee
JOINT ECONOMIC COMMITTEE
Vice Chairman, Democratic Policy Committee

June 20, 1994

Ms. Diane E. Thompson
Food and Drug Administration
Assoc. Commissioner for Leg. Affairs
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Thompson:

Enclosed is correspondence I received in reference to a matter involving your agency. Your assistance with the requests and concerns expressed in this case would be greatly appreciated.

It would be very helpful if you would reply in duplicate and return the enclosure. In your reply, please reference

Your correspondence should be mailed to my office at the address indicated above.

Again, thank you for your assistance.

Sincerely,

Charles S. Robb

CSR\jbp
Enclosure

APPEARS THIS WAY
ON ORIGINAL

Washington Office:
Russell Senate Office Building
1st & Constitution NE, Room 493
Washington, DC 20510-4603
(202) 224-4024

Regional Offices:

Dominion Towers, Suite 107
999 Waterside Drive
Norfolk, VA 23510
(804) 441-3124

8229 Boone Boulevard
Suite 888
Vienna, VA 22182
(703) 356-2006

1 Court Square
Suite 340
Harrisonburg, VA 22801
(703) 432-1561

Dominion Bank Building
Main Street
Clintwood, VA 24228
(703) 926-4104

Signet Bank Building
530 Main Street
Danville, VA 24541
(804) 791-0330

Crestar Bank Building
310 First Street SW, Suite 102
Roanoke, VA 24011
(703) 985-0103

94-5802

MIF 006091

FILE AF 13-253
Roussel-UCLAF

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 31 1994

The Honorable Charles S. Robb
United States Senate
Washington, D.C. 20510-4603

Dear Senator Robb:

This is in response to your letter of June 20, 1994, on behalf of [redacted] concerning the availability of the new drug RU-486 for treatment of endometriosis.

We are sorry to report that before a new drug is approved, we are precluded by law from releasing information on studies of the drug. For your information, we have enclosed the Food and Drug Administration's (FDA) formal statement before the Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, U.S. House of Representatives on May 16, 1994, a May 16, 1994, HHS Fact Sheet, and a May 16, 1994, HHS News release.

We hope this information is helpful. If we can be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
As stated above
Constituent's letter

cc: HFW-10(2)

R/D: 8/30/94
F/T: 8/30/94 (s:\wp RU-486

FDA Control No. 94-5802

505.6

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-2	TS	8/31						

*U.S. GPO: 1988-216-466

MIF 006092

The Honorable Charles S. Robb
Senator
U.S. Senate
493 Russell SB
Washington, DC 20510

Dear Senator Robb:

My husband and I are writing to you concerning the drug, Mifepristone, better known as RU-486. We have a genuine concern in this drug because studies in Europe have shown that it has been effective in treating some women who have endometriosis.

This disease can cause infertility in women. I have this disease. Not only does it cause me daily physical pain, but in nearly five years of trying, my husband and I have been unsuccessful in conceiving a baby. I have undergone two diagnostic laparoscopies to remove the endometriosis, taken fertility pills two different time frames, and taken Lupron Depot (medication given in the form of a shot).

Since none of these operations or treatments have been effective, I would welcome the opportunity to participate in a study or trial of RU-486. This drug could be so helpful to not only myself, but also the five million other women in the U.S. who suffer the pain and infertility of this awful disease.

Any information or help you could offer my husband and myself would be appreciated. Thank you for your help in this matter.

Sincerely yours,

/s/

/s/

FILE

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: AUG 18 1994

FROM: Chief, Institutional Review Branch, HFD-343

SUBJECT: Consultative Review of Consent, IND ——— Mifepristone

TO: ——————— HFD-510

You are not listed in the on-line telephone directory. It is not possible to send electronic mail to you. Nobody answers the phone when I call the number listed for HFD-510. Therefore, I must resort to sending you a memo by interoffice mail.

Your request for review of the above referenced consent cannot be completed without a copy of the protocol for the study. Please send the protocol to ——————— HFD-343, MPN ———

cc:
HFA-224
HFD-340:RF
HFD-———
DSI:IRB: ——————— 8/18/94

APPEARS THIS WAY
ON ORIGINAL

FILE

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: August 16, 1994

FROM: Prescription Drug Compliance Branch (HFD-313)
Division of Drug Labeling Compliance

SUBJECT: RU-486 Incoming Shipment

TO: _____ HFR-SE340
Compliance Branch

I spoke with _____ Division of Oncology and Pulmonary Products (HFD-150), today regarding the shipment of an investigational new drug under IND # _____ _____ talked with _____ to confirm the number used on the imported package and the name of the patient.

_____ is now treating the patient who was being treated by another doctor under IND # _____ According to _____ the necessary reports have been submitted by _____ and therefore, the shipment may be released. In the future, _____ should request shipment under IND _____ for this patient and his other listed patients.

APPEARS THIS WAY
ON ORIGINAL

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE COPY	HFD-313	/S/	8-16-94			
	HFD-313	/S/	8-16-94			

Memorandum

August 15, 1994

Note to PHS Executive Secretariat

Subject: White House Correspondence from ——— re RU-486 - PHS Tracer #T69910

——— letter to Mrs. Clinton was referred to the Food and Drug Administration on June 24. In this letter she asked for assistance in obtaining RU-486 on a compassionate use basis for her meningioma. Upon receipt, FDA's Oncologic Drugs Review Division contacted ——— and determined that she was not eligible for the SWOG protocol and, therefore, may be eligible for an emergency IND. Her physician, however, was not willing to be responsible for her treatment under an IND, and this delayed our ability to respond to her request. The review division was able to identify another physician in her area who is already treating a couple of other patients with RU-486. An emergency IND was issued to ——— on August 8, 1994, who agreed to treat ——— after her neurologist had declined to treat her. Thus, ——— letter can be "closed."

Please call me if you have any questions.

/S/

———

Senior Policy Analyst

APPEARS THIS WAY
ON ORIGINAL

THE WHITE HOUSE

WASHINGTON

6-17-94
DATE

MEMORANDUM

FOR: HHS / FDA

FROM: DIRECTOR, OFFICE OF AGENCY LIAISON

SUBJECT: WHITE HOUSE TELEPHONE MESSAGE

The attached telephone message received in the White House is forwarded to your office for response. Please return the original telephone message and a copy of your written or telephone response to me at the following address:

The White House
Washington, D.C. 20500

If you have any questions, please contact my office at

Thanks.

APPEARS THIS WAY
ON ORIGINAL

9406220016

T69910
TRACER

MIF 006097

JUL 19 1994

The Honorable William F. Clinger, Jr.
House of Representatives
Washington, D.C. 20515-3805

Dear Mr. Clinger:

This is in response to your letter of July 4, 1994, on behalf of [redacted] concerning approval of RU-486, an abortifacient approved in France.

RU-486 has not received approval from the Food and Drug Administration (FDA) for marketing, although this drug is in clinical trials.

FDA reviews drugs but does not test them. Drug sponsors, generally manufacturers, arrange for testing by experts, as well as shouldering the cost, and include the results in new drug applications (NDAs).

Before FDA will permit testing of a drug in humans, the sponsor of the drug must provide us with information demonstrating that the drug is reasonably safe to administer to humans. The sponsor must also provide manufacturing and control data, a detailed protocol of study, and names and qualifications of investigators who will be performing the clinical trials.

The Federal Food, Drug, and Cosmetic Act, which we administer, sets forth the criteria for approval of new drugs. Approval is based on submission of data collected during the course of an investigation which demonstrates the drug is safe and effective for the purpose of use. Our review is based on an impartial evaluation of the scientific data.

Ethical concerns similar to your constituent's have been expressed by others. We appreciate these concerns and respect their personal opinion. We hope, however, that you will understand that our authority is limited to safety and efficacy requirements mandated by law. We cannot refuse testing or approval of a new drug if the data to support such action are submitted to the agency.

THIS WAY
ORIGINAL

MIF 006099

We hope this information is helpful. If we can be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

cc: HFW-10 (2)
R/D: ——— :7/2/94
F/T:7/15/94 (s:\wp ———)4-6297)
(from 7/6/94 ltr to ——s from ———

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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*U.S. GPO: 1988-216-488