

THE ABORTION PILL

STUDY GUIDE

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1. INTRODUCTION

A. PRESS CLIPPINGS

The New York Times

New War Zone, New Tactics:

‘*The Abortion Pill* may well change the nature of the protests against abortion...the change in image from an operating table to a pill could mean a lessening of personal passion and, many Americans must hope, of the political passions that have swirled about this issue since the days of *Roe vs. Wade*.’

-Walter Goodman

USA Today

‘Balanced treatments of medical controversies: in *The Abortion Pill* the history of the RU486 is couched in the debates that have kept it from being distributed in the United States.’

- Matt Roush, Critic’s Corner

Time Out, New York

‘*The Abortion Pill* provides a thoughtful overview of the latest battleground in this continuing American conflict.’

- Julie Wiskirchen

Note: If you would like to begin a discussion with the video and do not need an introductory briefing, proceed to section 2: How to Use the Study-Guide.

B. WHAT IS RU486 AND HOW IS IT USED?

Known in the United States as Mifepristone, RU486, is an antiprogestin, one of a new generation of birth control drugs. It is a steroid that blocks the action of the hormone progesterone. Since progesterone is required to sustain an early pregnancy, if this support is blocked, the pregnancy is halted. A prostaglandin called cytotec, but known by its generic name in the U.S. as misoprostol, is taken two days later to cause uterine contractions which will expel any remaining tissue and insure that the abortion is complete. In essence, a mifepristone – misoprostol abortion has been called “biologically indistinguishable from a miscarriage.” RU486 offers women the opportunity for a medical rather than surgical abortion that takes place much earlier than the surgical procedure. The woman does not undergo a surgical operation, but rather ingests pills herself.

Developed in France, the drug has been used by more than two hundred thousand French women. 96% of women who were treated with RU486 and a prostaglandin before their seventh week had a complete abortion. Clinical trials in Britain have shown success rates similar to those in France. In the US, clinical trials on 3,000 women confirmed the European test data.

There have been side effects associated with RU486 abortions, including cardiovascular complications and excessive bleeding. Statistically, the side effects are not considered significant in the FDA's assessment of the regimen as "safe and effective."

xxany new health data

The use of RU486 as an abortifacient is best known; its additional roles, ranging from cervical dilation and labor induction to reduction of certain tumors, is one of the on-going areas of antiprogestin research.

C. THE CONTROVERSY BEHIND RU486

Abortion is one of the most divisive political issues in America today. In the center of this pitched controversy, RU486, known as "the abortion pill" by some and "the moral property of women" by others, has become a symbolic and real linchpin in the battle over abortion in the U.S. As of 1999, politics still blocked its entry to the U.S. market, where it is currently known by its generic name, mifepristone.

The *Abortion Pill* is a behind the scenes look at the issues and the people that have fueled the controversy surrounding RU486, showing what happens when a scientific discovery drops into a maelstrom of ethics, politics, religion, and business.

The documentary chronicles a decade of controversy:

- **The reasons for Roussel-Uclaf's (the French manufacturer of RU486) refusal to market the pill in the United States.**
- **The Food and Drug Administration's import ban on RU486 in June of 1989 and its repercussions for research.**
- **President Clinton's marked reversal of policy set by both Presidents Reagan and Bush.**
- **The clandestine use of the prostaglandin pill on the black market in Brazil.**
- **The Population Council's role in bringing RU486 to America, its role in staging clinical trials in the developing world and in the U.S.**
- **Why RU486 is still not available on the U.S. market in 1999.**
- **The experience of women in the U.S., in France, in England, China and India with RU486.**

D. RU486'S FUTURE

When the video was completed in 1997 Hoescht, the German manufacturer of RU486 had just relinquished all of its rights to the drug to Roussel Uclaf, its French subsidiary.

Roussel in turn gave their rights to Euouard Sakiz, who formed a company to oversee its marketing called Exelgyn. Despite early high expectations for more widespread distribution, the drug is now only distributed in France, England and Sweden. Hoescht AG and Roussel Uclaf abandoned the drug because it had become a high profile hot potato in the abortion battle, bringing with it the undesirable, and continuous attention of anti abortion activists.

In the United States, the FDA declared RU486 safe and effective in 1996, but withheld final approval until it received additional information on its manufacture and labeling. In the meantime, in mid-1998 the House attached a measure to an agriculture bill, in an attempt to block the FDA from using federal money to test, develop or approve any drug that would induce an abortion. Under threat from a veto by Clinton, the provision never materialized and it was dropped in conference.

The Population Council, a private, not for profit organization in New York city dedicated to “improving the well being and reproductive health of current and future generations around the world” holds the US rights to market the drug. They created a privately held company ‘Advances/Neogen’, now called the Danco Group, as licensee to handle manufacturing, distribution, and marketing in the US. Although it has suffered a series of setbacks, Danco expects to make Mifopristene available by the next century.

With importation of the drug banned, so far only women enrolled in clinical trials can legally obtain the drug in the United States. A New York abortion-rights group, the Abortion Rights mobilization (ARM) has been manufacturing a small amount in the US, cloned from the Chinese version. ARM is legally able to copy RU486 for clinical research as long as it does not sell it for profit. As of March 1999, ARM said that it had performed 3000 trials. ARM’s production capabilities do not extend beyond the manufacture of 100,000 pills at its secret US plant.

A Population Council study published recently in the Archives of Family Medicine found that among 2,121 women who participated in their clinical trials in the U.S., 96 percent would recommend the regimen to others, 91 percent would choose it again, and 88 percent found it very or moderately satisfactory.

xxpolitical updates?

2. HOW TO USE THIS STUDY GUIDE

The Abortion Pill is an hour long. For the sake of clarity and organization, questions have been grouped into four major areas. These questions can be used as a way to focus on a specific area of interest or as a way to generate a broader discussion of issues and ideas. Quotes from the documentary act as a catalyst, leading into the group discussion.

The sections have been grouped according to topic; different audiences should select the appropriate area of interest. There may be relevant questions in other topic areas as well.

A. THE WOMAN’S STORY

Anti-RU486

‘There is little doubt among those of us who work with post-abortion peer support groups that a woman who takes by her own hand the RU486 drug cocktail, which will

kill her child, could experience an emotional backlash of enormous proportions.’

- Olivia Gans, American Victims of Abortion

Pro-RU486

‘I think many women, myself included, realized that a non-surgical alternative to abortion seems for a lot of women, safer, more private, less invasive, and perhaps healthier. - Janet Benshoof, Center for Reproductive Law and Policy.

Anti-RU486

‘How can three visits to the abortionist be a private method of abortion? And we strongly disagree with the statements of its safety. We think it’s a very dangerous, powerful, synthetic steroid that can harm women in the short term, cause injuries and possibly deaths and can harm women in the long term in ways that we are not even sure of yet.’ – Dick Glasow, Right To Life

Pro-RU486

‘Taking a pill is like taking an aspirin, much more natural... With this I spend two or three hours and now I’m going to work. There were no problems. It’s very simple.’ – Catherine Nguyen: French woman.

Anti-RU486

‘As a doctor I believe that not only is Mifepristone safe and effective, but for some women, it may be the most appropriate means of terminating a pregnancy.’

- Dr. Paul Blumenthal, National Abortion Federation

Discussion

- A.1.** Since RU486 is followed 48 hours later with a prostaglandin, requiring two visits to a facility over a period of 3 days many people argue that with the pill, women will be taking greater responsibility for the decision to abort. Discuss how these differences might affect women (psychologically and otherwise) who use the pill.
- A.2.** What are the pros and cons of medical abortion compared to surgical abortion? In what ways will the more private nature of taking the abortion pill change the public debate surrounding abortion?
- A.3.** RU486 is now legal. What are the challenges now?

B. THE BUSINESS STORY

Anti-RU486

‘This is a company (Hoescht AG) that’s worried about its public image. It just seems inconceivable that a company that has this kind of smarts would want to get involved with a death drug.’

– Richard D. Glasow, Right to Life

Anti-RU486

‘Product liability will forever be the monster in the United States. It doesn’t matter what laws the Congress passed to protect this drug personally or privately or because of it’s political correctness or because a President likes it or a House Committee Chairman likes it. It will forever be vulnerable to product liability.’

– Ken Dupin, Minister, Anti-Abortion activist

Comment

‘Boycotts aren’t usually financially very effective. But what they do is distract a company from its main business.’

– Alta Charo, university of Wisconsin, Assistant Professor of Law and Ethics

Discussion

- B.1.** What is the role of the FDA and why did they place RU486 on an import alert ban?
- B.2.** It is unusual for a not-for-profit like the Population Council to be bringing a for-profit drug to the U.S. market. Discuss the implications of such a situation.
- B.3.** What is the role of public and not for profit agencies in developing reproductive technologies, as compared to other scientific developments?
- B.4.** What is the role of FDA testing in bringing a drug to market – how expensive is it, what does it accomplish?
- B.5.** The Population Council set up U.S. clinical trials when the FDA had concluded that European testing data was sufficient because of the extraordinary politicized history of RU486. What are the economic and political implications of this action?

xxupdate

C. THE SCIENTIFIC STORY

Pro-RU486

‘The discovery of antiprogestins has been called the most significant advance in birth control technology since the discovery of the Pill...’

- Carl Djerassi, Inventor of the birth control pill.

Pro-RU486

‘...what is really paradoxical [is] that in USA where you have so good science, women don’t have it.’ – Etienne Emile Baulieu, creator of RU- 486.

Pro-RU486

‘Science definitively, and in this field particularly, can help life of individuals and in that case ordinary women, all women, but there are controversies. But we know that the controversies are not medical, not scientific, they are of a social nature, due to society’s

conflicting ideologies. So, science will probably win anyway.’ – Etienne Emile Baulieu, creator of RU486.

Pro-RU486

‘The genie is out of the bottle on this technology and there is no stopping it now.’
-Joan Dunlop, International Women’s Health Project

Discussion

- C.1.** The inventor of RU486 has described its action as a ‘lock and key’ mechanism. Discuss more fully what is meant by this term and why this is such a scientific breakthrough.
- C.2.** How does RU486 mimic a miscarriage?
- C.3.** In the late 1980’s every major U.S. medical association passed resolutions in support of RU486. What role does the medical/scientific community have in supporting the approval of politically controversial drugs like RU486?
- C.4.** How can doctors and scientists deal with the increasing politicization of drugs to facilitate abortion as well as those to treat illnesses like HIV?

D. THE POLITICAL STORY

Anti-RU486

‘RU486 allows a woman to believe that she is not aborting; this moral ambiguity abuses the most basic human right.’
-Sidney Callahan, Professor of Psychology, Mercy College, N.Y.

Pro-RU486

‘...These circumstances rival the nonsense to be recalled in the Scopes Monkey Trial of the 1920's where logic and reason were challenged by zealots... Now the issue is abortion.’
-Gary Hodgen, Professor and President, Jones Institute for Reproductive Medicine, Eastern Virginia Medical School

Anti-RU486

‘The abortifacient RU486 allows us as a society for the first time the opportunity to escape the reality of abortion. One will merely take a trip to the medicine cabinet and somewhere behind the Zanax or the Valium will exist the ability to terminate life. I find this humanly very logical but morally repulsive.’
-Ken Dupin, Minister, Anti-Abortion activist

Anti-RU486

‘This is Saddam Hussein in pill form’ – Keith Tucci, Operation Rescue.

Pro-RU486

‘I feel that it is something that I thought would never happen in our country where politics would interfere with the progress of scientific development and health care in our country.’ – Eleanor Smeal, Fund for a Feminist Majority

Anti-RU486

‘How do you demonstrate against someone who’s doing something in private? Now, here’s the strategy: you picket against the company that makes the pill for American consumption.’ – Phil Donahue, talk show host

Discussion

- D.1.** Discuss how medical abortion might change the tactics of both pro-choice and anti-abortion groups.
- D.2.** What are some of the political “lessons” to be learned from the decade-long struggle to gain FDA approval for the drug and the on-going fight to introduce it to the U.S. market?
- D.3.** Can political considerations be eliminated from the drug approval process? If so, how?

E. THE INTERNATIONAL STORY

‘Because at that time, my economic circumstances didn’t allow me to have a child...One of my friends told me about a very good medication...She said it was expensive, but it was less than an abortion.’

– Dorothea Castro: Brazilian woman

Discussion

- E.1.** If an abortion pill is cheaper than surgery, this will make abortion more available to poor women in third world countries, discuss the economic implications of the abortion pill for women.
- E.2.** Discuss the different experiences that women face in the U.S., in France, in England, China and India with RU486.
- E.3.** Why is RU486 suitable in developing countries?
- E.4.** What are the problems that are posed with a three-stop procedure?
- E.5.** In the case of Brazil, where abortion is illegal, women use cytotec or mifegene, the second part of the procedure, to induce a medical abortion. What are the implications of the use of drugs designed for one purpose but used for another?

xxis it still illegal

3. OUTREACH RESOURCES

ORGANIZATIONS TO CONTACT:

Fund for a Feminist Majority **

<http://www.feminist.org>

(check out site for other links)

National Abortion Rights Action League (NARAL)

www.naral.org

National Organization for Women (NOW)

www.now.org

Planned Parenthood Federation of America

plannedparenthood.org

The Population Council

www.popcouncil.org

Medical Students for Choice

www.ms4c.org

National Right to Life

www.nrlc.org

4. APPENDICES

A. CHRONONLOGY OF RU486

1983

Clinical trials on the use of RU486 as a method of early abortion begin in the United States at the University of Southern California.

1988

RU486 becomes available in France in October 1988, after the French Minister of Health declares RU486 "the moral property of women" and orders Roussel Uclaf to return RU486 to the market following the company's decision to withdraw the drug in the wake of anti-abortion pressure.

Anti-abortion forces threaten Roussel Uclaf's parent company, Hoechst AG, with economic reprisal if RU486 is marketed in the United States.

1989

In March, Hoechst informs abortion opponents that "it is not our intention to market or distribute RU486 outside of France."

The U.S. Food and Drug Administration responds to pressure from anti-abortion Congressional representatives by banning the importation of RU486 for personal use.

1990

Congressman Ron Wyden holds hearings on RU486 before the House Small Business Committee. Scientists testify that the import alert has hindered research on non-abortion indications of RU486, including its use as a possible treatment for breast cancer. Following these hearings, Congressman Ron Wyden introduces legislation to remove the import alert.

1991

The American Association for Advancement of Science (AAAS) endorses the testing and use of RU486.

New Hampshire becomes the first state in the nation to pass a resolution urging the commencement of clinical trials of RU486 in that state. Subsequent RU486 resolutions are passed in other state legislatures.

1992

In the first direct challenge to the FDA import alert on RU486, a pregnant American woman, Leona Benten, returns from Europe with a prescription of RU486. Customs officials seize the RU486 upon the arrival of Benten and Larry Lader of Abortion Rights Mobilization at JFK Airport. Despite a lower court ruling in favor of Benten's right to RU486, the Supreme Court refuses to order Customs to return the RU486 to Benten or the FDA to overturn the import ban.

New England Journal of Medicine study concludes that RU486 is a safe, effective post-coital contraceptive, which has fewer side effects and is easier to use than the current "morning-after" pill.

Clinton is elected as President of the United States. During the campaign, Clinton pledged his support for bringing RU486 to this country.

FDA Commissioner David Kessler writes to Roussel Uclaf encouraging the company to submit an application to license RU486 in the U.S.

1993

President Clinton issues an executive order instructing the FDA to re-evaluate the RU486 import alert and directing the Secretary of Health and Human Services to "assess initiatives... [that can] promote the testing, licensing, and manufacturing of RU486 or other antiprogestins.'

Larry Lader of Abortion Rights Mobilization (ARM) announces that the Peking Union Medical College has given ARM permission to test the Chinese clone of RU486. Later in the year, he announces that the RU 486 compound has been replicated by scientists in New York State.

Hoechst AG and Roussel Uclaf say they will allow the Population Council to test and manufacture RU 486. However, Hoechst AG continues to prohibit Roussel Uclaf from selling RU486 to a U.S. distributor in the interim, while an American manufacturer is established and gains FDA approval

New England Journal of Medicine reports that RU486, in combination with misoprostol in pill form, is now 99% effective in terminating pregnancy during the first nine weeks. This oral prostaglandin, already used in France, replaces prostaglandin injection.

The Institute of Medicine releases a report recommending immediate submission to the FDA of a New Drug Application for the use of RU486 as a method of early abortion and calling for expedited U.S. research on the multiple medical uses of RU486 and other antiprogestins.

Negotiations to allow the Population Council to seek FDA approval for RU 486 stall.

1994

British health authorities allow Marie Stopes Clinic in London to administer RU 486 to American women who travel to Europe the early abortion procedure.

Roussel Uclaf assigns its U.S. patent rights for RU 486 without remuneration to the Population Council. Since this drug will not be licensed or developed in the U.S. by Roussel Uclaf, it no longer will be called RU486, but instead will be referred to by its scientific name, Mifepristone.

Population Council plans next steps of conducting clinical trials on early abortion use, identifying a manufacturer, and winning FDA approval. The Population Council begins clinical trials on mifepristone.

1995

The Population Council concludes clinical trials for mifepristone at over a dozen sites around the US, involving 2100 women.

Dr. Faina Rose announces study results showing that mifepristone inhibits the growth of cancer cells. Dr. David Weiner announces that mifepristone effectively prevents activation of the GR11 receptor. By blocking this glucocorticoid receptor, mifepristone may prevent the cell infection and subsequent replication of the HIV virus.

1996

The FDA Advisory Committee on Reproductive Health Drugs holds mifepristone safety and efficacy public hearings.

1997

Hoechst AG turns over world (non-U.S.) patent rights for mifepristone to Dr. Edouard Sakiz, whose new company, Exelgyn, will distribute the compound as a method of early abortion and will begin testing on the drug's other indications.

1998

Abortion Rights Mobilization announces expansion to U.S. clinical trials on their RU486 clone. To date, 1600 women have been treated at 12 sites.

Advances/Neogen, the commercial entity licensed by the Population Council to market mifepristone in the U.S., makes arrangements for the manufacture and distribution of regime. Advances/Neogen changes its name to the Danco Group.

1999

In March, Abortion Rights Mobilization says it has conducted 3000 clinical trials by March. Danco group says it expects to make mifopristene available by the end of this year.

xxupdate

B. Cast of Characters

(In order of appearance)

Nancy Miller

Aurora Health Services, Nurse
Seattle, WA

Sheryl Knowlen

Aurora Health Services, Client
Seattle, VA

Phil Donahue

Talk Show Host
NBC

Etienne Emile Baulieu

Researcher, Inventor of RU486
Universite, Paris – Sud
Paris, France

Sonya

Talk Show Host
CNN

George Grant

The Quick and the Dead: RU486 and the new chemical warfare against you family
Author

Sybil Shepard

Actress

Bernard Nathanson

The Silent Scream, Producer,
New York, NY

Edouard Sakiz

Roussel UCLAF, former president
Romainville, France

Claude Evin

Former Minister of Health
Paris, France

Catherine Nguyen

Hopital Broussis, client
Paris, France

Sophie Courtade

Hopital Broussais, client
Paris, France

Catherine Francoise

Society for the Protection of Unborn Children
London, England

Dillis Coffey

International Women's Health Coalition
London, England

Frances Perrow

Marie Stopes Clinic
London, England

Caroline Lee

Marie Stopes Clinic, patient
London, England

Helen Axby

Head of Marie Stopes Clinic
London, England

Jaqueline Pitanguy

CEPIA, Former Director
Rio de Janeiro, Brazil

Dorothy Castro

Made illegal use of Cytotec for abortion
Rio de Janeiro, Brazil

Marcos Dias, MD

(Ob-Gyn) Alexander Fleming Hospital
Rio de Janeiro, Brazil

George Bush

Former President of the United States of America

Jesse Helms
Republican Senator
North Carolina

John Wilke
National Right to Life Association, President
Washington, DC

Allan Rosenfield, MD
Columbia School of Public Health, Dean
New York, NY

Caroline Westoff, MD
American College of Obstetrics and Gynecologists
New York, NY

Joe Spidell
Hewlett Foundation, Program Officer
San Francisco, CA

Judith Brown
American Life League, Director
Arlington, VA

Keith Tucci
Operation Rescue, Director
South Carolina

Michelle Cramer
Operation Rescue, member
Melbourne, FL

Ken Dupin
Anti-RU486 activist
Kleinerville, North Carolina

Alta Charo
University of Wisconsin
Assistant Professor of Law and Ethics
Madison, WI

Ron Wyden
Democratic Congressman
Oregon

Robert Dornan

Republican Congressman
California

Mary Pendergast

Food and Drug Administration, Representative
Rockville, MD

Phil Corfman

Food and Drug Administration
Supervising Advisor for Fertility and Maternal Health
Rockville, MD

Eleanor Smeal

Fund for a Feminist Majority, Director
Arlington, VA

Andre Ullman

Roussel UCLAF, Medical Director
Romainville, France

Jennifer Jackman

Fund for a Feminist Majority, Spokesperson
Arlington, VA

Richard Glasgow, PhD

National Right to Life, Former Head of Research
Life Issues Institute, Consultant
Washington, DC

David Grow

Businessman with inoperable brain tumor
Texas

Leona Benton

Social Worker
Attempted to bring RU486 into US for her abortion
San Francisco, CA

Larry Lader

Abortion Rights Activist
Orchestrated Leona Benton's attempt to bring RU486 into US.

Janet Benshoof, JD

Center for Reproductive Law and Policy
New York, NY

Cidney Dawes

Aware Women's Services, Client
Melbourne, FL

Karroll Lucas

Planned Parenthood, Client
Philadelphia, PA

Randall B. Whitney, MD

Abortion Provider
Daytona beach, FL

Elizabeth Karlin, MD

Abortion Provider
Maison, WI

David Kessler

Head of the Food and Drug Administration
Rockville, MD

Maggie Catley Carlson

Population Council, President
New York, NY

Kurus Coyaji, MD

KEM Hospital
Pune, India

Sunari Ravindran

Reproductive Health Matters, Co-editor
Cairo, Egypt

Asok Sasane

Husband of woman who went public with bad experience of RU486
Bombay, India

Banoo Coyaji, Director

Pune, India

Julia Burns

Aurora health Services, Nurse Practitioner
Seattle, WA

Paul Blumenthal, MD

National Abortion Federation, member

Olivia Gans

American Victims of Abortion, Director

Paul Jung, MD

American Medical Students Association, President