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WILL FREEDOM RING SOON FOR THE REPRODUCTIVE RIGHTS MOVEMENT?

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On January 22, 1993, in one of the first acts of his presidency, President Clinton raised the stakes in the controversy surrounding the French-made "abortion pill," RU-486. Clinton signed an executive order allowing RU-486 to be imported into the United States for personal use,¹ and ordered a review of the Food and Drug Administration ("FDA") ban on private importation of the pill.² This order signified the end of a decade of politically motivated, abortion-related bans issued by the FDA.

The President was directly addressing the case of *Benten v. Kessler*,³ in which the FDA seized RU-486 pills from a twenty-nine-year-old woman who brought them to America from England for her own personal use. The *Benten* case followed years of political tension that had left RU-486 on the brink of illegal-drug status. To understand the political tension that surrounds RU-486, one must know how the pill works.

As part of a woman's natural reproductive cycle, the hormone progesterone is secreted, causing the uterine wall to thicken, allowing a fertilized ovum to implant and mature in the womb. Progesterone must be produced continually until the placenta is in

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1. The personal use exception permits a non-approved FDA drug that is not available domestically to be imported if a doctor certifies that the drug is to be used only for the personal use of a patient. *Benten v. Kessler*, 799 F. Supp. 281, 285 (E.D.N.Y. 1992).

2. Amy Goldstein & Richard Morin, *Clinton Cancels Abortion Restrictions of Reagan-Bush Era*, WASH. POST, Jan. 23, 1993, at A1; Karen Tumulty & Marlene Cmons, *Clinton Revokes Abortion Curbs*, L.A. TIMES, Jan. 23, 1993, at A1.

3. 799 F. Supp. at 284.

place.⁴ RU-486, which a physician administers and monitors, prohibits progesterone from entering the cells in the lining of the uterus. Without progesterone, the uterine lining deteriorates in a process similar to the menstrual cycle. Any ovum present in the uterus, implanted or not, is then naturally expelled from the body.

Thus, RU-486 is a safe, effective method of abortion which enables women to avoid the dangers of surgical abortion. Further, the pill makes an abortion more private and thus less subject to the influence of anti-abortion groups. The drug has many other possible benefits, including the reduction of breast cancer and the treatment of Cushing's syndrome,⁵ glaucoma, AIDS, and meningioma tumors.⁶ Those benefits have never been fully tested in the United States because RU-486 has remained a political, not a health care, controversy.

The FDA has never approved RU-486. In July 1988, responding to the needs of AIDS and cancer victims, the FDA began a pilot program permitting the importation of small doses of untested, unapproved drugs by mail. The program was an exception to the general prohibition against importing non-FDA-approved drugs. The drugs were to be imported only for personal use under the direction of a legitimate physician, provided that the drugs did not present an unacceptable risk to the patient's health. Based on the language of the regulation, RU-486 was included in this exception.⁷

In September 1988, the FDA issued Import Alert 66-813, which narrowed the mail program exception by stating specifically that the exception did not include RU-486.⁸ The District Court for the Eastern District of New York hypothesized that this action was based on political considerations that have no place in FDA decisions on health and safety.⁹

When the pilot program was approved in February 1989, as a formal revision in the FDA Regulatory Procedures Manual, the FDA included RU-486 in the "personal use" exception.¹⁰ Con-

4. Mindy J. Lees, *I Want a New Drug: C.U. RU-486 and the Right to Choose*, 63 S. CAL. L. REV. 1113, 1116 (1990).

5. Cushing's syndrome is a disease characterized by obesity, especially of the head, neck, and trunk, brownish streaks on the abdominal wall, muscular weakness, and porosity of bones. The syndrome is also associated with dysfunction of the adrenal cortex or of the anterior lobe of the pituitary body. WEBSTER'S THIRD NEW INTERN'L DICTIONARY 559 (1976).

6. Lees, *supra* note 4, at 1121.

7. *Benten*, 799 F. Supp. at 286.

8. *Id.* at 285.

9. *Id.* at 286.

10. *Id.* at 285.

servative legislators, however, pressured the FDA to reconsider this inclusion of RU-486. The agency capitulated to their demands and issued Import Alert 66-47.¹¹ This Alert dictated that agents “automatically detain all shipments of unapproved abortifacient drugs” because questions had been raised about RU-486 and because “the intended use of such drugs could pose a risk to the safety of the user.”¹² The court in *Benten* noted that none of the FDA’s actions conformed to the notice and comment procedure required for such agency actions.¹³

In *Benten v. Kessler*, Leona Benten brought suit to force the FDA to return her RU-486 pills, which FDA agents had seized pursuant to Import Alert 66-47. Benten alleged that the FDA illegally enacted the importation ban on RU-486 since the agency did not follow the mandatory notice and comment procedure.¹⁴ In July 1992, the District Court for the Eastern District of New York ordered the FDA to return the seized pills to Benten.¹⁵ The Second Circuit Court of Appeal, however, granted a stay pending appeal, which allowed the FDA to keep the confiscated pills.¹⁶ In an emergency proceeding, the United States Supreme Court voted to uphold the stay.¹⁷ Consequently, Benten ended her pregnancy through a surgical abortion.

President Clinton’s executive order significantly affected the RU-486 debate. The order allows importation of RU-486 for personal use, permitting a woman in Benten’s situation to exercise her right to privacy,¹⁸ keep the pills, and have a non-surgical abortion. However, it is still unknown whether RU-486 will ever be nationally marketed and available to every woman. Seeking to prevent the availability of the pill in the United States, anti-abortion groups have targeted Roussel-Uclaf, the French-based manufacturer of RU-486. In 1992, Roussel-Uclaf and its German parent firm, Hoechst AG, “decided to withdraw RU-486 from some clinical tests in the United States, and . . . other, smaller drug companies

11. *Id.* at 286.

12. *Id.* (citing FDA IMPORT ALERT 66-47).

13. 799 F. Supp. at 286. When considering the adoption of a regulation, all federal agencies must publish notice of the agency’s intent and invite and give time for comments to be made about the proposed regulation by any party. *Id.* at 285–86.

14. *Id.*

15. *Id.* at 291–92.

16. *Benten v. Kessler*, 112 S. Ct. 2929, 2030 (1992).

17. *Id.*

18. As explained in *Roe v. Wade*, 410 U.S. 113, 153 (1973), the right to privacy is found in the penumbras of the Bill of Rights and encompasses the right of a pregnant woman to terminate her pregnancy through abortion.

report they are reluctant to develop drugs similar to RU-486 because of what they perceive as a hostile atmosphere."¹⁹ Anti-abortion groups threatened to boycott all products of any drug company attempting to market RU-486.²⁰ In 1983, anti-abortion groups carried out their threats when they boycotted various Upjohn products after Upjohn began marketing abortion-inducing drugs.²¹

President Clinton also stated in his announcement that he is willing to allow marketing of the French pill in the United States.²² Roussel-Uclaf took Clinton seriously and recently met with the FDA to express an interest in marketing the pill in America.²³ However, Roussel-Uclaf, still wary of boycott threats, wishes to market RU-486 indirectly through a domestic pharmaceutical firm or research center.²⁴ Accordingly, Roussel-Uclaf very recently agreed to license RU-486 to the Population Council, a New York-based scientific research organization.²⁵ The Population Council is in charge of finding a manufacturer in the United States willing to perform clinical trials of the drug.²⁶

The ultimate goal of Roussel-Uclaf and the Population Council is to attain FDA marketing approval for the pill through the procurement of a manufacturer and performance of clinical trials. Hoechst/Roussel-Uclaf expressed the intent that they are "not willing to be involved in the distribution or production of RU-486 in the United States. [We] have agreed to transfer the technology necessary for producing the drug"²⁷ Despite the lack of direct involvement by Hoechst-AG and Roussel-Uclaf, pro-life groups reiterated their threats of boycott upon the announcement by Roussel-Uclaf. Douglas Johnson, legislative director of the National Right to Life Committee, stated that

[t]he pro-life movement in America will hold Hoechst and Roussel responsible if any entity applies for a license to market RU-

19. Michael Unger, *Women Urge Drop on RU-486 Ban*, NEWSDAY, July 29, 1992, at 15 (quoting Rep. Ron Wyden of the Small Business Subcommittee on Regulation).

20. Lees, *supra* note 4, at 1122 (citing John Langone, *After-the-Fact Birth Control*, TIME, Oct. 10, 1988, at 103).

21. Lees, *supra* note 4, at 1122-23 (citing Gina Kolata, *Boycott Threat Blocking Sale of Abortion-Inducing Drug*, N.Y. TIMES, Feb. 22, 1988, at A1).

22. *Clinton to Reverse 'Gag Rule,' Allow Importation of Abortion Drug*, ATLANTA J. & CONST., Jan. 17, 1993, at B5.

23. *Health Care*, L.A. TIMES, Feb. 26, 1993, at D2.

24. *RU-486: At Last, Hope for Progress*, L.A. TIMES, Mar. 1, 1993, at B6.

25. Marlene Cimons, *Abortion Pill Clears Hurdle Toward U.S. Sale*, L.A. TIMES, Apr. 21, 1993 at A1, A14.

26. *Id.* at A14.

27. *Id.*

486 for abortion What I mean by this is potential product boycotts and the like. Hoechst and Roussel don't get off the hook simply by using a surrogate or a proxy.²⁸

The pro-life movement will strongly resist the marketing of the abortion pill in America. Yet, it is not clear how significantly the movement will impact the marketing of RU-486 and, therefore, the pill still has a fighting chance of introduction in the United States.

President Clinton's and Roussel-Uclaf's actions may be a sign of more liberal decisions to come. The reproductive rights movement, however, must not become complacent. Making RU-486 available in the United States is just one step of many needed to conclusively secure the right to choose abortion. The fight is not yet over.

28. *Id.*

