DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 23 1996

The Honorable Tom A. Coburn
House of Representatives
Washington, D.C. 20515-3602

Dear Dr. Coburn:

This is in further response to your letters of November 10, 1995, to Secretary Donna E. Shalala and Commissioner David A. Kessler, requesting copies of documents relating to the drug RU-486 (mifepristone). As we stated in our December 28, 1995 letter to you, because of the government shut-down, we were unable to ascertain if additional responsive documents existed.

We are enclosing additional correspondence located in the files of the Food and Drug Administration (FDA). These documents have been redacted to remove patient identifiers. Also enclosed are copies of FDA public calendars for the years 1992-1995.

We now have provided all releasable documents in FDA's files that are responsive to this request. The Department will be responding to your request to Secretary Shalala separately.

If you have any questions, or need further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosures

cc: HFW-10 (3)
HFW-14
OS-CCU
R/D: 1/21/96
Edit: to reflect separate HHS response per discussion with 2/15/96
F/T:lmb:2/23/96(s:\wp\ \docreq1)
NOTE TO THE FILE: Documents were reviewed by FOI Staff.
FDA Control No. 95-1045[illegible]9

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW-2	/S/	2/23/96						
COPY									

TOM A. COBURN, M.D.
2D DISTRICT, OKLAHOMA
COMMITTEE ON COMMERCE
SUBCOMMITTEES
TELECOMMUNICATIONS AND FINANCE
HEALTH AND ENVIRONMENT
ENERGY AND POWER

Congress of the United States
House of Representatives
Washington, DC 20515–3602

WASHINGTON, DC 20515
202 225 2701
202 225 3038 FAX
215 STATE STREET, SUITE 215
MUSKOGEE, OK 74401
918 687 2533
918 682 8503 FAX

November 10, 1995

SPECIAL

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

As a Member of the House Commerce Committee's Subcommittee on Health and the Environment in the House, I write to request copies of documents in the possession of the Department of Health and Human Services relating to the drug known as RU 486 (mifepristone), developed by the company Roussel Uclaf SA.

I understand that the Population Council has an active investigational new drug application (IND) to use RU 486 for abortion. Several reports have appeared which indicate extensive communications between representatives of the Clinton administration and private companies and organizations, including the Population Council, concerning the future availability of RU 486 for use as an abortion pill in the United States. These reports, together with issues raised in a Citizens' Petition on RU 486 recently submitted to the FDA, have generated serious concern for public safety and the integrity of the drug approval process. Consequently, I am requesting that you provide the following information:

1) Any and all written or recorded communications, including electronic or telephonic communications, to or from the persons listed below relating to RU486 from January 1, 1992 up to the present (i.e., up until the time the document search is conducted).

When used in the above request, the word "communication" includes, but is not limited to: correspondence, electronic mail, memoranda, notes of conversations, notes of meetings, copies of the calendars of meetings, and telephone logs and message slips. It also includes all communications which do not specifically mention RU 486 but which may relate to its possible approval by FDA for use as an abortifacient (eg., communications relating to the acceptability of foreign data in the drug approval process). For each such communication, please indicate the date of the communication, the names and the professional or organizational affiliations of all persons involved or present, the locations of meetings, and the offices within the Department from which the communications were obtained. Also, please indicate which communications, if any, are confidential and may not be disclosed to the public.

This request includes all communications sent to or by the following persons from January 1, 1992 up to the present:

President Clinton, Mrs. Clinton, and White House staff

Other administration officials or personnel, including yourself, your assistant [redacted] of the Endocrine Drugs Division of the FDA

Edouard Sakiz, Dr. Andre Ulmann, and other officers, employees, or representatives of Roussel Uclaf

Margaret Catley-Carlson, Dr. Wayne Bardin, and other officers, employees, and representatives of the Population Council

David A. Grimes, M.D.

Daniel R. Mishell, M.D.

Suzanne Poppema, M.D.

Officers, employees and representatives of the following companies and organizations:

Hoechst AG of Frankfurt, Germany
Hoechst Celanese Corporation of Somerville, New Jersey
Hoechst-Roussel Pharmaceuticals of Somerville, New Jersey
Rhone-Poulenc of Paris
Schering AG of Berlin, Germany
G.D. Searle Company of Skokie, Illinois
Upjohn Company of Kalamazoo, Michigan
Gynopharma, Inc. of Somerville, New Jersey
Cabot Medical Corporation of Langhorne, Pennsylvania
Aurora Medical Services of Seattle, Washington
Fund for the Feminist Majority
Planned Parenthood Federation of America
Reproductive Health Technologies Project
National Abortion Federation
National Abortion and Reproductive Rights Action League (formerly the National Abortion Rights Action League)
Oregon Science Health University of Portland, Oregon
Center for Reproductive Law and Policy
National Organization for Women
Women's Issues Network

2) Any and all documents relating to the implementation of President Clinton's January 22, 1993, memorandum for the Secretary of Health and Human Services regarding the importation of RU 486.

a) "promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU-486 from the list of drugs that qualify for the personal use importation exemption;"

b) "immediately take steps to rescind Import Alert 66-47" if the "FDA concludes that RU-486 meets the criteria for the personal use importation exemption;" and

c) "promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU-486 and other antiprogestins."

When used in the above request, the word "document" includes, but is not limited to: internal and external documents of the Department of Health and Human Services, documents prepared by persons or offices outside the Department (including documents prepared by non-governmental persons, organizations, or companies), correspondence, electronic mail, memoranda, notes of conversations, notes of meetings, copies of the calendars of meetings, and telephone logs and message slips. It also includes all documents which do not specifically mention RU 486 but which may relate to its possible approval by FDA for use as an abortifacient (eg., criteria for the acceptance of foreign data, etc.). For each such document, please indicate the date of the document, the author or authors of the document, the persons to whom it was given or sent, and the offices within the Department from which the documents were obtained. Please separate the documents in this second request into three categories based on which of the three actions requested by the President the documents address. Again, please indicate which communications, if any, are confidential and may not be disclosed to the public.

Thank you for your attention to this inquiry. A similar request for documents has been submitted to Dr. Kessler at the Food and Drug Administration. I look forward to receiving the information by December 1, 1995. If you foresee any difficulty in fulfilling this request by that date, please notify me immediately. Roland Foster on my staff will be available to work with you on this.

Sincerely,

Tom A. Coburn, M.D.
Member of Congress

SPECIAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

FEB 06 1996

The Honorable Bill Barrett
Member, U.S. House of
Representatives
312 West 3rd
Grand Island, Nebraska 68801

Dear Mr. Barrett:

This is in response to your letter of January 17, 1996, on behalf of [redacted] regarding her desire to receive RU-486 for the treatment of her brain tumor.

The Food and Drug Administration (FDA) has been contacted by several Congressional offices on her behalf. We have been informed that [redacted] physician was planning to contact the French manufacturer of RU-486, Roussel Uclaf, about the possibility of receiving the drug to treat her. If they agree to provide the drug, [redacted] physician then should contact [redacted] in our Division of Oncology and Pulmonary Drug Products at [redacted] to receive guidance on submitting the Investigational New Drug Application.

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

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: [redacted] :1/31/96
F/T: [redacted] :1/31/96 [redacted] ru)
Control No. 96-651

APPEARS THIS WAY
ON ORIGINAL

FILE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
	HFW-2	/S/	2/5/96						
COPY									

MIF 006305

Congressman Bill Barrett
313 West Third
Grand Island, NE 68801

Dear Congressman Barrett:

Please accept this as a formal written appeal for your aid in helping me to obtain permission from the FDA for the usage of the drug RU-486 to treat my meningioma brain tumor.

I am granting you permission to obtain any and all medical records from my doctors. They also have X-Rays from MRI s which I release to you if needed.

My tumor is non-malignant, however it continues to grow despite all efforts to destroy or constrain it. The tumor was originally approximately the size of a large man's fist. In June of 1993 I underwent surgery performed by _____ to remove the tumor. It was a 23 1/2 hour surgery. I lost my right ear drum through the surgery and have some facial distortions as a direct result. Other than that, I was very lucky to live through the surgery at all and have suffered few other side effects until recently. Several MRI's later have determined that the tumor still exists and is attached to the brain stem where it will eventually cut off circulation to the brain if not stopped. In March of 1985, I underwent a very painful radiation surgery performed by Dr. _____ to eliminate the tumor. Another MRI in September of 1995 confirmed that the tumor remained unchanged. In December of 1995, I began to experience double vision. I was given a prescription of steroids which seemed to help for a time although was not totally effective, and have been informed by Dr. _____ that the most they can do is to keep me on the steroids permanently to help the vision. I am not open to this way of life. I do not feel that it is quality life and have no desire to continue with the steroids. Beyond that, I have been told by all three physicians mentioned in this letter that there is nothing else that can be done for me.

I am enclosing a newspaper article that was clipped from the Durant Daily Democrat printed in the latter part of August or early part of September, 1993 in Durant, Oklahoma. I, too, would like your help in petitioning the FDA to grant me permission to use the drug RU-486. I feel I have nothing to lose and everything to gain at this time, however, time is

crucial as the tumor continues to grow daily. Please do not give up on me as I feel many other have. I am not ready to quit as there are other horizons for me to explore and with your help I feel this is possible.

I do not know how helpful this will be, but I have petitions with over 500 names and addresses of people from across the country asking the FDA to grant me permission to use the drug RU-486. Please let me know if you can use these signatures.

Sincerely,

/s/

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

January 17, 19 95

Food and Drug Administration
Office of Congressional Affairs
Room 1555
5600 Fishers Lane
Rockville, MD 20857

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

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

[redacted]r expeditious attention to [redacted] request would be greatly appreciated. Thank you for your time and efforts in this matter. —

I'd like a response, in writing, by 1/31/96, to:
Rep. Bill Barrett
312 West 3rd
Grand Island, NE 68801

Very Truly yours,

Bill Barrett
M.C.

96-651

Nebraska's Third District.

Thanks!

APPEARS THIS WAY
ON ORIGINAL

MIF 006309

DEPARTMENT OF HEALTH AND HUMAN SERVICES

25 JAN 1996

The Honorable J. James Exon
United States Senator
287 Federal Building
Lincoln, Nebraska 68508

Dear Senator Exon:

This is in response to your inquiry of January 16, 1996, on behalf of [redacted] regarding her desire to receive RU-486 for the treatment of her brain tumor.

As discussed with Ms. Carolyn Walvoord of your staff on January 22, we also have been contacted by Senator Bob Kerrey's office on her behalf. Senator Kerrey's office informed us that [redacted] physician was planning to contact the French manufacturer of RU-486, Roussel Uclaf, about the possibility of receiving the drug to treat her. If they agree to provide the drug, [redacted] physician then should contact [redacted] in our Division of Oncology and Pulmonary Drug Products at [redacted] to receive guidance on submitting the Investigational New Drug Application.

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

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's correspondence

cc: HFW-10 (2)
HFW-14 [redacted]
R/D: [redacted] 1/23/96 [redacted] \ru-486.ind)
F/T:mts:1/23/96
Control 96-352

APPEARS THIS WAY
ON ORIGINAL

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW-12	/S/	1/24/96						

*U.S. GPO: 1988-214-488

MIF 006310

United States Senate

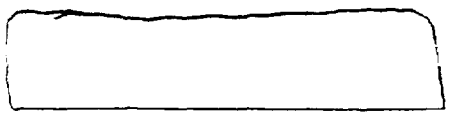
WASHINGTON, DC 20510

January 16, 1996

Congressional Liaison
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857-0001

Dear Sir:

I am enclosing a letter from:



whose problem appears to fall within your jurisdiction.

I would appreciate any information which will enable me to respond to my constituent's inquiry. Please return the enclosed correspondence with your report to:

Senator J. James Exon
287 Federal Building
Lincoln, NE 68508

Cordially,

Jim Exon
United States Senator

Enclosure

APPEARS THIS WAY
ON ORIGINAL

No. 96-352

MIF 006311

16 JAN

Senator Exon
287 Federal Building
Lincoln, NE 68508

Dear Senator Exon:

Please accept this as a formal written appeal for your aid in helping me to obtain permission from the FDA for the usage of the drug RU-486 to treat my meningioma brain tumor.

I am granting you permission to obtain any and all medical records from my doctors. (

). They also have X-Rays from MRI's which I release to you if needed.

My tumor is non-malignant, however it continues to grow despite all efforts to destroy or constrain it. The tumor was originally approximately the size of a large man's fist. In June of 1993 I underwent surgery performed by _____ _____ to remove the tumor. It was a 23 1/2 hour surgery. I lost my right ear drum through the surgery and have some facial distortions as a direct result. Other than that, I was very lucky to live through the surgery at all and have suffered few other side effects until recently. Several MRI's later have determined that the tumor still exists and is attached to the brain stem where it will eventually cut off circulation to the brain if not stopped. In March of 1985, I underwent a very painful radiation surgery performed by Dr. _____ to eliminate the tumor. Another MRI in September of 1995 confirmed that the tumor remained unchanged. In December of 1995, I began to experience double vision. I was given a prescription of steroids which seemed to help for a time although was not totally effective, and have been informed by Dr. _____ that the most they can do is to keep me on the steroids permanently to help the vision. I am not open to this way of life. I do not feel that it is quality life and have no desire to continue with the steroids. Beyond that, I have been told by all three physicians mentioned in this letter that there is nothing else that can be done for me.

I am enclosing a newspaper article that was clipped from the Durant Daily Democrat printed in the latter part of August or early part of September, 1993 in Durant, Oklahoma. I, too, would like your help in petitioning the FDA to grant me permission to use the drug RU-486. I feel I have nothing to lose and everything to gain at this time, however, time is

crucial as the tumor continues to grow daily. Please do not give up on me as I feel many other have. I am not ready to quit as there are other horizons for me to explore and with your help I feel this is possible.

I do not know how helpful this will be, but I have petitions with over 500 names and addresses of people from across the country asking the FDA to grant me permission to use the drug RU-486. Please let me know if you can use these signatures.

Sincerely,

/S/

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

FEB 26 1998

43-253
Russell 4 cc's

The Honorable Joe Barton
Chairman, Subcommittee on
Oversight and Investigations
Committee on Commerce
House of Representatives
Washington, D. C. 20515-6115

Dear Mr. Chairman:

This is in response to your letter of February 4, in which you asked two follow-up questions to the Food and Drug Administration's (FDA) January 16 response to your inquiry concerning the disclosure of adverse drug report (ADR) data for mifepristone (RU 486).

The following are our responses to your questions:

1. **Denominator data on overall use of RU 486 for the relevant categories in Tables I and II.**

Table I in FDA's January 16 response represented the serious ADRs reported to the new drug application (NDA). These reports represent "spontaneous" reports submitted to the sponsor by any source, as well as those that occurred in the two French clinical trials sponsored by the applicant. The total number of patients in the French trials is known (total n=2480 patients). A denominator for reports received after marketing is not known as the total number of persons using the drug is not known.

Table II represented the serious ADRs reported in the investigational new drug (IND) application and represents the United States clinical investigation. The total number of patients treated in that clinical trial was 2121.

2. **A written explanation as to why the FDA does not intend to request information from WHO.**

Throughout the NDA review process, FDA reviews the available data, including reported adverse events. A sponsor is required to provide, present and discuss all known adverse experiences. If the World Health Organization, or any other organization, maintains a database of adverse experiences, the sponsor would be expected to seek the information and provide it to their NDA.

5444

FILE COPY	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
	HFN-14	/S/	2-26-98						
	HF24	/S/	2/26/98						

This letter contains confidential information not releasable to the public under the Freedom of Information Act regulations. We ask that the Committee not publish or otherwise make public any information contained in this letter. We would be glad, of course, to discuss with the Committee staff the confidentiality of the information.

We hope this information is helpful.

Sincerely,

Sharon Smith Holston
Deputy Commissioner
for External Affairs

cc: Honorable Thomas J. Bliley, Chairman
Committee on Commerce

Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce

Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Commerce

bcc: HFW-10
HFW-2
HFW-14
HFD-580
HF-24
Draft language received from CDER 2/18/98: [redacted]

R/D: [redacted] 2/18/98
Reviewed: [redacted] :2/19/98
Revised: [redacted] :2/20/98
Reviewed: [redacted] :2/20/98
Reviewed: [redacted] :2/23/98
Reviewed: [redacted] :2/24/98
Reviewed: [redacted] 2/ /28
F/T:lmb:2/26/98 [redacted] 98-1116.wpd)
Control No. 98-1116

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

February 4, 1998

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

I have reviewed FDA's January 16, 1998 response to my inquiry about the disclosure of adverse event data for mifepristone (RU 486) from foreign countries. In its response, FDA provided the numbers of adverse drug reactions (ADRs) related to RU 486, but omitted denominator data on overall use of RU 486 for the relevant categories. In addition, FDA stated that FDA's Division of Reproductive and Urologic Drug Products had not requested ADRs related to RU 486 from the World Health Organization and that FDA does not intend to request information from WHO.

To assist the Subcommittee's work, please provide the following by February 18, 1998:

(1) Denominator data on overall use of RU 486 for the relevant categories in Tables I and II.

(2) A written explanation as to why the FDA does not intend to request information from WHO.

If you have any questions, please contact Mr. Alan Slobodin of the Committee staff at (202) 225-2927. I thank you in advance for your courtesy and attention to this matter.

Sincerely,

Joe Barton

Joe Barton
Chairman
Subcommittee on
Oversight and Investigations

No. 98-1116

[illegible] 032

cc: Honorable Tom Bliley, Chairman
Honorable John D. Dingell, Ranking Member
Honorable Ron Klink, Ranking Member
Subcommittee on Oversight and Investigations

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

HFH-004

July 2, 1997

43253

Roussel Corporation
Theresa Agami
Regulary Affairs Manager
102 Route De Noisy
93230 Romainville
France

Dear Requester:

We are enclosing the quality assurance profileS for Roussel Uclaf, 63480 Vertolaye, France and Roussel Uclaf, Neuville-sur-Saone Plant, France that you requested on January 9, 1997 from the Food and Drug Administration pursuant to the Freedom of Information Act.

Charges of $14.20 will be included in a monthly invoice by our Freedom of Information Staff. These charges include $ .20 reproduction and $14.00 for search and review time. Please do not remit payment until you receive an invoice. Please use F97-674 and F97-676 when referring to these requests.

Copies of EIR's and Forms 483 you requested will be responded to by other offices.

Sincerely,

(S)

Medical Products Quality
Assurancce Staff

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE HI 13 - 5 Raised issue

FEB 25 1997

The Honorable Bart Stupak
House of Representatives
Washington, D.C. 20515-2201

Dear Mr. Stupak:

This is in response to your letter of January 3, 1997, on behalf of _____ expressed concern that the "Food and Drug Administration has received special approval to withhold the name of the drug firm who is to make and distribute the abortion pill RU486 in this country." He also requested the name of the manufacturer/distributor.

We would like to clarify that the Food and Drug Administration (FDA) has not "received special approval" to withhold the name of the drug firm making RU486 (mifepristone). The law only requires that the name and place of business of the manufacturer, packer, or distributor be disclosed in a product's labeling (Section 502(b) of the Federal Food, Drug, and Cosmetic Act and FDA regulations at 21 CFR Section 201.1). In this case, it was mentioned at FDA's Reproductive Health Drugs Advisory Committee meeting on July 19, 1996, that the name of the distributor would be announced if and when RU486 is approved for marketing in the United States. It is not unusual for products to be marketed with the name of the distributor rather than the manufacturer. Should RU486 be approved, the distributor's name will be made available. It was announced previously that the Population Council is the sponsor of the drug application.

56-238 w

We hope this information has been helpful. If we may be of any further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
September 18, 1996 Talk Paper

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW-14	/S/	2/20/97						
COPY									

MIF 006320

cc: HFW-10 (2)
HFW-2
HFW-14
R/D: 2/6/97 (fr prev ltr)
Concur: :2/6/97
:2/10/97
Edit: ? \ru486\secret.nam)
F/T:mts:2/19/97
Control 97-273

APPEARS THIS WAY
ON ORIGINAL

BART STUPAK
1ST DISTRICT, MICHIGAN

317 CANNON BUILDING
WASHINGTON, DC 20515
(202) 225-4735
FAX: (202) 225-4744

COMMITTEE
COMMERCE
SUBCOMMITTEES
HEALTH AND THE ENVIRONMENT
COMMERCE, TRADE, AND
HAZARDOUS MATERIALS

CO-CHAIRMAN,
LAW ENFORCEMENT CAUCUS

REGIONAL WHIP

Congress of the United States

House of Representatives

Washington, DC 20515-2201

January 3, 1997

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

Dear Commissioner Kessler:

Please find enclosed a letter from one of my constituents. [redacted] would like to know the name of the company applying to manufacture the drug RU486. I would appreciate it if you could inquire into this issue on behalf of myself and my constituent.

Thank you for your time and consideration of my request. If you have any questions, please do not hesitate to contact me if I or a member of my staff may be of service.

Sincerely,

Bart

BART STUPAK
Member of Congress

BTS/jaz

Enclosure

cc: [redacted]

APPEARS THIS WAY
ON ORIGINAL

No. 97-273

PLEASE REPLY TO:

☐ 1229 W. WASHINGTON
MARQUETTE, MI 49855
(906) 228-3700

☐ 902 LUDINGTON STREET
ESCANABA, MI 49829
(906) 786-4504

☐ 616 SHELDEN
HOUGHTON, MI 49931
(906) 482-1371

☐ 1120 EAST FRONT STREET
SUITE D
TRAVERSE CITY, MI 49686
(616) 929-4711

☐ 111 E. CHISHOLM
ALPENA, MI 49707
(517) 356-0690

☐ 2 SOUTH 6TH STREET
SUITE 3
CRYSTAL FALLS, MI 49920
(906) 875-3751

TOLL FREE: 1-800-950-REP1 (1-800-950-7371)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 13 1997

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

Dear Senator Robb:

This is in response to your letter of October 30, 1996, on behalf of _____ and _____, regarding the drug RU-486 (mifepristone). _____ both expressed the opinion that RU-486 should be banned.

The Food and Drug Administration (FDA) enforces the Federal Food, Drug, and Cosmetic Act. With respect to drugs and devices, FDA's mandate is to ensure that these products are safe and effective for their intended uses. On September 18, 1996, FDA issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. This means that the sponsor has to satisfy certain conditions before FDA approval is granted. We are enclosing a September 18, 1996 FDA Talk Paper on this subject.

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

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
September 18, 1996 FDA Talk Paper

cc: HFW-10 (2)
HFW-2
HFW-14
R/D: _____ :2/3/97 _____ \newdrug\96-8500
F/T:mts:2/12/97
Control 96-8500

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW-12	/S/	2-12-97						
COPY									

MIF 006323

CHARLES S. ROBB
VIRGINIA

WASHINGTON OFFICE:
Russell Senate Office Building
First and Constitution Avenue, NE, Room 154
Washington, DC 20510
(202) 224-4024
Email: senator@robb.senate.gov

United States Senate

WASHINGTON, DC 20510-4603

COMMITTEES:
ARMED SERVICES
FOREIGN RELATIONS
INTELLIGENCE
JOINT ECONOMIC COMMITTEE
Vice Chairman
Democratic Policy Committee

October 30, 1996

[redacted]
[redacted] Legislative Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear [redacted]

My office has been contacted by [redacted] and [redacted] expressing concern about FDA's testing and conditional approval of RU-486. I am enclosing copies of the correspondence I have received.

I would appreciate it very much if you could review these letters and prepare a response that addresses their concerns of associated health risks. Many thanks for your consideration.

Sincerely,

Charles Robb

Charles S. Robb

CSR/jpn

APPEARS THIS WAY
ON ORIGINAL

No. 96-8502

State Office:
The Ironfronts, Suite 310
1011 East Main Street
Richmond, VA 23219
(804) 771-2221

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

First Union Bank Building
Main Street
Clintwood, VA 24228
(540) 926-4104

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

Crestar Bank Building
310 First Street SW, Suite 102
Roanoke, VA 24011
(540) 985-0103

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF 43-2 3
Round 1116

FEB 13 1997

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

Dear Senator Breaux:

This is in response to your letter of November 12, 1996, on behalf of _____ regarding the drug RU-486 (~~mifepristone~~). _____ expressed the opinion that RU-486 should be banned.

The Food and Drug Administration (FDA) enforces the Federal Food, Drug, and Cosmetic Act. With respect to drugs and devices, FDA's mandate is to ensure that these products are safe and effective for their intended uses. On September 18, 1996, FDA issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. This means that the sponsor has to satisfy certain conditions before FDA approval is granted. We are enclosing a September 18, 1996 FDA Talk Paper on this subject.

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

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

2 Enclosures
September 18, 1996 FDA Talk Paper
_____ correspondence

cc: HFW-10 (2)
HFW-2 _____
HFW-14 _____
R/D: _____ :2/3/97 _____newdrug\96-8498.bre)
F/T:mts:2/12/97
Control 96-8498

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW-12	/S/	2-12-97						
COPY									

MIF 006325

November 5, 1996

Dear Senator:

Over the past several weeks, numerous articles have appeared in the press concerning the abortion pill, RU-486, and there has also been considerable hoop-la in the broadcast media about the use of combinations of legitimate drugs (those normally used for the treatment of cancer and other illnesses) to produce so-called "medical" abortions. Under pressure from the Clinton administration, and with the direct help of Clinton appointees, the Food and Drug Administration (FDA) has been reviewing these dangerous agents on a fast track basis for the purpose of releasing them for abortion use in the U.S., as you are doubtless aware. In all this to-do, several things have been conveniently forgotten -- or deliberately misrepresented -- by abortion proponents. The following should clarify some of the issues:

First, despite their (inaccurately) touted safety for the mother, they are NEVER safe for her child, who, at the time of their "recommended" use, already has developed at least to the point that his (her) heart is beating, other organ systems are being laid down, and brain waves may be detected. Death of the *fetus* (a Latin word meaning "young one") virtually always occurs; however, if not initially successful at producing the abortion, these drugs commonly cause serious malformations, which are then "treated" by surgical evacuation of the womb and direct destruction of the unborn baby.

Second, the Hippocratic Oath -- which has regulated medical practice and has helped to protect patients from unethical physicians (and physicians from unscrupulous rulers) for the past 2,000 years -- states unequivocally, "I [the physician] ... will not give to a woman an instrument [i.e. the means] to produce an abortion." This identifies the currently constituted FDA as totally at odds with its mandate to protect the public, with actions that further legitimize the unethical behavior of those medical degree holders who choose to ignore their Oath. In effect, they are helping the outlaws to continue their actions, but no longer as renegades.

Finally, we should remember that every American who has ever lived (or will live) -- *including the reader* -- once passed through (or will pass through) all the same stages of human development in his or her mother's womb, and, therefore, has been (or will be) entitled to the same legitimate right to life written about in the U.S. Constitution -- unless aborted.

RU-486 and its kind should be totally banned, not only from use, but also from manufacture, in analogy to other non-medical "designer" drugs. Please do what you can in this regard!

Thank you for your attention.

Sincerely,

JOHN BREAUX
LOUISIANA

MINORITY
CHIEF DEPUTY WHIP
COMMITTEES:
COMMERCE, SCIENCE, AND TRANSPORTATION
FINANCE
SPECIAL COMMITTEE ON AGING

WASHINGTON OFFICE
(202) 224-4623
TDD (202) 224-1986

senator@breaux.senate.gov
http://www.senate.gov/~breaux

United States Senate

WASHINGTON, DC 20510-1803

STATE OFFICES:

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

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

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

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

CENTRAL LOUISIANA
(318) 487-8445

November 12, 1996

Ms. Diane Thompson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
1555 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Thompson:

I have been contacted by ———— regarding concerns over the use of RU-486 and other drugs to induce abortion.

Please investigate the enclosed information sent to me and provide me with a report. Please give the views and concerns of my constituent every appropriate consideration within federal guidelines. Your reply may be forwarded to the attention of Justin Oliver.

Thank you for your attention and assistance.

Sincerely,

JOHN BREAUX
United States Senator

JB/jco
Enclosure

APPEARS THIS WAY
ON ORIGINAL

No 96-8498

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NDA 19-533
Revised-Ltr

FEB 07 1997

The Honorable Joe Barton
Chairman, Subcommittee on Oversight
and Investigations
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6116

Dear Mr. Chairman:

This is to complete our response to your letter dated September 17, 1996, regarding further information related to the Food and Drug Administration's (FDA) consideration of RU 486 (mifepristone).

As we discussed with Mr. Alan Slobodin of your staff on November 14, 1996, we indicated that we would send you, once a compilation had been made, a list of all meetings on RU 486 between the review division and persons outside the executive branch concerning or related to RU 486. We have enclosed this list of all the meetings between FDA's Division of Reproductive and Urologic Drug Products (and previously, the Division of Metabolic and Endocrine Drug Products) and the outside persons.

The enclosed 5-page list contains confidential commercial information and other privileged information not releasable to the public under the Freedom of Information regulations promulgated by FDA. We request that the Subcommittee not publish or otherwise make public any part of this letter or any information contained within it. In addition, given the sensitivity of this subject, we have redacted the names of certain individuals associated with the clinical trials and application review.

These review division meetings are not listed in the FDA public calendar because such meetings are confidential meetings with the investigational new drug application (IND) or new drug application (NDA) sponsor. These meetings deal with confidential commercial information and we are careful not to publicize this information. Also, such meetings are typically attended by the team of reviewers who will actually work on the application. Sometimes the division director may attend. Neither division directors nor review staff (medical officers, chemists, pharmacologists, project officers, etc.) are required to report their meetings on the public calendar pursuant to Title 21, Code of Federal Regulations, section 10.100(b)(3).

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFWD	S	2/6/97						
COPY	HFW1	S	2/7/97						
	HF24	S	2/7/97						

MIF 006329

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF 15-2[illegible]
FILE Council Letter

FEB 07 1997

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

Dear Senator Graham:

This is in response to your letter of January 9, 1997, on behalf of [redacted], regarding the drug RU-486 (mifepristone). [redacted] expressed her opinion that RU-486 should be banned.

The Food and Drug Administrations (FDA) enforces the Federal Food, Drug, and Cosmetic Act. With respect to drugs and devices, FDA's mandate is to ensure that these products are safe and effective for their intended uses. On September 18, 1996, FDA issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. This means that the sponsor has to satisfy certain conditions before FDA approval is granted. We are enclosing a September 18, 1996 FDA Talk Paper on this subject.

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

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: HFW-10 (2)
HFW-2 [redacted]
HFW-14 [redacted]
R/D: [redacted]2/5/97 [redacted] \ru486\antidrug)
F/T: [redacted]2/6/97
Control 97-308

S94.4

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW-12	/S/	2/7/97						
COPY									

MIF 006330

We trust this information responds to your concerns. Please let us know if you have any questions.

Sincerely,

Sharon Smith Holston
Deputy Commissioner
for External Affairs

Enclosures

cc: The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce

The Honorable John Dingell
Ranking Minority Member
Committee on Commerce

The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations

bcc: HFW-10(2)
HFW-1
HFW-2
HFW-14
HF-24

R/D:
concur: 12/20/96
,GC:1//7/97
1/29/97
:1/29/97
F/T: 2/5/97 (,ru486\ 2.96)
96-6905 continued follow-up

APPEARS THIS WAY
ON ORIGINAL

Bob Graham
Florida

United States Senate

Washington, D.C.

Date 1/9/97

Legislative Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

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 the information that has been presented and providing me with a written response. Please send your reply to the attention of:

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

904-422-6100

Your cooperation and assistance are appreciated.

With kind regards,

Sincerely,

Bob Graham

United States Senator

Constituent's Name: _____

#97-308

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

DEC 13 1996

The Honorable Joe Barton
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in further response to your letter dated September 17, 1996, regarding further information related to the Food and Drug Administration's (FDA) consideration of RU 486 (mifepristone). You raised five issues.

As per discussions with Mr. Alan Slobodin of your staff, on November 14, FDA provided documents responsive to questions two and three. Answers to the remaining questions follow:

Issue 1
Concerning senior officials did not report several meetings on the public calendar as required by Agency regulations (21 C.F.R. 10.100) . . .

(a) Please list the dates, brief description of subject matter, and attendees of all meetings between FDA officials and persons outside the executive branch concerning or relating to RU 486.

(c) You asked that we provide an explanation as to why the meetings were not reported on the public calendar pursuant to 21 C.F.R. 10.100.

As discussed with Mr. Slobodin, the following is a list of all meetings between senior FDA officials and persons outside the executive branch concerning or related to RU 486. We indicate if the meeting was on the public calendar and if not, why it was not reported. This list does not include meetings the review division may have had, if the meeting did not include a senior FDA official. We will provide information on any other meetings that may have occurred between review division staff and persons outside the executive branch as soon as that information is gathered.

2/24/93 David Kessler, _____ and _____ of FDA met with Dr. Sakiz and Dr. Ulmann, from Roussel Uclaf. Subject was a discussion of RU 486.[1]

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFA-12	/S/	12/6/96						
COPY	HFW-1	/S/	12/13/96						
	HF-24	/S/	12/13/96						

MIF 006333

Discussed clinical and manufacturing data on the drug that FDA would need in considering an NDA for an abortificient indication. At that meeting, FDA received a strong commitment from Roussel Uclaf to continue to make the drug available for research on other potential uses. While asserting that RU 486 should be made available in the United States, the firm emphasized the importance of finding a way to achieve that goal without the involvement of Roussel Uclaf. FDA and Roussel Uclaf agreed to continue to work on this matter until remaining issues can be resolved.[2,3] This meeting was reported in FDA public calendar for the week of February 19, 1993.

4/20/93 David Kessler, [redacted], Jane Henney, [redacted] and others from the Center for Biologics Evaluation and Research, Drew Altman of the Kaiser Family Foundation, Wayne Bardin, George Brown, Margaret Catley-Carlson, James Boynton, and Beverly Winikoff of the Population Council, Edouard Sakiz and Catherine Evouard of Roussel Uclaf. Discussed RU 486.[1]

This meeting was listed in the FDA public calendar for the week of April 16, 1993.

10/4/93 Meeting with Chief of Staff, Roussel Uclaf's lawyers from Swidler and Berlin, and [redacted] during which it is explained that the company's demands for indemnification and patent seizure are not likely to be met in the United States.[2] This meeting was not listed in the FDA public calendar because a meeting is to be reported by the most senior official attending (21 CFR 10.100(b)(1), 40 FR 40602, 40693, September 3, 1975). The most senior official was Harriet Rabb of the Department of Health and Human Services, and therefore, was not reported by any FDA official in the FDA public calendar.

In your letter you cited that the meetings of December 6, 1993 and April 14, 1994, were not listed in the public calendar.

The "December 6, 1993 pre-IND meeting" was not listed in the FDA public calendar because such meetings are confidential meetings with the investigational new drug application (IND) sponsor. The pre-IND meetings deal with confidential commercial information and we are careful not to publicize this information. Pre-IND meetings are typically attended by the team of reviewers who will actually work on the application.

Sometimes the division director may attend. Neither division directors nor review staff (medical officers, chemists, pharmacologist, project officers, etc.) are required to report meetings on the public calendar pursuant to 21 CFR 10.100(b)(3). Consequently, the fact that this meeting was not listed on the public calendar is typical for such meetings.

You asked about the "April 14, 1994 meeting between Lester Hyman and David Kessler, [redacted]." We have researched this meeting and have not been able to establish that this meeting occurred.

You also asked about a trip or trips by [redacted] to France to meet with Roussel Uclaf officials. [redacted] has not traveled to France or Europe to meet with Roussel Uclaf officials regarding RU 486. Consequently, there are no listings of any such meetings in the FDA public calendar.

(b) Please provide all unexpurgated books, records, . . . mentioning or pertaining to all meetings and telephone conversations between FDA officials and persons outside the executive branch concerning or relating to RU 486.

All relevant documents are enclosed at Tab A. The documents that are public and releaseable under the Freedom of Information Act are listed separately from those documents that are confidential. The confidential documents or confidential versions of public documents have not previously been released.

(4) All precedents and legal authority that support the propriety of FDA officials encouraging, urging or soliciting a submission of an IND or new drug application.

Pursuant to a presidential memorandum dated January 22, 1993, the Secretary of Health and Human Services directed that FDA promptly assess initiatives to promote testing, licensing, and manufacturing of RU 486 in the United States. 58 Fed. Reg. 7459, 7468 (February 5, 1993). Under section 903(b)(2)(E) of the Federal Food, Drug, and Cosmetic (FDC) Act, the Commissioner of Food and Drugs is responsible for executing the Act and performing such other functions as the Secretary may prescribe. In carrying out the directive, FDA officials acted to facilitate the submission of a new drug application for RU 486.

FDA's mission is, essentially, to promote and protect the public health. The promotion and protection of the public health often requires the Agency to be proactive in disseminating information about public health issues. See sections 705, 903(b)(2)(E) of the FDC Act; see also section 310(b) of the Public Health Service Act. FDA believes

that facilitating the submission of marketing applications for potentially significant drug products is appropriate and consistent with the Agency's mission. Although it is not possible to identify "all precedents" in this area, as requested, the following are among many possible examples.

In a 1973 Federal Register publication, FDA announced its intention to consider new drug applications on diethylstilbestrol for use as an emergency postcoital contraceptive. 38 Fed. Reg. 26809 (September 26, 1973). Similarly, in 1978, the Agency published in the Federal Register a request for the submission of new drug applications for potassium iodide for use as a thyroid blocking agent in radiation emergencies. 43 Fed. Reg. 58798 (December 15, 1978).

More frequently, however, FDA facilitates the submission of marketing applications through more informal interactions with potential sponsors. For example, where a promising combination drug to treat drug-resistant tuberculosis had been approved in several foreign countries, FDA contacted the sponsor to encourage the submission of an NDA for that product.

In another case, FDA asked the sponsor of an approved animal drug to submit an NDA for use of the same drug in humans to treat strongyloidiasis and onchocerciasis. Among other examples, FDA made special efforts to facilitate the submission of a marketing application for an acellular pertussis (whooping cough) vaccine and solicited NDAs for a drug to treat neonatal apnea and a drug for heart arrhythmia. FDA also facilitated the submission of marketing applications for a drug to assist in the diagnosis of asthma and for a drug to be used with heart valve surgery to reduce the risk of another heart attack. In another case, FDA solicited INDs from potential sponsors for a drug with the potential to treat HIV-related wasting syndrome, aphthous ulcers, and leprosy.

It is very common for FDA to engage in dialogue with potential sponsors beginning at the initial research stages and continuing until the Agency ultimately decides to approve or deny an application. FDA involvement at the research stage occasionally results in the Agency asking the sponsor to submit a treatment IND based on the preliminary analysis of test results. See 21 CFR 312.83.

FDA solicitations have resulted in NDA submissions for many orphan drugs, including drugs to treat Hydatid disease, neurocysticercosis, homocystinuria, Wilson's disease, and urea cycle disorders. As a result of FDA's initiative,

FDA has also played an active role in facilitating marketing applications to alleviate shortages of many medically necessary drug products. For example, FDA widely encouraged firms to seek marketing approval for a drug to treat a type of drug-resistant tuberculosis and succeeded in finding a sponsor for an application that was subsequently approved.

In addition, on several occasions, the Agency has facilitated the submission of an IND, sometimes in coordination with the CDC, to allow the importation of a medically necessary drug that was not available domestically. In this manner, FDA facilitated the availability of drugs to treat tuberculosis, cystic fibrosis, and toxoplasmosis encephalitis. In other instances, FDA's assistance in locating sources of scarce bulk drug substances, and soliciting application supplements to allow the use of such substances, has averted shortages of drugs necessary to treat renal impairment and systemic fungal infections associated with AIDS.

(5) All unexpurgated books, records, . . . mentioning or pertaining to FDA's implementation of President Clinton's memorandum of January 22, 1993 concerning RU 486.

A list of the documents and the documents are enclosed at Tab B.

This letter and the enclosed lists and documents contain confidential commercial information and other privileged information not releasable to the public under the Freedom of Information regulations promulgated by FDA. We request that the Subcommittee not publish or otherwise make public any part of this letter or any information contained within it. In addition, given the sensitivity of this issue, we have redacted the names of certain individuals associated with the clinical trials and application review.

We trust this information responds to your concerns. Please let us know if you have any questions.

Sincerely,

Sharon Smith Holston
Deputy Commissioner
for External Affairs

Enclosures

cc: The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce

The Honorable John Dingell
Ranking Minority Member
Committee on Commerce

The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations

bcc: HFW-10(2)
HFW-1
HFW-2
HF-24
R/D:
reviewed:
additions:
concur:
12/11/96
12/11/96
F/T: :12/12/96
file: s:\wp\ \ru486\ ru.wpd
96-6905 continued follow up

APPEARS THIS WAY
ON ORIGINAL

TAB A:

FOIA documents:

- Letter to [redacted], FDA, dated January 3, 1992 form Andre Ulmann, Rousell Sanei R. et D.
- Memorandum to Subcommittee on Regulation, Business Opportunities, and Energy, dated January 6, 1992, from [redacted] FDA.
- Letter to Ron Wyden, dated January xx, 1992, from Kay Holcombe, FDA.
- Statement by President Clinton, dated January 22, 1992 -- Remarks by the President During the Signing of Presidential Memoranda.
- Memorandum for the Secretary of Health and Human Services, regarding the Importation of RU-485, signed by the President, dated January 22, 1992.
- Letter to Ron Wyden, dated August 7, 1992, from Carol Scheman, FDA.
- Statement of Ruth Merkatz, FDA before the Subcommittee on Regulation, Business Opportunities, and Energy, Committee on Small Business, May 8, 1992.
- Letter to Ron Wyden, dated December 8, 1992, from Edouard Sakiz, Roussel Uclaf.
- Letter to Dr. E. Sakiz, Roussel uclaf, dated December 14, 1992, from David Kessler, FDA.
- Letter to David Kessler, FDA, dated December 17, 1992, from Dr. E. Sakiz, Roussel uclaf.
- Letter to Ron Wyden, dated January 19, 1993, from Marc Scheineson, FDA. Attached--Letters to Dr. Edouard Sakiz, dated December 14, 1992, from David Kessler; letter to David Kessler, dated December 17, 1992, from Edouard Sakiz, Roussel Uclaf, and letter to David Kessler, dated January 14, 1993, from Ron Wyden, House of Representatives.
- Letter to Dr. Edouard Sakiz, dated January 22, 1993, from David Kessler, FDA.
- Record of Telephone conversation with Andre Ulmann, Roussel Uclaf, dated January 25, 1996, from [redacted] FDA.

- Email Talk Paper on RU 486, to all States, dated February 25, 1993, from FDA.
- Letter to David Kessler, FDA, dated January 27, 1993, from
- Talk Paper on Meeting with Roussel uclaf on RU 486, dated February 25, 1993, from FDA.
- Letter to Dr. Edouard Sakiz, Roussel uclaf, dated March 3, 1993, from
- Letter to Professor Wolfgang Hilger, dated March 12, 1993, from Secretary Shalala.
- Letter to Secretary Shalala, DHHS, dated March 18, 1993, from Dr. Edouard Sakiz, Roussel uclaf.
- Letter to Secretary Shalala, DHHS, dated March 23, 1993, from Professor Wolfgang Hilger, Hoechst.
- Letter to Secretary Shalala, DHHS, dated March 31, 1993, from Lawrence Lader, Abortion Rights Mobilization.
- Letter to David Kessler, FDA, dated April 15, 1993, from Professor W. Hilger, Hoechst.
- Letter to Lawrence Lader, Abortion Rights Mobilization, dated May 11, 1993, from , DHHS.
- Letter to FDA, dated January 11, 1994, from John R. Fleder, Olsson, Frank and Weeda.
- Letter to Ron Wyden, dated February 8, 1994, from Secretary Shalala. Attached--Letter to Secretary Shalala, dated December 22, 1993, from Ron Wyden, House of Representatives
- Memorandum to Secretary, DHHS, dated April 13, 1994, from Advisor to the Commissioner of Food and Drugs.
- HHS Fact Sheet on Mifepristone (RU 486): Brief Overview, dated May 16, 1994.
- HHS News on Roussel Uclaf donates US Patent Rights for RU 486 to Population Council, dated May 16, 1994.
- Testimony of David Kessler, FDA before the Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, dated May 16, 1994.

- Letter to _____ FDA, dated May 19, 1994, from Pascal Chevit, French Ambassador to the United States. Copy of Letter to David Kessler attached, dated May 19, 1994, from Pascal Chevit, French Ambassador.

- Letter to Secretary Shalala, dated May 30, 1994, from Dr. Edouard Sakiz, Roussel Uclaf.

- Letter to Secretary Shalala, dated June 8, 1994, from _____

- Letter to Ron Wyden, dated June 16, 1994, from Diane E. Thompson, FDA.

Confidential Documents:

These documents contain confidential commercial information and other privileged information not releasable to the public under the Freedom of Information regulations promulgated by FDA. We request that the Subcommittee not publish or otherwise make public any part of this letter or any information contained within it.

- Telefax letter to _____ FDA, dated February 28, 1993, from Catherine Euvrard, Roussel Uclaf.

[redacted]

- Memorandum to the Secretary of DHHS, dated April 12, 1994, from _____ Advisor to the Commissioner of Food and Drugs.

- Fax to _____ FDA, dated April 11, 1994, from _____ with Christy and Viener.

- Note to _____ Presidential Letters, Office of Correspondence, dated May 31, 1994, from _____ FDA.

- Memorandum to _____ FDA, dated May 17, 1994, from _____ Presidential Letters. Office of Correspondence.

- Letter to James Boynton, Christy and Viener, and Lester Hyman, Swidler and Berlin, dated April 22, 1994, from [redacted] FDA.

- Memorandum to Assistant Secretary for Health, DHHS, dated July 14, 1993, from [redacted] FDA. Attached -- Memorandum to the Secretary, not dated or signed, from the Assistant Secretary for Health, DHHS.

- Note to Secretary Donna Shalala, dated September 14, 1994, from [redacted] FDA.

- Memorandum for [redacted] undated, from [redacted]

- Note to [redacted] Executive Secretary, dated October 25, 1994, from [redacted] Advisor to the Commissioner. Attached -- Summary, and Population Council Press Package.

- Memorandum to the Secretary, DHHS, dated October 25, 1994, from the Commissioner of Food and Drugs. Attached -- Summary Update on Medical Abortion, Talking Points, and Questions and Answers.

- Note to [redacted] and [redacted] DHHS, dated August 14, 1995, from [redacted] Includes faxed cover sheets. Attached -- Subject Areas for Fact Sheets on Women's Health, Fact Sheet on Alcohol and Illicit Drugs.

- Letter to Andre Ullman, Roussel Uclaf, dated September 14, 1994, from [redacted] FDA.

APPEARS THIS WAY
ON ORIGINAL

TAB B

- Statement by President Clinton, dated January 22, 1992 -- Remarks by the President During the Signing of Presidential Memoranda.
- Memorandum for the Secretary of Health and Human Services, regarding the Importation of RU 486, signed by the President, dated January 22, 1992.
- Memorandum for the Secretary of Health and Human Services, from the [redacted] Advisor to the Commissioner of Food and Drugs, dated April 12, 1994.
- HHS News on Roussel Uclaf Donates US Patent Rights for RU 486 to Population Council, May 16, 1994.
- HHS Fact Sheet, Mifepristone (RU 486): Brief Overview, dated May 16, 1994.

Sources:

1. Source -- Public Calendar

2. Source -- Confidential version of the "RU 486 Overview Chronology", attachment to April 12, 1994 memorandum to the Secretary from [redacted] Advisor to the Commissioner of Food and Drugs.

3. Source -- FDA Talk Paper dated February 25, 1993.

APPEARS THIS WAY
ON ORIGINAL

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

September 17, 1996

The Honorable David A. Kessler, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Room 14-71 (HF-1)
5600 Fishers Lane
Rockville, MD 20857

Incoming

Dear Dr. Kessler:

On June 27, 1996 and July 11, 1996, I sent letters to you requesting information and documents concerning data integrity in clinical trials sponsored by the Population Council. To date, I have not received a complete response to the June 27, 1996 letter nor have I received any response to the July 11, 1996 letter. Please expedite the responses to these letters.

In addition, the Subcommittee seeks further information related to the FDA's consideration of RU-486. Accordingly, please provide the following by October 1, 1996:

1. According to available records, senior FDA officials did not report several meetings on the public calendar as required by Agency regulations (21 C.F.R. 10.100). These meetings concerning RU-486 appear to have involved senior FDA officials and persons outside the executive branch. Those meetings not reported on the public calendar include the following: October 4, 1993 meeting between the Swidler and Berlin law firm and HHS

December 6, 1993 pre-IND meeting; April 14, 1994 meeting between Lester Hyman and David Kessler, [redacted] and a trip or trips of unknown date(s) by [redacted] to France to meet with Roussel Uclaf officials. Section (b)(3) of 21 C.F.R. 10.100 states that the Commissioner and his deputies are required to report their meetings with outside individuals on the public calendar.

(a) Please list the dates, brief description of subject matter, and attendees of all meetings between FDA officials and persons outside the executive branch concerning or relating to RU-486.

96-6905

(b) Please provide all unexpurgated books, records (including FOIA requests and travel voucher memoranda), correspondence, notes, phone logs, memoranda, documents (including all drafts and without regard to whether they are on paper or recorded electronically), and electronic mail (irrespective of how stored, including but not limited to those stored on individual PCs or on file servers that are part of local area or wide area networks) mentioning or pertaining to all meetings and telephone conversations between FDA officials and persons outside the executive branch concerning or relating to RU-486.

(c) Please provide an explanation as to why the meetings were not reported on the public calendar pursuant to 21 C.F.R. 10.100.

2. All unexpurgated books, records (including FOIA requests), correspondence, notes, phone logs, memoranda, documents (including all drafts and without regard to whether they are on paper or recorded electronically), and electronic mail (irrespective of how stored, including but not limited to those stored on individual PCs or on file servers that are part of local area or wide area networks) mentioning or pertaining to the July 19, 1996 Reproductive Health Drugs Advisory Committee meeting, including materials related to the individual members of the Advisory Committee, and all materials relating to all ethical issues concerning each member of the Advisory Committee.

3. All unexpurgated books, records (including FOIA requests), correspondence, notes, phone logs, memoranda, documents (including all drafts and without regard to whether they are on paper or recorded electronically), and electronic mail (irrespective of how stored, including but not limited to those stored on individual PCs or on file servers that are part of local area or wide area networks) mentioning or pertaining to FDA's consideration of the issue of the possible breast cancer risk factor in connection with RU-486.

4. All precedents and legal authority that support the propriety of FDA officials encouraging, urging or soliciting a submission of an IND or new drug application.

5. All unexpurgated books, records (including FOIA requests), correspondence, notes, phone logs, memoranda, documents (including all drafts and without regard to whether they are on paper or recorded electronically), and electronic mail (irrespective of how stored, including but not limited to those stored on individual PCs or on file servers that are part of local area or wide area networks) mentioning or pertaining to FDA's implementation of President Clinton's memorandum of January 22, 1993 concerning RU-486.

If you have any questions, please contact Mr. Alan Slobodin of the Subcommittee staff at (202) 225-2927. I appreciate your cooperation in this matter.

Sincerely,

Joe Barton

Joe Barton
Chairman
Subcommittee on
Oversight and Investigations

cc: Honorable Thomas J. Bliley, Jr., Chairman
Honorable John D. Dingell, Ranking Minority Member
Honorable Ron Klink, Ranking Minority Member
Subcommittee on Oversight and Investigations

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NOV 0 7 1996

The Honorable Richard G. Lugar
United States Senate
Washington, D.C. 20510-1401

Dear Senator Lugar:

This is in response to your October 4, 1996 letter on behalf of _____ expressed his concern that the Food and Drug Administration (FDA) may allow the company that makes RU-486 to market the pill in the United States without revealing its name.

The law only requires that the name and place of business of the manufacturer, packer or distributor be disclosed in a product's labeling (Section 502(b) of the Federal Food, Drug, and Cosmetic Act and FDA regulations at 21 CFR Section 201.1). It is not unusual for products to be marketed with the name of the distributor rather than the manufacturer.

We hope this information has been helpful. If we may be of further assistance, please let us know.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10 (2)
HFW-14

r/d _____ 10/29/96 (per telephone conversation with _____ and _____ OGC)
F/T:aor:11/05/96
s:\wp\ _____ \labeling\96-7555
FDA Control 96-7555

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFW	/S/	11/6/96						
COPY									

MIF 006347

96 SEP 30 PM 12:32

I heard that the abortion pill RU-486 is likely to be approved by the FDA. My concern is that I have heard that the FDA may allow the company that makes this pill to market it in the US without revealing their name. In other words I have heard that the FDA will allow the company to remain anonymous to avoid protests. I hope this is not legal and if it is, I hope congress will do something to change that.

RICHARD G. LUGAR
INDIANA

306 HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510
202-224-4814

COMMITTEES
AGRICULTURE, NUTRITION, AND FORESTRY
CHAIRMAN
FOREIGN RELATIONS
SELECT COMMITTEE
ON INTELLIGENCE

United States Senate

WASHINGTON, DC 20510-1401

October 4, 1996

Office of Legislative Affairs
Food and Drug Administration
Parklawn Building, Room 1555
HFW1, 5600 Fishers Lane
Rockville, Maryland 20857

Dear [redacted]

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/dwl
enclosure

No. 96-7555

F D A
TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

T96-61
Sept. 18, 1996

Lawrence Bachorik
(301) 443-1130

FDA ISSUED APPROVABLE LETTER FOR MIFEPRISTONE

The Food and Drug Administration today issued an approvable letter to the Population Council for mifepristone, when used in combination with misoprostol, for the termination of early pregnancy. As announced by the Population Council, the Agency has determined that the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision, but additional information on other issues, including manufacturing practices and labeling, must be submitted before a final approval decision can be made. The following can be used to answer questions:

An FDA advisory committee voted 6-0 (with two abstentions) on July 19, 1996, that clinical data show that the benefits of a mifepristone and misoprostol regimen for terminating early pregnancy outweigh its risks. The studies presented to the Committee involved women treated under close medical supervision within 49 days of the beginning of their last menstrual period. The data come from two French trials, involving 2,480 women, that

-MORE-

showed the combination of mifepristone and misoprostol, an oral prostaglandin, to be about 95 percent effective.

In addition, the Population Council, a non-profit research organization, presented to the Committee preliminary safety data from U.S. trials, involving more than 2,000 women. Trials were conducted in the U.S. to complement the European data and to confirm whether the drug regimen could be safely used in the American medical system.

The regimen used in the clinical trials consisted of 3 tablets (600 milligrams) of oral mifepristone followed two days later by 2 tablets (400 micrograms) of oral misoprostol.

Adverse events seen in clinical trials include painful contractions of the uterus, nausea, vomiting, diarrhea, pelvic pain and spasm, and headache. A very small percentage of patients in the clinical trials required hospitalization, surgical treatment, and/or blood transfusions.

The Population Council's new drug application was filed on March 18, 1996. Under the Prescription Drug User Fee Act, priority drugs such as mifepristone have a six-month goal for initial Agency action.

####

The Population Council

One Dag Hammarskjold Plaza, New York, New York 10017 Telephone: (212) 339-0500 Telex: 234722 POCO UR Facsimile: (212) 755-6052 Cable: POPCOUNCIL NEW YORK

News Release

For further information, contact:
Sandra Waldman, 212/339-0525

18 September 1996
FOR IMMEDIATE RELEASE

FDA Issues Approvable Letter for Mifepristone Medical Abortion

NEW YORK--The Population Council announced today (18 September 1996) that the U.S. Food and Drug Administration has issued an Approvable Letter for mifepristone, in combination with misoprostol, for early medical abortion. The FDA letter, which the Council received earlier today, states that the agency has determined that substantial clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under medical supervision.

An Approvable Letter is an action frequently used by the FDA to indicate that safety and efficacy data have passed agency review, but that additional information must be submitted before final approval for marketing is granted. The FDA Approvable Letter to the Council said that a few parts of the application, including those related to labeling and additional information about the manufacturing process, remain to be completed by the Council. An FDA Advisory Committee recommended on July 19 that the agency approve the regimen for early medical abortion. The Council's 164-volume New Drug Application was submitted in March 1996.

In a statement, the Population Council said, "This FDA action marks another major step in the long and complex process to make mifepristone available to American women as it is to women in other countries. We are delighted to have an Approvable Letter. We are sure we will be able to provide the FDA the outstanding information necessary for approval."

# # #

LYNN WOOLSEY
6TH DISTRICT, CALIFORNIA

COMMITTEES:
BUDGET
ECONOMIC AND EDUCATIONAL OPPORTUNITIES

WASHINGTON OFFICE:
439 CANNON BUILDING
WASHINGTON, DC 20515–0506
TELEPHONE: (202) 225–5161

Congress of the United States

House of Representatives

Washington, DC 20515–0506

DISTRICT OFFICES
1101 COLLEGE AVE., SUITE 200
SANTA ROSA, CA 95404
TELEPHONE: (707) 542–7182
FROM PETALUMA CALL:
(707) 795–1462

NORTHGATE BUILDING
1050 NORTHGATE DRIVE, SUITE 140
SAN RAFAEL, CA 94903
TELEPHONE: (415) 507–9554

INTERNET ADDRESS:
woolsey@hr.house.gov

September 17, 1996

Dr. David A. Kessler
Commissioner of Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
ATTENTION: Congressional Liaison

Dear Dr. Kessler:

I am in receipt of a letter that my constituent, [redacted] recently wrote to you regarding RU 486. [redacted] is concerned that the FDA has received external pressures that are prohibiting a scientific decision about the approval of RU 486. I would appreciate it if you would look into this matter and respond to [redacted] concerns in writing.

Please respond directly to [redacted] at:

[redacted]

and forward a copy of your correspondence to my Washington office. If you have any questions, please contact Katherine Saul of my staff at (202) 225-5161. Thank you very much for your attention to this matter.

Sincerely,

Lynn Woolsey

Lynn Woolsey
Member ~~of Congress~~

LW:kcs

APPEARS THIS WAY
ON ORIGINAL

No. 96-7083

PRINTED ON RECYCLED PAPER

MIF 006353

7th DISTRICT, WISCONSIN

DISTRICT OFFICE:
FEDERAL BUILDING
317 FIRST STREET
WAUSAU, WI 54403-5454
PHONE: 715-842-5606

DISTRICT REPRESENTATIVE:
JERRY MADISON

WASHINGTON OFFICE:
JOSEPH R. CRAPA
STAFF DIRECTOR

DAVID R. OBEY

Congress of the United States

House of Representatives

Washington, DC 20515-4907

APPROPRIATIONS COMMITTEE
RANKING MEMBER

RANKING MEMBER:
LABOR—HEALTH AND
HUMAN SERVICES—EDUCATION

EX OFFICIO MEMBER:
REMAINING 12 APPROPRIATIONS
SUBCOMMITTEES

DEMOCRATIC STEERING AND
POLICY COMMITTEE
VICE CHAIR FOR
RESEARCH OPERATIONS

WASHINGTON OFFICE:
2462 RAYBURN HOUSE OFFICE
BUILDING
PHONE: 202-225-3365

May 8, 1996

Mr. David Kessler
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Kessler:

Enclosed is a letter I received from a constituent of mine, [redacted]
She is concerned with funding for research into the applications of RU-486.

I would appreciate it if you would respond directly to [redacted] concerns and provide my office with a copy of your response. Her address is:

[redacted]

Thank you for your attention to this matter.

Sincerely yours,

David R. Obey
Member of Congress

DRO:bs
Enclosure
L000223897

No. 96-4086

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE

SEP 25 1996

The Honorable Dan Coats
United States Senate
Washington, D.C. 20510

Dear Senator Coats:

This is in further response to your letters of April 11, 1996, to Secretary Donna E. Shalala and David A. Kessler, M.D., in which you expressed concern for the public safety and the integrity of the drug approval process in relation to the future availability of mifepristone (RU-486) as an abortifacient in the United States.

You have asked for additional information besides that provided in our letter of May 22, 1996. In response to your request, we have enclosed copies of those documents related to the drug, mifepristone, that are obtainable under the Freedom of Information Act. As you know, the Food and Drug Administration (FDA) Reproductive Health Drugs Advisory Committee discussed on July 19, 1996, at a meeting with public participation, the clinical data regarding the use of mifepristone and misoprostol regimen for terminating early pregnancies. The advisory committee concluded in a 6 to 0 vote (with 2 abstentions) that the data showed that the benefits of this regimen outweighed the risks. As you know, FDA issued an approvable letter, on September 18, 1996, to the Population Council for mifepristone for the termination of early pregnancy. The Agency has determined that the submitted clinical data demonstrate the safety and efficacy of mifepristone in combination with misoprostol when used under close medical supervision. Additional information is needed, however, on other issues including information on manufacturing practice and labeling before a final approval decision can be made.

We assure you that the application for mifepristone is being reviewed in accordance with the same stringent scientific and legal standards as any other applications that is submitted to the Agency. Thank you for your continued interest and concern.

Sincerely,

Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosures

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	HFWD	/S/	9/23/96						
COPY	HFW1	/S/	9/23/96						

MIF 006355

cc: HFW-10(2)
GCF-1
drafted: 8/13/96
edited: 8/16/96
concur: 8/27/96
concur: 8/27/96
edit: 8/26/96
f/t: 9/18/96
edit:9/??/96
re-f/t: :9/23/96
file: \ru486\coats.let
follow-up to 96-2902

APPEARS THIS WAY
ON ORIGINAL

RU-486
Index to Package 1:

1) Memorandum dated April 12, 1994 to the Secretary of the Department of Health and Human Services, from the [redacted] Advisor to the Commissioner of Food and Drugs. Including Tabs A, B and C. Tab E is a two page "Summary of Other Events."

2) Note to Assistant Secretary of Health, from the [redacted] Advisor to the Commissioner of Food and Drugs, dated July 14, 1993.

3) Note to Secretary Donna Shalala, from [redacted] dated September 14, 1994.

4) Note to [redacted] from the [redacted] Advisor to the Commissioner of Food and Drugs; dated October 25, 1994 and attachments A and B.

5) List of members of the Advisory Committee for Reproductive Health Drugs.

6) Talk Paper on FDA Advisory Committee Reviews Mifepristone, July 19, 1996

7) Public Calendars from December 29, 1995 through July 13, 1996. (There is no public calendar for the dates March 3 through July 13, 1996).

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 22, 1996

The Honorable Dan Coats
United States Senate
Washington, D.C. 20510

Dear Senator Coats:

This is in response to your letters of April 11, 1996 to Secretary Shalala and me in which you expressed concern for the public safety and the integrity of the drug approval process in relation to the future availability of mifepristone (RU-486) as an abortifacient in the United States. I want to assure you that neither the safety of the American public nor the integrity of the new drug approval process will be put in jeopardy by the Food and Drug Administration's (FDA's) actions.

As you may know, early in this Administration, the Secretary of Health and Human Services was directed by the President to promote the testing, licensing, and manufacturing in the United States of RU-486 and to direct the FDA to reassess whether RU-486 qualifies for FDA's personal use importation exemption. In response to that directive, FDA has been encouraging and facilitating the submission of a new drug application because we firmly believe that if a safe and effective medical alternative to any surgical procedure is available, American women should have access to that drug regimen. It is not unusual for FDA to encourage the development of new products for diseases and conditions for which there is an inadequate medical armamentarium, and if found to be safe and effective in accordance with established statutory and regulatory standards, to speed their availability to the American public. However, FDA's primary concern is public health and safety, and definitive conclusions about a drug's safety or effectiveness cannot be determined without first reviewing the studies and other data that would be submitted in a new drug application. Also, because of our concerns regarding the health and safety of American women, the import alert on mifepristone remains in effect and importation of the drug under the agency's personal use import policy is not appropriate.

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. The manufacturer or sponsor of the drug has the responsibility for conducting studies on which safety and effectiveness is based and submitting these data to FDA in the form of a new drug application. FDA's role is to review the data submitted and then make a determination as to whether a product is safe and effective for its intended use.

As you may know, the Population Council recently announced that it had submitted to FDA a new drug application for mifepristone for use in the termination of pregnancy. You have my assurance that that application is being reviewed in accordance with the same stringent scientific and legal standards as any other application that is submitted to the agency.

Thank you for your interest and concern.

Sincerely,

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

APPEARS THIS WAY
ON ORIGINAL

DAN COATS
INDIANA

404 RUSSELL SENATE OFFICE BUILDING
(202) 224-5623

INDIANAPOLIS OFFICE
1180 MARKET TOWER 10 WEST MARKET STREET
INDIANAPOLIS, IN 46204
(317) 226-5555

COMMITTEE:
ARMED SERVICES
LABOR AND HUMAN RESOURCES

United States Senate

WASHINGTON, DC 20510

April 11, 1996

SPECIAL

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, Southwest
Washington, D.C. 20201

Dear Secretary Shalala:

As chairman of the Senate Committee on Labor and Human Resources Subcommittee on Children and Families, I request copies of documents in the possession of the Food and Drug Administration, including any of its advisory committees, relating to the drug known as RU 486 (mifepristone), developed by the company Roussel Uclaf SA.

I understand that the Population Council has an active investigational new drug application (IND) to use RU 486 for abortion. Several reports indicate extensive communications between representatives of the Clinton administration and private companies and organizations, including the Population Council, concerning the future availability of RU 486 for use as an abortion pill in the United States. These reports, together with issues raised in a Citizens' Petition on RU 486 submitted last year to the FDA, have generated serious concern for public safety and the integrity of the drug approval process. Consequently, I request that you provide the following information:

(1) Any and all written or recorded communications, including electronic or telephonic communications, involving one or more of the persons listed below and relating to RU 486 from January 1, 1992, up to the present (i.e., up until the time the document search is conducted).

When used in the above request, the word "communication" includes, but is not limited to: correspondence, electronic mail, memoranda, notes of conversations, calendars, notes of meetings (including the agenda, the list of those in attendance and the time, date and location of each meeting), telephone logs, message slips, and the travel logs of administration employees. It also includes all communications that do not specifically mention RU 486 but that may relate to its possible approval by FDA for use as an abortifacient (e.g., communications relating to the acceptability of foreign data in the drug approval process, communications with drug companies that produce a prostaglandin that is or could be used in conjunction with RU 486, etc.).

For each such communication, please indicate the date of the communication, the names and the professional or organization affiliations of all persons involved or present, and the offices within the FDA from which the communications were obtained. Also, please indicate which communications, if any, are confidential and may not be disclosed to the public.

This request includes all communications involving the following persons from January 1, 1992, up to the present:

President Clinton, Mrs. Clinton, and White House staff
Other administration officials or personnel, including yourself, [redacted] of the Endocrine Drugs Division of the FDA
Edouard Sakiz, Dr. Andre Ulmann, and other officers, employees, or representatives of Roussel Uclaf
Margaret Catley-Carlson, Dr. Wayne Bardin, and other officers, employees, and representatives of the Population Council
David A. Grimes, M.D.
Daniel R. Mishell, M.D.
Suzanne Poppema, M.D.
Officers, employees and representatives of the following companies and organizations:
- Hoechst AG of Germany
- Hoechst Celanese Corporation
- Hoechst-Roussel Pharmaceuticals
- Rhone-Poulenc of France
- Schering AG of Germany
- G.D. Searle Company
- Upjohn Company
- Gynopharma, Inc.
- Cabot Medical Corporation
- Aurora Medical Services
- Fund for the Feminist Majority
- Planned Parenthood Federation of America
- Reproductive Health Technologies Project
- National Abortion Federation
- National Abortion and Reproductive Rights Action League (formerly the National Abortion Rights Action League)
- Oregon Science Health University of Portland, Oregon
- Center for Reproductive Law and Policy
- National Organization for Women
- Women's Issues Network

(2) Any and all documents relating to the implementation of President Clinton's January 22, 1993, memorandum for the Secretary of Health and Human Services regarding the importation of RU 486.

In this memorandum, the President asked the Secretary to take the following three actions:

a) "promptly instruct the FDA to determine whether there is sufficient evidence to warrant exclusion of RU 486 from the list of drugs that qualify for the personal use importation exemption" ;

b) " immediately take steps to rescind Import Alert 66-47" if the "FDA concludes that RU 486 meets the criteria for the personal use importation exemption"; and

c) "promptly assess initiatives by which the Department of Health and Human Services can promote the testing, licensing, and manufacturing in the United States of RU 486 and other antiprogestins."

When used in the above request, the word "document" includes, but is not limited to: internal and external documents of the Food and Drug Administration, documents prepared by persons or offices outside the FDA (including documents prepared by non-governmental persons, organizations, or companies), correspondence, electronic mail, memoranda, notes of conversations, calendars, notes of meetings (including the agenda, the list of those in attendance and the time, date and location of each meeting), and telephone logs, message slips, and travel logs of administration employees. It also includes all documents that do not specifically mention RU 486 but which may relate to its possible approval by FDA for use as an abortifacient (e.g., criteria for the acceptance of foreign data, the use of a prostaglandin with RU 486, etc.). For each such document, please indicate the date of the document, the author or authors of the document, the persons to whom it was given or sent, and the offices within the Department from which the documents were obtained. Please separate the documents in this second request into three categories based on which of the three actions requested by the President the documents address. Again, please indicate which communications, if any, are confidential and may not be disclosed to the public.

With respect to both requests (1) and (2) above, I ask that the information provided be complete, and that you not withhold documents or excise portions of documents on grounds of relevancy. If you assert executive privilege as to any document, please identify each one by providing the following information: the type of document and a summary of its contents; the date, author(s), and recipient(s) of document, the basis for withholding it from Congress, and an explanation if that basis was asserted on any document(s) in the 103rd Congress.

Please inform me if any communications (particularly, but not exclusively, e-mails) have been destroyed and the policy of the FDA on the destruction of e-mail messages. I request that every person involved in filling this requests, be asked if he or she has had e-mail messages related to RU 486 that have been destroyed and, if so, to provide a description of the subjects of those messages.

Finally, I wish to know the process used to comply with this letter, and to receive copies of all communications (memos, electronic mail, letters, etc.) produced in furtherance of filling this request for documents.

Thank you for your attention to this inquiry. I look forward to receiving the information by May 15, 1996. If you foresee any difficulty in fulfilling this request by that date, please notify me immediately. Vince Ventimiglia of my staff will be available to work with you if you have any questions. He can be reached at 202-224-1133.

Sincerely,

Dan Coats
U.S. Senator

SPECIAL

cc: Dr. David A. Kessler

BARBARA A. MIKULSKI
MARYLAND

SUITE 709
HART SENATE OFFICE BUILDING
WASHINGTON, DC 20510-2003

(202) 224-4654
TDD: (202) 224-5223

United States Senate

WASHINGTON, DC 20510-2003

July 27, 2000

Ms. Melinda K. Plaisier
Acting Associated Commissioner
Department of Health & Human Services
Food and Drug Administration
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857

Dear [redacted]

I am writing to request your consideration of the attached correspondence from [redacted] Please respond directly to [redacted] and send a copy to Stephanie Sterling of my staff. If you have any questions, please call Ms. Sterling at (202) 224-4654.

Thank you for your assistance.

Sincerely,

Barbara A. Mikulski

Barbara A. Mikulski
United States Senator

BAM:ss
Enclosure

APPEARS THIS WAY
ON ORIGINAL

No. 00-5146

SUITE 253
WORLD TRADE CENTER
BALTIMORE, MD 21202-3099
(410) 962-4510

SUITE 202
60 WEST STREET
ANNAPOLIS, MD 21401-2448
(410) 263-1805

SUITE 406
6404 IVY LANE
GREENBELT, MD 20770-1407
(301) 345-5517

94 WEST WASHINGTON STREET
HAGERSTOWN, MD 21740-4804
(301) 797-2826

SUITE 1, BLDG. B
1201 PEMBERTON DRIVE
SALISBURY, MD 21801-2403
(410) 546-7711

http://mikulski.senate.gov/

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE 4/5 2nd

SEP 12 2000

The Honorable Amory Houghton
House of Representatives
Washington, D.C. 20515-3231

Dear Mr. Houghton:

Thank you for your continued interest generally in women's health issues, and specifically in the approval status of mifepristone (RU-486). This is in response to your letter of August 4, 2000, expressing your concerns about information reported by the press regarding alleged restrictions the Food and Drug Administration (FDA or the Agency) might be considering for RU-486.

As you know, there are strict limits on what FDA may legally disclose about a pending new drug application. In reviewing any product, science guides our decision-making. One of the fundamental things that is considered in any application is the safety of the product. No medical product is without risk. In the safety assessments, the benefits are considered as well as how the risks can be best recognized, managed, and kept to a minimum. The evidence on efficacy is also considered by the review team. This combination of determining safety and efficacy for the product's intended use is the one most well understood. Less frequently understood, but also important, are considerations as to how the product will be distributed. This again is a risk management consideration. Generally, if the risks of a product can be understood and managed by the consumer, the product is made available over-the-counter. If, however, a physician's involvement is needed to assist in managing risk, the product is designated as a prescription drug. Among prescription products, most are available to any licensed practitioner, but some are more limited in the scope of distribution.

The other pivotal elements of the review process relate to the manufacture of the product in question and whether the company

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
FILE	OL	/S/	9/11/00						
COPY									

is in compliance with current good manufacturing practices, which assures that the approved product can be consistently manufactured.

Some of these issues with respect to RU-486 were discussed in an open Advisory Committee. Enclosed is the transcript, of that meeting for your review. It is also available on the Internet at:

www.fda.gov/ohrms/dockets/ac/cder96+.htm#Reproductive HealthDrugs.

As with all other products under review, we are working closely with the sponsor of the application for RU-486, as they seek approval of their product for marketing.

Thanks again for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

APPEARS THIS WAY
ON ORIGINAL

bcc: HFW-10
HFW-1
HFW-14
HFD-001
Rd: 6/22/00
Edits: 6/29/00
Revised: 6/29/00
Cleared: 6/30/00
Cleared: 6/30/00
Reviewed/Revised: OCC: 7/7/00
Cleared: 7/7/00
Cleared: :7/10/00
F/T:brl:9/1/00:G:\WP\ \00-5190.doc
Control No. 00-5190

APPEARS THIS WAY
ON ORIGINAL

AMO HOUGHTON
1110 LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-3231

PHONE: (202) 225-3161
FAX: (202) 225-5574

COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON TRADE
SUBCOMMITTEE ON OVERSIGHT
CHAIRMAN

COMMITTEE ON INTERNATIONAL RELATIONS
SUBCOMMITTEE ON AFRICA

Congress of the United States
House of Representatives

August 4, 2000

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fisher's Lane
Rockville, Maryland 20857

Dear Dr. Henney:

RU-486 - it's a subject that keeps coming up. I know it's a political issue, but we're concerned about where it stands. Can you share your thoughts on if and/or when it will be approved?

All the best,

Amo

Amo Houghton

AH/ft

APPEARS THIS WAY
ON ORIGINAL

00-5190

32 DENISON PARKWAY WEST
CORNING, NY 14830
(607) 937-3333
1-(800) 562-7431

FEDERAL BUILDING, ROOM 122
JAMESTOWN, NY 14701
(716) 484-0252

700 WESTGATE PLAZA
OLEAN, NY 14760
1-(800) 562-7431

69 SOUTH STREET
AUBURN, NY 13021
(315) 255-3045
1-(800) 562-7431

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FILE 4/3 200

SEP 12 2000

The Honorable Lynn C. Woolsey
House of Representatives
Washington, D.C. 20515-0506

Dear Ms. Woolsey:

Thank you for your continued interest generally in women's health issues, and specifically in the approval status of mifepristone (RU-486). This is in response to your letter of June 22, 2000, expressing your concerns about information reported by the press regarding alleged restrictions the Food and Drug Administration (FDA or the Agency) might be considering for RU-486.

As you know, there are strict limits on what FDA may legally disclose about a pending new drug application. In reviewing any product, science guides our decision-making. One of the fundamental things that is considered in any application is the safety of the product. No medical product is without risk. In the safety assessments, the benefits are considered as well as how the risks can be best recognized, managed, and kept to a minimum. The evidence on efficacy is also considered by the review team. This combination of determining safety and efficacy for the product's intended use is the one most well understood. Less frequently understood, but also important, are considerations as to how the product will be distributed. This again is a risk management consideration. Generally, if the risks of a product can be understood and managed by the consumer, the product is made available over-the-counter. If, however, a physician's involvement is needed to assist in managing risk, the product is designated as a prescription drug. Among prescription products, most are available to any licensed practitioner, but some are more limited in the scope of distribution.

The other pivotal elements of the review process relate to the manufacture of the product in question and whether the company

	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
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is in compliance with current good manufacturing practices, which assures that the approved product can be consistently manufactured.

Some of these issues with respect to RU-486 were discussed in an open Advisory Committee. Enclosed is the transcript, of that meeting for your review. It is also available on the Internet at:

www.fda.gov/ohrms/dockets/ac/cder96+.htm#Reproductive HealthDrugs.

As with all other products under review, we are working closely with the sponsor of the application for RU-486, as they seek approval of their product for marketing.

Thanks again for contacting us regarding this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

APPEARS THIS WAY
ON ORIGINAL

bcc: HFW-10
HFW-1
HFW-14
HFD-001
Rd: 6/22/00
Edits: 6/29/00
Revised: 6/29/00
Cleared: 6/30/00
Cleared: 6/30/00
Reviewed/Revised: OCC: 7/7/00
Cleared: 7/7/00
Cleared: :7/10/00
F/T:brl:9/1/00:G:\WP\ \00-4336.doc
Control No. 00-4336

APPEARS THIS WAY
ON ORIGINAL

LYNN WOOLSEY
6TH DISTRICT, CALIFORNIA

COMMITTEES:
SCIENCE
EDUCATION AND THE WORKFORCE
STEERING

E-MAIL ADDRESS:
lynn.woolsey@mail.house.gov

WEB PAGE ADDRESS:
http://www.house.gov/woolsey/

Congress of the United States

House of Representatives

Washington, DC 20515–0506

WASHINGTON OFFICE
439 CANNON BUILDING
WASHINGTON, DC 20515–0506
TELEPHONE: (202) 225–5161

DISTRICT OFFICES
1101 COLLEGE AVE., SUITE 200
SANTA ROSA, CA 95404
TELEPHONE: (707) 542–7182

NORTHGATE BUILDING
1050 NORTHGATE DRIVE, SUITE 140
SAN RAFAEL, CA 94903
TELEPHONE: (415) 507–9554

June 22, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

I am writing to express my support for the Food and Drug Administration's (FDA) effort to review mifepristone (RU-486) for approval. However, I am deeply concerned about recent press reports about proposed restrictions.

I understand that the FDA has not publicly issued its proposed guidelines or a formal statement about the release of RU-486. As you know, there has been a public dialogue about possible restrictions that would severely limit which doctors can prescribe RU-486. I am concerned that only allowing those trained in abortion procedures to prescribe RU-486 would drastically limit its access for women who rely on general practitioners or clinics for medical treatment. This could disproportionately affect women with low incomes or residents in rural areas.

Further, I have strong concerns about the proposed restrictions that require doctors administering RU-486 to be listed on a national registry. Considering the threats, harassment, and acts of violence that have been committed against pro-choice doctors, health clinics, and women throughout the United States, I fear that such a list would severely threaten their security.

Please know that ensuring all women in the U.S. retain their constitutional right to make safe reproductive health choices is a top priority of mine. Thank you for your attention to my concerns, ~~and I look~~ forward to receiving your response.

Sincerely,

Lynn Woolsey
Member of Congress

No. 00-4336

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MF 43-253

Rousel 11Cl

JUL 10 2000

The Honorable Barbara Boxer
United States Senate
Washington, D.C. 20510-0505

Dear Senator Boxer:

Thank you for your continued interest generally in women's health issues, and specifically in the approval status of mifepristone (RU-486). This is in response to your letter of June 9, 2000, expressing your concerns about information reported by the press regarding alleged restrictions the Food and Drug Administration (FDA or the Agency) might be considering for mifepristone.

As you know, there are strict limits on what FDA may legally disclose about a pending new drug application. In reviewing any product, science guides our decision-making. One of the fundamental things that is considered in any application is the safety of the product. No medical product is without risk. In the safety assessments, the benefits are considered as well as how the risks can be best recognized, managed, and kept to a minimum. The evidence on efficacy is also considered by the review team. This combination of determining safety and efficacy for the product's intended use is the one most well understood. Less frequently understood, but also important, are considerations as to how the product will be distributed. This again is a risk management consideration. Generally, if the risks of a product can be understood and managed by the consumer, the product is made available over-the-counter. If, however, a physician's involvement is needed to assist in managing risk, the product is designated as a prescription drug. Among prescription products, most are available to any licensed practitioner, but some are more limited in the scope of distribution.

The other pivotal elements of the review process relate to the manufacture of the product in question and whether the company is in compliance with current good manufacturing practices,

5494

APPEARS THIS WAY ON ORIGINAL

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COPY								

which assures that the approved product can be consistently manufactured.

Some of these issues with respect to RU-486 were discussed in an open Advisory Committee. Enclosed is the transcript, (in two versions, one with an index) of that meeting for your review.

As with all other products under review, we are working closely with the sponsor of the application for RU-486, as they seek approval of their product for marketing.

Thank you for your continued interest in this matter.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

APPEARS THIS WAY
ON ORIGINAL

bcc: HFW-10
HFW-1
HFW-14
Rd: 6/22/00
Edits: 6/29/00
Revised: 6/29/00
Cleared: 6/30/00
Cleared: 6/30/00
Reviewed/Revised: : OCC: 7/7/00
Cleared: 7/7/00
Cleared: :7/10/00
F/T:brl:7/10/00:G:\WP\ boxer2.doc
Control No. 00-3973

APPEARS THIS WAY
ON ORIGINAL

United States Senate
HART SENATE OFFICE BUILDING
SUITE 112
WASHINGTON, DC 20510-0505
(202) 224-3553
senator@boxer.senate.gov
http://boxer.senate.gov

BUDGET
ENVIRONMENT AND PUBLIC WORKS
FOREIGN RELATIONS

June 9, 2000

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

Dear Dr. Henney:

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

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

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

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

Barriers to RU-486 could discourage women from receiving a safe and effective alternative to surgical abortion, prevent effective treatment of other diseases (such as breast cancer, Cushing's disease, AIDS, endometriosis, infertility, and uterine fibroids), compromise the physical safety of women and physicians at reproductive health facilities, and threaten privacy.

I certainly trust that the press reports will prove erroneous. Please contact my health aide, Dana Lewis ~~(224-1~~966), on this urgent matter.

Sincerely,

Barbara Boxer
United States Senator

Original ltr to fax rec'd
NB.00-3973

1700 MONTGOMERY STREET
SUITE 240
SAN FRANCISCO, CA 94111
(415) 403-0100

312 N. SPRING STREET
SUITE 1748
LOS ANGELES, CA 90012
(213) 894-5000

501 'I' STREET
SUITE 7-600
SACRAMENTO, CA 95814
(916) 448-2787

1130 'O' STREET
SUITE 2450
FRESNO, CA 93721
(559) 497-5109

600 'B' STREET
SUITE 2240
SAN DIEGO, CA 92101
(619) 239-3884

201 NORTH 'E' STREET
SUITE 210
SAN BERNARDINO, CA 92401
(909) 888-8525

43-253

MAY 25 2000 Roussel UCLAF

The Honorable Robert C. Byrd
United States Senate
Washington, D.C. 20510-6025

Dear Senator Byrd:

Thank you for the letter of March 13, 2000, on behalf of your constituent, [redacted] who wrote concerning the status of the drug product, mifepristone (French brand name - RU486).

The current status of this product application is that it has not been approved by the Food and Drug Administration (FDA or the Agency), and final action on the new drug application (NDA) is still pending. On February 18, 2000, FDA issued a second "approvable" letter to the sponsor, The Population Counsel of New York City. The first one was issued on September 18, 1996. A copy of each is enclosed for your information.

An "approvable" letter is an interim measure the Agency can take when, at the end of a review period, the application substantially meets the requirements of the regulations but specific additional information or material is needed to complete the application. As indicated in the press release, under the Prescription Drug User Fee Act, the Agency was required to take some action within six months of receiving additional information from the sponsor that was in response to an original action.

Confidentiality rules prohibit the Agency from disclosing any details about the contents of an approvable letter unless this information has first been made public by the sponsor of the application. In addition, FDA does not give an advance indication when or whether or not an application will actually receive a final approval until a decision has been made by the reviewers and first is announced to the sponsor.

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Thank you for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

2 Enclosures

APPEARS THIS WAY
ON ORIGINAL

bcc: HFW-10
HFW-1
HFW-14
R/D: [redacted]:5/12/00
F/T:brl:5/17/00:G:\WP[redacted]\00-1974.doc
Control No. 00-1974

APPEARS THIS WAY
ON ORIGINAL

United States Senate

COMMITTEE ON APPROPRIATIONS
WASHINGTON, DC 20510–6025

March 13, 2000

Ms. Melinda K. Plaisier
Associate Commissioner for Legislative Affairs
Food and Drug Administration
Parklawn Building
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857

Dear Ms. Plaisier:

The enclosed communication is respectfully referred for your consideration, since it appears to be a matter that falls within your jurisdiction.

I would appreciate your looking into this matter and providing me with comments that might serve as the basis for a reply to [redacted]

With kind regards, I am

Sincerely yours,

Robert C. Byrd

Robert C. Byrd

RCB:spp
Enclosure

No 00-1974

MIF 006380

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 21 2000

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your continuing interest in the safety of the nation's drug supply. This is in response to your letter of October 27, 2000, requesting documents related to the Shanghai Medicinal Company, No. 15 Pharmaceutical Factory.

You asked that the Food and Drug Administration (FDA or the Agency) provide "all records relating to the Drug Master File and inspection records" concerning the subject facility. In a telephone conversation with [redacted] of my staff on November 2, 2000, Mr. Alan Slobodin, Senior Oversight Counsel, indicated that inspection records on or after January 1, 1997, would meet the Committee's needs at this time.

Documents responsive to your request are enclosed. Some of the enclosed documents contain confidential commercial and trade secret information protected from disclosure to the public. We ask that the Committee not publish or otherwise make public any such information contained in this letter. We would be glad, of course, to discuss with Committee staff the confidentiality of any specific information.

Thanks again for your continuing interest in this matter. If you have further questions, please let us know.

Sincerely.

151

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures

(See Separate file)

cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce

bcc: HFW-10
HFW-1
HFW-14
R/D: [redacted] :11/20/00
Clr: [redacted] :11/21/00
F/T:ue:11/21/00: [redacted]
Control No. 00-6597

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

October 27, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
Room 14-71 (HF-1)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

Pursuant to its public health oversight responsibilities under Rules X and XI of the U.S. House of Representatives, the Committee has been investigating FDA's activities relating to counterfeit bulk drugs since August 4, 1998. As part of this effort, the Subcommittee on Oversight and Investigations held hearings on June 8, 2000 and October 3, 2000.

Last month Committee staff and the FDA's Associate Commissioner for Regulatory Affairs accompanied FDA inspectors during inspections of bulk drug plants in China and India. These visits further highlighted the concerns about bulk drug manufacturing in the Far East and the challenges that FDA faces in monitoring this manufacturing. As a result of these visits and other recent matters brought to the Committee's attention, I request that the FDA immediately provide the following by November 10, 2000:

1. All records relating to the Drug Master File and inspection reports concerning Shanghai Medicinal Co., No.15 Pharmaceutical Factory.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the Attachment to this letter.

00-6597

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

Tom Bliley
Chairman

cc: The Honorable John D. Dingell, Ranking Member

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 22 2000

The Honorable Thomas J. Bliley, Jr.
Chairman
Committee on Commerce
House of Representatives
Washington, D.C. 20515-6115

Dear Mr. Chairman:

Thank you for your continued interest in the issue of counterfeit bulk drugs. This letter is in final response to your letter of September 25, 2000, requesting documents relating to two companies.

Our letter of October 10, 2000, contained a partial response that included Establishment Inspection Reports and Form 483 documents regarding Southwest Synthetic Pharmaceutical Co., Ltd., and Shanghai Hualian Pharmaceutical Co., Ltd.

For this final response, Mr. Slobodin recently requested the Drug Master Files relating to the two companies. [redacted] Southwest Synthetic Pharmaceutical Co., Ltd. [redacted] With regard to Shanghai Hualian Pharmaceutical Co., Ltd., the Food and Drug Administration has no record of Drug Master Files for any products manufactured by this company.

Information contained in the enclosed, unredacted documents include commercial confidential and trade secret information that is considered confidential under the Trade Secrets Act, the Freedom of Information Act, and regulations implementing these Acts. We ask, therefore, that none of this information or the documents be released to the public. We would be glad, of course, to discuss the confidentiality of any particular information.

Thanks again for your continued interest in this issue. If we may be of further assistance, please let us know.

Sincerely

/S/

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosures
(See Separate Ltr)

cc: The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce

bcc: HFW-10
HFW-1
HFW-14
Drafted: [redacted] 12/21/00
R/E/Cleared [redacted] 12/21/00
R/E: [redacted] 12/22/00
F/T:lcg:12/22/00: [redacted]
Control No. 00-5922

U.S. House of Representatives
Committee on Commerce
Room 2125, Rayburn House Office Building
Washington, DC 20515–6115

September 25, 2000

The Honorable Jane Henney, M.D.
Commissioner
Food and Drug Administration
Room 14-71 (HF-1)
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Henney:

Pursuant to its public health oversight responsibilities under Rules X and XI of the U.S. House of Representatives, the Committee has been investigating FDA's activities relating to counterfeit bulk drugs since August 4, 1998. As part of this effort, the Subcommittee on Oversight and Investigations held a hearing on June 8, 2000 and will be holding a follow-up hearing on October 3, 2000.

This month Committee staff and the FDA's Associate Commissioner for Regulatory Affairs accompanied FDA inspectors during inspections of bulk drug plants in China and India. These visits further highlighted the concerns about bulk drug manufacturing in the Far East and the challenges that FDA faces in monitoring this manufacturing. As a result of these visits and other recent matters brought to the Committee's attention, I request that the FDA immediately provide the following by September 27, 2000:

1. All records relating to the Drug Master File and inspection reports concerning Southwest Synthetic Pharmaceutical Co., Ltd.

2. All records relating to the Drug Master File and inspection reports concerning Shanghai Hualian Pharmaceutical Co., Ltd.

This quick response is appreciated as this background information should be useful for the preparations of the October 3rd hearing.

Please note that, for the purpose of responding to these requests, the terms "records" and "relating" should be interpreted in accordance with the Attachment to this letter.

60-5922

Thank you for your assistance. If you have any questions, please contact Alan Slobodin of the Committee staff at (202) 225-2927.

Sincerely,

Tom Bliley
Chairman

cc: The Honorable John D. Dingell, Ranking Member

Attachment

ATTACHMENT

1. The term "records" is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.

2. The terms "relating," "relate," or "regarding" as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.

ROUSSEL UCLAF

Docteur Edouard Sakiz
Président du Conseil de Surveillance

Paris, May 25th, 1994

Food and Drug Administration
5600 Fishers Lane - Rm. 14-81
Rockville, MD 20857
USA

Dear —

It gives me tremendous pleasure to write to you on behalf of all of us at Roussel Uclaf, in order to say how thankful and grateful we are to you for your personal involvement in the RU 486 project.

Without your help and Dr. Kessler's assistance, the successful resolution that Secretary Shalala announced on May 16th could not have taken place.

Your professionalism and dedication made a great impression on us. I am sure that American women will appreciate that their Government has proved its determination to give them access to a new drug in order to protect their health and safety.

I look very much forward to meeting you again if an opportunity should arise and remain,

With best regards,

Sincerely,

APPEARS THIS WAY
ON ORIGINAL

35, Boulevard des Invalides 75007 Paris
Tél. + 33 (1) 40 62 44 28 Fax. +33 (1) 40 62 44 90 Tlx. GRUPA 200 675 F
Roussel Uclaf, Société Anonyme à Directoire et Conseil de Surveillance
au capital de 505 672 940 F - R.C.S. Paris B 542 008 081

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE

June 9, 1994

Docteur Edouard Sakiz
Président du Conseil de Surveillance
Roussel Uclaf
35, Boulevard des Invalides
75007 Paris, France

Dear Edouard,

I want to thank you very much for your kind letter of May 25. I also want you to know what a pleasure it has been working with you over the past year.

Although we faced some difficult moments together, I recognize that our mutual success was brought about in large part through your personal dedication, hard work, and conviction that RU-486 should be made available to women in this country if it is found to be safe and effective through our regulatory review process. I also want to express my appreciation to others at Roussel Uclaf who made this possible.

If I return to Paris and have an opportunity to visit with you, I will certainly let you know. Until then, my very best wishes to you.

Sincerely yours,

(S)

APPEARS THIS WAY
ON ORIGINAL

RU-486
Roussel UCLAF

JUL 16 1991

~~June 26, 1991~~

Memorandum of Meeting

Roussel UCLAF Representatives:

Andre Ulmann, M.D., Ph.D. - Head, Clinical Research
Clinical Research Department
Louise Silvestre, M.D. - International Product Manager, Endocrinology

FDA Staff:

NIH Staff:

Dr.

Purpose:

The meeting was requested by Dr. Ulmann to discuss the status of RU-486 in Europe.

Discussion and Conclusions:

Dr. Ulmann indicated the following:

1. The French government has asked Rousell UCLAF to undertake a 1000-women study of the safety and efficacy of the use of the Searle orally active prostaglandin, Cytotec, as an alternative to the subcutaneously administered PG (Sulprostone) or the vaginal suppository PG (Gemprost) currently used in France. (Neither product, however, has this use in its labelling.)

2. Approval of RU-486 in the UK is imminent, but approval of the French regime (RU-486 followed by a PG in two days) may be compromised by the fact that the company which markets the approved prostaglandin (Gemprost) may not be willing to add this indication to its label.

3. Roussel UCLAF intends to study several other indications for RU-486, including labor induction (in France) and breast cancer (in France and Canada).

4. The current contract with the Population Council concerning RU-486 for abortion would permit the PC to expand on its current IND ad lib and/or apply for a NDA.

/S/ 7/16/91

ROBERT L. LIVINGSTON
1ST DISTRICT, LOUISIANA

APPROPRIATIONS COMMITTEE
SUBCOMMITTEE
DEFENSE

PERMANENT SELECT COMMITTEE
ON INTELLIGENCE

WASHINGTON OFFICE
ROOM 2412
RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-3015

DISTRICT OFFICE:
111 VETERANS BLVD
SUITE 700
METAIRIE, LA 70005
(504) 589-2753

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

December 2, 1988

Dr. Frank E. Young
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Young:

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

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

Sincerely,

ROBERT L. LIVINGSTON
Member of Congress

RLL/tc

Enclosure

APPEARS THIS WAY
ON ORIGINAL

MIF 006395

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 28 1988

A.F. 4B-553 FILE

The Honorable Robert L. Livingston
House of Representatives
Washington, D.C. 20515

Dear Mr. Livingston:

This is in response to your letter of December 2, 1988, 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 in the United States. However, 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 and therefore, clinical testing was allowed to proceed.

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

We understand your constituent's concern and respect the personal position expressed about abortion in general. However, we hope that he will understand that our authority is limited to safety and efficacy of a new drug if the data to support such action are submitted to the Agency.

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
Constituent's letter

cc: HFW-10(2)
R/D: :8/25/88
R/D:wgr:12/20/88
R/T:wgr:12/21/88 .8:RU-486)

ED - 12/20/88

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
OLA	-IST-	12/28/88						

FILE COPY

MIF 006396

N ov 20, 1988

NOV 28 1988

Dear Congressman Livingston

I am very proud to have you as my representative in the Congress. Few men have the courage to stand up for what is right. I believe you are one of these men Mr Livingston. You have on every available opportunity stood up for the most helpless of our society, the unborn. Abortion has claimed approximately 23 million lives in the U.S. since Roe vs Wade.

I am writing you today about a new threat to the unborn child, the "at home abortion pill" such as the french version, RU 486, which is soon to be mass produced and made available in France.

The home is the last stronghold of preserving the sacredness and unity of the American family. We must never allow the home to become a killing ground and the parents the executioners. Abortion is tearing the moral fabric of our society, and if we allow abortions in the home, the moral fabric of our society will be torn to shreds.

I am asking you today to please work with other members of congress in banning RU 486 and any other type of "at home abortion pill" in the United States before they come on the market.

I know I can depend on you, but most of all the unborn children are depending on you to secure for them their God given right to life. Thank you again for all of your support for the unborn over the years and hopefully we will stop this holocaust soon.

We'll be praying for you to receive Divine guidance and strength. Please let us know if it is possible for you to put forth this legislation.

Sincerely,

[redacted]

[redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

A.F. 43-253

The Honorable Dan Quayle
United States Senate
Washington, D.C. 20510

AUG 29 1988

Dear Senator Quayle:

This is in response to your letter of July 22, 1988, 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.

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 and therefore, clinical testing was allowed to proceed.

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

We understand your constituent's concern and respect the personal position expressed about abortion in general. However, we hope that she will understand that our authority is limited to safety and efficacy of a new drug if the data to support such action are submitted to the Agency.

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

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

cc: HFW-10(2) :8/25/88
R/D: .8:RU-486)
R/T:wgr:8/26/88
f/T:wgr:8/26/88

FILE

COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFW12	/S/	8/29						

MIF 006399

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COMMITTEES
ARMED SERVICES
BUDGET
LABOR AND HUMAN RESOURCES

July 22, 1988

Dept. of Health & Human Services
Food & Drug Administration
Congressional Liaison
Rockville, Maryland 20857

Dear Sir:

Enclosed you will find a copy of a letter I received from _____. I have indicated to my constituent that I have brought this matter to your attention and would appreciate your thoughts and comments.

Please direct your response to my Washington office marked to the attention of Carolyn Washington.

Thank you for your assistance and consideration in this matter.

Sincerely,

Dan Quayle
United States Senator

DQ/cw
Enclosure

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