HOUSE OF REPRESENTATIVES
SIXTEENTH LEGISLATURE, 1992
STATE OF HAWAII

H.C.R. NO. 34

HOUSE CONCURRENT RESOLUTION

URGING THE PRESIDENT AND CONGRESS TO SUPPORT THE AVAILABILITY OF THE ANTIPROGESTERONE STEROID MIFEPRISTONE, KNOWN AS RU-486, AND OTHER RELATED AGENTS FOR APPROPRIATE RESEARCH AND CLINICAL TRIALS IN THE UNITED STATES.

WHEREAS, RU-486, a major new drug, has been in use in France since 1988, has more recently been approved for use in Great Britain and is likely to be marketed soon in the Scandinavian countries; and

WHEREAS, when prescribed with another drug, RU-486 has been shown to be an effective, safe and non-invasive treatment for the termination of early pregnancy; and

WHEREAS, research continues under the auspices of a task force of the World Health Organization on RU-486's potential for contraceptive use, and

WHEREAS, RU-486 has also been found to be useful in easing labor and an effective treatment for Cushing's syndrome; and

WHEREAS, the medical community has identified RU-486 as a promising treatment for a number of other conditions, including some breast and brain cancers, prostate cancer, endometriosis, ovarian cancer, osteoporosis and AIDS; and

WHEREAS, before RU-486 can be made available for use in the United States it must be subjected to clinical trials by the Federal Drug Administration; and

WHEREAS, the drug's maker, Roussel-Uclaf, and its parent company, Hoechst, have indicated that they will not ask to market the drug in this country because of the perceived political climate and their fear of a possible boycott of all their other products; and

WHEREAS, the FDA has given no indication that it will conduct such tests and in 1989 banned the importation of RU-486 for personal use; and

HCR HMIA 92-224

H.C.R. NO. 34

WHEREAS, RU-486 has been used safely over 80,000 times in France where there has been only one fatality in a high risk patient; and

WHEREAS, the ban not only denies Americans access to an important drug, it has also caused most American research in this area to come to a stop; and

WHEREAS, 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 have formally recognized the importance of RU-486 and have acted to support the testing of of Ru-486 and related agents in the United States; and

WHEREAS, the Hawaii State Legislature, together with the above organizations, supports freedom of medical research for American scientists and decries barriers to access to promising drugs and important new technologies; and

WHEREAS, political considerations should not stand in the way of the right of American women to have access to the least invasive and safest care available in terminating early pregnancies; now, therefore

BE IT RESOLVED by the House of Representatives of the Sixteenth Legislature of the State of Hawaii, Regular Session of 1992, the Senate concurring, that the Hawaii State Legislature urges the President of the United States and the Congress to rescind the ban imposed by the Food and Drug Administration and support the use of RU-486 and other related agents for all appropriate research and, if indicated, clinical trials; and

BE IT FURTHER RESOLVED that certified copies of this Resolution be transmitted to the President of the United States, the President of the United States Senate, the Speaker of the House of Representatives, Hawaii's congressional delegation, to the manufacturer of RU-485, Roussel-UCLAF, 35 Boulevard des Invalides 75007, Paris France and to the Commissioner of the federal Food and Drug Administration.

OFFERED BY:

HCR HMIA 92-224

Senator Robert W. Kasten, Jr.
Senate Office Building
Washington, DC 20510

Re: Continuing Ban On Use of RU486 In America

Dear Senator Kasten:

Without going into the issue of whether choice in abortion should be permitted, the reason for which I am writing about RU486 has nothing to do with that. It has a more personal meaning to my family. As a result of the activity of the anti-abortion forces in this country, there has been an effective blocking of the introduction or use of RU486 in this country which has the effect of also blocking it for things other than abortions. This development could be tragic for my family. I have a son-in-law who has developed a bone malady diagnosed as Cushing's disease. Frankly, his situation is serious. The doctors are trying everything to try to arrest its progress. Maybe something will work, maybe not. If nothing works, probably I hate to say it, we will lose a son-in-law and my two grandchildren will be fatherless and my daughter without a husband.

I have read literature that demonstrates RU486 as being effective in the treatment of Cushing's disease. (See enclosure.) That being so why should he be caught in the middle of a political situation poising the antis against the pros. It is intolerable that anybody should be able to block an efficacious treatment not only for my son-in-law's disease, but, as I am informed, the treatment for a number of other conditions including breast cancer.

I am informed that Congressman Ron Wyden of Oregon has introduced legislation to reverse the FDA's ban on the importation of RU486 even for purposes of experimental inquiry. To Representative Sensenbrenner I say take the humanitarian position and sign on as a sponsor of this bill. To Senators Kohl and Kasten I say if ~~there~~ isn't already a companion bill in the Senate, please be a prime mover in seeing that one is introduced and moved forward.

It is ~~reprehensible~~ that zealots should be able to effectuate the doom of my son-in-law.

Very truly yours,

/s/

Encl.

A.F. _____ 116

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 09 1992

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

Dear Senator Breaux:

This is in response to your inquiry of May 12, 1992, on behalf of _____ Louisiana, concerning RU-486, an abortifacient developed in France.

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

Before we will permit testing 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. These requirements were met by the Population Council, New York, New York.

The Federal Food, Drug, and Cosmetic (FDC) 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.

We appreciate the concerns expressed by _____ 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.

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

Sincerely yours,

/S/

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter
cc: HFW-10(2)
R/D: _____ 6/3/92
F/T: _____ 6/3/92
re/t: _____ 5/5/92
CONG-8002 NO. 9600(_____ \DURGLTR\STOPRU.486)

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW2	_____	6/5/92						

*U.S. GPO: 1989-624-401

FILE COPY

MIF 005905

1992 MAY -7 AM 9:15

May 3, 1992

Senator John Breaux
U.S. Senate
Washington, D.C. 20510

RE: Stop FDA approval of RU486

Dear Senator Breaux,

I know that you can see through the smoke screen of the RU 486 pill. It is just another way to kill the unborn child. Please use your power and influence to stop the FDA approval of this abortion pill.

A supporter of life,

/S/

John Breaux
Louisiana

Committees:
Commerce, Science, and Transportation
Finance
Special Committee on Aging

United States Senate

WASHINGTON, DC 20510-1803

WASHINGTON OFFICE:
(202) 224-4623

CENTRAL LOUISIANA OFFICE:
534 MURRAY STREET
ALEXANDRIA, LA 71301
(318) 473-7370

SOUTH LOUISIANA OFFICE:
THE FEDERAL BUILDING
705 JEFFERSON STREET, ROOM 103
LAFAYETTE, LA 70501
(318) 264-6871

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

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

May 12, 1992

Ms. Kay Holcombe
Associate Commissioner (Acting)
Office of Legislative Affairs
Food & Drug Administration
5600 Fishers Lane, Room 1555
Rockville, Maryland 20857

Dear Ms. Holcombe:

I have been contacted by _____ regarding his views and concerns about the possible FDA approval of the RU 486 pill. _____ writes to express his opposition to the approval of this drug.

Please investigate the enclosed information sent to me and provide me with a report on the status of the approval of the RU 486 pill. Your reply may be forwarded to the attention of Denise G. Riemer.

Thank you for your attention and assistance.

Sincerely,

John Breaux

JOHN BREAUX
United States Senator

JB:dgr
Enclosure

#F9600

May 20, 1992

Our Reference: F92-16084
Your Reference: GC-142-E

Virginia Leitav
Pantoquimica
Sociedade Farmaceutica LDA
P.O. Box 21090
1127 Lisboa Codex
PORTUGAL

Dear Ms. Leitav:

Reference is made to your Freedom of Information request of April 3, 1992 for a copy of the last inspection report for Roussel UCLAF, Compiegne, France. 43-253

Enclosed is the requested document dated 10/31/90. FILE

Certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request to the following address:

Food and Drug Administration
Freedom of Information Staff, HFI-35
5600 Fishers Lane
Rockville, Maryland 29857

Should the Agency then deny this information, you have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

The following charges will be included in a monthly invoice:
Reproduction $.30; Search $11.50; Review $11.50; Total $23.30.

The above charges may not reflect final charges for this request. Please DO NOT send any payment until you receive an invoice from the Freedom of Information Staff (HFI-35).

Sincerely,

Policy and Guidance Branch, HFD-323
Division of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research
Telephone:

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 15 1992

The Honorable Arlen Specter
United States Senator
Federal Building, Suite 2031
Pittsburgh, Pennsylvania 15222

Dear Senator Specter:

This is in response to your letter of March 12, 1992, on behalf of _____ regarding the unapproved new drug, RU-486 for the treatment of breast cancer.

As you may know, RU-486 is a drug that is approved in France through a limited distribution system for early abortion when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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.

/S/

Please be assured that we are committed to facilitating the availability of products that could be beneficial.

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-42	/S/	5/14/92						

/S/
5/15

FILE COPY

*U.S.GPO:1990-0-213-082

MIF 005909

For your information, a number of studies with RU-486 for the treatment of various diseases, including meningiomas, Cushing's syndrome, Alzheimer's diseases, endometriosis, and breast cancer are underway in the country. FDA officials also have met with an official of Roussel-Uclaf to discuss the continued availability of the drug for clinical trials in this country. They were informed that the company is interest in pursuing studies in the United States.

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

/S/
Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted] :5/3/92
F/T; var:5/11/92
CONG-7310 and No. 8784
[redacted]\DRUGLTRS\STUDY.RU)

APPEARS THIS WAY
ON ORIGINAL

ARLEN SPECTER
PENNSYLVANIA

COMMITTEES
AGING
BANKING
JUDICIARY
APPROPRIATIONS
VETERANS' AFFAIRS

☐ 303 HART SENATE BUILDING
WASHINGTON, DC 20510-3802
202-224-4254

United States Senate

WASHINGTON, DC 20510-3802

STATE OFFICES
☐ 600 ARCH STREET, SUITE 9400
PHILADELPHIA, PA 19106
215-597-7200
☒ SUITE 2031, FEDERAL BUILDING
PITTSBURGH, PA 15222
412-644-3400
☐ ROOM 118, FEDERAL BUILDING
ERIE, PA 16501
814-453-3010
☐ ROOM 1159, FEDERAL BUILDING
HARRISBURG, PA 17101
717-782-3951
☐ ROOM 201, POST OFFICE BLDG.
ALLENTOWN, PA 18101
215-434-1444
☐ SUITE 503, PARK PLAZA
SCRANTON, PA 18503
717-346-2006
☐ ROOM 306, 116 S. MAIN ST
WILKES-BARRE, PA 18701
717-826-6265

March 12, 1992

Congressional Liaison
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Gentlemen:

My office has been contacted by [redacted] regarding the use of RU-486 for the treatment of breast cancer. I am forwarding to you a copy of the correspondence that I have received.

Your findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to my Assistant, Mrs. Rebecca M. Hairston, at the following address:

Senator Arlen Specter
The Federal Building
Liberty Avenue and Grant Street
Pittsburgh, PA 15222

Thank you for your assistance with the aforementioned matter.

Sincerely,

Arlen Specter

AS/rmh
Enclosure

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
92 MAR 23 PM 1:54
OFFICE OF LEGAL COUNSEL

#8784

ALICE S. LANGTRY, MEMBER
1750 N. HIGHLAND ROAD
PITTSBURGH, PENNSYLVANIA 15241
PHONE: (412) 831-0888

HOUSE POST OFFICE BOX 197
MAIN CAPITOL BUILDING
HARRISBURG, PENNSYLVANIA 17120-0088
PHONE: (717) 787-8481

COMMITTEES

APPROPRIATIONS
TRANSPORTATION,
SUBCOMMITTEE CHAIRMAN ON
PUBLIC TRANSPORTATION

House of Representatives
COMMONWEALTH OF PENNSYLVANIA
HARRISBURG

March 3, 1992

JJB

1A-26

COPY

Dear ——

I am so terribly sorry to read of your sister's death because of breast cancer.

Implicit in your letter is the possibility that RU-486 may have saved her life and may save the lives of other women suffering from breast cancer. Indeed, the article you enclosed stated that RU-486 "...might well be effective against breast cancer."

If this is so surely the testing of this drug as a possible cure for breast cancer should be of the highest priority.

The safety and effectiveness of any drug is the responsibility of the Food and Drug Administration, an agency of the federal government.

Therefore, by copy of this letter, and yours, to Senator Wofford, Senator Specter and Representative Santorum, I am requesting that they urge the Food and Drug Administration to determine if RU-486 is a safe and effective medication for the treatment of breast cancer.

Very truly yours,

Alice Langtry

Alice S. Langtry
Representative
40th Legislative District

ASL/lls

cc: Senator Specter
Senator Wofford
Representative Santorum

APPEARS THIS WAY
ON ORIGINAL

January 18, 1992

[ ]

The Honorable Alice Langtry
1750 North Highland Rd.
Upper St. Clair, PA 15241

Dear Congresswoman Langtry,

On ——— my sister, ——— died of breast cancer. She was only 47 years old. ——— was a kind, loving, giving person with a wonderful sense of humor. She loved her family, her friends, her job, and her life. We had so much fun together from growing up on a Wisconsin dairy farm to our middle age. I wanted to grow old with her, share stories of our grandchildren and compare wrinkles. A bright light has gone from my life and the lives of many who loved ——— We miss her very much.

A day after ——— was buried, this article appeared in the Wisconsin State Journal. I am, therefore, asking you to see what you can do about getting RU-486 to this country. Thousands of sisters, daughters, granddaughters, aunts, and mothers die from breast cancer in this country every year. It is too late for my sister, but in her memory, I urge you to speak out for all of our sisters.

Sincerely,

/s/

lt
Enc.

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 13 1992

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

Dear Senator Moynihan:

This is in response to your letter of March 5, 1992, on behalf of _____ regarding the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France through a limited distribution system for early abortion when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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.

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

/S/
4/13

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	/S/	4/6/92						

FILE COPY

*U.S.GPO:1988-0-213-062

MIF 005915

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, publicity regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country, which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance on the importation of unapproved drugs.

It is extremely important to point out that this import alert in no way restricts the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the House Small Business Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990, which contains additional information on this complex issue.

Please be assured that we are committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under existing law, and I can assure you that any protocol for research and testing of RU-486 submitted to FDA will be given a fair review based on the scientific issues involved.

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

/S/
Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

3 Enclosures
Constituent's letter
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted]:3/20/92
F/T; var:4/1/92
CONG-7218 and No. 8688
[redacted]DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

December 23, 1991

Honorable Daniel Patrick Moynihan
United States Senator
733 Third Avenue
New York, NY 10017

Dear Senator Moynihan:

Why is this great country of ours so inappropriately handling the quest for life-saving new drugs? The F.D.A. seems to have its head stuck in the sand. These are great times we are living in. The pharmaceutical companies seem to be at the threshold of victory against such diseases as Aids, breast cancer, and Alzheimer disease. Yet drugs that may cure these afflictions are being denied the public, in some cases for years, until all exhausting testing has been complete.

What the F.D.A.'s current policy means is that many of our people will not be alive when these drugs are finally approved for distribution. I can understand the need to protect healthy people from untested drugs. I cannot understand the withholding of potential life-saving new drugs from terminally ill people who are rapidly approaching death. Give them every opportunity to live, even if it means they're being treated by potentially life-saving drugs that are, as yet, in need of more testing.

A French pharmaceutical company, Roussel-Uclaf, has by-passed the United States in favor of Canada for widespread testing of a new drug, R.U.-486. This drug is destined to join the fight against breast cancer, but because of our own F.D.A.'s overbearing caution, we are not even getting the drug to test. Toxal is another new drug that represents a major breakthrough in the treatment of breast cancer that, as yet, is not available to the public.

My wife has metastatic breast cancer. She wants to live as I assume all people with her disease do. She needs these drugs now, not when it's too late. The present policy of the F.D.A. will doom countless thousands of people. I exhort you to help do something about it now.

Very truly yours,

/s/

DANIEL P. MOYNIHAN
NEW YORK

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

United States Senate

WASHINGTON, DC 20510-3201

March 5, 1992

Dr. ~~Frank B. Young~~
Food and Drug Administration
Department of Health and Human Services
Room 14-71, PKLN
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Dr. Young:

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

MIF 005919

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 1992

The Honorable Alan J. Dixon
United States Senate
Washington, D.C. 20510

Dear Senator Dixon:

This is in response to your letter of February 6, 1992, on behalf of _____ regarding the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France through a limited distribution system for early abortion when used with one of two prostaglandins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for diseases such as breast cancer, Cushing's syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug, and Cosmetic Act (FDC), 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.

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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.

Strictly interpreted, the FDC Act prohibits the import and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	/S/	4/2/92						

/S/ 4/6

FILE COPY

*U.S.GPO:1988-0-213-062

MIF 005920

patients, many of whom suffer from serious or life-threatening diseases, FDA has, as a matter of enforcement discretion, long permitted individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, however, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks to the American public. This is because the intended use of RU-486 makes it likely that it could be used without supervision by a physician, and that indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin, also not approved in the United States, further complicating the safety issue.

Also, because RU-486 is not proposed for treatment of a serious condition for which no alternative treatment exists (one of the criteria set forth in the Pilot Guidance document), yet poses safety risks, we do not believe that our import policy can be appropriately applied to permit the importation of RU-486. Moreover, publicity regarding the availability of the drug overseas raised for FDA the possibility that a demand would be created in this country, which in turn would foster importation of the drug for commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is sound public health policy and is consistent with our policy guidance on the importation of unapproved drugs.

It is extremely important to point out that this import alert in no way restricts the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome and some forms of cancer.

For your information, we are also enclosing a copy of testimony presented at a hearing before the House Small Business Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990, which contains additional information on this complex issue.

Please be assured that we are committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under existing law, and I can assure you that any protocol for research and testing of RU-486 submitted to FDA will be given a fair review based on the scientific issues involved.

We hope the information provided will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

/s/
Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: 3/27/92
F/T; var:3/30/92
CONG-6835 and No. 8268
(DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

MAJORITY
CHIEF DEPUTY
WHIP

United States Senate

WASHINGTON, DC 20510-1301

ARMED SERVICES
BANKING, HOUSING AND URBAN AFFAIRS
SMALL BUSINESS

February 6, 1992

Ms. Kay Hocombe
Acting Associate Commissioner
for Legislative Affairs
Food and Drug Administration
United States Department of Health
and Human Services
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Hocombe:

Enclosed is a letter I received from my constituent, [redacted] regarding RU486.

Because of my desire to be responsive to all communications, I request your response to this matter.

It would be most appreciated if you would forward your findings directly to the attention of my assistant, Bradley G. Hunt. Thank you in advance for your assistance.

Kindest personal regards.

Sincerely,

Alan J. Dixon

Enclosure

APPEARS THIS WAY
ON ORIGINAL

WASHINGTON, DC OFFICE:
202-224-2854
331 HART BUILDING
WASHINGTON, DC
20510-1301

CHICAGO OFFICE:
312-353-5420
230 SOUTH DEARBORN
CHICAGO, IL
60604

SPRINGFIELD OFFICE:
217-492-4126
6TH AND MONROE
SPRINGFIELD, IL
62701

EAST ST. LOUIS OFFICE:
618-398-7920
8787 STATE STREET
EAST ST. LOUIS, IL
62203

MOUNT VERNON OFFICE:
618-244-6703
105 SOUTH 6TH STREET
MOUNT VERNON, IL
62864

SDT

January 2, 1992

1992 JAN -8 AM 9:44

Senator Alan Dixon
U. S. Senate
Washington, DC 20510-1301

Dear Senator Dixon:

In the December 29 edition of the Sunday Chicago Tribune, on the front page of the editorial section, there was an article on the drug RU486. According to this article, this drug has several proven and potential uses, but is being withheld from testing for sale in the United States because of pressure from abortion opponents. As you may know, RU486 has been used in France since 1987 for several purposes, one of which is to bring about the termination of an unwanted pregnancy (if taken within the first seven weeks of pregnancy).

According to the Tribune article, the Food and Drug Administration is delaying processing of the drug for approval for sale in this country. The purpose of this letter is to request that you use your position as a member of Senate to investigate these charges and, if true, do what you can to get this policy changed.

I am a strong advocate of reproductive rights and family planning. I have thought long and hard about the abortion issue, and I feel that a woman's decision whether or not to have an abortion is a decision best left to her and those she chooses to assist her. The government should not intrude into this most personal issue, except to allow her the freedom to attain whatever information she might need to make an informed choice. That is why I hope that you will be active in support of any efforts to void the recent Supreme Court decision to deny such iformation to some women.

I don't see too much difference in the actions of the Communist Chinese government, which is alleged to sometimes force women to have abortions, and an American government which would force a woman to continue a pregnancy against her will.

Everyone, in every nation of the world, should have the right to be left alone to live one's life in peace without fear of unreasonable government coercion.

Thank you for your consideration. I would appreciate a response explaining your position in these matters.

Sincerely.

/S/

[ ]

R.F. _____ FILE

The Honorable Arlen Specter
United States Senator
Suite 9400, Federal Building
600 Arch Street
Philadelphia, Pennsylvania 19106

Dear Senator Specter:

This is in response to your letter of August 21, 1992, on behalf of _____ regarding the importation of RU-486 into the United States.

It is extremely important, at the outset, to point out that the import alert in effect for RU-486 in no way restricts the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome, some forms of cancer, and the disorders such as those mentioned by Ms. Fisher. Rather, it is intended to restrict the drug's importation for personal use for the reasons described below.

Let me begin by providing you with some specific background information on the Food and Drug Administration (FDA) procedures relative to unapproved new drugs. RU-486, currently an unapproved new drug, has not been treated any differently than any other product in that category. As you may know, FDA's drug review responsibilities and authority under the Federal Food, Drug, and Cosmetic Act (FDC Act) are limited to determinations based on the data and information requirements mandated by that statute. FDA's regulations require a person who wishes to conduct a clinical investigation on an unapproved drug to submit to FDA an Investigational New Drug application (IND), and to comply with all applicable regulatory requirements governing the conduct of clinical investigations. An IND becomes effective within thirty days unless FDA notifies the sponsor of the investigation that the proposed clinical trial should not proceed. The grounds for taking the latter action are that (1) the sponsor has not provided sufficient information to evaluate the risks of the drug, (2) the risks to the subjects are unreasonable, (3) the investigators are not qualified, or (4) the information provided to the investigators is misleading. Certain investigations to determine effectiveness must also have protocol designs that clearly are sufficient to meet their stated objectives.

Strictly interpreted, the FDC Act prohibits the importation and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	/S/	9/8/92						/S/ 9/22
								/S/

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

MIF 005925

patients, many of whom suffer from serious and life-threatening diseases, FDA, as a matter of enforcement discretion, may permit individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks. This is because the intended use of RU-486 makes it likely that potential users might well not be under the care of a physician; indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin that also is not approved in the United States. This further complicates the safety issue.

Furthermore, FDA's procedures specify that importation of an unapproved drug is only appropriate under certain other conditions. One of the most significant of these is that the drug is proposed for treatment of a serious condition for which no alternative treatment exists. (A copy of the Regulatory Procedures Manual, Part 9-71, is enclosed.) In addition to its safety risks, RU-486 also does not satisfy this criterion.

For both of these reasons, we do not believe that the importation of RU-486 can be permitted under our import policy. Moreover, the publicity in this country regarding the availability of the drug overseas raises the clear possibility that a demand could be created in this country that could foster importation of the drug for unapproved commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is not only consistent with our policy guidance on the importation of unapproved drugs, but also sound public health policy.

For your information, I am enclosing a copy of testimony presented at a hearing before the House Small Business Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990, which contains additional information on this complex issue.

Please be assured that we are committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under existing law, and I can assure you

that any protocol for research and testing of RU-486 submitted to FDA will be given a fair review based on the scientific issues involved.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

3 Enclosures
Regulatory Procedures Manual
FDA Testimony

cc: HFW-10(2)
(VALARIE\DRUGLTR\RU486NEW.MDG)
F/D: [redacted]:9/14/92
F/T: — .9/17/92
CONG-9106 and No. 10878

[redacted]

APPEARS THIS WAY
ON ORIGINAL

ARLEN SPECTER
PENNSYLVANIA

COMMITTEES:
AGING
BANKING
JUDICIARY
APPROPRIATIONS
VETERANS' AFFAIRS

☐ 303 HART SENATE BUILDING
WASHINGTON, DC 20510-3802
202-224-4254

United States Senate
WASHINGTON

STATE OFFICES:

☐ 600 ARCH STREET, SUITE 9400
PHILADELPHIA, PA 19106
215-597-7200

☐ SUITE 2031, FEDERAL BUILDING
PITTSBURGH, PA 15222
412-644-3400

☐ ROOM 118, FEDERAL BUILDING
ERIE, PA 16501
814-453-3010

☐ ROOM 1159, FEDERAL BUILDING
HARRISBURG, PA 17101
717-782-3951

☐ ROOM 201, POST OFFICE BLDG.
ALLENTOWN, PA 18101
215-434-1444

☐ SUITE 503, PARK PLAZA
SCRANTON, PA 18503
717-346-2006

☐ ROOM 306, 116 S. MAIN ST.
WILKES-BARRE, PA 18701
717-826-6265

August 21, 1992

Congressional Liaison
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir/Madame:

My office has been contacted by [redacted] I am forwarding to you a copy of the correspondence that I have received.

Your substantive findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to my Assistant, Mary Clark, at the following address:

Senator Arlen Specter
Suite 9400, Federal Building
600 Arch Street
Philadelphia, PA 19106

Thank you for your assistance with the aforementioned matter.

Sincerely,

Arlen Specter

AS/mc
Enclosure

RECEIVED
92 AUG 27 PM 4:42
FOOD AND DRUG ADMIN.

No. 10878

PRINTED ON RECYCLED PAPER

MIF 005928

Arlen Specter

U.S. SENATOR PENNSYLVANIA

SUITE 9400, FEDERAL BUILDING
600 ARCH STREET
PHILADELPHIA, PENNSYLVANIA 19106

Dear Friend:

Thank you for your request that I contact the appropriate Federal agency for information that might prove helpful. I will be very glad to be of assistance in this matter.

Under the Privacy Act of 1974, which went into effect in September of 1975, I must have written permission of the individual whose records will be disclosed. This law was written to protect every American citizen from unauthorized disclosure of personal information with his or her consent.

If the person whose file is involved will sign the release form below and return it to my Philadelphia office, I will do what I can to obtain the necessary information.

Sincerely,

Arlen Specter

Arlen Specter

****

I grant permission to release information requested in my behalf to U.S. Senator Arlen Specter.

NAME _____

ADDRESS _____

TELEPHONE NUMBER _____

SOCIAL SECURITY NUMBER _____

ANY CLAIM OR I.D. NUMBER _____

FEDERAL AGENCY INVOLVED _____

PROBLEM OR ASSISTANCE NEEDED RU-486 a pill used to cure Cushing Syndrome or Cushinoid at this time banned by the Food and Drug Administration

DATE 6-17-92 SIGNATURE 151

MIF 005929

A.F. _____ FILE

The Honorable John McCain
United States Senator
151 North Centennial Way
Suite 1000
Mesa, Arizona 85201

Dear Senator McCain:

This is in response to your inquiry of August 20, 1992, on behalf of _____ regarding the availability of RU-486 for the treatment of Mrs. Hausman's metatistic breast cancer.

In order for her to receive RU-486, her physician should contact the manufacturer, Roussel Uclaf, directly regarding 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 _____ Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug application.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure
Const. Ltr.

cc: HFW-10(2)
R/D: _____ /14/92
F/T; ~~9~~/18/92
_____ DISK\ _____ .IND)
CONG-9120 and NO. 10892

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-2	/S/	9/21/92						/S/

*U.S. GPO: 1988-216-468

MIF 005930

92 AUG 19 AM 9:43

August 17, 1992

The Honorable John McCain
151 N Centennial Way
Mesa, Arizona 85201

Dear Senator McCain:

In my quest to preserve my life, I have reached the point where I am in need of assistance.

Last Friday, my oncologist and I reached the conclusion that the last therapy available for me in the USA to fight metastatic breast cancer was not working. I have been fighting this disease since the fall of 1983 and at the present time I still feel very aware of my responsibility to continue raising three teen-agers and living.

Enclosed is an article from the Tribune newspaper explaining my request. After reading reports on the effectiveness of RU 486 in the treatment of advanced breast cancer, I have become aware that it would behoove me to take it. Rather than treat the drug illegally, through borders, I too would like to request permission to use it in the states under my physician's care as did the gentleman in Atlanta.

At present, the cancer is in the bone and soft tissue and my health has deteriorated to the point where I have lost 40 lbs and my spine is compressing, making it possible to receive a fracture of the spine and the possibility of spinal injury or death. Therefore, in my present state, the feasibility of traveling would almost be out of the question.

May I count on your support to help? Expediency is important because of the rapid deterioration of my body.

I can reached reached at: [redacted] My address:

[redacted]

My doctor is: [redacted]

Sincerely,

[redacted]

MIF 005931

COMMITTEE ON ARMED SERVICES
COMMITTEE ON COMMERCE, SCIENCE AND TRANSPORTATION
SELECT COMMITTEE ON INDIAN AFFAIRS
SPECIAL COMMITTEE ON AGING
SELECT COMMITTEE ON POW/MIA AFFAIRS

United States Senate

111 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510-0303
(202) 224-2235

151 NORTH CENTENNIAL WAY
SUITE 1000
MESA, AZ 85201
(602) 835-8994

5353 NORTH 16TH STREET
SUITE 190
PHOENIX, AZ 85016
(602) 640-2567

6151 EAST BROADWAY
SUITE 170
TUCSON, AZ 85711
(602) 670-6334

TELEPHONE FOR HEARING IMPAIRED
(202) 224-7132
(602) 248-0174

August 20, 1992

Marc Scheineson
Food and Drug Administration
Assoc. Commissioner for Legis. Affairs
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Marc:

Refer to: 2233840006

I wish to bring to your attention a matter concerning my constituent, _____ who has encountered a problem with obtaining RU-486 to cure her cancer. Please investigate the statements made in the enclosed letter and return the response to me with the enclosures. MARK ALL CORRESPONDENCE TO:

Attn: Mary Turner
Office of Senator John McCain
151 North Centennial Way
Suite 1000
Mesa, AZ 85201

The assistance you provide my constituent will be most appreciated. If you should have any questions in the meantime, you can reach my office at (602) 835-8994. I look forward to your reply at your earliest convenience.

Sincerely,

John McCain
United States Senator

JM/zmt
Enclosure

No. 10892

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
92 AUG 28 PM 4:19
SENATE MAIL ROOM
OFFICE OF LEGISLATIVE AFFAIRS

A.F. _____ FILE

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

Dear Mr. Sarpalius:

This is in response to your letter of August 19, 1992, 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.

We are unable to predict whether, or when RU-486 will be approved for marketing. You may be assure _____ 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
[illegible]	/S/	[illegible]						

/S/

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

MIF 005934

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure
New Drug Development in
the United States

cc: HFW-10(2)
F/D: :9/18/92
F/T: 9/18/92
Cong-9114 and No. 10886(\DRUGLTR\NEWRU.MDG)

BILL SARPALIUS
13TH DISTRICT, TEXAS

Committees:
Agriculture
Small Business
Select Committee on Children, Youth & Families

Congress of the United States
House of Representatives
Washington, D.C. 20515

2B Cannon House Office Building
Washington, DC 20515
(202) 225-4705

317 South Polk
Amarillo, Texas 79101
(806) 371-8844

1000 Lamar #205
Wichita Falls, Texas 76301
(817) 767-0541

August 19, 1992

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

Dear Commissioner Kessler:

I am writing to call your attention to a recent comment I received from a constituent of mine, _____ of the _____

As you can see from the enclosed notation of _____ phone call to my Washington office, he is disappointed in the FDA's slow approval process for new and innovative drugs. Specifically he cites the lack of FDA approval for RU-486. I would appreciate your addressing his concerns regarding this issue, and I will look forward to hearing from you so that I can respond to my constituent.

Thank you for your assistance. If I can be of assistance, please do not hesitate to let me know.

Sincerely,

Bill Sarpalius

BS/eg
Enclosure

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
92 AUG 27 PM 5:04

No. 10886

165159/

MAIL: 36847
TO..:
FROM:
DATE: 29 JUL 1992
TIME: 04:02PM
SUBJ: OPINION

*

RESPONSE TO LETTER:
SAW A TV PROGRAM ABOUT FDA BEING SO SLOW ABOUT APPROVING MEDICATIONS IN THE US. THERE IS A BIRTH CONTROL PILL THEY; DO NOT WANT HERE, BUT IT WOULD HELP NUMEROUS PEOPLE THAT ARE ILL. OTHER MEDICATIONS THAT ARE IN OTHER COUNTRIES WOULD ALSO BE BENEFICIAL TO AID ILL IN THE US.

A.F. _____

SEP 02 1992

The Honorable Patricia Schroeder
House of Representatives
Washington, D.C. 20515

Dear Ms. Schroeder:

This is in response to your inquiry of August 10. 1992, on behalf of _____ regarding the availability of RU-486 for the treatment of her meningioma.

As discussed with Ms. Wendy Wasserman of your staff, Ms. Ferris' physician should contact the manufacturer, Roussel Uclaf, directly regarding 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 _____ Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug application.

In addition, a study with RU-486 for the treatment of certain brain tumors, sponsored by the National Institutes of Health (NIH), is about to begin. Her physician may wish to contact the NIH at (301) 496-7912 regarding possible participation in the study.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D: _____ :8/25/92
R/T: ~~:8/25~~/92
F/T; var:8/26/92
re/t: var:8/27/92
_____ DISK\ _____ .IND)
CONG-8912 and NO. 10653

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	8/27/92						

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

MIF 005938

PATRICIA SCHROEDER
1ST DISTRICT, DENVER, COLORADO

WASHINGTON OFFICE:
2208 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-0601
(202) 225-4431

DISTRICT OFFICE:
1600 EMERSON STREET
DENVER, CO 80218
(303) 861-1220

Congress of the United States
House of Representatives
Washington, DC 20515-0601

ARMED SERVICES COMMITTEE
CHAIRWOMAN, SUBCOMMITTEE ON MILITARY INSTALLATIONS AND FACILITIES
POST OFFICE AND CIVIL SERVICE COMMITTEE
JUDICIARY COMMITTEE
CHAIRWOMAN, SELECT COMMITTEE ON CHILDREN, YOUTH, AND FAMILIES
CONGRESSIONAL CAUCUS FOR WOMEN'S ISSUES, CO-CHAIR

August 10, 1992

U.S. Food and Drug Administration
Legislative Affairs
5600 Fishers Lane
Rockville, MD 20857

Dear _____

_____ contacted our office last week. She is a meningioma patient, and, with her doctor's advice, wants to participate in RU-486 treatments.

I do not have her doctor's name, but you can reach _____ at _____ is just one of the many people around the country in need of RU-486. I know you will be able to help her.

Sincerely,

Wendy Wasserman
Legislative Aide

APPEARS THIS WAY
ON ORIGINAL

#I0653

A.F. _____

SEP - 1 1992

The Honorable Thomas S. Foley
House of Representatives
Washington, D.C. 20515

Dear Mr. Foley:

This is in response to your letter of June 1, 1992, on behalf of _____, regarding the importation of RU-486 into the United States.

It is extremely important, at the outset, to point out that the import alert in effect for RU-486 in no way restricts the importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome, some forms of cancer, and the disorders such as those mentioned by Ms. Gibson. Rather, it is intended to restrict the drug's importation for personal use for the reasons described below.

Let me begin by providing you with some specific background information on the Food and Drug Administration (FDA) procedures relative to unapproved new drugs. RU-486, currently an unapproved new drug, has not been treated any differently than any other product in that category. As you may know, FDA's drug review responsibilities and authority under the Federal Food, Drug, and Cosmetic Act (FDC Act) are limited to determinations based on the data and information requirements mandated by that statute. FDA's regulations require a person who wishes to conduct a clinical investigation on an unapproved drug to submit to FDA an Investigational New Drug application (IND), and to comply with all applicable regulatory requirements governing the conduct of clinical investigations. An IND becomes effective within thirty days unless FDA notifies the sponsor of the investigation that the proposed clinical trial should not proceed. The grounds for taking the latter action are that (1) the sponsor has not provided sufficient information to evaluate the risks of the drug, (2) the risks to the subjects are unreasonable, (3) the investigators are not qualified, or (4) the information provided to the investigators is misleading. Certain investigations to determine effectiveness must also have protocol designs that clearly are sufficient to meet their stated objectives.

Strictly interpreted, the FDC Act prohibits the importation and distribution in interstate commerce of drugs that have not been approved by the FDA. However, out of compassion for individual

151

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFM-12	/S/	8/26/92						

MIF 005940

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

patients, many of whom suffer from serious and life-threatening diseases, FDA, as a matter of enforcement discretion, may permit individuals to bring into the United States for personal use limited quantities of drugs sold abroad but not approved in the United States. In exercising this discretion, it is incumbent upon the Agency, in its charge to protect the public health, to allow the importation of unapproved drugs only if there is no unreasonable safety risk and only if the other criteria are met.

With regard to RU-486, a conclusion was reached that use of the drug posed unacceptable safety risks. This is because the intended use of RU-486 makes it likely that potential users might well not be under the care of a physician; indiscriminate or unsupervised use could be hazardous to health. In addition, to be optimally effective, RU-486 must be used in conjunction with another drug, a prostaglandin that also is not approved in the United States. This further complicates the safety issue.

Furthermore, FDA's procedures specify that importation of an unapproved drug is only appropriate under certain other conditions. One of the most significant of these is that the drug is proposed for treatment of a serious condition for which no alternative treatment exists. (A copy of the Regulatory Procedures Manual, Part 9-71, is enclosed.) In addition to its safety risks, RU-486 also does not satisfy this criterion.

For both of these reasons, we do not believe that the importation of RU-486 can be permitted under our import policy. Moreover, the publicity in this country regarding the availability of the drug overseas raises the clear possibility that a demand could be created in this country that could foster importation of the drug for unapproved commercial use. Thus, we believe that our decision to restrict the importation of RU-486 is not only consistent with our policy guidance on the importation of unapproved drugs, but also sound public health policy.

For your information, I am enclosing a copy of testimony presented at a hearing before the House Small Business Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990, which contains additional information on this complex issue.

Please be assured that we are committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under existing law, and I can assure you

that any protocol for research and testing of RU-486 submitted to FDA will be given a fair review based on the scientific issues involved.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

2 Enclosures
Regulatory Procedures Manual
FDA Testimony

cc: HFW-10(2)
\DRUGLTR\RU486NEW.MDG)
F/D: :8/18/92
F/T: var:2/12/92
CONG-8534 and No. 10187

APPEARS THIS WAY
ON ORIGINAL

THE SPEAKER

PLEASE REPLY TO
CONGRESSIONAL OFFICE
☐ 201 LONGWORTH HOB
WASHINGTON, DC 20515-4705
AREA CODE (202) 225-2006

Congress of the United States

House of Representatives

Washington, DC 20515

☐ WEST 601 FIRST AVENUE
SECOND FLOOR WEST
SPOKANE, WA 99204
AREA CODE (509) 353-2155

☐ E. 12929 SPRAGUE
SPOKANE, WA 99216-0735
AREA CODE (509) 926-4434

☐ 28 A MAIN
WALLA WALLA, WA 99362-0910
AREA CODE (509) 522-[illegible]

June 1, 1992

Dear Ms. Holcombe:

Please find enclosed a copy of a letter I received from my constituent, _____.

As you will note, _____ is concerned about the Food and Drug Administration's ban on the importation of RU-486. If you could take note of her comments and address the issues she raises in her letter, it would be most helpful.

Thank you for your assistance in this matter.

With best wishes.

Sincerely,

Thomas S. Foley

Thomas S. Foley
Member of Congress

Ms. Kay M. Holcombe
Commissioner for Legislative Affairs
Food and Drug Administration
Parklawn Building, Room 15-55
5600 Fishers Lane
Rockville, MD 20857

TSF:hmd
Enclosure

RECEIVED
92 JUL 14 PM 3:38

#10187

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 7 1992

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

Dear Mr. Chairman:

As a followup to discussions with your staff, the Food and Drug Administration (FDA) is gravely concerned about the public release of confidential proprietary information in conjunction with the Subcommittee's July 28, 1992, hearing on the drug RU-486. The release of this information violates our fundamental understanding with the Subcommittee concerning the Agency's responses to document requests.

On two different occasions, at the request of the Subcommittee, FDA provided the Subcommittee with a list of applications for investigational new drugs (INDs) on file with the Agency for studies involving RU-486 -- after the Subcommittee's May 8, 1992, field hearing on women's health issues, and more recently in response to your written requests dated July 22, 1992. In both instances, the information was transmitted to the Subcommittee with a cover letter emphasizing the confidential nature of some of the information provided. As is FDA's practice, we offered to discuss the matter with your staff in the event you sought the public release of any of this information. Your staff did not discuss the public release of the IND list with the Agency; yet, either at the hearing or subsequent to it, information from those lists was made publicly available.

FDA's regulations implementing the Freedom of Information Act are very specific with regard to the availability for public disclosure of information in INDs. In fact, the very existence of an IND is confidential by law unless the sponsor has publicly disclosed such information. (See 21 CFR 312.130 and 314.430, enclosed for your information.)

FDA takes very seriously its responsibility to protect the confidentiality of data and information submitted to us. We also take very seriously our responsibility to provide Congress with information requested in the conduct of its oversight of the FDA. It is extremely important that this /S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA	/S/	8/6/92						
	/S/	8/7/92						

*U.S. GPO: 1989-624-401

MIF 005944

exchange of information be conducted in an atmosphere of mutual trust and cooperation. We hope you will honor our request to preserve the confidentiality of this type of information when it is transmitted to the Subcommittee in the future. If there is any uncertainty about whether particular information should be kept confidential, we encourage and expect consultation with you or your staff in advance of any public release of the information. Please notify me immediately if this understanding is unsatisfactory in any way.

I appreciate your continued cooperation in addressing this matter.

Sincerely yours,

Carol R. Scheman
Deputy Commissioner
for External Affairs

Enclosures

R/D: [redacted] :7/29/92
Edited: [redacted]:GCF-1:8/4/92
Edited: [redacted] GCF-1:8/4/92
Edited: [redacted] :HF-1:8/4/92
Edited: [redacted] :HFW-1:8/5/92

cc: HF-24
HFW-1
HFW-TO
GCF-1

APPEARS THIS WAY
ON ORIGINAL

A.F. FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUL 28 1992

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

Dear Mr. Chairman:

This is in response to your letter of July 15, 1992, regarding the legal validity of the import alert imposed by the Food and Drug Administration (FDA) on the unapproved new drug RU-486.

As you know, after the ruling by the U.S. District Court for the Eastern District of New York (Judge Sifton), the Court of Appeals for the Second Circuit issued a stay of that order. The Supreme Court subsequently affirmed that stay. The Agency is currently reviewing Judge Sifton's ruling in preparation for further court proceedings in the Second Circuit. We will keep you informed of additional activities related to this issue.

We appreciate receiving your viewpoint concerning the ruling by the District Court and your continued interest in this important public health issue.

Sincerely yours,

/S/

Marc J. Scheineson
Associate Commissioner
  for Legislative Affairs

cc: HFW-1
HFW-10(2)
HFW-12
R/D: :7/21/92
R/T: 7/21/92
Edit: :7/21/92
7/22/92
7/22/92
:7/23/92
for :GCF-1:7/24/92
Re/t: :7/24/92
F/T: :7/27/89
CHRM 308 and DCF 1028
(DISK:RU-486.IMP)

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-2	/S/	9/28/92						
HFW-1	/S/	7/28/92						

FILE COPY

MIF 005946

102d Congress

United States House of Representatives
Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

B-363 Rayburn House Office Building
Washington, DC 20515-6318

July 15, 1992

Dr. David Kessler, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Kessler:

As you know, this subcommittee has been investigating the legal validity of the Food and Drug Administration's import alert regarding the drug, RU 486.

I have just reviewed yesterday's written decision by Judge Sifton of the U.S. District Court, the Eastern District of New York, involving a lawsuit against this alert. Rarely have I read a judicial order more critical of an agency's action. As Judge Sifton states, "This was a lawsuit waiting to happen."

The import alert should be recognized for what it is: an embarrassing and obnoxious decision that has made many Americans question the agency's fairness and objectivity.

I recommend that the alert be rescinded immediately.

As you know, I first raised the concerns detailed in Judge Sifton's decision nearly 20 months ago. Indeed, our record of congressional hearings held in 1990 and 1991, and which resulted in pending legislation (H.R. 875) which is co-sponsored by approximately 70 of my House colleagues, mirrors key points in the judge's ruling.

Regarding the efforts by the agency to bend the rules to keep RU 486, an abortifacient drug, out of the United States, Judge Sifton says:

> "The record before this court reveals a history of political and bureaucratic timidity mixed with well-intentioned blundering in dealing with two of the most charged and significant issues of our time: AIDS and abortion."

Regarding the agency's flaunting of custom and process:

> "In the face of political outcry (from anti-abortion groups), a retreat was ordered by the FDA, again without investigation, notice or comment required by law. Now, a plaintiff has taken advantage of this sink of illegality to relieve her own understandable anxieties over employing surgical procedures to end her unwanted pregnancy. She has imported the abortion drug under a personal use exception, alleging that the ban on importation of that drug was illegally promulgated by the FDA."

Regarding the political considerations which obviously poisoned the FDA's decision-making:

> "While the reason given for the ban that '[t]he intended use of such drugs could pose a risk of safety to the user' hardly serves to distinguish the drug from other drugs approved for importation under the personal use exception where the risks are 'reasonable' or not 'significant,' it appears much more likely from the history outlined above that the decision to ban the drug was based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."

I understand that the judge's ruling is a narrow one, and that it does not rescind the import alert in total. Also, I am well aware that this matter has been appealed to the Supreme Court and that Sifton may well be overruled. No matter the outcome, however, or the narrowness of the order, Sifton's ruling, yesterday, heaps gasoline on a political fire within your agency. It demonstrates that your predecessors went to extraordinary lengths in pursuit of a political agenda and ignored good science.

Dr. Kessler, as you know RU 486 is at the forefront of a family of new drugs known as antiprogestins. These drugs, while often having an abortifacient effect, also may be important new treatments for a variety of illnesses and debilitating conditions ranging from Cushing's syndrome to breast cancer. Testimony before the subcommittee made clear that an increasing number of drugs from this category may serve such dual purposes, some of which may be politically controversial. It should not be necessary that the fate of every one of these drugs must be decided in the U.S. Supreme Court because your agency ignores fair regulatory process and good science.

It is time for the FDA to demonstrate clearly that these drugs will be treated like all other drugs under the law. To do otherwise will invite the kind of public embarrassment your agency suffered yesterday.

You have an opportunity to regain the faith of all Americans and retrieve your agency from yesterday's debacle by ending this import alert, today.

No matter what the outcome of the appeal, this subcommittee will continue its oversight of the FDA's treatment of RU 486. Therefore, I request that you reply to this letter within ten working days.

Should you have any questions concerning this letter, 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

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUL 24 1992

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

Dear Mr. Chairman:

This is in response to your letter of July 22, 1992, requesting information on the Investigational New Drug (IND) applications for RU-486 on file with the Food and Drug Administration.

We are enclosing an update of the list provided to you with our letter of June 12, 1992.

In an effort to comply with the request within the timeframe requested, we have included only the information that is currently in our files regarding the status of these applications. However, as you requested, we have included telephone numbers for all of the sponsors. More precise information may be obtained by contacting them directly. In addition, they will be able to provide information about whether or not they are receiving new shipments of the drug or using existing supplies, since this is information that they would not normally submit to their IND file. Also, as discussed with your staff, in lieu of a description of each study, we have included the indication for which the drug is being studied.

Some of the enclosed information is confidential and is not releasable to the public under the Freedom of Information Act. We therefore request that the Subcommittee not publish or otherwise make public any of this information. We would be happy to discuss the confidentiality of this information with the Subcommittee staff.

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs /S/

Enclosure

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFV-12	/S/	7/23/92						
HFD-1	/S/	7/24/92						

*U.S. GPO: 1989-624-401

MIF 005950

102d Congress

United States House of Representatives
Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

B-363 Rayburn House Office Building
Washington, DC 20515-6318

July 22, 1992

Dr. David Kessler, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Bethesda, Maryland 20857
Via Fax: (301) 443-2567

Dear Dr. Kessler:

Pursuant to our on-going inquiry into the actions of your agency involving the French drug RU 486, I request the following:

-- A complete list of all investigational new drug (IND) approvals granted by your agency to persons or institutions conducting clinical trials with RU 486.

-- A brief description of those trials, individually.

-- Your understanding regarding the status of those trials, individually (Is experimentation on-going? Do researchers currently have quantities of RU 486, or are they receiving the drug from the company?).

-- The name and telephone number of a contact person for each IND.

As I believe this information is readily available, and may have been recently collated and up-dated by your staff, I request that your response be telefaxed to my subcommittee staff by close-of-business, Thursday. Their number is (202) 225-8950.

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.

Thank you for your assistance in this matter.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

#10290

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 15, 1992

Representative Ron Wyden
Chairman
Subcommittee on Regulation,
Business Opportunities, and Energy
House of Representatives
B-363 Rayburn House Office Building
Washington, D.C. 20515-6318

Dear Mr. Wyden:

This is in response to your letter of December 10, 1992, regarding the drug mifepristone (RU-486) manufactured by Roussel-Uclaf, in which you ask several questions.

You asked first whether the Food and Drug Administration would consider clinical trials in Europe as adequate evidence of the drug's safety and efficacy for purposes of approval in the United States for interruption of early pregnancy and whether additional human testing might be necessary to fulfill United States requirements. As with any other drug, the FDA is willing to consider foreign clinical trials as evidence of safety and efficacy, although we always reserve the right to audit the data according to our usual procedures. We recently approved an oral contraceptive (Desogen) based entirely on clinical studies conducted in the United Kingdom. Other drugs have also been approved on the basis of foreign trials alone. Agency staff who will be responsible for reviewing any mifepristone application report that, based on publicly available information and literature reports, the available data may well be sufficient to permit an adequate review. Therefore, further clinical trials may not be required. However, without an application submitted to the Agency for review, we cannot give a definitive answer on this question.

You also ask for an estimate of the length of time and the costs involved for a company seeking to obtain approval of mifepristone in the United States. While we are not experts on cost issues, the costs of preparing a new drug application for this product should not be excessive because much of the necessary information is already available. The Pharmaceutical Manufacturers Association, or its member companies, may be able to be more helpful on this issue. Based on our current knowledge regarding the data on the drug's safety and effectiveness, we estimate that the review process at the FDA would take approximately four to six months, which would include the involvement of a public advisory committee.

In response to your last question, an unresolved issue would be obtaining access in this country to a prostaglandin which, as you know, under the terms of the foreign approvals, must be taken in conjunction with mifepristone. In addition, as you are aware, distribution of mifepristone is closely controlled under the terms of the foreign approvals. The appropriate distribution system for mifepristone in this country would also need to be resolved.

Sincerely yours,

/S/

Carol R. Scheman
Deputy Commissioner
for External Affairs

APPEARS THIS WAY
ON ORIGINAL

Cleared: HFD-510:12/11/92
Cleared: HFD-510:12/11/92
Cleared w/comments: HFD-1:12/11/92
Edit: HF-43:12/14/92
Cleared w/edits: HFD-500:12/14/92
Edit: HF-43:12/14/92
Reviewed: HF-43:12/14/92
Discussed HF-1:12/15/92
Edit HF-43:12/15/92 12/15/92
wyden.bml

102d Congress

United States House of Representatives
Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

B-363 Rayburn House Office Building
Washington, DC 20515-6318

December 10, 1992

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

Via Fax: (301) 443-3100

Dear Dr. Kessler,

This subcommittee is investigating several issues relating to the U.S. regulation of, and marketplace opportunities for the French drug RU 486, manufactured by Roussel Uclaf. Key to this inquiry is the current view of the U.S. Food and Drug Administration regarding the safety and efficacy proofs which will be required should the manufacturer decide to market this drug in the United States, and the time burden likely to face the company should it seek a new drug approval from your agency.

While the agency should not -- and does not -- intend to in any way lessen the normal burden of proof required for any new drug, in the case (prospectively) of RU 486, we are interested in whether scientists within the FDA's new drug approval section have any views regarding the breadth and quality of experience with this drug in France, and in other foreign markets.

In this context, I have several questions for the agency:

-- To what extent does the agency deem European experience with this drug, including more than 100,000 clinical medical cases in France since 1988, as evidence of the drug's safety and efficacy for purposes of approval in the United States?

-- If European experience with RU 486 is directly applicable to requirements demanded within the FDA standard drug approval process, is it possible to attach some comparative value to that which is already known about the drug?

Specifically, can you give a rough estimate as to the percentage or portion of the usual U.S. drug approval process, including demands for extensive human testing, which may already be satisfied by the European experience?

-- Similarly, can you provide any estimate as to how long a U.S. drug approval process would take in light of the extensive evidence of safety and effectiveness already available for RU 486? Perhaps the agency can point to the case of another foreign drug used extensively, and safely, overseas prior to the manufacturer's application for a U.S. drug approval?

-- Subcommittee staff have spoken with a number of U.S. pharmaceutical companies which have an interest in licensing and distributing RU 486, or a similar drug, in the U.S. These companies have suggested that U.S. approval of this drug, for the reasons mentioned above, would be relatively swift and inexpensive.

The representative of one firm interviewed by subcommittee staff estimated that the total cost would be well under $5 million -- a marked difference from the average cost of a full-scale, full-phase, drug approval process estimated by Tufts University at more than $200 million.

While this estimate of the possible cost of taking RU 486 through the U.S. drug approval process obviously is very speculative, would you say that this forecast still could be in the ballpark given what we know of the European experience with RU 486 in terms of safety and effectiveness, and whatever additional proofs may be demanded by the agency?

-- Finally, are you aware of any unusual or unique circumstances involving this drug which could delay, jeopardize or otherwise seriously impede its review in the FDA's drug approval process, should the company come forward with an application?

Thank you for your attention to these questions. I would very much appreciate your earliest possible response. Should you have any questions, please don't hesitate to contact me, or Steve Jenning of the subcommittee staff at (202) 225-7797.

Sincerely,

RON WYDEN
Chairman

cc. Congressional Affairs, FDA.

APPEARS THIS WAY
ON ORIGINAL

IND 43-253 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 30 1992

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 November 24, 1992, on behalf of [redacted] regarding the availability of RU-486 for the treatment of his daughter's meningioma. We were very sorry to hear of her illness and can certainly understand his personal interest in this unapproved new drug.

In order for his daughter to receive RU-486, her physician should contact the manufacturer, Roussel Uclaf, directly regarding 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.

In addition, as you know, a study with RU-486 for the treatment of certain brain tumors, sponsored by the National Institutes of Health (NIH), is underway. Her physician may wish to contact the NIH at (301) 496-7912 regarding possible participation in the study.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
F/D; [redacted] 12/22/92
F/T:var:12/29/92
CONG-10117 and No. 12024
[redacted] DISK\ [redacted] .IND)

5301

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-23	ISI	12/30/92						

ISI 12/30

November 12, 1992

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

Dear Senator Mack:

I am enclosing a letter which I have written to Senator Alan J. Dixon, Illinois, a personal friend of mine, concerning my Daughter, _____ of Tallahassee.

I am seeking your assistance as well as that of Senator Graham and Senator Dixon, concerning this matter, which is of grave importance to me and the others of my family.

My Daughter has a brain tumor (meningioma) for which she has had two surgeries and extensive radiation. Neither surgery nor additional radiation is an alternative we have been told.

My Daughter saw a Congressional hearing concerning the use of the drug RU-486 as a treatment for this type tumor, and in an on-going research program in California, it has been shown to have treated numerous candidates successfully.

After the hearing, which was held Tuesday July 28, 1992, ("HEARING ON THE EFFECT OF FEDERAL BAN ON RU-486 ON MEDICAL RESEARCH, NEW DRUG DEVELOPMENT, AND PHARMACEUTICAL MANUFACTURERS"). a Mr. David Grow was assigned an IND Number by the FDA, allowing him to acquire and use this drug.

My Daughter received the radiation treatment from _____ Radiation/Oncologist, Tallahassee. I am told that you know _____ personally, and I would be pleased if you could talk to him about her case and the efforts we are making to obtain this drug for her use.

Senator Dixon has said that he will do everything in his power to assist us in obtaining the IND Number to allow her to obtain and use this drug.

Obviously, we are quite anxious about her condition, Dr. Bilek has told her that in the latest MRI, he has seen new growth of this tumor.

——— surgeon, ——————— of Tallahassee, told me after the last surgery, that he could not remove all of the tumor since it was in very close proximity to her right optic nerve and the carotid artery, therefore we believe that surgery is not an option, and since she has had all of the radiation which ——— feels she can have, that also is gone as an option.

It appears that this RU-486 is our only option at this time.

——— is the Mother of three young children, she is at present unemployed, and has no health insurance, her husband allowing it to lapse after the first surgery, when he lost his business. She is beyond child-bearing age, therefore the abortion feature of this drug would not have any effect.

We do hope that you will be able to assist us in this matter.

has told that he would administer the drug for her, if we are able to obtain it.

Thank you very much for any assistance you might be able to give us in this matter.

Very truly yours

/S/

cc: Frank Bilek, M.D.
Frank Davis, M.D., F.A.C.S.
Senator Mack, Ft. Myers Office

CONNIE MACK
FLORIDA

United States Senate

WASHINGTON, DC 20510-0904

November 24, 1992

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

FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 14 1992

The Honorable Phil Gramm
United States Senate
2323 Bryan, Suite 1500
Dallas, Texas 75201

Dear Senator Gramm:

This is in response to your inquiry of October 16, 1992, on behalf of _____ regarding _____ and the availability of RU-486 for the treatment of her brain cancer. We were very sorry to hear of _____ illness.

In order to explore the possibility of _____ being treated with RU-486, her physician should contact the manufacturer, Roussel Uclaf, directly regarding 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 _____ Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug application.

In addition, a study with RU-486 for the treatment of certain brain tumors, sponsored by the National Institutes of Health (NIH), is about to begin. Her physician may wish to contact the NIH at (301) 496-7912 regarding possible participation in the study.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
F/D; _____ 11/27/92
F/T:var:12/9/92
_____ DISK _____ .IND)
CONG-9713 and NO. 11558

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-10	/S/	12/1/92						

/S/ 12/14

FILE COPY

MIF 005962

BANCROFT, MOUTON & WOLF

A Professional Corporation
ATTORNEYS AT LAW
109 WEST FOURTH STREET
P. O. BOX 1030
BIG SPRING, TEXAS 79721-1030

G. BEN BANCROFT
Board Certified - Civil Trial Law
Texas Board of Legal Specialization
DREW MOUTON
Board Certified - Civil Trial Law
Texas Board of Legal Specialization
TROYCE G. WOLF

TEL. No. (915) 267-2505
FAX No. (915) 263-6782

September 1, 1992

Troy Fraser
208 W. 3rd
Big Spring, TX 79720

Re: _____ terminal brain cancer patient

Dear Troy:

_____ has been diagnosed with terminal brain cancer. _____ have been following the request of a Atlanta, Georgia man, John David Grow, to receive Congressional approval for experimental use of the drug RU-486. Within the last couple of weeks, the FDA approved the experimental use of that drug in Mr. Grow's case. Representative Ron Wyden, D-Ore., is on the House subcommittee that has held hearings regarding this drug and may have had some involvement in receiving special approval for Mr. Grow to receive it.

_____ feel that _____ situation is very similar to Mr. Grow's and would like to lay the groundwork for a request somewhere in the next 30-60 days for the same approval for _____ I would appreciate it if you would forward my letter to someone with Senator Phil Gramm's office who could assist me in establishing the appropriate lines of communication to pursue such a request.

I appreciate your help.

Very truly yours,

Drew Mouton

DM/jh

_____.LTR:DM-LTR

Phil Gramm
Texas

United States Senate

MEMORANDUM

RECEIVED
92 OCT 23 PM 11:13
OFFICE OF
LEGISLATIVE AFFAIRS

Date: 10-16-92

Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

A constituent has sent the enclosed communication. A response which addresses his/her concerns would be appreciated.

Please send your response, together with the constituent's correspondence, to the following address:

Office of Senator Phil Gramm
2323 Bryan, Suite 1500
Dallas, Texas 75201

Attention: Sharon Spencer

FF 11558

APPEARS THIS WAY
ON ORIGINAL

TROY FRASER
TEXAS HOUSE OF REPRESENTATIVES

P.O. BOX 2910
AUSTIN, TEXAS 78768-2910
512-463-0688

208 W. 3RD
BIG SPRING, TEXAS 79720
915-263-1307

October 9, 1992

The Honorable Phil Gramm
2323 Bryan, Suite 1500
Dallas, Texas 75201

Dear Senator Gramm,

I received this attached letter from ——— a local constituent, who is very concerned about the future of a bright young woman who has been diagnosed with terminal brain cancer. The family is trying to secure FDA approval of an experimental drug which may help the young lady. Could you be of assistance to them in their request?

Thank you for your attention to this matter.

Sincerely,

Troy Fraser
State Representative
District 69

TF/bk

A.F. FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 13 1992

The Honorable Dennis DeConcini
United States Senate
Washington, D.C. 20510

Dear Senator DeConcini

This is in response to your inquiry of September 28, 1992, on behalf of [redacted] concerning the unapproved new drug, RU-486.

It is extremely important, at the outset, to point out that there are no restrictions on importation of this drug for research purposes to determine its usefulness for diseases such as Cushing's syndrome, some forms of cancer, and other disorders.

I would also like to provide you with some specific background information on the Food and Drug Administration's (FDA) procedures relative to unapproved new drugs. The Federal Food, Drug, and Cosmetic Act, which the 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.

We are unable to predict whether, or when RU-486 will be approved for marketing. You may assure [redacted] 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-1A	/S/	9/9/92						

MIF 005966

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

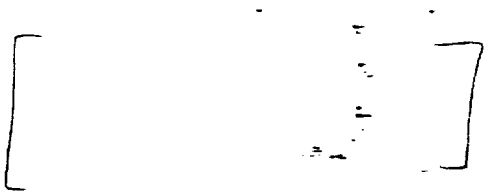
Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

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

cc: HFW-10(2)
F/D: 11/4/92
F/T: var:11/6/92
Cong-9114 and No. 11377 \DRUGLTR\APPROVE.PIL)

APPEARS THIS WAY
ON ORIGINAL



The Honorable Dennis DeConcini
Senate
U.S. Senate
328 Senate Dirksen Office Bldg
Washington, DC 20510

Dear Senator DeConcini:

I have read of the recent use of the French so-called abortion pill being used for the treatment of a cancer victim who would otherwise be intreatable. This is a find gesture as far as it goes. Why should we not allow the importation of this pill so that many other cancer sufferers may use the benefits of such a wonderful discovery.

I am aware of the fact that the Food and Drug Administration has not as yet approved this drug, and that it would take years to gain this approval. I can see no reason why this approval should not be given immediately, utilizing the research, development, and usage of this drug in France, other than the dollars involved in our greedy drug companies, and the monies involved in this approval by the FDA.

Further, the main intent of this drug would be to allow safe and private abortions by women and thwart the "back-alley" type of abortions which can easily result in dangerous infections and even death to the woman. It would put an end to the controversy of the Pro-Lifers and the Pro-Choice group.

I whole-heartedly support the immediate lifting of the ban on importation of this very necessary and favorable drug.

Sincerely yours,

/s/

DENNIS DeCONCINI
ARIZONA

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

COMMISSION ON
SECURITY AND COOPERATION
IN EUROPE/ CHAIRMAN

United States Senate

WASHINGTON, DC 20510

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

PHOENIX OFFICE
323 WEST ROOSEVELT #C-100
PHOENIX AZ 85003
(602) 261-6756

SOUTHERN ARIZONA OFFICE
2424 EAST BROADWAY
TUCSON AZ 85719
(602) 629-6831

EAST VALLEY OFFICE
40 NORTH CENTER STREET #110
MESA AZ 85211
(602) 261-4998

September 28, 1992

The attached inquiry from:

[redacted]

is respectfully referred to:

The Food and Drug Administration

Your comments regarding this matter will be most appreciated.

Sincerely,

Dennis DeConcini

DENNIS DeCONCINI
United States Senator

Please reply to:

The Honorable Dennis DeConcini
United States Senate
Washington, D.C. 20510

attention: Ms. Susan D. Scott

#11377

APPEARS THIS WAY
ON ORIGINAL

RECEIVED
92 OCT -8 AM 11:59

MIF 005969

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OCT 2 1992

The Honorable Lloyd Bentsen
United States Senator
961 Federal Building
Austin, Texas 78701

Dear Senator Bentsen:

This is in response to your inquiry of September 14, 1992, on behalf of _____ regarding the availability of RU-486 for the treatment of a specific type of brain tumor. We were sorry to hear of his illness and can certainly understand his personal interest in this unapproved new drug.

RU-486 is a drug that is approved in France through a limited distribution system for early abortion when used with one of two prostagladins also approved in France. In addition, studies have been conducted on the treatment uses of this drug for disease such as breast cancer, brain tumors, Cushing's syndrome, and other types of disorders .

In order for him to possibly receive RU-486, as described in the news article, his physician should contact the manufacturer, Roussel Uclaf, directly regarding 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, his physician should contact _____, Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug application.

In addition, a study with RU-486 for the treatment of certain brain tumors, sponsored by the National Institutes of Health (NIH), is about to begin. _____ may wish to have his physician contact the NIH at (301) 496-7912 to discuss the possibility of his participation in the study.

We wish him well and hope that this information will be helpful. If we can be of any further assistance, please let us know.

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D; _____ :10/9/92
F/T: var:10/15/92
CONG-9364 and No. 11171
_____\DRUGLTRS\OTHERUSE.RU)

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-1 2x	/S/	10/19/92						

/S/ 10/21

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

MIF 005970

LLOYD BENTSEN
TEXAS

COMMITTEES
FINANCE
COMMERCE, SCIENCE, AND TRANSPORTATION
JOINT ECONOMIC
JOINT COMMITTEE ON TAXATION

United States Senate

WASHINGTON, DC 20510-4301

September 14, 1992

Dr. David A. Kessler
Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Building
Rockville, Maryland 20857

Dear Commissioner Kessler:

I recently received the enclosed constituent inquiry, and I would very much appreciate your providing me with any pertinent information you might have regarding the matter.

Your kind assistance is greatly appreciated.

Sincerely,

Lloyd Bentsen

Lloyd Bentsen

Enclosure

PLEASE REPLY TO:

961 Federal Building
Austin, Texas 78701
ATTN: Patricia Ruiz-Davis

APPEARS THIS WAY
ON ORIGINAL

11171

MIF 005971

M.F. 4 FILE

OCT 01 1992

The Honorable Donald W. Riegle, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Riegle:

This is in response to your inquiry of August 27, 1992, on behalf of [redacted] regarding RU-486 for the treatment of her aunt.

Although she was not specific regarding her aunt's disease, RU-486 is being investigated for several types of cancer. Because certain information on file with the Food and Drug Administration is confidential and not publicly available under the Agency's Freedom of Information Act regulations, we are unable to provide her with specific information on these studies. She may, however, have her aunt's physician contact the manufacturer, Roussel Uclaf, directly about the possibility of her aunt being included on one of the studies. The address is 35 Boulevard Des Invalides, F-75323 Paris, CEDEX-07, France. [redacted] may also wish to contact the National Institutes of Health at (301) 496-7912 for information on studies they may be sponsoring.

We were very sorry to hear of her aunt's illness and hope this information will be helpful.

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D: [redacted] :9/25/92
R/T: [redacted] .9/25/92
CONG-9231 and No. 11016
([redacted] DISK\RU-486.CAN)

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-2	/S/	10/1/92						

/S/ 10/1

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

MIF 005972

DONALD W. RIEGLE, JR.
MICHIGAN

COMMITTEES
BANKING, HOUSING, AND URBAN AFFAIRS: Chairman
FINANCE
Subcommittee on Health for Families and the Uninsured: Chairman
BUDGET

United States Senate

WASHINGTON, DC 20510-2201
(202) 224-4822

August 27, 1992

MICHIGAN REGIONAL OFFICES

CENTRAL
705 Washington Square Bldg
109 W. Michigan Ave
Lansing, MI 48933
(517) 377-1713

WAYNE MONROE
1155 Brewery Park Blvd
Suite 343
Detroit, MI 48207
(313) 226-3188

EASTERN
Suite 910
352 S. Saginaw St.
Flint, MI 48502
(313) 766-5115

SOUTHEASTERN
Century Center Bldg. 3d Floor
30800 Van Dyke
Warren, MI 48093
(313) 573-9017

UPPER PENINSULA
Room 323, P.O. Bldg
200 W. Washington
Marquette, MI 49855
(906) 228-7457

WESTERN
Suite 716 Federal Bldg
110 Michigan Ave. N.W.
Grand Rapids, MI 49503
(616) 456-2592

Telecommunications Device for the Deaf
(517) 377-1899

NORTHERN LOWER
309 Front Street
Traverse City, MI 49685
(616) 946-1300

FDA

5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Fromer:

Recently, I was contacted by several constituents who expressed concern about a matter within your agency's jurisdiction. I am enclosing a copy of the constituent's correspondence for your information.

I would appreciate your response to the concerns raised in the attached letter. Please direct any questions or correspondence to Gary Ewart, of my staff, at Dirksen Senate Office Building, Washington, D.C. 20510.

Thank you for your attention to this matter.

Sincerely,

Donald W. Riegle, Jr.

DWR/gea

Enclosure

#11016

RECEIVED
92 SEP 11 PM 3:15
OFFICE OF LEGISLATIVE AFFAIRS

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 25 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 April 22, 1993, on behalf of _____ regarding the Investigational New Drug (IND) application filed for her to be treated with RU-486.

_____ request to proceed under the IND was denied because there appeared to be no scientific rationale for the use of RU-486 in this patient. In addition, the indication for the treatment was unclear. Treatment with mastectomy results in cure rates of 98-99 percent in patients with intraductal carcinoma of the breast. There is no evidence that adjuvant therapy with RU-486 is likely to be beneficial and there are significant risks associated with chronic use of the drug.

The decision by the French manufacturer to license the drug to the Population Council for distribution in the United States does not have any bearing on this case.

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

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D: _____ with input from _____ :5/12/93
R/T: 5/12/93
F/T: var:5/17/93
cong-11306 and No. 13305
(S: _____ DENIAL.IND)

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	5/24/93						

MIF 005974

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 MESA 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 85003-1386
(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

April 22, 1993

Food and Drug Administration
Office of Consumer and Legislative Affairs
HFD - 365
5600 Fishers Lane
Rockville, Maryland 20857

Dear Sir or Madam:

Senator DeConcini has been contacted by his constituent, ——— and her doctor, ——— regarding RU-486 treatment for ———

I understand that ——— submitted an Investigational New Drug Application recently and it was denied.

It would be greatly appreciated if you would respond to why this application was denied and what criteria is used in determining whether a patient is qualified to use RU-486. Please note the clipping from the newspaper in where it states that the French manufacturer has agreed to license the drug to a population-control group for eventual U.S. distribution. Please comment on how this might effect ——— and patients in the same situation.

I appreciate your consideration and assistance in this matter. If you have any questions, please feel free to contact me at the address below.

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

OFFICE OF LEGISLATIVE AFFAIRS
APR 28 4 15 PM '93
RECEIVED

#13305

PRINTED ON RECYCLED PAPER

MIF 005975

A.F. 43-2-2 FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 25 1993

The Honorable Paul David Wellstone
United States Senate
Washington, D.C. 20510

Dear Senator Wellstone:

This is in response to your inquiry of November 2, 1992, regarding your concern about the Food and Drug Administration's (FDA) import alert for RU-486.

As you know, President Clinton has asked that FDA determine whether there is sufficient evidence to warrant exclusion of RU-486 from qualifying for the personal use importation exemption. A copy of the memorandum from the President to the Secretary of Health and Human Services is enclosed for your information. That analysis is currently underway. We will inform you as soon as we have reached a conclusion on this matter.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

Enclosure
Memorandum:1/22/93

APPEARS THIS WAY
ON ORIGINAL

S/2/25

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-2	/S/	2/3/93						/S/ 2/25
HFA-12	/S/	2/25/93						

MIF 005976

cc: HFW-10(2)
HF-1
HF-24
GCF-1

R/D: 11/23/92
R/T: :11/23/92
Edit: :11/23/92
Edit: :12/3/92
Edit: :12/7/92
ReT: :12/7/92
Edit: :12/9/92
ReT: :12/15/92
Revised: 1/26/93
ReT: :1/26/93
Edit: , GCF-1:1/28/93
Init: :2/9/93
ReT: 2/11/93
Init: 2/19/93
F/T:var:2/23/93
(S:\ \RU-486.IMP)
CONG-9906 and No. 11773

APPEARS THIS WAY
ON ORIGINAL

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release January 22, 1993

January 22, 1993

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Importation of RU-486

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

# # #

PAUL D. WELLSTONE
MINNESOTA

United States Senate

WASHINGTON, DC 20510-2303

November 2, 1992

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
Room 1471
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I am quite concerned with the FDA's import alert on Abortifacient Drugs as it applies to RU486. The import alert, purportedly issued because "[t]he intended use of such drugs could pose a risk to the safety of the user", appears to be inconsistent with FDA's Regulatory Procedure Manual. That Manual provides in relevant part that FDA may exercise discretion to allow the personal shipment of drugs "when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a **significant health risk**"....(emphasis added). So that I may better understand the actions of FDA in issuing the Import Alert for abortifacient drugs, please provide the information requested below.

1. Please explain whether there is a difference between (a) "a risk to the safety of the user" presented by a drug, the language used in the Import Alert for abortifacient drugs, and (b) a "significant health risk" presented by a drug, the language used in FDA's Regulatory Procedure Manual for determining when to exercise discretion under the personal importation policy. If so, please describe the difference.

2. Please identify all drugs in addition to abortifacient drugs that are currently the subject of an "Import Alert", and describe in detail the "risk to the safety of the user" presented by each of those drugs that resulted in each such drug being placed on an Import Alert.

3. Please identify all drugs for which FDA has exercised its discretion to allow the drug's release under the personal importation policy. Please explain whether there is any "risk to the safety of the user" presented by any of the identified drugs, and if so, describe the risk. In addition, please explain whether there is any "significant health risk," presented by any such drugs (assuming there is a difference between "a risk to the safety of the user" and "a significant health risk"), and if so, describe the risk.

11773

As I am presently planning my Labor Committee health policy work for the coming session, I would appreciate receiving the requested information by mid-December if practicable. If you have any questions or problems meeting this time frame, please call Alan Schoem of my staff at 202-224-1472.

Sincerely,

Paul D Wellstone

Paul David Wellstone
United States Senator

PDW:ahs

APPEARS THIS WAY
ON ORIGINAL

PAUL D. WELLSTONE
MINNESOTA

United States Senate

WASHINGTON, DC 20510-2303

November 2, 1992

David A. Kessler, M.D.
Commissioner
Food and Drug Administration
Room 1471
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

I am quite concerned with the FDA's import alert on Abortifacient Drugs as it applies to RU486. The import alert, purportedly issued because "[t]he intended use of such drugs could pose a risk to the safety of the user", appears to be inconsistent with FDA's Regulatory Procedure Manual. That Manual provides in relevant part that FDA may exercise discretion to allow the personal shipment of drugs "when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a **significant health risk**"....(emphasis added). So that I may better understand the actions of FDA in issuing the Import Alert for abortifacient drugs, please provide the information requested below.

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2. ~~Please~~ identify all drugs in addition to abortifacient drugs that are currently the subject of an "Import Alert", and describe in detail the "risk to the safety of the user" presented by each of those drugs that resulted in each such drug being placed on ~~an~~ Import Alert.

3. Please identify all drugs for which FDA has exercised its discretion to allow the drug's release under the personal importation policy. Please explain whether there is any "risk to the safety of the user" presented by any of the identified drugs, and if so, describe the risk. In addition, please explain whether there is any "significant health risk," presented by any such drugs (assuming there is a difference between "a risk to the safety of the user" and "a significant health risk"), and if so, describe the risk.

11773

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Sincerely,

Paul D Wellstone

Paul David Wellstone
United States Senator

PDW:ahs

FILE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 22, 1993

VIA FACSIMILE
LETTER TO THE EDITOR OF THE SAN FRANCISCO CHRONICLE:

Your column by Beverly Zakarian about RU-486 ("Open Forum," 1/11/93) reflected a widespread and fundamental misunderstanding of the policy of the Food and Drug Administration.

The FDA has not obstructed import of the drug for medical research on its various potential uses. In fact, FDA has authorized a number of scientific studies of RU-486 to be conducted in this country under Investigational New Drugs applications (INDs).

Under the law, FDA is precluded in most cases from publicly discussing studies in progress under an IND. Your readers should know, however, that the National Institutes of Health, whose studies are public information, is using RU-486 in biochemical research and is investigating its potential for treatment of Cushing's disease and other serious conditions. Other RU-486 studies, for ailments that include several kinds of cancer, are being carried out by non-governmental entities.

All of this research uses RU-486 that has been imported legally and with FDA's approval under the IND process. The import alert on RU-486 relates only to illegal attempts to bring the drug into this country.

The basic obstacle to more widespread availability of RU-486 in the U.S. is not FDA, but the fact that the French manufacturer has declined to apply with the agency for the drug's approval.

Sincerely,

/S/

Carol R. Scheman
Deputy Commissioner for
External Affairs

9300320

MIF 005983

43-253

DEPARTMENT OF HEALTH AND HUMAN SERVICES — FILE

JAN 19 1993

The Honorable Ron Wyden
Chairman, Subcommittee on Regulation,
Business Opportunity, and Energy
Committee on Small Business
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

EU 43-

This is in response to your letter of January 14, 1993, requesting a December 14, 1992, letter from the Food and Drug Administration (FDA) to the President of Roussel-Uclaf and any subsequent reply.

The information requested is enclosed.

It should be emphasized that this correspondence is considered confidential commercial information and is not releasable to the public under the Freedom of Information Act and the FDA's implementing regulations. We request that the Committee not publish or otherwise make public any of the information contained in these documents. We would, of course, be glad to discuss with the Committee staff the confidentiality of any specific document.

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

Enclosures

cc: HFW-1
HFW-10(3)
HFW-12

cc: The Honorable Jan Meyers
Ranking Minority
cc: Roger McClung

R/D: :1/15/93
R/T: 1/15/93
F/T: var:1/19/92
CHRM-349 and NO. 12294
F:\ RU-486.LTR)

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-10	/S/	1/19/93						
HFW-12	/S/	1/19/93						
HFW-2	/S/	1/19/93						

102d Congress

United States House of Representatives
Committee on Small Business

Subcommittee on Regulation, Business Opportunities, and Energy

B-363 Rayburn House Office Building
Washington, DC 20515

January 14, 1993

Dr. David Kessler, M.D.
Commissioner
The Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Kessler:

As you are aware, the Subcommittee on Regulation, Business Opportunities and Energy has been following the development of the drug RU-486 with great interest. Recently, the subcommittee has been particularly interested in whether or not the manufacturer of the drug will move to introduce the drug in the U.S. market.

I read with interest the enclosed copy of a January 12, 1993, editorial in The Wall Street Journal. The editorial mentions a December 14, 1992, letter from you to the President of Roussel/Uclaf, Dr. Edouard Sakiz, wherein the prospects for approval of the drug in the U.S. market are discussed. I request that the subcommittee be provided with a copy of this correspondence and any subsequent reply from Dr. Sakiz or his representative.

As always, the subcommittee appreciates your cooperation and assistance. Should you have any questions regarding this request, please don't hesitate to contact Graydon Forrer of the subcommittee staff at (202)225-7797.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

RW/gjf
enclosure

#12294

DEPARTMENT OF HEALTH AND HUMAN SERVICES AF 43-252 FILE

JAN 14 1993

The Honorable Bob Graham
United States Senator
Post Office Box 3050
Tallahassee, Florida 32315

Dear Senator Graham:

This is in response to your inquiry of December 17, 1992, on behalf of _____ regarding the availability of RU-486 for the treatment of his daughter's meningioma. We were very sorry to hear of her illness and can certainly understand his personal interest in this unapproved new drug.

In order for his daughter to receive RU-486, her physician should contact the manufacturer, Roussel Uclaf, directly regarding 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 _____ Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug application.

In addition, as you know, a study with RU-486 for the treatment of certain brain tumors, sponsored by the National Institutes of Health (NIH), is underway. Her physician may wish to contact the NIH at (301) 496-7912 regarding possible participation in the study.

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

Sincerely yours,

Marc J. Scheineson
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
F/D; _____ .1/4/93
F/T:var:1/12/93
CONG-10285 and No. 12204
(_____DISK\ _____.IND)

APPEARS THIS WAY
ON ORIGINAL

599.4

/S/

OFFICE	SIGNATURE	DATE	OFFICE	SIGNATURE	DATE	OFFICE	SIGNATURE	DATE
HFW12	/S/	1/14/93						

FILE COPY

MIF 005986

U.S. GPO: 1988-216-488

Bob Graham
Florida

United States Senate
Washington, D.C.

Date 12/17/92

Legislative Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 29857

RECEIVED
DEC 28 2 41 PM '92
OFFICE OF
LEGISLATIVE AFFAIRS

Enclosed is a letter from one of my constituents who has concerns which come under the jurisdiction of your agency.

I would appreciate your reviewing this situation and providing me with an appropriate response. Please direct your reply to:

Pat Grisé
Office of Senator Bob Graham
P.O.Box 3050
Tallahassee, FL 32315

904/422-6106 or 422-6100

Your cooperation and assistance are appreciated.

With kind regards,

Sincerely,

Bob Graham

United States Senator

Constituent's Name: _____

#12204

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 17 1993

NOV 31 11 05 AM '93

The Honorable Carol Moseley-Braun
United States Senate
Washington, D.C. 20510-1303

Dear Senator Moseley-Braun:

Thank you for your letter regarding President Clinton's request that this Department assess initiatives to promote the testing, licensing, and manufacturing in the United States of RU-486 as well as for the Food and Drug Administration (FDA) to reassess whether RU-486 qualifies for importation under FDA's personal use importation policy.

As you know, FDA is the component of the Public Health Service responsible for ensuring the safety and effectiveness of drugs for marketing in the United States. FDA has been actively working with The Population Council, a non-profit scientific and technical organization, the National Institutes of Health (NIH), and other individuals and organizations in an effort to facilitate the availability of RU-486 and other antiprogestins in the United States.

One result of these efforts has been that Roussel-Uclaf, the manufacturer of RU-486, has announced that it plans to license RU-486 to The Population Council to permit the testing of RU-486 as an abortifacient in this country. Clinical testing of the drug in the United States would allow the collection of data on the drug, including information on how the drug could be used properly in this country; it would provide an opportunity to train doctors in the careful administration of the drug; and it would give American women who participate in the clinical trial access to the drug. FDA is monitoring the negotiations between Roussel-Uclaf and The Population Council in hopes that agreement will be reached. FDA is committed to an expeditious review of these data once they are submitted to the Agency so that American women can have access to this alternative to surgical abortion, if it is found to be safe and effective.

Concerning the importation of RU-486 under FDA's personal use importation policy, a number of complex issues need to be resolved before we can come to any conclusion on this matter. I want to assure you that I am personally committed to a thoughtful and thorough consideration of this issue.

/S/

FDA

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE

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

MIF 005988

Finally, the PHS is also exploring the clinical use of RU-486 for several diseases. In light of the Hyde amendment, NIH has funded only limited studies on RU-486, including its potential use as treatment for endometriosis, uterine fibromas, breast cancer, meningiomas, Cushing syndrome caused by ectopic secretion of the hormone ACTH, management of labor, anorexia nervosa, depression, and as a potential contraceptive.

Meanwhile, other antiprogestational compounds are being developed. On February 5, 1993, the National Institute of Child Health and Human Development (NICHD) issued a Program Announcement calling for applications to conduct antiprogestin research focusing on their use in reproductive medicine, including endometriosis, contraception, and induction of labor. The NICHD is also pursuing the development of an antiprogestin for use as a post-coital emergency contraceptive.

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

Sincerely,

Donna E. Shalala

Donna E. Shalala

cc: HF-1
HFW-1
HFW-10 (2)
ES/PHS
CCU
R/D: ——— :8/19/93
Edit: —— :8/23/93
——— :8/24/93
Input from NIH:GGaines(NICHD):8/26/9
Init.: ——— :8/29/93
Edit: ——:8/30/93
Init.: ——— :8/30/93
F/T: — :8/30/93
Revised: ——— :9/9/93
Edit: ——— :9/30/93
ReT: ——10/1/93
F/T: — :10/1/93 (S:\wp\ —— \clinton.ru4)
Retyped: —:11/5/93
Cong. HHS-110 - No. 14450 (931653)
OS #08030042
PHS #59158
Clinton.RU4

A.F. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEP 29 1993

The Honorable Sherrod Brown
Member, United States
House of Representatives
15561 West High Street
Middlefield, Ohio 44062-9292

Dear Mr. Brown:

This is in response to your inquiry of August 24, 1993, on behalf of _____ regarding the availability of RU-486 for the treatment of his meningioma.

In order for him to be treated with RU-486, his 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, his physician should contact _____ Division of Oncology and Pulmonary Drug Products at _____ to receive guidance on submitting the Investigational New Drug Application.

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

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

cc:HFW-10(2)
R/D: _____ :9/17/93
F/T:vaj:9/22/93:(s:\wp\ _____ . _____
Re/T:vaj:~~9/29~~/93
CONG #12707
No. 14786

APPEARS THIS WAY
ON ORIGINAL

/S/
FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	9/29/93						

/S/
9/29

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

MIF 005990

SHERROD BROWN
THIRTEENTH DISTRICT
OHIO

COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS (VICE-CHAIRMAN)
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON FOREIGN AFFAIRS
COMMITTEE ON POST OFFICE AND CIVIL SERVICE

Congress of the United States
House of Representatives
Washington, DC 20515

WASHINGTON OFFICE
1407 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3514
(202) 225-3401

LORAIN COUNTY DISTRICT OFFICE
5201 ABBE RD
ELYRIA, OH 44035-1451
(216) 365-5877—ELYRIA
(216) 934-5100—LORAIN

MEDINA COUNTY DISTRICT OFFICE
MEDINA COUNTY ADMINISTRATION BUILDING
144 NORTH BROADWAY
MEDINA, OH 44256-1902
(216) 722-9262

GEAUGA COUNTY DISTRICT OFFICE
15561 WEST HIGH STREET
MIDDLEFIELD, OH 44062-9292
(216) 632-5913

August 24, 1993

Department of Health & Human Services
Food and Drug Administration
5600 Fishers Lane
HFW-1 Room 15-05
Rockville, MD 20857

Attn: Gerald Mande

Dear Mr. Mande:

_____ has contacted my office regarding information on the drug RU-486. For your information I am enclosing a copy of his letter to me.

I am concerned with my constituent's situation and want to be of every possible service to him. I would appreciate whatever assistance you can provide in looking into this matter and advising me of your findings. Please address your response to my Middlefield district office listed above.

Sincerely,

Sherrod Brown

SHERROD BROWN
Member of Congress

SB/je
Encl.

APPEARS THIS WAY
ON ORIGINAL

#14786

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 23 1993

The Honorable Phil Gramm
United States Senator
2323 Bryan Street, #1500
Dallas, Texas 75201

Dear Senator Gramm:

This is in response to your letter of May 21, 1993, on behalf of _____ regarding the availability of RU-486 for the treatment of Cushing's Disease.

The National Institutes of Health (NIH) has been conducting a study with RU-486 for the treatment of Cushing's Disease. _____ physician may wish to contact the NIH directly at _____ about the possibility of her participation in the study.

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

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: _____ 6/22/93
F/T:as:6/23/93

Cong. #11734
No. 13761

APPEARS THIS WAY
ON ORIGINAL

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	6/23/93						/S/

MIF 005992

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 02 1993

The Honorable Joe Barton
Member, United States
House of Representatives
303 West Knox Street, Suite 101
Ennis, Texas 75119

Dear Mr. Barton:

This is in response to your inquiry of April 29, 1993, on behalf of [redacted] regarding the availability of RU-486 for the treatment of Cushings Disease.

The National Institutes of Health (NIH) has been conducting a study with RU-486 for the treatment of Cushings Disease. [redacted] physician may wish to contact the NIH directly at [redacted] about the possibility of her participation in the study.

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

Sincerely,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: [redacted]/21/93 (per discussion with [redacted]
F/T:eph:5/24/93 (S:\WP\ [redacted] \RU-486. [redacted]

Cong. 11426 - No. 13429

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	6/1/93						

MIF 005993

*U.S. GPO: 1988-216-468

April 21, 1993

TO WHOM IT MAY CONCERN:

I am writing to you in regards to a matter of great importance to me, MY LIFE. I had a brain tumor removed in October, 1989. My health improved and for about six months I was feeling much better. Then my health started deteriorating again. The tumor was located on my pituitary gland at the base of the brain. The pituitary is the master gland that controls all the other glands in the body. The "Medical Experts" believe that either the tumor has returned or there is scar tissue causing problems. My pituitary is telling my adrenal glands to overproduce steroid hormones. I have a condition called Cushings Disease. It causes you to maintain mass weight, I have become very obese. It causes a pad of fat to develop between your shoulder blades which looks like a hunch-back. It causes my face to be red, fat and very round. I have lost muscle strength in my arms and legs. I feel weak and tired all the time. The weight on my legs has caused me to have problems in my lower extremities. The tumor also caused damage to my eyes and I have to wear glasses.

What are they doing for me now? Well, they wanted an MRI of my head. When I went for this test I was told I would not fit in the machine. So my doctor ordered a CAT scan which did not give him a clear picture of the area he wanted to see. He can see something but he does not know if the tumor has returned or if it is scar tissue. My doctor then ordered radiation treatments. I went for all the consultations before treatments were to begin. Then I was informed that the table I had to lay on for these treatments would not hold my weight. I believe this is discrimination of the worst kind. A person can not get proper medical attention to save their life because of weight limits on tables.

I applied for Social Security Disability, but I was denied these benefits. I appealed, and was awarded benefits in December, 1992. I also have an 8 year old son who receives benefits. We receive a total of $805.00 a month which turned out to be barely over what they consider poverty level. The state took away my medicaid. I will have medicare benefits starting May 1, 1993. This will cover most hospital and doctor visits, but it will not pay for any of my prescription drugs. I also now have NO medical insurance for my son.

My doctor now tells me there is only one drug that can help me. It is a drug called RU-486 and has been labeled the French Abortion Pill. In France the drug has already been tested and proven to cure some cancers and Cushing Disease like I have. Thanks to all the anti-abortion activist, they have not allowed this drug into our country. This drug, RU-486, could save my life and allow me to watch my son grow up. I do not think it is fair or constitutional to deny me access to this drug. I have been sick for 4 years and can't take much more.

I need help in my battle to survive.

With much gratitude,

/s/

[redacted]

JOE BARTON
6TH DISTRICT, TEXAS

HOME OF THE
SSC
NATIONAL LABORATORY

1514 LONGWORTH BUILDING
WASHINGTON, DC 20515-4306
(202) 225-2002

DEPUTY REPUBLICAN WHIP

COMMITTEE ON
ENERGY AND COMMERCE

COMMITTEE ON
SCIENCE, SPACE, AND TECHNOLOGY

Congress of the United States
House of Representatives
Washington, DC 20515-4306

April 29, 1993

Office Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Room 15-55
Rockville, Maryland 20857

Dear Sir:

Enclosed is information from [redacted] concerning use of drug RU-486.

I would appreciate any assistance and/or information you could provide in regard to this matter. Please direct correspondence pertaining to this inquiry to my Ennis, Texas district office, 303 West Knox Street, Suite 101, Ennis, Texas 75119.

Thank you for your interest and consideration.

Sincerely,

Joe Barton
Member of Congress

JB:bt

APPEARS THIS WAY
ON ORIGINAL

#F13429

ARLINGTON OFFICE:
2019 EAST LAMAR BOULEVARD, SUITE 100
ARLINGTON, TX 76006

ENNIS OFFICE:
303 WEST KNOX, SUITE 101
ENNIS, TX 75119-3942
817-543-1000 (main number for all offices)

FORT WORTH OFFICE:
3509 HULEN, SUITE 103
FORT WORTH, TX 76107-6811

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 24 1993

The Honorable Harry Johnston
Member, United States
House of Representatives
1501 Corporate Drive
Suite 250
Boynton, Beach, Florida 33426

Dear Mr. Johnston:

This is in response to your inquiry of April 26, 1993, on behalf of [redacted] regarding the availability of RU-486 for the treatment of her 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,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D; :5/11/93
F/T: :5/21/93

CONG-11409 and NO. 13411
(P: [redacted] \DRUGLTRS\RUIND.AVL)

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	[redacted]	5/24/93						

MIF 005997

AF 92-5-3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 24 1993

The Honorable Harry Johnston
Member, United States
House of Representatives
1501 Corporate Drive
Suite 250
Boynton, Beach, Florida 33426

Dear Mr. Johnston:

This is in response to your inquiry of April 26, 1993, on behalf of [redacted], regarding the availability of RU-486 for the treatment of her 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,

Jerold R. Mande
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
R/D; [redacted] :5/11/93
F/T: var:5/21/93

CONG-11409 and NO. 13411
(P: [redacted] DRUGLTRS\RUIND.AVL)

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	[redacted]	5/24/93						

MIF 005998

HARRY JOHNSTON
CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-0919

April 26, 1993

Ms. Kay Hocombe
Acting Associate Commissioner
Legislative Affairs
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Hocombe:

IN REPLY PLEASE REFER TO
DOCUMENT NUMBER: 14694-jb

The attached letter was recently received in my office and is forwarded to you for your consideration.

I would appreciate your assistance in this matter, and I welcome any comments you might be able to provide that would help me in formulating a response to my constituent's inquiry.

Thank you in advance for your attention to my request.

With warm regards,

Sincerely,

HARRY JOHNSTON, M.C.

HJ:jb

#13411

19TH DISTRICT, FLORIDA
MAJORITY WHIP-AT-LARGE
CHIEF OF STAFF
SUZANNE STOLL
DISTRICT ADMINISTRATOR
DIANE BIRNBAUM

COMMITTEES
BUDGET
FOREIGN AFFAIRS
SUBCOMMITTEES
AFRICA, CHAIRMAN
INTERNATIONAL ECONOMIC
POLICY & TRADE
INTERNATIONAL OPERATIONS

WASHINGTON OFFICE
204 CANNON HOUSE
OFFICE BUILDING
WASHINGTON, DC 20515-0919
202-225-3001

BROWARD COUNTY OFFICE
MARGATE CITY HALL
5790 MARGATE BOULEVARD
MARGATE, FL 33063
305-972-6454 X-378

PALM BEACH COUNTY OFFICE
1501 CORPORATE DRIVE
SUITE 250
BOYNTON BEACH, FL 33426
407-732-4000
305-428-4888

HARRY JOHNSTON
CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515-0919

April 26, 1993

Ms. Kay Hocombe
Acting Associate Commissioner
Legislative Affairs
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Ms. Hocombe:

IN REPLY PLEASE REFER TO
DOCUMENT NUMBER: 14694-jb

The attached letter was recently received in my office and is forwarded to you for your consideration.

I would appreciate your assistance in this matter, and I welcome any comments you might be able to provide that would help me in formulating a response to my constituent's inquiry.

Thank you in advance for your attention to my request.

With warm regards,

Sincerely,

HARRY JOHNSTON, M.C.

HJ:jb

APPEARS THIS WAY
ON ORIGINAL

#13411

19TH DISTRICT, FLORIDA
MAJORITY WHIP-AT-LARGE
CHIEF OF STAFF
SUZANNE STOLL
DISTRICT ADMINISTRATOR
DIANE BIRNBAUM

COMMITTEES
BUDGET
FOREIGN AFFAIRS
SUBCOMMITTEES
AFRICA, CHAIRMAN
INTERNATIONAL ECONOMIC
POLICY & TRADE
INTERNATIONAL OPERATIONS

WASHINGTON OFFICE
204 CANNON HOUSE
OFFICE BUILDING
WASHINGTON, DC 20515-0919
202-225-3001

BROWARD COUNTY OFFICE
MARGATE CITY HALL
5790 MARGATE BOULEVARD
MARGATE, FL 33063
305-972-6454 X-378

PALM BEACH COUNTY OFFICE
1501 CORPORATE DRIVE
SUITE 250
BOYNTON BEACH, FL 33426
407-732-4000
305-428-4888