Senator
Brock Adams
Room 513 Hart Building
Washington, DC 20510

Re.: RU-486

Sir:

I have a question: who writes the laws of the land? The Congress and Supreme Court or the FDA? I refer to the political action by the FDA to block import of RU-486, thus preventing further research on the drug's potential benefits in cancer and other disease treatment.

My mother died of breast cancer at age 54, and a girlfriend succumbed to leukemia at 41. Another girlfriend (51) underwent a radical mastectomy this year, my husband (64) underwent cancer surgery and treatment this year. To say nothing of all the other people in my acquaintance currently battling the disease.

Are we to understand that the right to life of these living, breathing, feeling, thinking, loving and loved human beings is to be disregarded, simply because the drug that might help save them could also be used to terminate an agglomeration of cells unable to think or feel or reason and, what's more, not wanted and most likely headed for a life of neglect and abuse.

Are religious zealots running this country back into the Dark Ages or is this the United States of America at the end of the Twentieth Century?

Sincerely,

151

BROCK ADAMS
WASHINGTON

COMMITTEES
APPROPRIATIONS
LABOR AND HUMAN RESOURCES
RULES AND ADMINISTRATION

United States Senate

WASHINGTON, D.C. 20510

February 11, 1991

Food & Drug Administration
Mr. Hugh Cannon
1555 Parklawn Bldg., 5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

Enclosed please find a copy of a request from my constituent, _____

I would appreciate it if you could address my constituent's inquiries concerning FDA blockage of the import of RU-486 for cancer research.

Thank you for your attention to this matter. I look forward to your response.

Sincerely,

Brock Adams

BROCK ADAMS
United States Senator

BA/mcm
Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005802

DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 2 1991

A.F. 43-353 FILE

The Honorable Scott Klug
House of Representatives
Washington, D.C. 20515

Dear Mr. Klug:

This is in response to your letter of March 5, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HF-12	/S/	4/2/91						

151 4/2/91
151

FILE COPY

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

MIF 005803

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: [redacted] 3/25/91
F/T; var:4/1/91
CONG-3560 and No. 4140
[redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

SCOTT KLUG
SECOND DISTRICT, WISCONSIN

EDUCATION AND LABOR COMMITTEE
GOVERNMENT OPERATIONS COMMITTEE

Congress of the United States

House of Representatives

Washington, DC 20515

March 5, 1991

Mr. Hugh Cannon
Congressional Liaison
F D A
1555 Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

Enclosed is a letter from _____ who questions the FDA's approval process for RU-486.

Please address her concerns and send your response to my Legislative Assistant Richard Strasbaugh. Thanks for your assistance in this matter.

Sincerely,

Scott Klug
Member of Congress

SK/rs

APPEARS THIS WAY
ON ORIGINAL

#4140

PLEASE RESPOND TO:

☐ 1224 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2906

☐ 16 NORTH CARROLL STREET
ROOM 600
MADISON, WI 53703
(608) 257-9200

Bob Graham
Florida

United States Senate

Washington, D.C.

Date 4/29/91

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

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

904/681-7726

Your cooperation and assistance are appreciated.

With kind regards,

Sincerely,

United States Senator

#4696

Constituent's Name: _____

MIF 005807

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 7 1991

The John C. Danforth
United States Senate
Washington, D.C. 20515

Dear Senator Danforth:

This is in response to your letter of April 30, 1991, on behalf of _____, concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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 beer approved by the FDA. However, out of compassion for individual

/S/

/S/
6/7/91

MIF 005808
FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN18	/S/	6/6/91						

*U.S.GPO:1990-0-213-062

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

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

Sincerely yours,

Hugh C. Cannon
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: ——— :5/26/91
F/T; var:6/5/91
CONG-3971 and No. 4617
——— \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

March 28, 1991

Senator John Danforth
U.S. Senator from Missouri
U.S. Senate Building
Washington, D.C. 20510-2502

Dear Senator Danforth:

I am enclosing a photocopy of a recent newspaper editorial which generated great outrage in me.

As the brother of a physician, I hope you share this outrage. For the FDA to drag its feet on permitting RU-486 into this country for medical testing for treating breast cancer is not permissible. Breast cancer afflicts one out of nine women in this country. Women close to you and me are at risk.

I want your views on this matter. Please, do not write and tell me you will take my views into consideration when appropriate legislation is before you. I want to know what YOUR views are.

Please note: My stance is not an under-the-table way for getting the drug into this country for abortion use. I am a physician who cannot stand by and see a potential therapy for a killer-disease to go unused for political/religious/philosophical reasons without raising my voice.

Most sincerely yours,

/S/

United States Senate

WASHINGTON, D.C. 20510

April 30, 1991

Congressional Liaison
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Congressional Liaison:

A constituent, _____ has brought to my attention a matter which falls within the jurisdiction of your agency.

I refer this matter to your office for a preliminary examination. I would appreciate receiving your comments, in duplicate, together with the return of the correspondence.

Your attention to this matter is appreciated.

Sincerely,

John C. Danforth

Enclosure

#4617

APPEARS THIS WAY
ON ORIGINAL

MIF 005812

A.F. _____ MIF

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 22 1991

The Honorable Ted Stevens
United States Senate
Washington, D.C. 20510

Dear Senator Stevens:

This is in response to your letter of April 2, 1991, 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 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.

...PS THIS WAY
...RIGINAL

MIF 005813

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-12	/S/	5/21/91						

(51) 5/2:
(51)

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

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
New Drug Development in
the United States

cc: HFW-10(2)
F/D: ———— :5/14/91
F/T: var:5/21/91
Cong-3787 No. 4398(——— DRUGLTR\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON APPROPRIATIONS
WASHINGTON, DC 20510-6025

April 2, 1991

Hugh C. Cannon, Associate Commissioner
Office of Legislative Affairs
Food & Drug Administration
Room 15-55, Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

Dear Mr. Cannon:

Enclosed is a copy of a letter from ———————— ——— concerning the drug RU 486. I would appreciate your providing information on any testing or research done on this drug in the United States.

Thank you for your assistance.

With best wishes,

Cordially,

Ted Stevens

TED STEVENS

Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 005815

A.F. [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 22 1991

The Honorable Barbara F. Vucanovich
House of Representatives
Washington, D.C. 20515

Dear Ms. Vucanovich:

This is in response to your inquiry of April 15, 1991, on behalf of [redacted] 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 [redacted]. Please assure her that approval of this, or any product, will only be granted if the safety and efficacy requirements mandated by law are satisfied.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
F/D: [redacted] :5/14/91
F/T; var:5/21/91
CONG-3898 NO. 4537
[redacted] \DURGLTR\STOPRU.486)

MIF 005816
FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	5/21/91						

/S/ 5/22
/S/

BARBARA F. VUCANOVICH
2D DISTRICT, NEVADA

HOUSE APPROPRIATIONS COMMITTEE

COMMITTEE ON INTERIOR
AND INSULAR AFFAIRS

CONGRESSIONAL TRAVEL AND
TOURISM CAUCUS

CONGRESS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

206 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-6155

FEDERAL BUILDING
300 BOOTH STREET, SUITE 3038
RENO, NV 89509
(702) 784-5003

401 RAILROAD ST. #307
ELKO, NV 89801
(702) 738-4064

19 W. BROOK AVENUE SUITE B,
NORTH LAS VEGAS, NV 89031-1320
(702) 399-3555

April 15, 1991

Dr. David Kessler
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

Dear David:

I am writing you to request your assistance in a matter that has recently been brought to my attention.

One of my constituents, ———, has written me regarding a drug (RU486) which is used to abort a fetus. I would greatly appreciate your reviewing and addressing the concerns of ——. I have enclosed a copy of the letter for your convenience.

Thank you in advance for your time and attention to this matter.

Sincerely,

Barbara

BARBARA F. VUCANOVICH
Member of Congress

BFV:kc

APPEARS THIS WAY
ON ORIGINAL

#4537

A.F. _____ MLE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 10 1991

The Honorable Richard H. Bryan
United States Senate
Washington, D.C. 20515

Dear Senator Bryan:

This is in response to your letter of April 24, 1991, on behalf of _____, concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

MIF 005818

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-12	/S/	5/6/91						

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

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ———— 5/2/91
F/T; var:5/6/91
CONG-3934 and No. 4578
(——— \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

RICHARD BRYAN
NEVADA

COMMITTEES:
BANKING, HOUSING, AND URBAN AFFAIRS
COMMERCE, SCIENCE, AND TRANSPORTATION
JOINT ECONOMIC

United States Senate

WASHINGTON, DC 20510-2804

April 24, 1991

Mr. James Benson
Acting Commissioner
5600 Fishers Lane
Rockville, Md. 20857

Dear Mr. Benson:

Enclosed please find a copy of correspondence I received from _____ who would like for the drug RU 486 to be approved for sale in the United States for use as treatment for several health problems. I thought you would be interested to know that there is public support for this drug.

I appreciate your time and attention to such an important and sensitive matter.

Sincerely,

Richard H. Bryan
United States Senator

RHB/dh

#4528

APPEARS THIS WAY
ON ORIGINAL

MIF 005821

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 8 1991

A.F. 173-233 FILE

The Honorable Ted Stevens
United States Senate
Washington, D.C. 20510

Dear Senator Stevens:

This is in response to your letter of Apirl 12, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

MIF 005822

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	[S]	5/2/91						/S/5/8/9

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

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: _____ 5/1/91
F/T; var:5/1/91
CONG-3915 and No. 4556

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON APPROPRIATIONS
WASHINGTON, DC 20510-6025

April 12, 1991

Hugh C. Cannon, Associate Commissioner
Office of Legislative Affairs
Food & Drug Administration
Room 15-55, Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

Dear Mr. Cannon:

Enclosed is a copy of a letter from ——— a constituent of mine who is concerned about the availability of the drug RU-486 to cancer patients. Any information you can provide that addresses my constituent's concerns is greatly appreciated.

Thank you for your assistance.

With best wishes,

Cordially,

Ted Stevens

TED STEVENS

Enclosure

#4556

APPEARS THIS WAY
ON ORIGINAL

MIF 005825

A.F. _____ rILt

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 7 1991

The Honorable Sam Nunn
United States Senator
75 Spring Street, South West
Suite 1700
Atlanta, Georgia 30303

Dear Senator Nunn:

This is in response to your letter of April 2, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-2	/S/	5/7/91						

(S) 5/7/91

FILE COPY

*U.S.GPO:1990-0-213-062

MIF 005826

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: 5/1/91
F/T; var:5/1/91
CONG-3783 and NO.4394

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON ARMED SERVICES
WASHINGTON, DC 20510-6050

April 2, 1991

Mr. Hugh C. Cannon
Associate Commissioner for Legislative Affairs
Congressional Liaison Office
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Cannon:

I recently received the enclosed constituent inquiry. Because of my desire to be responsive to all inquiries, I would appreciate your looking into this matter and providing me with any information you have available on this subject, of course, consistent with your established policies and procedures. I look forward to hearing from you in the near future.

Your kind assistance is greatly appreciated.

Sincerely,

Sam Nunn

Sam Nunn

Enclosure

SN/lkj

PLEASE REPLY TO:
75 Spring Street, S.W.
Suite 1700
Atlanta, Ga. 30303
Attn: Laura Johnson

#4394

91 APR 10 PM 3:27

MIF 005829

A.F. [redacted] FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 7 1991

The Honorable Guy Vander Jagt
House of Representatives
Washington, D.C. 20515

Dear Mr. Vander Jagt:

This is in response to your letter of March 28, 1991, on behalf of [redacted] concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

syndrome, and other types of cancer.

To provide you background information, the Federal Food, Drug,

patients, many of whom suffer from serious or life-threatening diseases. FDA has, as a matter of enforcement discretion, [redacted]

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.

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It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ~~~~~~~ 5/1/91
F/T; var:5/1/91
CONG-3747 and No. 4355

APPEARS THIS WAY
ON ORIGINAL

GUY VANDER JAGT
9TH DISTRICT, MICHIGAN

2409 RAYBURN HOUSE OFFICE BUILDING
TELEPHONE: (202) 225-3511

COMMITTEE:
WAYS AND MEANS
SUBCOMMITTEES
TRADE
SELECT REVENUE MEASURES
JOINT COMMITTEE ON TAXATION

Congress of the United States
House of Representatives
Washington, DC 20515-2209

DISTRICT OFFICES
ROOSEVELT PARK
950 WEST NORTON AVENUE
MUSKEGON, MI 49441-4193
(616) 733-3131

186 SOUTH RIVER AVENUE
HOLLAND, MI 49423-2848
(616) 396-3849

900 EAST FRONT STREET
TRAVERSE CITY, MI 49684-2706
(616) 946-3832

CHIEF OF STAFF
JIM SPARLING

March 28, 1991

Mr. Hugh Cannon
Associate Commissioner for Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Room 1555
Rockville, Maryland 20857

Dear Mr. Cannon:

I am contacting you on behalf of my constituent, _____ who has asked for my assistance.

I am enclosing self-explanatory correspondence regarding the drug RV-486 for your review. I would sincerely appreciate your providing me with all available information so that I can fully respond to my constituent.

Thank you very much for your attention to and consideration of this request.

With all good wishes,

Sincerely,

Guy

Guy Vander Jagt
Member of Congress

GVJ/ef

#4355

APPEARS THIS WAY
ON ORIGINAL

91 APR -4 P12:54

MIF 005833

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 7 1991

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

Dear Mr. Foley:

This is in response to your letter of March 26, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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

recommended uses. A new drug may not be distributed interstate (except for clinical study) until we have approved a new drug

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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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.

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It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

2 Enclosures
New Drug Development in
the United States
FDA Testimony

cc: HFW-10(2)
F/D: ———— :5/1/91
F/T; var:5/1/91
CONG-3801 and NO.4414

APPEARS THIS WAY
ON ORIGINAL

THOMAS S. FOLEY
5TH DISTRICT, WASHINGTON

THE SPEAKER

CONGRESSIONAL OFFICE
1201 LONGWORTH HOB
WASHINGTON, DC 20515-4705
AREA CODE (202) 225-2006

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

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

E. 12929 SPRAGUE
SPOKANE, WA 99216-0736
AREA CODE (509) 926-4434

28 W. MAIN
WALLA WALLA, WA 99362-2816
AREA CODE (509) 522-6370

March 26, 1991

Dear Mr. Cannon:

Please find enclosed a copy of a letter from my constituent, _____ is concerned about the availability of RU-486 in this country -- particularly because she understands the drug may have be potentially beneficial to cancer patients. If you would address the issues and concerns she raises in her letter, it would be most helpful.

Thank you for your kind assistance.

With best wishes.

Sincerely,

Thomas S. Foley

Thomas S. Foley
Member of Congress

The Honorable Hugh C. Cannon
Associate Commissioner
for Legislative Affairs
Food and Drug Administration
200 Independence Avenue S.W., Room 15-55
Washington, D.C. 20201

TSF:hmd
Enclosure

91 APR 12 P 2:23

#4414

APPEARS THIS WAY
ON ORIGINAL

MIF 005837

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 7 1991

The Honorable Phil Gramm
United States Senate
Washington, D.C. 20510

Dear Senator Gramm:

This is in response to your letter of April 16, 1991, on behalf of _____ concerning the unapproved new drug, RU-486.

As you may know, RU-486 is a drug that is approved in France for early abortion through a limited distribution system 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-7	/S/	5/9/91						

5/5/9/91

FILE COPY

MIF 005838

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, the publicity in this country 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 and the importation of unapproved drugs.

It is extremely important to point out that this import alert does in no way restrict 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 Subcommittee on Regulation, Business Opportunities and Energy on November 19, 1990 which contains additional information on this complex issue.

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

Sincerely yours,

Hugh C. Cannon
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: ——— :5/1/91
F/T; var:5/1/91
CONG-3859 and NO. 4491

APPEARS THIS WAY
ON ORIGINAL

3/25/91

The Honorable Phil Gramm
U.S. Senate
Washington, D.C. 20510

Dear Senator Gramm,

The drug, RU-486, being researched in France, has been shown to block the action of hormones causing breast cancer and other diseases affected by certain hormones. Dr. Gary D. Hodgen of the Eastern Virginia Medical School says the drug could successfully treat as much as 40% of all breast cancers, could do away with the need for 10% of all Caesarean section deliveries and may be valuable in treating endometriosis (which commonly results in a hysterectomy). In addition RU-486 is also being successfully prescribed in France as a treatment for Cushing's Syndrome, a serious endocrine disorder that can cause high blood pressure, weight gain and emotional disturbances.

Since the drug can also be used to induce abortion early in a pregnancy, policy makers in the Reagan administration who disagreed with abortion outlawed any research or use of the drug in the United States.

Abortion is one thing, and every person has a right to work against a practice that he or she believes in immoral but, saving lives with a drug that just also happens to be able to be used as an abortifacient has **nothing** to do with abortion. To forbid testing and use of RU-486 is to sentence victims of diseases that could be treated by it to intense suffering and death when the drug might cure them. This is immoral. It is also cruel and uncaring.

I believe it is wrong **not** to give RU-486 a chance to save the lives of American women and to deny the treatment of Cushing's Syndrome.

Sincerely,

151

Phil Gramm
Texas

United States Senate

MEMORANDUM

Date: 4-16-91

My constituent has sent me the enclosed communication, and I would appreciate a response which addresses his/her concerns.

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

Office of Senator Phil Gramm
370 Russell Senate Office Building
Washington, D.C. 20510-4302

Attention: Jeff Hassmann

#4491

APPEARS THIS WAY
ON ORIGINAL

MIF 005842

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUL 26 1991

The Honorable William Zellif, Jr.
House of Representatives
Washington, D.C. 20515

Dear Mr. Zellif:

This is in response to your letter of July 1, 1991, transmitting a copy of the New Hampshire House Concurrent Resolution 11 relative to RU486.

We appreciate receiving the bill and have forwarded it to our Division of Federal - State Relations for their information.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

cc:HFW-10(2)
HFC-150
R/D: :7/24/91
F/T:eph:7/25/91(A:\RU486.VAL)

CONG# 4522 (No. 5264)

APPEARS THIS WAY
ON ORIGINAL

/S/

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	7/26/91						

/S/ 7/24/

*U.S. GPO: 1989--

MIF 005843

WILLIAM H. ZELIFF, JR.
1ST DISTRICT, NEW HAMPSHIRE

COMMITTEE ON PUBLIC WORKS AND TRANSPORTATION
SUBCOMMITTEES:
SURFACE TRANSPORTATION
WATER RESOURCES

COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEES:
COMMERCE, CONSUMER AND MONETARY AFFAIRS
HUMAN RESOURCES AND INTERGOVERNMENTAL AFFAIRS

CO-CHAIRMAN REPUBLICAN TASK FORCE ON TAX POLICY AND JOB CREATION

512 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-5456
(202) 225-4370 (FAX)

DISTRICT OFFICE:

340 COMMERCIAL STREET
MANCHESTER, NEW HAMPSHIRE
(603) 669-6330
(603) 669-6446 (FAX)

TOLL FREE IN NEW HAMPSHIRE
1-800-649-7290

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

July 1, 1991

Mr. David A. Kessler
Commissioner
Food and Drug Administration
5600 Fishers Lane #14-71
Rockville, MD 20857

Dear Commissioner Kessler:

By this letter I am transmitting for your review and consideration New Hampshire House Concurrent Resolution 11. This resolution urges that New Hampshire be the site for clinical trials if a company or business decides to introduce the French abortion pill RU486 in the United States.

Please give this resolution your utmost attention. Thank you.

Sincerely,

William H. Zeliff, Jr.
Member of Congress

APPEARS THIS WAY
ON ORIGINAL

1991 SESSION

0321L

91-0284

01

HOUSE BILL - FINAL VERSION

HOUSE CONCURRENT RESOLUTION NO. 11

INTRODUCED BY: Rep. Gilmore of Strafford Dist. 7; Rep. K. Wheeler of Strafford Dist. 4; Rep. Burling of Sullivan Dist. 1; Sen. McLane of Dist. 15.

REFERRED TO: Health, Human Services and Elderly Affairs

A RESOLUTION relative to abortion drug RU486.

ANALYSIS

This concurrent resolution urges that New Hampshire be the site for clinical trials if a company or business decides to introduce the French abortion pill RU486 in the United States.

- -

EXPLANATION: Matter added appears in ***bold italics***.
Matter removed appears in [brackets].
Matter which is repealed and reenacted or all new appears in regular type.

APPEARS THIS WAY
ON ORIGINAL

0321L
91-0284
01

HOUSE BILL - FINAL VERSION

HCR 11

STATE OF NEW HAMPSHIRE

In the year of Our Lord one thousand
nine hundred and ninety-one

A RESOLUTION

relative to abortion drug RU486.

Whereas, the antiprogesterone known as RU486 has been approved and available in France since November of 1988; and

Whereas, RU486 has proven to be a safe and effective method of terminating a pregnancy as early in the term as possible; and

Whereas, RU486 is a nonsurgical procedure and is therefore a safe, noninvasive method of abortion; and

Whereas, RU486 offers no risks from injury or infection caused by physicians' instruments, nor from complications of anesthesia; and

Whereas, RU486 has shown considerable efficacy in treating certain kinds of breast cancer and brain tumors, Cushing's syndrome and other diseases; now, therefor, be it

Resolved by the House of Representatives, the Senate concurring:

That the introduction of RU486 into the United States be encouraged for its significant medical value; and

That if a company or business decides to introduce RU486 in the United States, that it be encouraged to choose New Hampshire as the site for clinical trials and submit the data from such clinical trials to the Food and Drug Administration; and

That copies of this resolution, signed by the speaker of the house and the president of the senate be by them forwarded to the manufacturer of RU486 Roussel UCLAF 35 Boulevard des Invalides 75007 Paris, France and to the members of the New Hampshire congressional delegation who shall forward such copies to appropriate persons in the Food and Drug Administration.

Adopted by the House March 19

Harold W. Burns, Speaker

Adopted by the Senate May 16

Edward C. Dupont, Jr. President

DEPARTMENT OF HEALTH AND HUMAN SERVICES A.F. _____ FILE

JUL 5 1991

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

Dear Senator Bentsen:

This is in response to your letter of June 3, 1991, 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
HFWH2	/S/	7/2/91						

/S/ 7/5/91

FILE COPY

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

MIF 005847

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.

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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.

APPEARS THIS WAY
ON ORIGINAL

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

Sincerely yours,

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: [redacted] :6/20/91
R/T; var:6/27/91
Edit: [redacted] :6/28/91
F/T: var:7/1/91
CONG-4253 and No. 4959([redacted] \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

LLOYD BENTSEN
TEXAS

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

United States Senate

WASHINGTON, DC 20510-4301

June 3, 1991

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, or any assistance you might be able to give in routing it to the proper authorities.

Your kind consideration is greatly appreciated.

Sincerely,

Lloyd Bentsen

Lloyd Bentsen

Enclosure

PLEASE REPLY TO:

961 Federal Building
Au[illegible]

APPEARS THIS WAY
ON ORIGINAL

#4959

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 27 1991

The Honorable Charles J. Luken
House of Representatives
Washington, D.C. 20515

Dear Mr. Luken:

This is in response to your letter of July 31, 1991, 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

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFN-12	/S/	8/22/91						

JSI 8/12

FILE COPY

MIF 005851

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.

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

Sincerely yours,

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: ———— 8/8/91
F/T; var:8/21/91
CONG-4844 and No. 5642(——— \DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

CHARLES J. LUKEN
1ST DISTRICT, OHIO

WASHINGTON OFFICE
ROOM 1632
LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-2216

DISTRICT OFFICE
THE GWYNNE BUILDING, SUITE 1300
602 MAIN STREET
CINCINNATI, OH 45202
(513) 684-2723

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

COMMITTEE ON BANKING, FINANCE AND URBAN AFFAIRS

SUBCOMMITTEE ON FINANCIAL INSTITUTIONS SUPERVISION, AND INSURANCE

SUBCOMMITTEE ON ECONOMIC STABILIZATION

SUBCOMMITTEE ON POLICY RESEARCH AND INSURANCE

COMMITTEE ON GOVERNMENT OPERATIONS

July 31, 1991

Congressional Relations HFW-12, Rm. 1555
Department of Health and Human Services
F.D.A. Office of Legislative Affairs
5600 Fishers Ln.
Rockville, MD 20857

Dear _____

I am writing with regard to the enclosed letter from a constituent of mine, _____ She would like to have information on the use of RU486, the "abortion pill", as an effective treatment for breast cancer. She would also like to know why this drug has not been permitted into this country if it does treat breast cancer. I would appreciate it if you would investigate this situation and provide me with a response.

Thank you very much for your kind consideration in this matter.

Sincerely,

Charles J. Luken

CHARLES J. LUKEN
Member of Congress

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 09 1991

The Honorable Dick Swett
House of Representatives
Washington, D.C. 20515

Dear Mr. Swett:

This is in response to your letter of July 1, 1991, transmitting a copy of the New Hampshire House of Concurrent Resolution 11 relative to RU-486.

We appreciate receiving the bill and have forwarded it to our Division of Federal - State Relations for their information.

Sincerely yours,

Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-10(2)
HFC-150
R/D: :7/29/91
F/T; var:8/1/91
CONG-4705 and No. 5478
\DRUGLTRS\RU-NHRES.MDG)

APPEARS THIS WAY
ON ORIGINAL

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
[illegible]	/S/	7/91						

/S/
8/2/91

FILE COPY

MIF 005855

*U.S.GPO:1988-0-213-052

DICK SWETT
2ND DISTRICT, NEW HAMPSHIRE

WASHINGTON OFFICE:
128 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-5206

CONCORD DISTRICT OFFICE:
18 NORTH MAIN STREET
CONCORD, NH 03301
(603) 224-6621

NASHUA DISTRICT OFFICE:
5 COLISEUM AVENUE
NASHUA, NH 03063
(603) 880-6142

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

PUBLIC WORKS AND
TRANSPORTATION COMMITTEE

SUBCOMMITTEES:
SURFACE TRANSPORTATION
AVIATION
ECONOMIC DEVELOPMENT

SCIENCE, SPACE, AND
TECHNOLOGY COMMITTEE

SUBCOMMITTEES:
ENVIRONMENT
TECHNOLOGY AND
COMPETITIVENESS

SELECT COMMITTEE ON AGING

July 1, 1991

Mr. David Kessler
Commissioner
Food And Drug Administration
5600 Fishers Lane #14-71
Rockville, Maryland 20857

Dear Commissioner Kessler,

Enclosed is a copy of New Hampshire House Concurrent Resolution 11 which I have been asked to forward to you by the New Hampshire legislature. This non-binding legislation requests that the State of New Hampshire be made a testing site for RU 486, the French abortion pill, should a U.S. company decide to introduce the drug into this country.

In making any decision about the availability of this drug in the U.S., I am confident you will carefully and thoroughly determine its safety as required by FDA standards.

With warmest regards,

Dick Swett
Member of Congress

APPEARS THIS WAY
ON ORIGINAL

FF 5478

1991 SESSION

0321L
91-0284
01

HOUSE CONCURRENT RESOLUTION NO. 11

INTRODUCED BY: Rep. Gilmore of Strafford Dist. 7; Rep. K. Wheeler of Straffrod Dist. 4; Rep. Burling of Sullivan Dist. 1

REFERRED TO: Health, Human Services and Elderly Affairs

A RESOLUTION relative to abortion drug RU486.

ANALYSIS

This concurrent resolution urges that New Hampshire be the site for clinical trials if a company or business decides to introduce the French abortion pill RU486 in the United States.

- -

EXPLANATION: Matter added appears in ***bold italics***.
Matter removed appears in [brackets].
Matter which is repealed and reenacted or all new appears in regular type.

0321L
91-0284
01

HCR 11

STATE OF NEW HAMPSHIRE

In the year of Our Lord one thousand
nine hundred and ninety-one

A RESOLUTION

relative to abortion drug RU486.

Whereas, the antiprogesterone known as RU486 has been approved and available in France since November of 1988; and

Whereas, RU486 has proven to be a safe and effective method of terminating a pregnancy as early in the term as possible; and

Whereas, RU486 is a nonsurgical procedure and is therefore a safe, noninvasive method of abortion; and

Whereas, RU486 offers no risks from injury or infection caused by physicians' instruments, nor from complications of anesthesia; and

Whereas, RU486 has shown considerable efficacy in treating certain kinds of breast cancer and brain tumors, Cushing's syndrome and other diseases; now, therefor, be it

Resolved by the House of Representatives, the Senate concurring:

That the introduction of RU486 into the United States be encouraged for its significant medical value; and

That if a company or business decides to introduce RU486 in the United States, that it be encouraged to choose New Hampshire as the site for clinical trials and submit the data from such clinical trials to the Food and Drug Administration; and

That copies of this resolution, signed by the speaker of the house and the president of the senate be by them forwarded to the manufacturer of RU486 Roussel UCLAF 35 Boulevard des Invalides 75007 Paris, France and to the members of the New Hampshire congressional delegation who shall forward such copies to appropriate persons in the Food and Drug Administration.

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 05 1991

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. Wyden:

This is in response to your letter regarding issues related to the unapproved new drug, RU-486. As you may remember you raised this issue during our October 29 meeting. I sincerely apologize for the lengthy delay in responding.

First, let me emphasize the strong commitment of the Food and Drug Administration (FDA) both to appropriate implementation of the law and to making important therapies available to those who need them. We firmly believe that it is the pre-eminent responsibility of the FDA to protect the public health.

You expressed concern about the current import alert on RU-486, and especially about a potential adverse impact on research. It was public health reasons that led FDA to restrict the importation of RU-486 for personal use. The rationale for that decision, discussed by FDA witnesses at a November 19, 1991 hearing before your Subcommittee, included concerns about the potential risk of serious adverse effects such as excessive uterine bleeding to patients who, because of the intended use of the product, might not be under the care of a physician. In addition, as Mr. Chesemore stated at that time, RU-486 does not fit current criteria for allowing for personal importation of an unapproved drug; that is, as an abortafacient, RU-486 is not proposed for treatment of a serious condition for which no alternative therapy exists, a primary consideration in the development and implementation of our personal importation policy.

It is my understanding that the import alert in no way restricts the importation of this drug for research purposes. FDA also has provided clarification to its field offices relative to the importations of unapproved drugs for non-clinical research, stating that such importation will be allowed if certain regulatory requirements are met. A copy of that guidance is enclosed for your information.

/S/

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	12/2/91						
HFW2	/S/	12/2/91						

/S/ 12/3/91

FILE COPY
MIF 005861

*U.S.GPO:1990-0-213-062

FDA's drug review authority under the Federal Food, Drug, and Cosmetic Act is limited to determinations based on the data and information requirements mandated by the statute. Our regulations governing the conduct of clinical investigations 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. Studies using RU-486 have been allowed by FDA under INDs for a number of years and have in some cases been supported by the National Institutes of Health. 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 such action are that (1) the sponsor has not provided sufficient information to evaluate the risks of the drug, (2) the risks to the subject are unreasonable, (3) the investigators are not qualified, or (4) the information provided to the investigator is misleading.

Finally, your letter raises the issue of a fair and unbiased review of any application received by FDA. Let me emphasize that we are committed to maintaining the scientific integrity of FDA's new drug testing and approval process carried out under existing law. I can assure you that any protocol submitted to FDA will be given a fair review based on the scientific issues involved.

I appreciate your perspective on this complex issue and your commitment to improving the public health of all Americans

Sincerely yours,

Carol R. Scheman
Deputy Commissioner
for External Affairs

Enclosure
cc: HFW-1
HFW-10(2)
HFW-12
HF-24
HF-40
HF-41
R/D: 11/21/91
R/T: var:11/21/91
Edit: 11/21/91
:11/22/91
re/t: var:11/22/91
Reviewed: :11/27/91
11/27/91
F/T: var:12/2/91 PRIORITY\RU-486.DEP)

HHS-36 and NO 3436

MAJORITY MEMBERS
RON WYDEN, OREGON
CHAIRMAN

ELIOT L. ENGEL, NEW YORK
JIM OLIN, VIRGINIA
MICHAEL R. McNULTY, NEW YORK

101st 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

MINORITY MEMBERS
WM. S. BROOMFIELD, MICHIGAN
MELTON D. HANCOCK, MISSOURI
JOEL HEFLEY, COLORADO

STEVE JENNING
SUBCOMMITTEE STAFF DIRECTOR
202-225-7797

PAUL RUSINOFF
MINORITY SUBCOMMITTEE PROFESSIONAL STAFF MEMBER
202-225-6135

December 5, 1990

The Honorable Louis W. Sullivan
Secretary
U.S. Department of Health and Human Services
H.H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Secretary:

I know we share a deep interest in the public health concerns facing this nation, and in the fundamental role played by the federal government in creating a healthier society.

You may be aware of important medical research that has been undertaken in this country using the French anti-progesterone RU 486. Medical researchers testifying before my subcommittee have termed this drug a breakthrough invention which could have great -- perhaps unique -- utility in treating a variety of debilitating and deadly disease, from cancer to Cushing's Syndrome.

However, as I have related to you in previous communications, it is apparent that a combination of anti-abortion fervor in this country and an arbitrary import ban imposed by the Food and Drug Administration has discouraged the drug's manufacturer, Roussel UCLAF, from continuing existing clinical trials with this drug or providing the drug for new research projects.

This is tragic. Sick and dying Americans could be helped with this drug. And today I urge you to take several actions which I believe could help remedy this unnecessary and embarrassing problem which has stained our nation's reputation as a leader in health care policy and research.

Mr. Secretary, I urge you to act as quickly as possible on the following proposals:

-1- Lift the ban on personal importation of RU 486. It is unnecessary and appears to have been ordered solely to assuage anti-abortion groups. Our review of FDA files found that (1) there was no record of surreptitious importation of this drug in any form, (2) that there was no indication that a black market in RU 486 existed, and (3) that the FDA failed to consult

with either the medical community or other public health officials prior to the issuance of the June 1989 ban.

Moreover, it appears that while this ban does not specifically restrict medical research with the unapproved drug, since the imposition of the alert no new RU 486-related clinical trials in this country have been initiated. Earlier trials with the drug have been concluded, or are winding down, in some cases because the drug's manufacturer has declined to make available new quantities of RU 486. I believe that the company's decision is in part a response to the FDA's import alert.

-2- Short supplies of the drug in this country have closed highly successful therapeutic programs for treatment of Cushing's Syndrome -- a sometimes fatal auto-immune disease. It is my understanding that RU 486 is the only known drug treatment for this illness.

New clinical trials of this treatment at the National Institutes of Health have been placed on hold because the company will not guarantee that new quantities of the RU 486 will be made available for Cushing's Syndrome patients. This will mean more suffering for some, and perhaps an early death for others.

Therefore, I ask you to use the good offices of your position and request that the company give quantities of RU 486 to NIH to expand this important clinical trial.

-3- Your department and the FDA must make affirmative statements that (1) this Administration without qualification supports medical research in the United States using RU 486, and (2) that Roussel UCLAF, related companies, its subsidiaries or its licensees will receive a fair and politically unbiased hearing when and if a new drug approval application for RU 486 is submitted.

On this question, perhaps you could initiate these important statements by responding to me, in writing, the views of your department and the Administration regarding for research with, and licensing of RU 486 in this country.

My subcommittee has a clear jurisdiction to investigate, assess and recommend changes in federal regulation as it impacts the competitiveness of American enterprise. I believe that the FDA's decision in this area has created a significant roadblock for U.S. drug research and development efforts insofar as they are dependent on investigations with RU 486, its companion drugs, or new drugs which may be developed on similar chemical models.

I also believe that the FDA has clearly abused its discretionary regulatory authority in the case of RU 486, and that its blatantly insufficient arguments before this subcommittee demonstrate an obvious disregard of the agency's congressional mandate.

If I may quote from a Monday, December 3, 1990, editorial on this subject in the Los Angeles Times: "The FDA is a partner in medicine, certifying scientists' claims for their new drugs. As such, it shares the responsibility of physicians to provide help. In this case, the agency is hiding, not providing, and the White House must set it straight."

As the nation's chief health officer, you, I believe, are in a unique position to begin setting this issue straight. Should you have any questions regarding this request, please don't hesitate to call on me or Steve Jenning of the subcommittee staff at (202) 225-7797.

Sincerely,

Ron Wyden

RON WYDEN
Chairman

cc. David Kessler, Commissioner, Food and Drug Administration

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

SECRETARY'S CORRESPONDENCE

From: RON WYDEN
On Behalf Of:

OS#: 9012070052
DOL: 12/05/90

Type: Congressional Dt Inc Rec'd: 12/07/90 Code: 1

Org: U.S. REPRESENTATIVE
Add: WASHINGTON, DC

26 (FAX PER L)
Due in OS/ES: 12/[illegible]/90

Subject:
CONCERNED THAT THE IMPORT BAN OF RU 486 BY FDA HAS DISCOURAGED THE DRUG'S MANUFACTURER FROM CONTINUING EXISTING CLINICAL TRIALS WITH THIS DRUG OR PROVIDING THE DRUG FOR NEW RESEARCH PROJECTS....RECOMMENDS THAT THE BAN BE LIFTED AND GIVES PROPOSALS.

Assigned to: —— On: 12/07/90

Action: SEC SIG ES Dep: —— PC: ——

Info Copies: ——————

Interim (Y/N): N
Reply Rec'd in OS/ES:

Interim Signed:
Final Signed:

OPDIV/STAFFDIV ROUTING SECTION
(Recipient should sign & date when received)

SENT TO	DATE	TIME	RECEIVED BY	DATE	TIME

Comment: ——

File Index: PO-4

CCC: WER

MIF 005866

PHS CORRESPONDENCE

36212

REFERRAL DATE: 12/10 **DUE DATE:** 12/21

TO:

- [X] ASH
- [X] DEPUTY ASH
- [ ] SG
- [X] EA/ASH
- [ ] DASH-O
- [X] DASH-P&E
- [ ] DASH-DPHP
- [ ] DASH-PA
- [ ] DASH-IGA
- [ ] SEN ADV/EA
- [ ] ADAMHA
- [ ] ATSDR
- [ ] CDC
- [X] FDA
- [ ] HRSA
- [ ] IHS
- [X] NIH
- [ ] NAPO
- [ ] NCHSR
- [ ] OM
- [ ] PUB AFF
- [ ] OHL
- [ ] OGC/H
- [ ] OSG
- [ ] OIH
- [ ] OMH
- [ ] NVP
- [ ] PCPFS
- [X] ES/PHS
- [ ] OTHER

URGENT

ACTION:

- [X] SECRETARY'S SIGNATURE
- [ ] ASH SIGNATURE
- [ ] DIRECT REPLY
- [ ] _____ SIGNATURE
- [ ] DRAFT FOR OS SIGNATURE (WHITE HOUSE REFERRAL)
- [ ] REVIEW/CLEARANCE
- [ ] NECESSARY ACTION
- [X] FOR YOUR INFORMATION

SPECIAL INSTRUCTIONS

DEC 13 AM 9:35

Routed to:

FYI

HF-43

HFW-1

HFW-12

LB

Action

MIF 005867

STATE CAPITOL
ROOM 3196
P.O. BOX 942849
SACRAMENTO, CA 94249-0001
(916) 445-3614

Assembly
California Legislature

CHIEF CLERK

OCT 31 11 38 AM '91

October 21, 1991

RU 486 petition

FILE

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

Dear Dr. Kessler:

I have been directed to invite your attention to Assembly Joint Resolution No. 40, relative to Mifepristone (RU-486).

Accordingly, a copy of this resolution is enclosed for your information.

Very truly yours,

L. Murman

LAWRENCE A. MURMAN
Acting Chief Clerk

LAM:wp:mah

Enclosure

11/14/91

310-010-C2

ISI

RECEIVED
OFFICE OF EXECUTIVE
SECRETARIAT STAFF
91 NOV -6 PM 12:00

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 28 1993

The Honorable Richard G. Lugar
United States Senate
Washington, D.C. 20510

Dear Senator Lugar:

This is in response to your letter of January 13, 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 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.

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFA-12	/S/	2/27/92						

/S/ 2/28

FILE COPY

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

MIF 005869

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

Sincerely yours,

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

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

cc: HFW-10(2)
F/D: ——— :2/18/92
F/T: var:2/21/92
Cong-6569 and No. 7750 ——— \DRUGLTR\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

RICHARD G. LUGAR
INDIANA

SH 306 SENATE OFFICE BUILDING
WASHINGTON, D.C. 20510
202-224-4814

COMMITTEES:
FOREIGN RELATIONS
AGRICULTURE, NUTRITION AND FORESTRY

United States Senate

WASHINGTON, D.C. 20510

January 13, 1992

Mr. Hugh Cannon
Food and Drug Administration
Office of Legislative Affairs
5600 Fishers Building, Rm. 15-55
Parklawn Building
Rockville, Maryland 20857

Dear Mr. Cannon:

Because of the desire of this office to be responsive to all inquiries and communications, your consideration of the attached is requested.

Your findings and views, in duplicate form, along with the return of the enclosure, will be greatly appreciated. Please direct your reply to the attention of Darlee Williams of my Washington office.

Thank you for your thoughtful attention.

Sincerely,

Richard G. Lugar
United States Senator

RGL/brl
Enclosure

APPEARS THIS WAY
ON ORIGINAL

#7750

MIF 005871

Date _____

[redacted]

Comment: Please support the approval of RU486 by the FDA-it would be very helpful to those who have certain types of cancer.

Name/Address/Phone

Opinion or Request

Taken by

Please Complete

MIF 005872

K.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Bill Bradley
United States Senator
One Greentree Centre, Suite 303
Route 73
Marlton, New Jersey 08053

FEB 28 1993

Dear Senator Bradley:

This is in response to your letter of January 29, 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.

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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.

We are unable to predict whether, or when RU-486 will be approved for marketing. You may be assure _____ and the other cosigners 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-12	/S/	2/22/93						/S/

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

MIF 005873

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

Sincerely yours,

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

Enclosure
New Drug Development in
the United States

cc: HFW-10(2)
F/D: ———— :2/18/92
F/T: var:2/21/92
Cong-6690 and No. 8023: ——— \DRUGLTR\NEWRU.MDG)

APPEARS THIS WAY
ON ORIGINAL

BILL BRADLEY
NEW JERSEY

COMMITTEES:
FINANCE
ENERGY AND NATURAL RESOURCES
SELECT COMMITTEE ON INTELLIGENCE
SPECIAL COMMITTEE ON AGING

United States Senate

WASHINGTON, DC 20510

DATE: January 29, 1992

TO: Ms. Kay Holcomb
Associate Commissioner for Legislative Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

ENCLOSURE FROM: [redacted]

I forward the attached for your consideration and would appreciate receiving information in regard to this inquiry as soon as possible. Please direct your reply to the attention of the member of my staff listed below.

Thank you very much for your time and assistance in this matter.

Sincerely,

Bill Bradley
United States Senator

Please direct reply to:

Senator Bill Bradley
One Greentree Centre, Suite 303
Route 73
Marlton, New Jersey 08053

ATTENTION: G. Robertson

#8023

RECEIVED
92 FEB -5 PM 3:14
OFFICE OF LEGISLATIVE AFFAIRS

731 HART BUILDING
WASHINGTON, DC 20510
(202) 224-3224

P.O. BOX 1720
UNION, NJ 07083
(201) 688-0960

1 GREENTREE CENTRE
SUITE 303
ROUTE 73
MARLTON, NJ 08053

ine American women will be found
o have the disease. So it's sad and
ven infuriating that one very
romising drug treatment can't be
ested in this country.

The drug is RU-486, which might
ell be effective against breast can-
er. But RU-486 is a safe and effec-
ive abortion agent. And Roussel-
Uclaf, the French company that de-
eloped RU-486 won't even test it
n this country because it fears that
American anti-abortion activists
vill stop buying its other pharma-
euticals.

There may be a way, though, for
American women to override Rous-
el-Uclaf's pusillanimity. Let them
ake a leaf from the book of those
who raise their voices on behalf of
eople with AIDS.

here are intelligent ways to pro-
est to Congress about the control
mposed by a noisy minority over
the lives of millions of women.

The New York Times

TO OUR SENATORS AND REPRESENTATIVES --

We, the undersigned, encourage our representatives in Washington to do everything in their power to make this drug available to the American public - we are tired of minority rule.

RECEIVED JAN 11 3 1992

MIF 005876

M.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

The Honorable Bob Graham
United States Senate
Washington, D.C. 20510

FEB 28 1993

Dear Senator Graham:

This is in response to your inquiry of January 7, 1992, on behalf of _____. 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.

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 _____ 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.

Sincerely yours,

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

cc: HFW-10(2)
R/D: _____ 2/12/92
R/T: var:2/18/92
F/T; var:2/21/92
CONG-6502 NO. 7656
_____ DURGLTR\STOPRU.486)

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	2/27/92						/S/ 2/28

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

MIF 005877

BOB GRAHAM
FLORIDA

United States Senate

WASHINGTON, DC 20510-0903

January 7, 1992

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

Dear Ms. Holcombe:

My office has been contacted by [redacted]
regarding the RU-486 abortion pill.

I thought you would want to be aware of his concerns and have enclosed a copy of his letter expressing his opposition to this drug.

Thank you for your consideration in this matter.

With kind regards,

Sincerely,

United States Senator

BG/kmb

Enclosure

APPEARS THIS WAY
ON ORIGINAL

#7652

December 16, 1991

The Honorable Bob Graham
325 John Knox Road
Building 600
Tallahassee, Florida 32303

Dear Senator Graham:

As a physician I am strongly opposed to the introduction of RU-486 or similar "abortion pills" in the United States of America. The primary medical usage of these pills is as an abortifacient. If these pills were widely available they would be used in an uncontrolled fashion and result in numerous complications and deaths. This pill is only appropriately used under very close supervision of a physician.

Also as a physician, I am appalled at the unethical and unproven claims that RU-486 has wide application for many other uses other than for abortion. There are pro-abortion physicians who are attempting to mislead and frighten the United States citizenry into believing that they are being denied an extremely useful drug if RU-486 is banned. Currently there appears to be only a very limited research application for RU-486 for any purpose other than abortion.

Once again, please oppose any attempts to legalize and widely distribute RU-486 in the United States.

Sincerely yours,

/s/

A.F. _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB

The Honorable David N. Dinkins
Office of the Mayor
New York, New York 10007

Dear Mayor Dinkins:

This is in response to your letter to President Bush, regarding the importation of RU-486 into the United States. I sincerely apologize for the delay in our response.

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 and some forms of cancer. 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 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 (FD&C 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. A copy of these regulations, which apply equally to all investigational drugs, is enclosed.

Strictly interpreted, the FD&C 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 patients, many of whom suffer from serious and life-threatening diseases, FDA, as a matter of enforcement discretion, may

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

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 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.

I have enclosed information related to your comments about the World Health Organization. If you should have additional questions or concerns please contact Dr. James Sarn, Deputy Assistant Secretary for International Health at (301) 443-4000.

If I can be of any further assistance, please do not hesitate to contact me.

Sincerely yours,

/S/
Carol R. Scheman
Deputy Commissioner
for External Affairs

4 Enclosures
Regulatory Procedures Manual
FDA Testimony
Copy 21 CFR regulations
Background on WHO

cc: HFW-1
HFW-2
HFW-10(2)
HFW-12
HF-24
ES/PHS

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ON ORIGINAL

R/D: ——— 6/21/91
R/T: var:6/21/91
Edit: — :6/24/91
——— 6/25/91
re/t: var:7/9/91
Edit: ——— 7/9/91
re/t: var:7/9/91
——— \DRUGLTR\RU486NEW.MDG)
Revised per PHS revisions and comments: ——— :8/23/91
re/t: 8/26/91
Edit: ——— 8/28/91
re/t: —:10/21/91
Edit: ——— 2/2/92
re/t: var:2/4/92
var:2/7/92
Edit: ——— :2/7/92
Edit: ——— per comment ——— :2/11/92
F/T: var:2/12/92

THE CITY OF NEW YORK
OFFICE OF THE MAYOR
NEW YORK, N.Y. 10007

April 4, 1991

The Honorable George H. Bush
President
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear Mr. President:

I know and respect your personal opposition to abortion. As you know, however, I am in full accord with the 1973 U.S. Supreme Court ruling, Roe v. Wade, which established that women have a constitutionally-protected right to choose abortion. As an elected official, I believe I have the duty to do all I can to ensure that women have the opportunity to freely exercise that right if they so choose.

I am enclosing a copy of a letter that I have sent to Roussel Uclaf, the French pharmaceutical company that manufactures antiprogestin mifepristone -- better known as RU 486 -- a drug that induces abortion in the very early stages of pregnancy.

All of the medical evidence so far suggests that RU 486 is a safe and effective alternative to early surgical abortion. Last March, an article in the New England Journal of Medicine discussed the results of tests conducted on over 2000 French women and reached this conclusion. And the American Medical Association has endorsed clinical testing.

The drug also shows promise in treating breast cancer (which kills 44,000 American women each year), brain cancer, Cushing's disease, and endometriosis, a leading cause of infertility in women. But this potentially life-saving research is being blocked as long as the drug cannot find its way into the country.

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TRACER

The problem, in my view, is not so much medical as political. Roussel Uclaf, the French pharmaceutical company that developed the drug, has exported it for testing to Great Britain (where it will soon be marketed), the Netherlands and the Scandinavian countries. But it refuses to export it to the U.S., blaming the "political climate" here -- specifically, threats from anti-choice activists to boycott the products of Roussel Uclaf and its German parent company, Hoechst, if RU 486 is exported to America. Fearing lost sales, Hoechst and Roussel Uclaf have so far yielded to these threats.

I am also concerned that political considerations are subverting a scientific review of the drug's effectiveness. In 1989, the Food and Drug Administration issued an "import alert" barring individuals from personally bringing RU 486 into the country or receiving it in the mail. The ban prevented scientists who are investigating the non-abortifacient applications of RU 486 from conducting their research.

Finally, Roussel Uclaf has signed an agreement with the World Health Organization (WHO), giving the WHO access to RU 486 for independent research; in return, Roussel Uclaf has agreed to make RU 486 available at a preferential price to developing countries that request it. The New York Times reported on July 29, 1991 that the WHO is holding off approving the drug for use in those countries out of fear that the United States will retaliate and cut contributions to its budget. In the meantime, 200,000 women in the developing world die each year from botched abortions.

Because I think that American women deserve the same lawful, safe and affordable options to abortion as women in France, and because I think that the WHO should have the freedom to set health policy free from political pressure, I respectfully ask you two questions:

*Would you agree to urge your Secretary of Health and Human Services, Louis Sullivan, and your Commissioner at the Food and Drug Administration, David A. Kessler, to remove RU 486 from the "import alert" and treat it no better and no worse than other new drugs that come before the Federal government for review?

*Can you assure the WHO that your Administration would not retaliate if it chose to distribute the drug in the Third World?

APPEARS THIS WAY
ON ORIGINAL

Of course, I do not ask nor do I expect you to change your personal beliefs about abortion. But I do ask you to preserve the integrity of the medical and scientific regulatory process and to protect the constitutionally guaranteed rights of women in the United States.

Thank you for your time and concerns.

Sincerely yours,

David N. Dinkins
M A Y O R

APPEARS THIS WAY
ON ORIGINAL

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

JAN 27 1992

Dear Mr. Foley:

This is in response to your letter of January 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.

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

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFD-12	/S/	1/24/92						

/S/
1/2

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★U.S.GPO:1988-0-213-052

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.

APPEARS THIS WAY
ON ORIGINAL

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: [redacted] :1/17/92
F/T; var:1/23/92
CONG-6484 and No. 7636
[redacted] DRUGS\RU486.MDG)

APPEARS THIS WAY
ON ORIGINAL

THOMAS S. FOLEY
5TH DISTRICT, WASHINGTON

THE SPEAKER

PLEASE REPLY TO:
☐ CONGRESSIONAL OFFICE:
1201 LONGWORTH HOB
WASHINGTON, DC 20515-4705
AREA CODE (202) 225-2006

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

PLEASE REPLY TO:
DISTRICT OFFICES:
☐ WEST 601 FIRST AVENUE
SECOND FLOOR WEST
SPOKANE, WA 99204
AREA CODE (509) 353-2155

☐ E. 12929 SPRAGUE
SPOKANE, WA 99216-0736
AREA CODE (509) 926-4434

☐ 28 W. MAIN
WALLA WALLA, WA 99362-2816
AREA CODE (509) 522-6372

January 6, 1991

Dear Ms. Holcombe:

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

_____ has breast cancer which has metastasized and is concerned about the ban on the importation of RU-486 imposed by the Food and Drug Administration (FDA), particularly given preliminary studies which suggest it may halt the growth of some types of breast cancer tumors. If you could address the issue she raises in her letter and comment on the FDA's position, it would certainly be 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

APPEARS THIS WAY
ON ORIGINAL

#7636

Health 3-[illegible] 4 Oct. 5, 1991

Congressman Tom Foley
W. 601 - 1st #210
Spokane, WA 99201

1201
DC.

Dear Congressman Foley,

I am enclosing a copy of an article from the Spokesman Review.

I have heart cancer, which has metastasized, and it makes me furious that the Bush administration is withholding a drug that could save my life simply to appease the right to life interest groups.

I would be very interested in knowing what could be done to permit research in this country.

Thank you for any help.

Sincerely,

[redacted]

A.F. _____ FIL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 22 1992

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. Wyden:

We are writing because we are concerned about statements made at your December 5, 1991, hearing on RU-486.

Specifically, on page 147, lines 3357-3361, of the transcript, you attribute to Dr. Solomon Sobel a statement regarding the Administration's position on abortion research. You stated: "He said that there was no problem with abortion research as far as the Bush Administration is concerned." We believe that you may be referring to Dr. Sobel's comments at your Subcommittee's November 19, 1990, hearing on RU-486. I refer specifically to page 40 of the printed record of that hearing, where Dr. Sobel is discussing the RU-486 import alert and its impact on research on potential uses of this drug. He said: "Even in regard to abortion, the agency has not taken a position of stopping investigational use." This is a correct statement of the FDA policy. Because we believe this statement is not in accord with your characterization at the December 5 hearing, we respectfully request that this hearing record be corrected.

In addition, you stated at the December 5 hearing (page 141, lines 3236-3242) that "now we checked with the FDA as of yesterday, there were two compassionate use approvals, no new investigational drug applications for research within the last three years." I would like to clarify for the record conversations between our staffs just prior to the December 5 hearing regarding investigational new drug applications (INDs). Specifically, your staff was informed that while we could (and did) share with the Subcommittee information on the existence of new INDs, our regulations prohibit public discussion of such new applications. Further, we advised your staff that because a number of the previously disclosed studies (applications) had been either completed or discontinued, the number of active ongoing studies had declined. We did not characterize the status of current research as "moribund." The agency currently has six active research INDs for RU-486 (one of which was submitted in 1991) and five compassionate use INDs for RU-486 (five of which were submitted since June 1991).

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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HFW(2)	ISI	1/22/92						
HFW 2	ISI	1/22/92						

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MIF 005892

*U.S.GPO:1988-0-213-052

We would greatly appreciate a clarification of the record of your December 5, 1991, hearing. If you have any questions, please feel free to contact me.

Sincerely yours,

/S/
Kay Holcombe
Acting Associate Commissioner
for Legislative Affairs

cc: HFW-1
HFW-10(2)
HFW-12
R/D: [redacted] .11492
R/T: [redacted] 1/14/92
Edit: [redacted] :1/15/92
Edit: [redacted] :1/15/92
[redacted] :1/15/92
Concur on citing numbers of applications: [redacted] :1/16/92
cc: [redacted] :1/16/92
Edit: [redacted] :1/21/92
F/T: [redacted] 1/21/92
([redacted] \DRUGLTRS\RU-486.TX)

A.F. _____ FILE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAN 1992

The Honorable Robert W. Kasten, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Kasten:

This is in response to your letter of November 21, 1991, on behalf of _____, Wisconsin, 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 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.

/s/
01/14/92

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/s/	1/8/92						

/s/ 1/8/

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MIF 005894

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

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

Sincerely yours,

/S/

Kay Holcombe
Associate Commissioner
for Legislative Affairs

Enclosure
"New Drug Development in
the United States..."

cc: HFW-10(2)
F/D: ———— 12/30/91
F/T: — 1/6/91
Cong-6253 No. 7352(——— \DRUGLTR\NEWRU.MDG)

ROBERT W. KASTEN, JR.
WISCONSIN

United States Senate

WASHINGTON, DC 20510-4902

November 21, 1991

Mr. Hugh C. Cannon
Legislative Affairs
Food & Drug Administration
U.S. Dept. of Health & Human Svcs.
5600 Fishers Lane - 1555
Rockville, Maryland 20857

Dear Mr. Cannon:

Please find enclosed correspondence I received from _____. Because of my desire to be responsive to the constituents in my state, I am referring this matter to you for your review.

I would like to request your assistance in evaluating the information provided. I would greatly appreciate your forwarding your findings in duplicate form to Jane Morris, on my staff, at your earliest convenience.

Again, many thanks for your time and attention to this matter.

Best regards,

Robert W. Kasten, Jr.

RWK/jcm
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Chron

FILE

June 29, 1992

Mr. Gerald I. Miyoshi
Clerk, House of Representatives
State of Hawaii
State Capitol
Honolulu, Hawaii 96813

Dear Mr. Miyoshi:

I am writing regarding the Hawaii State Legislature's House Concurrent Resolution No. 34, transmitted to me via your May 14, 1992, cover letter. The resolution refers to the Food and Drug Administration's (FDA) 1989 ban on the importation of RU-486 for personal use and calls on the President and Congress to rescind the ban and support the availability of RU-486 and other related agents for all appropriate research and clinical trials in the United States.

I want to assure you that FDA's import alert on RU-486 is not designed to thwart appropriate research or clinical trials with the drug, but to prevent the unsafe personal use of RU-486 without medical supervision. FDA's import restrictions do not prevent importation of RU-486 or other drugs for research for any therapeutic use if an approved Investigational New Drug (IND) Application exists.

To clarify FDA's procedures and responsibilities, I will provide a short summary of our drug approval process. In order to be marketed in this country, a new drug product must, according to law, be shown by substantial evidence to be safe and effective for its labeled use. However, FDA has neither the legal responsibility nor the resources necessary to conduct the preclinical (laboratory and animal) studies or clinical (human) trials that provide the data on which safety and effectiveness decisions must be based. The responsibility for conducting these studies rests with the manufacturer or sponsor of the drug product. FDA's function is to review the data submitted in the form of a new drug application (NDA), and then make a determination as to whether the product can be marketed.

Studies that will be submitted in an NDA are conducted under an Investigational New Drug Application (IND). Before FDA can permit testing of the drug in humans, the sponsor of the drug must provide us with information demonstrating that the drug is reasonably safe to initiate human trials. The sponsor must also provide manufacturing and control data, a detailed protocol of

L-MIYOSHI/DK-IMPORT RU-486
CHRON
DRUGS

9204494

MIF 005897

the study, and names and qualifications of the investigators who will be performing the clinical trials. FDA reviews these data, submitted as an IND and, if the data support testing in humans, studies may be initiated 30 days from submission.

Under the Freedom of Information Act and FDA's implementing regulations, FDA is precluded in most cases from publicly discussing, or even acknowledging the existence of, studies being conducted under an IND. However, because studies being conducted on RU-486 at the National Institutes of Health under INDs are public information, we can share with you that RU-486 is currently under study in this country in biochemical research and for use in Cushing's disease and psychiatric conditions. This research is conducted using RU-486 imported legally, in keeping with FDA policy.

FDA remains willing to review applications for investigation or marketing in the U.S. of RU-486, or any other drug, in accordance with established legal and scientific criteria. I hope this letter clarifies FDA's position.

Sincerely yours,

David A. Kessler, M.D.
Commissioner of Food and Drugs

APPEARS THIS WAY
ON ORIGINAL

bcc list:

HF-20
HF-22
HF-24
HF-26
HF-28
Chron
HFA-224
HF-40
HFD-510
HFD-500
HFD-500
HFD-1
HF-22
HF-1
GCF-1
GCF-1

APPEARS THIS WAY
ON ORIGINAL

HOUSE OF REPRESENTATIVES
THE SIXTEENTH LEGISLATURE

STATE OF HAWAII
STATE CAPITOL
HONOLULU, HAWAII 96813

2 05 PM '92

May 14, 1992

Mr. James S. Benson
Commissioner
Federal Food and Drug Administration
300 Ala Moana Boulevard, Suite 6320
Honolulu, Hawaii 96850

Dear Mr. Benson:

I transmit herewith a copy of House Concurrent Resolution No.34, which was adopted by the House of Representatives of the Sixteenth Legislature of the State of Hawaii, Regular Session of 1992.

Very respectfully,

Gerald I. Miyoshi
Clerk, House of Representatives

APPEARS THIS WAY
ON ORIGINAL

MIF 005900