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RU 486 in the United States and Great Britain: A Case Study in Gender Bias

INTRODUCTION

On July 3, 1991, Great Britain became the third country in the world to approve RU 486¹ for use as an abortifacient.² The Committee on the Safety of Medicines³ (CSM), the British equivalent of the U.S. Food and Drug Administration⁴ (FDA), licensed RU 486 after determining it would be safe and effective.⁵ The FDA reached the opposite conclusion about RU 486, and imposed an Import Ban on June 9, 1989.⁶ The Import Ban prohibits personal use of RU 486 and constitutes the first major policy statement by the U.S. government on this drug.⁷ In July 1992, the U.S. Supreme Court rejected a legal challenge to the Import

¹ Roussel-Uclaf, a French company whose major stockholder is the German chemical firm Hoechst, manufactures RU 486. The scientific name of RU 486 is mifepristone, and its trade name is mifegyne. *The Safety and Effectiveness of the Abortifacient RU 486 in Foreign Markets; Opportunities and Obstacles to U.S. Commercialization: Hearing Before the Small Business Subcommittee on Regulation, Business Opportunities & Energy*, 102d Cong., 2d Sess. 1-3, 7-8 (Dec. 5, 1991)[hereinafter *RU 486 in Foreign Markets*](testimony of Professor Etienne-Emille Baulieu, M.D., Ph.D., Professor of Biochemistry, School of Medicine, University of Paris-Sud, inventor of RU 486).

² Daniel Green, *Abortion Pill Wins Approval*, FIN. TIMES, July 4, 1991, at 8. An abortifacient is a chemical which induces an abortion. France licensed RU 486 for commercial distribution in September 1988. The People's Republic of China also disburses the drug. *RU 486 in Foreign Markets*, *supra* note 1, at 3, 5.

Norway, Sweden, and Finland are scheduled to begin using RU 486 on January 1, 1993. Holland, Spain, and Italy are likely to follow this trend. Aaron J. Lopez, *Where RU 486 Is Used*, Gannett News Service, July 22, 1992, available in LEXIS, Nexis Library, Omni File. In April 1992, the German Hessen Health Ministry announced that clinical trials involving RU 486 as an abortifacient would begin soon. THE FEMINIST MAJORITY FOUNDATION, 1992 *The RU 486 Report*, No. 1, at 1 [hereinafter *RU 486 Report*].

³ The Committee on the Safety of Medicines (CSM) was established under the authority of the Medicines Act of 1968. S.I. 1970, No. 1257. Its purpose is to advise the Medicines Commission on safety, quality, and effectiveness. *Id.*

⁴ 21 U.S.C. §§ 301-393 (1989).

⁵ Clinical trials in London and Edinburgh involving 2,000 women demonstrated that RU 486 successfully induced abortions in 94-96 percent of the women. Caroline Lees, *Abortion Pill Available in Summer*, THE TIMES (London), June 30, 1991, at Home News.

⁶ The Import Ban is officially referred to as Import Alert No. 66-47. See generally *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10516 (E.D.N.Y. July 14, 1992).

⁷ *RU 486: The Import Ban and Its Effect on Medical Research: Hearing Before the Small Business Subcommittee on Regulation, Business Opportunities & Energy*, 101st Cong., 2d Sess. 36 (Nov. 19, 1990)[hereinafter *Import Ban*].

Ban brought by a woman who attempted to import RU 486 from Great Britain to the United States.⁸

Thus, the United States and Great Britain utilized identical criteria to evaluate RU 486, yet promulgated policies regarding the use of RU 486 which are diametrically opposed. This Note assesses the legal climate surrounding RU 486 in the United States by means of comparison with Great Britain. Part I describes how RU 486 works and its numerous potential medical benefits. Part II compares the governmental and regulatory decision-making of the FDA and the CSM. The policy goals underlying the regulatory framework in both countries are used to highlight differences in the U.S. and British health care systems. Against this background, Part III considers the role of gender perceptions in decision-making and the degree to which U.S. and British health care is responsive to gender-specific concerns. The U.S. policy regarding RU 486 is considered within the context of Equal Protection jurisprudence. The analysis in Part IV concludes that the contrast between the British decision to distribute RU 486 and the U.S. imposition of an Import Ban may be attributed to differing conceptions of health care—policies which in the United States reflect, at least in part, inherent gender bias.

I. RU 486: PHYSIOLOGICAL EFFECTS AND POTENTIAL APPLICATIONS

RU 486 has many potential uses, but the most extensive testing to date—and the most controversial—involves its effectiveness as an abortifacient. The drug is an antiprogestin, which means it interferes with the body's normal functioning of the hormone progesterone.⁹ A combination therapy is used to terminate early pregnancy: RU 486 is taken in combination with prostaglandin, another hormone, which further enhances the expelling forces of the uterus.¹⁰ Use in France indicates that RU 486 taken with

⁸ *Benten v. Kessler*, 112 S.Ct. 2929, 1992 U.S. LEXIS 4756 (July 17, 1992) (per curiam); see *infra* notes 118–35 and accompanying text.

⁹ RU 486 blocks the receptor for progesterone inside cells of the uterus. Without progesterone, the lining of the uterus breaks down and is expelled, as in normal menstruation. *E.g.* WORLD HEALTH ORGANIZATION (WHO), *Research in Human Reproduction*, Biennial Report 1988–89 38 (1990).

¹⁰ *Id.* Roussel-Uclaf initially cited the unavailability of prostaglandins in the United States as one of the reasons the company would not pursue U.S. distribution. Michael

a prostaglandin fully expels the contents of the uterus more than 95 percent of the time.¹¹ Studies of RU 486 by the World Health Organization since 1983 in ten countries demonstrate efficacy rates similar to those observed in France.¹² Available data suggests that RU 486 taken in conjunction with prostaglandins may be safer than surgical abortion because the treatment avoids the risks of anesthesia and surgical complications.¹³ Moreover, if side effects occur, researchers believe they are temporary because RU 486 remains in the body less than forty-eight hours.¹⁴

In addition to being an effective abortifacient, RU 486 has potential use in the treatment of numerous diseases and disorders.¹⁵ RU 486 appears to be particularly effective in the treatment of breast cancer.¹⁶ In a 1987 French clinical trial, RU 486 halted the growth of breast cancer in twelve out of twenty-two

Klitsch, Alan Guttmacher Inst., *RU 486: The Science and the Politics* 13 (1989)[hereinafter *Science & Politics*]; Ronald Kotulak, *In U.S., Claims of New Uses Fuels Debate Over Abortion Pill*, CHI. TRIB., Dec. 29, 1991, at C1.

The lack of compatible prostaglandins may soon be resolved by the use of a second pill, misoprostol. Dr. Baulieu reported that this new therapy proved effective in 95 percent of women ranging in age from 18 to 37. Lawrence K. Altman, *A Simpler Way to Employ RU 486 is Reported*, N.Y. TIMES, Apr. 9, 1991, at C3. J.D. Searle Co. licensed misoprostol in the United States in 1988 for the prevention of ulcers. *Id.*

¹¹ *RU 486 in Foreign Markets*, *supra* note 1, at 2 (testimony of Dr. Baulieu).

¹² Multicentre trials have been conducted in the People's Republic of China, Cuba, Hong Kong, Hungary, India, Italy, Singapore, Sweden, the United Kingdom, and Yugoslavia. WHO, *supra* note 9, at 40.

The World Health Organization (WHO) discovered that blood loss may be greater for Chinese women in Hong Kong and Singapore, suggesting that racial and/or ethnic differences in responsiveness to RU 486 needs to be studied further. Testing by WHO also indicates that it may be possible to obtain the same rate of complete abortion with much lower doses of RU 486 than the 600mg dose recommended by the manufacturer. *Id.*

¹³ See Mindy J. Lees, *I Want a New Drug: RU 486 and the Right to Choose*, 63 S. CAL. L. REV. 1113, 1119 (1990). Complications of surgical abortion include cervical injury, perforation of the uterus, and scarring of the lining of the uterine cavity. *RU 486 in Foreign Markets*, *supra* note 1, at 4 (testimony of David Grimes, Professor of Obstetrics and Gynecology and Preventative Medicine, University of Southern California School of Medicine, at Los Angeles).

Complications from use of RU 486 as an abortifacient in France, such as heavy bleeding necessitating curettage and/or blood transfusions, are infrequent and have occurred in about 0.8 percent and 0.1 percent of 65,000 treated women, respectively. WHO, *supra* note 9, at 39.

¹⁴ *E.g.*, Lees, *supra* note 13, at 1118.

¹⁵ See *infra* notes 16–31 and accompanying text.

¹⁶ THE FEMINIST MAJORITY FOUNDATION, 1991 *RU 486 and Breast Cancer*, No. 1, at 1 [hereinafter *Breast Cancer*].

patients after the failure of all other known treatments.¹⁷ The same study demonstrated that RU 486 reduces pain from the growth of bone cancer cells.¹⁸ Before the end of 1992, the National Cancer Institute of Canada Clinical Trials Group intends to begin breast cancer trials using RU 486 at Queens University in Kingston, Ontario.¹⁹

RU 486 is equally promising in the treatment of a type of cancer known as Cushing's Syndrome.²⁰ Treatments with the drug achieved complete regression and actual reversal of Cushing's Syndrome in over half of the patients to whom it was administered.²¹ Ongoing research also documents the efficacy of RU 486 in reducing the size of uterine fibroid tumors, the leading cause of hysterectomies.²² Moreover, the drug has potential for treating meningiomas,²³ reducing pelvic pain in individuals suf-

¹⁷ G. Romieu et al., *The Anti-Progesterone RU 486 in Advanced Breast Cancer: Preliminary Clinical Trial*, 74 BULL. CANCER 455 (1987). Dr. Romieu discovered that RU 486 affected tumors which had become resistant to anti-estrogen drugs such as tamoxifen. *Id.*; see also G.H. Bakker et al., *Treatment of Breast Cancer with Different Anti-Progestins: Preclinical and Clinical Studies*, 37 J. STEROID BIOCHEMISTRY & MOLECULAR BIOLOGY 789 (1990).

In the Netherlands, animal studies with RU 486 showed that the drug reduced breast cancer tumors as effectively as tamoxifen. Tumor sizes were further reduced by administering the drugs simultaneously. J. Klijn et al., *Anti-Progesterones, a New Form of Endocrine Therapy for Human Breast Cancer*, 49 CANCER RES. 2851, 2853 (1989).

¹⁸ Romieu, *supra* note 17, at 456.

¹⁹ *RU 486 Report*, *supra* note 2, at 1. The trial will include fifteen women with evidence of disease recurrence and is the first to involve patients who have not been treated with any other hormones or drugs. *Id.*

²⁰ Cushing's Syndrome is caused by an overproduction of cortisol, a natural glucocorticoid hormone. RU 486 is an antiglucocorticoid, so that it binds to the glucocorticoid receptors in the body. Treatments with RU 486 thus prevent cortisol from binding to the glucocorticoid receptors. THE FEMINIST MAJORITY FOUNDATION, 1991 *RU 486 and Cushing's Syndrome*, No. 1, at 1.

²¹ *Import Ban*, *supra* note 7, at 10. Efficacy was 100 percent for five of the eight individuals who were gravely ill with inoperable tumors caused by the disease. The condition of these five individuals continued to improve while treatment with RU 486 continued. The side effects observed with RU 486 were mild or transient in nature. *Id.* (testimony of George P. Chrousos, M.D., Senior Investigator and Section Chief, Pediatric Endocrinology, National Institute of Child Health and Human Development, National Institutes of Health).

²² Ana Murphy et al., *Responses of Uterine Fibroids to the Anti-Progesterone RU 486: A Pilot Study*, Paper Presented at Annual Meeting of the American Fertility Society (Oct. 21-24, 1991).

²³ S. Grunberg et al., *Treatment of Unresectable Meningiomas with the Antiprogestosterone Agent Mifepristone*, 74 J. OF NEUROSURGERY 861, 861 (1991). During 1992, the National Cancer Institute began trials with RU 486 for meningioma involving 200 patients. *RU 486 Report*, *supra* note 2, at 2.

fering from endometriosis,²⁴ inducing labor,²⁵ countering depression,²⁶ and offsetting the effects of high blood pressure.²⁷ Researchers are also investigating RU 486 as a treatment for Alzheimer's disease.²⁸

In addition, RU 486 is being investigated abroad as a once-a-month contraceptive pill and as a "morning after" pill.²⁹ Furthermore, foreign use demonstrates its possible efficacy as a treatment for osteoporosis and glaucoma, to aid childbirth, and to lessen the need for Caesarian sections.³⁰ Finally, researchers believe RU 486 may be beneficial for burns, wounds, high blood pressure, and even AIDS.³¹

It is important to note, however, that the medical community is not unanimously in favor of RU 486. Three researchers who characterize themselves as pro-choice feminists published a comprehensive review of the studies documenting RU 486.³² Raymond, Klein, and Dumble are highly critical of the lack of long-

²⁴ L.M. Kettel et al., *Endocrine Responses to Long-term Administration of the Anti-Progesterone RU 486 in Patients with Pelvic Endometriosis*, 56 FERTILITY & STERILITY 402, 404 (1991).

²⁵ C. Baton et al., *Progesterone Antagonist for Labor Induction at Term: A Double Blind Study: RU 486 (Mifepristone) Versus Placebo*, Paper Presented at Annual Meeting of the American Fertility Society (Oct. 21-24, 1991).

²⁶ *The Effect of the Federal Ban of RU 486 on Medical Research, New Drug Development, and Pharmaceutical Manufacturers: Hearing Before the Small Business Subcommittee on Regulation, Business Opportunities & Energy*, 102d Cong., 2d Sess. (July 28, 1992)[hereinafter *RU 486 and Medical Research*](testimony submitted by Bernard J. Carroll, M.D., Ph.D., Professor, Department of Psychiatry, Duke University Medical Center).

²⁷ *Id.* (testimony submitted by Charles O. Wattlington, M.D., Ph.D., Professor of Medicine, Division of Endocrinology & Metabolism, Medical College of Virginia, Virginia Commonwealth University).

²⁸ The NYU Medical Center conducted a six-week clinical trial during the summer of 1992 to study what effect RU 486 has on individuals suffering from Alzheimer's disease. *RU 486 Report*, *supra* note 2, at 2.

²⁹ Researchers at the National Institutes of Health (NIH) reported results of animal trials suggest that RU 486 "would have significant advantages over the birth control pill" as an oral contraceptive for women who are over 35 and/or smoke. M. Batista et al., *Daily Administration of the Progesterone Antagonist RU 486 Prevents Implantation in the Cycling Guinea Pig*, 165 AM. J. OBSTETRICS & GYNECOLOGY 82, 82 (1991); *see also RU 486 "Shows Promise" For Use as a Contraceptive*, July 31, 1992, available in LEXIS, Nexis Library, AbtrRpt File.

A study in Edinburgh, Scotland revealed that RU 486 is highly effective as a "morning after" contraceptive for up to 72 hours after intercourse. Anna Glasier et al., *Mifepristone (RU 486) Compared With High-Dose Estrogen and Progesterone for Emergency Postcoital Contraception*, 327:15 NEW ENG. J. MED. 1041, 1043 (Oct. 8, 1992).

³⁰ *RU 486 and Medical Research*, *supra* note 26, at 2 (testimony of Marjorie Braude, M.D., on behalf of the American Medical Women's Association).

³¹ Kotulak, *supra* note 10, at C1.

³² JANICE G. RAYMOND ET AL., *RU 486: MISCONCEPTIONS, MYTHS AND MORALS* 41 (1991).

term follow-up studies to evaluate the effects of RU 486 and prostaglandins on menstrual cycles and later pregnancies.³³ Another outspoken critic of RU 486 is Richard Glasow, education director for the National Right to Life Committee.³⁴ Glasow has legitimately focused on the fact that current use of RU 486 as an abortifacient requires strict medical supervision; its use in Third World countries, where facilities often are not available, therefore could be potentially very dangerous.³⁵

Regardless of its medical benefits or potential drawbacks, the use of RU 486 as an abortifacient suggests a variety of moral and ethical dilemmas. RU 486 completely defines, and redefines, the abortion debate.³⁶ The highly-politicized, embittered, and even hysterical debate surrounding abortion has been discussed extensively elsewhere,³⁷ and is not intended to be the focus of this Note. Rather, the analysis considers RU 486 within the context of gender-specific concerns. While RU 486 highlights issues of reproductive control, the drug has clear implications for a wide array of women's health concerns.

II. DECISIONS INVOLVING RU 486: A COMPARATIVE PERSPECTIVE

A. *The Regulatory Environment*

Drug approval procedures are one indication of a nation's approach to medical risks and benefits.³⁸ Describing standard

³³ *Id.* at 76.

³⁴ He claims that "there's no proven use for RU 486 except to kill babies," and that potential medical uses have been "exaggerated as a smokescreen." Kotulak, *supra* note 10, at C1.

³⁵ *RU 486 in Foreign Markets*, *supra* note 1, at 9 (testimony of Richard Glasow, Ph.D., Education Director, National Right to Life Committee).

³⁶ Both sides of the current U.S. debate focus on the right to privacy. The use of RU 486 as an abortifacient makes the choice to have an abortion a confidential matter between a woman and her doctor, rather than a decision communicated to the public by the woman's visit to an abortion clinic. The drug thus cuts to the essence of the right to privacy and alters "the very nature of the abortion issue by placing the question of early abortion beyond the control of our courts and legislatures." See Jane Cohen, Review Essay, *Comparison-Shopping in the Marketplace of Rights*, 98 *YALE L.J.* 1235, 1256 (1989).

³⁷ Commentary and analysis of the abortion debate spans well over twenty years. For recent in-depth discussions of abortion and the intense legal and political controversy, see, for example, LAWRENCE TRIBE, *ABORTION: THE CLASH OF ABSOLUTES* (1991); MARLENE FRIED, ED., *FROM ABORTION TO REPRODUCTIVE FREEDOM* (1990); RUTH BADER GINSBURG, *CONTESTED LIVES* (1989); MARY ANN GLENDON, *ABORTION AND DIVORCE IN WESTERN LAW: AMERICAN FAILURES, EUROPEAN CHALLENGES* (1987).

³⁸ John Patrick Dillman, *Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures*, 44 *VAND. L. REV.* 925, 925 (1991).

drug approval procedures in the United States and Great Britain does not, however, immediately suggest any substantial divergences in approach.³⁹ Both countries employ a multi-phase licensing scheme for any new drug.⁴⁰ The first step by a company seeking a license is preclinical investigations and animal testing, followed by clinical testing in several phases with increasingly larger samples of the population, and ending with review by either the FDA or the CSM.⁴¹ While the procedures are similar, certain phases of the U.S. process are more time-consuming: preclinical investigations for the FDA take twice as long as the CSM, and the FDA employs a lengthier review process after the completion of clinical trials.⁴² Shorter testing and review periods in Great Britain may be explained by the fact that the FDA requires domestic data be used in conjunction with foreign data, whereas the CSM more frequently uses foreign data for both preclinical and clinical testing.⁴³

The procedural differences between the two drug approval processes are the result of markedly dissimilar perspectives. The exacting standards and more extensive testing required by the FDA focus on establishing safety prior to marketing.⁴⁴ The FDA's approach is more *laissez-faire*, as it will not unilaterally undertake investigation of any drug that is not already licensed.⁴⁵ Instead,

³⁹ Harvey Teff, *Drug Approval in England and the United States*, 33 AM. J. COMP. L. 567, 576 (1985).

⁴⁰ *Id.*

⁴¹ See Dillman, *supra* note 38, at 928–31. In Phase I testing, the goal is to collect basic data on the safety of the new drug by conducting tests on a small group of healthy subjects (typically 100 or fewer). Phase II testing focuses on the effectiveness and short-term side effects of the new drug by conducting tests on several hundred patients who are divided into treatment and control groups. Phase III testing can involve thousands of patients over a period of years and is intended to establish the drug's efficacy, long-term side effects, and optimal dosage levels. *E.g.* Beth Myers, *The Food and Drug Administration's Experimental Drug Approval System: Is it Good for Your Health?*, 28 Hous. L. REV. 309, 320 (1991).

⁴² Dillman, *supra* note 38, at 932. The FDA's clinical testing begins with a Notice of Claimed Investigational Exemption for New Drug (IND). When all three steps of testing are completed by the manufacturer, the results are submitted for FDA review in the form of a New Drug Application (NDA). See 21 U.S.C. § 355 (a)(i),(b)(1),(c)(1), and (d).

⁴³ *Id.* at 928, 932.

⁴⁴ Teff, *supra* note 39, at 579. For example, the requirement of randomized controlled clinical trials in Phase III is very costly and time-consuming. This requirement reflects an attempt to ascertain all possible side effects and longer-term consequences of the proposed drug. See *id.* at 576, 584.

⁴⁵ Wendy K. Mariner, *Equitable Access to Biomedical Advances: Getting Beyond the Rights Impasse*, 21 CONN. L. REV. 571, 602 (1989).

drug manufacturers begin preclinical testing of drugs before applying to the FDA and initiating the U.S. licensing process.⁴⁶ Critics frequently charge, however, that the FDA is responsive to political pressures.⁴⁷ In contrast, the CSM is viewed as being more objective.⁴⁸ Expert apolitical committees assume a central role in the decision to approve a particular drug, thereby operating independently of the pharmaceutical market.⁴⁹ The CSM's autonomous approach arguably minimizes the influences of government and industry by relying on experts' independent judgments rather than on test results submitted by the drug's manufacturer.⁵⁰ Also, while the FDA utilizes restrictive premarketing approval methods, the CSM monitors adverse reactions after licensing a drug.⁵¹ Postmarketing surveillance by the CSM is premised on the assumption that, even with extensive premarket testing, serious rare side effects will not become apparent until a larger population has used the drug.⁵²

Postmarket monitoring of drugs is well-suited to Great Britain because of the structure and size of the society.⁵³ In particular, the British centralized health care system and societal attitudes regarding the medical profession facilitate postmarketing surveillance.⁵⁴ The National Health Service (NHS) enables the CSM to follow-up a drug after its distribution by collecting data from every doctor prescribing the drug.⁵⁵ The practice of monitoring a drug after approval also presupposes a degree of public trust in the medical profession.⁵⁶ In contrast, the FDA's stringent pre-

⁴⁶ *Import Ban*, *supra* note 7, at 36.

⁴⁷ *Id.* at 934; see also D. Benac, *FDA Officials Subpoenaed in Insider Trading Probe*, THE TENNESSEAN, Apr. 4, 1991, at E4.

⁴⁸ Dillman, *supra* note 38, at 934.

⁴⁹ Teff, *supra* note 39, at 581. The CSM is not well known outside the medical profession. It consists of 19 eminent experts, 14 of whom occupy academic positions. *Id.*

⁵⁰ *Id.* But see *UK Drug Advisory Bodies Declare Industry Links*, FIN. TIMES, Jan. 6, 1989, available in LEXIS, Nexis Library, Pbnws File (annual reports from drug advisory bodies in Great Britain reveal that 13 of 21 members of the CSM had financial interests in pharmaceutical companies in 1989).

⁵¹ Teff, *supra* note 39, at 579.

⁵² *Id.* Potential harm is minimized by limiting the right to prescribe certain drugs to hospital pharmacies or to particular specialists. In comparison, the FDA does not devote much time to postapproval monitoring so that re-evaluation, recall, or relabeling are unlikely. Dillman, *supra* note 38, at 929.

⁵³ Teff, *supra* note 39, at 579.

⁵⁴ See *id.*

⁵⁵ Dillman, *supra* note 38, at 932-33.

⁵⁶ Teff, *supra* note 39, at 582. *R. v. Ethical Comm. of St. Mary's Hosp.* demonstrates that at least the judiciary in Great Britain defers to clinical judgments. 1 F.L.R. 512 (Q.B.

marketing approval process and the U.S. tort liability system are inter-related.⁵⁷

The divergent policies of the FDA and CSM also reflect differences in government accountability.⁵⁸ The U.S. government views its role as a trustee of official information for the public.⁵⁹ As a result, the FDA's rule-making activities are more elaborate and formal than those of the CSM.⁶⁰ Continual congressional oversight of the FDA reveals a greater degree of government accountability in the United States and further contributes to administrative complexity.⁶¹ The CSM, in comparison, is able to remain more autonomous than the FDA because the British place less emphasis on government accountability.⁶² The British govern-

1988). That case involved a challenge to a doctor's decision to refuse an applicant for *in vitro* fertilization. The court held that the doctor-patient relationship is beyond the scope of administrative law, and that clinics have the right to deny provision of treatments like *in vitro* fertilization when "information indicates the need to do so." *Id.* at 520, 524.

⁵⁷ See Dillman, *supra* note 38, at 948. Teff comments that a regulator has "little or nothing to lose by refusing, or at least delaying, the grant of a license, and everything to lose if [a] thalidomide [is approved]." Teff, *supra* note 39, at 591. Thalidomide was a remedy for morning sickness developed in the 1950s which caused thousands of serious birth defects in Great Britain. *Id.*; see also Myers, *supra* note 41, at 320.

Pharmaceutical manufacturers in the United States must always consider the threat of liability exposure. Silicone breast implants are a recent example. On January 6, 1992, the FDA imposed a moratorium on the sale of breast implants after documents revealed the implants were marketed before the results from animal testing were complete. Deborah Mesce, *Breast Implant Firm Combats Charges of Insufficient Testing*, BOSTON GLOBE, Jan. 14, 1992, at 3. Dow Corning Wright, the largest maker of silicone gel breast implants, subsequently withdrew the devices from the market and no longer manufactures silicone gel implants. Marlene Cimons, *Dow Corning to Stop Making Gel Implants*, L.A. TIMES, Mar. 19, 1992, at A1.

One market participant, however, stated that, contrary to popular belief, product liability represents a cost of substantially less than one percent of sales. *RU 486 and Medical Research*, *supra* note 26, at 2 (testimony of R.L. Mackenzie, Chairman & CEO, Gynopharma, Inc.).

⁵⁸ See Teff, *supra* note 39, at 580.

⁵⁹ See *id.*

⁶⁰ See *id.* at 579. There is no British equivalent to the requirements for a notice and comment period or publication in the Federal Register. See *id.* at 580.

⁶¹ The forty or so annual formal hearings on the drug industry are more exacting and intrusive than comparable British procedures. *Id.* at 581. Yet, there are charges that even such a closely monitored approach does not prevent dangerous products from reaching consumers. The House Energy and Commerce subcommittee staff issued a report entitled "Filthy Food, Deceitful Drugs and Defective Devices: the Legacy of FDA's Antiquated Statute," recommending that the FDA be granted the authority to order recalls of products or the destruction of goods that risk human or animal health, the power to grant subpoenas when products are being investigated, the ability to enter and inspect places of business when criminal activity is suspected, and the ability to set civil penalties for violations. *FDA Can't Stop Bad Products, Report Claims*, BOSTON GLOBE, Oct. 7, 1991, at 19.

⁶² Teff, *supra* note 39, at 580.

ment restricts access to official information by claiming ownership of public information.⁶³

The results of such differing perspectives and policy assumptions are tangible.⁶⁴ It is undisputed that there is a drug lag in the United States—new drugs reach the market more slowly in the United States than in other sophisticated drug-producing nations.⁶⁵ Critics in both countries have recommended modifications to the drug approval systems.⁶⁶ In Great Britain, the CSM employed an exemption scheme to permit earlier clinical trials in some cases and more narrowly tailored data requirements for clinical testing to reduce unnecessary delays.⁶⁷ In the United States, proposals for extensive change are finally being seriously considered.⁶⁸ Regulators suggested a reduction in product licensing time and methods to control costs involved in developing drugs.⁶⁹ Reform may not occur anytime soon, though, because the FDA may delay adopting the proposals.⁷⁰ Furthermore, some lawmakers have expressed opposition to what they see as an attempt to disempower the FDA's watchdog role.⁷¹

B. Health Care Systems

Regulatory decisions, particularly those made by the FDA or the CSM, naturally reflect the nation's overall conception of

⁶³ There is no dialogue with the public in Great Britain and as of yet, no freedom of information legislation to encourage it. *Id.*

⁶⁴ See Dillman, *supra* note 38, at 934–35.

⁶⁵ *Id.* at 936.

⁶⁶ See *id.* at 940–47.

⁶⁷ Medicines Act (Exemption from Licenses) (Clinical Trials), 1981, No. 164 (Eng.).

⁶⁸ Negotiations between the FDA, the Japanese Ministry of Health and Welfare, and the European Commission began the harmonization of drug industry regulations. Paul Abrahams, *A Tricky Balancing Act for Regulators*, FIN. TIMES, NOV. 15, 1991, at 19.

⁶⁹ *Id.* Specifically, the new plan calls for the FDA to shorten current review and approval times of all drugs by contracting organizations outside the government to review new drugs, and by recognizing foreign tests to avoid duplicate tests on animals and humans. *Id.*

⁷⁰ The FDA's attitude seems to be the main institutional obstacle to harmonization; it warned that it could take more than eighteen months to adopt the proposals. See Abrahams, *supra* note 68.

⁷¹ Marlene Cimos, *Three Lawmakers Seek to Delay Effort to Accelerate FDA Drug Approval*, L.A. TIMES, NOV. 14, 1991, at A23. Senator Edward Kennedy (D-MA), chairman of the Senate Labor and Human Resources Committee, and Reps. John Dingell (D-Mich), chairman of the House Energy and Commerce Committee, and Henry Waxman (D-CA), chairman of the Energy Panel's Subcommittee on Health and the Environment, support the plan to speed new drugs for life-threatening and other serious conditions, but they questioned the need to accelerate the process for all other drugs. *Id.*

health care.⁷² Although the United States and Great Britain have comparable cultures, their health care policies differ vastly.⁷³ The British system is noted for being more equitable and more successful at containing costs.⁷⁴ The values most closely associated with British health care policies are equality, economic security, and social solidarity.⁷⁵ The U.S. health care system, on the other hand, exhibits the underlying cultural values of individualism, private property, and free trade.⁷⁶ The British tend to construe liberty as freedom from physiological problems and the financial burdens that accompany them, whereas U.S. citizens are more likely to define liberty as freedom from government intervention.⁷⁷

There are complaints of administrative waste and mismanagement in both countries, but figures suggest that the U.S. health care bureaucracy has been growing faster in size and influence without providing comparable benefits.⁷⁸ The United States spends more per year per person for health care than any other country.⁷⁹ In fact, Great Britain spends one-half as much as the U.S. and maintains comparable mortality and morbidity rates.⁸⁰

⁷² See generally Mariner, *supra* note 45.

⁷³ See *infra* notes 74–89 and accompanying text.

⁷⁴ Christopher Potter & Janet Porter, *American Perceptions of the British National Health Service: Five Myths*, 14 J. HEALTH POL., POL'Y & L. 341, 342 (1989).

⁷⁵ Charles Lockhart, *Values and Policy Conceptions of Health Policy Elites in the United States, the United Kingdom, and the Federal Republic of Germany*, 6 J. HEALTH POL., POL'Y & L. 98, 100 (1981) ("The way the British provide for their citizens' health care needs has created a public program that enables a broad segment of the population to feel they share something worthwhile.").

⁷⁶ Potter & Porter, *supra* note 74, at 343. Lockhart notes that individuals active in the formulation of health care policy in the United States were more likely than their British counterparts to isolate health policy from other aspects of society, such as housing, employment, working conditions, and the environment. Lockhart, *supra* note 75, at 101.

⁷⁷ Lockhart, *supra* note 75, at 103.

⁷⁸ John Lister, *The Politics of Medicine in Britain and the United States*, 315 NEW ENG. J. MED. 168, 170 (1986). In 1991, European health expenditures accounted for between 7 and 9 percent of each country's gross national product, while in the United States the figure was more than 12 percent. Abrahams, *supra* note 68, at 19. It would seem that the United Kingdom is on the low end of the European figure: in 1986 it was reported that health care costs accounted for 6 percent of the gross national product in Great Britain. David Himmelstein & Steffie Wolhander, *Cost Without Benefit: Administrative Waste in U.S. Health Center*, 314 NEW ENG. J. MED. 441, 442 (1986).

⁷⁹ *The Health Care Crisis*, BOSTON GLOBE, Oct. 7, 1992, at 18.

⁸⁰ Potter & Porter, *supra* note 74, at 363; see also Lister, *supra* note 78, at 169. Dr. Allukian has testified to the same effect: "Our country is currently spending over \$660 billion a year for health services, more than any other nation in the world. Yet . . . we have dropped from fifth to twenty-second in our infant mortality standing. . . ." *Import*

Commentators attribute Great Britain's relative efficiency to its centralized health care system.⁸¹

The British NHS offers every citizen comprehensive health services free at the time of use.⁸² Individuals do not pay a fee for services; rather, the government directly provides financial support.⁸³ Most hospitals, clinics, ambulances, and laboratories are owned by the government, and all NHS staff are on the government payroll.⁸⁴ Yet, the NHS is nationalized health care and differs from "socialized medicine" in that there is both public and private ownership of facilities and fairly strong professional organizations.⁸⁵ Health care in Great Britain is best described as a state-supported consumer good.⁸⁶

The United States stands in sharp contrast to Great Britain as one of the only industrialized countries without a national health insurance program.⁸⁷ The current U.S. alternatives to comprehensive funding by the NHS are Medicare, for individuals who are over age sixty-five, and Medicaid, for individuals who meet certain income guidelines. The crucial distinction between the two systems is the American view that health care is not a right, but a consumer good which is purchased through the free market.⁸⁸ Means of payment for medical care in the United States—private or government insurance and personal financial reserves—provide an impetus for the use of elaborate and expensive methods of treatment.⁸⁹ Critics identify the major problem with this approach as a lack of concern with efficiency or equal distribution.⁹⁰

Ban, *supra* note 7, at 29 (testimony of Myron Allukian, Jr., DDS, MPH, Immediate Past President, American Public Health Association).

⁸¹ See generally Potter & Porter, *supra* note 74, at 344–45.

⁸² Lister, *supra* note 78, at 169. The NHS originated under the British Socialist Party and was officially established in 1946. The initial conception of health care was "an exercise in paternalistic social engineering . . . to make the workforce healthier and thereby increase productivity." Potter & Porter, *supra* note 74, at 344–45.

⁸³ Potter & Porter, *supra* note 74, at 345.

⁸⁴ *Id.*

⁸⁵ *Id.* at 344.

⁸⁶ *Id.*

⁸⁷ See Lockhart, *supra* note 75, at 101.

⁸⁸ *Id.* at 104.

⁸⁹ E.P. Steinberg et al., *X-Ray, CT and Magnetic Resonance Imagers*, 313 *NEW ENG. J. MED.* 863 (1985), quoted in Potter & Porter, *supra* note 74, at 353.

⁹⁰ *Id.*

C. *Governmental Decision-Making and RU 486*

1. Great Britain

RU 486 became available in Great Britain in July 1991 through the NHS.⁹¹ The CSM licensed RU 486 ten months after Roussel-Uclaf submitted its application,⁹² although on average it takes a new drug 19 months to be granted a license for use in Great Britain.⁹³ The short delay between the manufacturer's application and the licensing of RU 486 prompted accusations that Roussel-Uclaf had "fast-tracked" the drug.⁹⁴ As an abortifacient, RU 486 currently costs slightly more than a surgical abortion.⁹⁵ RU 486 is used up through the ninth week of pregnancy,⁹⁶ although its provision is subject to strict controls.⁹⁷

2. The U.S. Import Ban

a. *Background*

In the United States, the Import Ban on RU 486, officially referred to as Import Alert 66-47, is the first major policy state-

⁹¹ *RU 486 in Foreign Markets*, *supra* note 1, at 18-19.

⁹² Roussel-Uclaf applied for a license in September 1990 and the CSM approved RU 486 at the beginning of July 1991. "Abortion Pill" High on List for Licenses, *THE INDEPENDENT*, Jan. 3, 1991, at Home News 2.

⁹³ Rowan Dore, *Minister Pledges Tight Controls on Abortion Drug*, July 23, 1991, available in LEXIS, Nexis Library, Intl File.

⁹⁴ *Id.* Statement by Sir Bernard, a former health minister. Kenneth Hind (Lancashire W) responded to these charges by explaining to the House that the Health Department did not carry out any independent research on the drug. *Id.*

⁹⁵ *Id.* NHS surgical abortions currently cost £185, or approximately \$323.00, whereas Roussel-Uclaf is currently selling the three tablets required for the treatment for £43, or approximately \$75.00. Administrative and facility costs, however, make RU 486 more expensive than a surgical abortion.

⁹⁶ Interview with Dr. Louise Tryer, Gynecologist for Leona Benten, CNN, July 10, 1992, available in LEXIS, Nexis Library, Omni File.

⁹⁷ Celia Hall, *Newly-licensed 'Abortion Pill' Subject to Strict Controls*, *THE INDEPENDENT*, July 4, 1991, at Home News 4. Supplies are not available to family doctors or over the counter. RU 486 may only be obtained by written request to the manufacturer from a named hospital or clinic purchaser, supported by the names of the consultants who will prescribe the drug to the patient. In addition, the drug will be tracked to every purchaser and subscriber by means of a coding system. *Id.*

Critics of these controls claim the law in Britain is too restrictive for proper use to be made of RU 486. Alliance, an umbrella organization for pro-choice groups, stated that by the time most women get an appointment with two doctors in a hospital it will be too late to use this method. Linda Jackson, *Now Abortion By Pill*, July 3, 1991, available in LEXIS, Nexis Library, Intl File.

ment regarding RU 486.⁹⁸ Numerous changes in the FDA's regulatory scheme preceded, and in fact, provided the impetus for the Import Ban. In July 1988, the FDA instituted what it termed a temporary change in its policy regarding mail import of untested drugs.⁹⁹ Individuals suffering from AIDS or cancer were permitted to import small doses for personal use with the supervision of their physician.¹⁰⁰ In September 1988, the FDA made it clear that its policy on mail import of unauthorized drugs did not apply to RU 486.¹⁰¹

At that time, the FDA regularly issued permits for medical research with RU 486 because it concluded in November 1988 that the drug was reasonably safe.¹⁰² On February 1, 1989, the FDA extended its temporary policy regarding mail import of AIDS-related and cancer-related drugs; the agency created the personal use exception by revising its Regulatory Procedures Manual (RPM).¹⁰³ On May 5, 1989, Congressmen Robert K. Dornan, Henry Hyde, and John LaFalce sent a letter to the then-Commissioner of the FDA, complaining of the FDA's failure to bar RU 486 from this personal use exception.¹⁰⁴ Within two

⁹⁸ *Import Ban*, *supra* note 7, at 2.

⁹⁹ *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10516, at *9 (E.D.N.Y. July 14, 1992).

¹⁰⁰ *Id.*

¹⁰¹ Import Alert 66-813, *cited in* *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10516, *application to vacate stay*, app. A, (No. A-40), July 15, 1992, *available in* LEXIS, Genfed Library, Extra File.

¹⁰² Diane Walker, the FDA's Consumer Safety Officer, stated in a letter dated November 28, 1988 that the FDA determined RU 486 to be reasonably safe. *Import Ban*, *supra* note 7, at 43.

¹⁰³ The relevant part of the Regulatory Procedure Manual (RPM) states as follows:

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel should consider a more permissive policy in the following situations:

when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or when (1) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically, either through commercial or clinical means; (2) there is no known commercialization or promotion to persons residing in the United States . . . ; (3) the product is considered not to represent an unreasonable risk; and (4) the individual seeking to import the product affirms in writing that it is for the patient's own personal use. . . .

RPM 9-71-30(C).

¹⁰⁴ *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10156, at *12 (E.D.N.Y. July 14, 1992). The legislators stated, *inter alia*, that "the U.S. government should not be involved in abetting abortion." *Id.*

weeks, the FDA also received a letter from Senator Jesse Helms.¹⁰⁵ Senator Helms' letter demanded an immediate ban on RU 486, citing the risks of complications and the probability of mail order purchase of the drug.¹⁰⁶ Nineteen days later, the FDA issued Import Alert 66-47.¹⁰⁷ Agency documents supporting the Import Ban closely track the actual language of the legislators' letters.¹⁰⁸ No notice and comment procedure followed the change in policy.¹⁰⁹

b. *Effect*

FDA Import Alert 66-47 directs customs officials to "[a]utomatically detain all shipments of unapproved abortifacient drugs" to prevent unsupervised use or clandestine distribution.¹¹⁰ The Import Ban does not directly prohibit research on RU 486, as most scientists in the United States have been given exemptions to continue receiving supplies of the drug.¹¹¹ The FDA intended to permit ongoing research with RU 486 by issuing permits for investigation.¹¹² The Import Ban, has been criticized as adversely affecting critical research unrelated to abortion which requires supplies of RU 486.¹¹³

¹⁰⁵ *Import Ban*, *supra* note 7, at 44.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10156, at *13 (E.D.N.Y. July 14, 1992).

¹¹⁰ *Import Ban*, *supra* note 7, at 45-46. While the Import Ban does not specifically identify RU 486, Dr. Sobel, the FDA's Director of the Metabolism and Endocrine Drug Products Division, testified that he did not know of any other compounds to which this ban could apply. Ronald Cheesmore, the FDA's Associate Commissioner of Regulatory Affairs, testified that the Import Ban was issued in anticipation of a black market, despite the fact that the FDA had no evidence that RU 486 had been used outside the tightly controlled circumstances imposed by Roussel-Uclaf. *Id.* at 37.

¹¹¹ Dr. Sobel testified that any scientist would be able to receive an IND from the FDA, so that supplies of RU 486 could be imported. *Id.* at 39 (testimony of Solomon Sobel, M.D., Director, Division of Metabolism and Endocrine Drug Products).

¹¹² *Id.* at 37.

¹¹³ Numerous studies on RU 486 slowed down or ceased entirely after June 1989. *Id.* at 2. The Subcommittee on Regulation, Business Opportunities, and Energy found that of the thirteen clinical trials listed as "current" by the FDA, only five appeared to be truly active. The Chair of the Subcommittee explained that "[t]he remainder [of the clinical trials] have been stalled, primarily by the manufacturer's decision to withdraw RU 486 from the trials, or the researcher's concern that this drug has become so politicized that working with it can have damaging professional repercussions." *RU 486 and Medical Research*, *supra* note 26, at 2.

Research is impeded primarily because the manufacturer, Roussel-Uclaf, refuses to export RU 486 to the United States.¹¹⁴ Some scientists believe the Import Ban constitutes a significant deterrent to Roussel-Uclaf's decision not to apply for a license to distribute RU 486 in the United States.¹¹⁵ Indeed, the American Medical Association and the American Society for the Advancement of Science recently passed resolutions condemning the "hostile political climate" that has almost completely locked the drug out of U.S. research institutions.¹¹⁶ Moreover, given the continuing uncertainty over whether abortion will remain legal in the United States, Roussel-Uclaf is reluctant to invest time and money in a market which might soon be eliminated.¹¹⁷

3. *Benten v. Kessler*

On July 1, 1992 Leona Benten attempted to import RU 486 under the FDA's personal use exemption.¹¹⁸ Benten and her physician notified U.S. officials when and where they would be returning with the drug; customs officials at Kennedy International Airport subsequently confiscated Benten's RU 486 pills.¹¹⁹ Benten brought action pursuant to the Administrative Procedures Act,¹²⁰ to enjoin enforcement of the FDA ban on the import of RU 486.¹²¹ She claimed that the FDA illegally promulgated the ban on RU 486.¹²² The district court characterized the action

¹¹⁴ *Id.* at 2.

¹¹⁵ Dr. Horwitz believes the "import alert has a chilling effect on RU 486 research in this country and . . . it is not just a question of importing a drug like this into the United States, but also a question of American pharmaceutical manufacturers developing similar drugs in this country." *Id.* at 19.

It is interesting to note that the generic drug firm Apotex Inc. stated it would produce a copy of RU 486 if Roussel-Uclaf would only grant it the rights. Allan Thompson, *Apotex Seeks Right to Copy French Abortion Pill*, TORONTO STAR, July 29, 1992, at F3. In response, Dr. Andre Ulmann, a spokesperson for Roussel-Uclaf, said that Roussel-Uclaf would be interested in hearing from Apotex because his company has already tried unsuccessfully to find a U.S. company to buy the rights to RU 486. *Id.*

¹¹⁶ Kotulak, *supra* note 10, at C1.

¹¹⁷ *RU 486: Manufacturer Has "No Plans" to Seek U.S. Approval*, July 28, 1992, available in LEXIS, Nexis Library, AbtrRpt File (expressing the opinion that after the *Benten* case, Roussel-Uclaf may be more wary than ever about seeking FDA approval for RU 486).

¹¹⁸ *US Woman Challenges Ban on Abortion Pill*, BOSTON GLOBE, July 2, 1992, at 3.

¹¹⁹ *Id.*

¹²⁰ Administrative Procedures Act, 5 U.S.C. §§ 553, 706 (2)(A) (1988); 21 C.F.R. § 10.70 (1988).

¹²¹ *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10156, at *3 (E.D.N.Y. July 14, 1992).

¹²² *Id.* at *2.

as “a lawsuit waiting to happen”¹²³ and termed the FDA’s treatment of RU 486 “arbitrary and capricious.”¹²⁴

Regarding the personal use exemption, “no notice was given of the agency’s [FDA’s] intent to adopt this major revision in the agency’s regulatory stance towards unapproved drugs, nor was comment invited either before or after it was adopted.”¹²⁵ The district court judge found that the FDA’s decision to ban RU 486 was not based on “any bonafide concern for the safety of the users of the drug.”¹²⁶ Rather, the Import Alert much more likely resulted from “political considerations having no place in FDA decisions on health and safety.”¹²⁷

The FDA argued that, notwithstanding the legitimacy of its policy, Benten had no right to import RU 486.¹²⁸ Moreover, the FDA asserted that the Import Alert did not impose new duties on the agency.¹²⁹ The district court held, however, that the February 1989 revision of the RPM created Benten’s right to a case-by-case discretionary decision by the FDA regarding her request to import RU 486 for her personal use.¹³⁰

Although the district court ordered the FDA to immediately release the impounded dosage of RU 486,¹³¹ later that same day a three-judge appellate panel stayed the lower court’s injunction against the seizure.¹³² Benten’s attorneys filed an emergency appeal with the Supreme Court that night.¹³³ In a two-paragraph

¹²³ *Id.* at *1.

¹²⁴ Judge Sifton wrote that the record “reveals a history of political and bureaucratic timidity mixed with well-intentioned blundering.” *Id.*

¹²⁵ *Id.* at *12.

¹²⁶ *Id.* at *14. A request made pursuant to the Freedom of Information Act revealed that no documents exist in the FDA’s files which explain any factual basis for the change in policy. *Id.* at *27–28.

¹²⁷ *Id.* at *15. Judge Sifton commented that counsel for the FDA “went out of his way to offer to return the drug to the plaintiff for use in some other country, a somewhat paradoxical position given the safety concerns defendants have voiced in other contexts.” *Id.* at *18.

¹²⁸ *Id.* at *23.

¹²⁹ *Id.*

¹³⁰ *Id.* The court also stated that the nondiscretionary detention of RU 486 established by the FDA ban did in fact create a new duty on FDA personnel. *Id.*

¹³¹ *Id.* at *28,*30.

¹³² *US High Court to Rule on Ban of Abortion Pill*, BOSTON GLOBE, July 15, 1992, at 3.

¹³³ *Id.* Justice Thomas oversees cases from the Second Circuit. When he received Benten’s petition for an emergency appeal, Justice Thomas requested an opinion from the Justice Department. The Bush administration argued that federal judges do not have the power to overturn the FDA ban because agency officials were enforcing a clearly valid statute. *US Asks Court to Back Ban on Abortion Pill*, BOSTON GLOBE, July 17, 1992, at 3.

opinion, the Supreme Court denied Benten's application to vacate the Court of Appeals stay.¹³⁴ The per curiam opinion simply stated that the petitioners failed to demonstrate a substantial likelihood of success on the merits.¹³⁵

4. Legislative Initiatives

a. *Federal*

In February 1992, Representative Ron Wyden (D-OR) introduced a bill to make the FDA Import Alert ineffective with respect to RU 486.¹³⁶ Officially referred to as the RU 486 Regulatory Fairness Act, H.R. 875, Wyden's bill had sixty-one sponsors at the end of the summer of 1992.¹³⁷ Senator Alan Cranston (D-CA) subsequently proposed a Senate version of Wyden's bill.¹³⁸ Late in July 1992, Representative Patricia Schroeder (D-CO) introduced a bill specifically to reverse the Supreme Court's action in *Benten v. Kessler* and permit Leona Benten to take RU 486.¹³⁹ After the Court's decision, however, Benten had only a few days remaining in which she could safely use RU 486. As anticipated, Schroeder's legislation did not receive the necessary votes in time. Wyden's bill is still pending.

b. *State Legislation and Advocacy*

In 1991, the New Hampshire legislature passed a resolution to make the state a test site for RU 486.¹⁴⁰ California passed an

¹³⁴ *Benten v. Kessler*, 112 S.Ct. 2929, 1992 U.S. LEXIS 4756, (July 17, 1992) (per curiam).

¹³⁵ *Id.* Justices Blackmun and Stevens dissented. Justice Stevens dissented on the grounds that, in accordance with the FDA's personal use exemption, the only legitimate governmental interest in seizing Benten's RU 486 is the interest in avoiding significant health risks. He believed the FDA did not demonstrate this interest and that its stated reason for the seizure did not justify the "burdensome consequences" on Benten. *Id.* at *2-3.

¹³⁶ *Bills and Resolutions Introduced February 6*, The Bureau of National Affairs, Inc., Feb. 8, 1992, available in LEXIS, Nexis Library, Lglnew File.

¹³⁷ *RU 486 Report*, *supra* note 2, at 2.

¹³⁸ The Senate legislation is S 2268. *Bills and Resolutions Introduced February 26*, The Bureau of National Affairs, Inc., Feb. 28, 1992, available in LEXIS, Nexis Library, Lglnew File.

¹³⁹ David Lawsky, *Bill Offered to Make French Abortion Drug Available*, July 20, 1992, available in LEXIS, Nexis Library, Lglnew File. Rep. Schroeder explained that the "medical McCarthyism" of the FDA prompted her to introduce the legislation. *RU 486 and Medical Research*, *supra* note 26, at 2 (testimony of Rep. Patricia Schroeder (D-CO)).

¹⁴⁰ NH H.C.R. 11, Reg. Sess., (May 17, 1991). Gary Gilmore is the New Hampshire

identical resolution the following week.¹⁴¹ A number of other states have now enacted similar legislation to encourage new research with RU 486 and counteract the effects of the FDA's Import Ban.¹⁴² In addition, numerous groups and organizations have expressed their support for research involving RU 486 and contacted the manufacturer directly.¹⁴³ Over 3000 scientists and health professionals have now signed petitions to Roussel-Uclaf and Hoescht, demanding that RU 486 be marketed in the United States.¹⁴⁴ Moreover, a recent survey reveals that the general public

state representative who sponsored the RU 486 resolution. The state legislature passed the legislation on May 5, 1991. Voting on the resolution was 211 in favor and 130 against, and 14 in favor and 10 against in the state House of Representatives and the state Senate, respectively. Mr. Gilmore believes that the FDA's Import Ban is merely symbolic, and cannot be justified by any scientific reasons. He notes that the potential medical benefits of RU 486 convinced even representatives who are Catholic and strongly opposed to RU 486 as an abortifacient of the importance of a resolution regarding testing. The public relations division of Roussel-Uclaf contacted Mr. Gilmore the day after the vote on the RU 486 resolution to confirm the results. Telephone Interview with Gary Gilmore, New Hampshire State Representative, (Sept. 20, 1991).

¹⁴¹ CA A.J.R. 40, Reg. Sess., (May 21, 1991).

¹⁴² The resolutions request Congress to rescind the Import Ban and/or authorize new clinical testing of RU 486 in the United States. AK H.J.R. 58, 17th Leg., 2d Reg. Sess., (Jan. 14, 1992); FL S.R. 1102, Reg. Sess., (Jan. 14, 1992); HI S.C.R. 18, 16th Leg., Reg. Sess., (Jan. 23, 1992); KS H.R. 6020, 74th Leg., 2d Reg. Sess., (Jan. 30, 1992); ME S.B. 971, 115th Leg., 2d Reg. Sess., (March 27, 1992); MN S.B. 1593, 77th Leg., Reg. Sess., (May 20, 1991); WI A.J.R. 106, 90th Leg., Reg. Sess., (Jan. 23, 1992). *Contra* RI S.B. 2028, Reg. Sess., (Feb. 12, 1992) (prohibiting state from investing funds in companies or institutions which make loans to companies involved in manufacture, distribution, or sale of RU 486); LA S.B. 1069, 1990 Reg. Sess., (April 30, 1990) (prohibiting production, manufacture, distribution, and possession of RU 486).

¹⁴³ The American Medical Women's Association has focused on negotiations with Roussel-Uclaf in an attempt to convince the company to make the drug available in the United States. *RU 486 and Medical Research*, *supra* note 26, at 3 (testimony of Marjorie Braude, M.D., on behalf of the American Medical Women's Association); *see also American Jewish Congress Urges U.S. to Make RU 486 Available for Widespread Use*, PR Newswire, Aug. 12, 1992, available in LEXIS, Nexis Library, Omni File; The Endocrine Society Council, *Resolution on RU 486 and Freedom of Scientific Inquiry*, June 18, 1991, presented to Small Business Subcommittee on Regulation, Business Opportunities & Energy, July 28, 1992; Gale Scott, *HHC [Health and Hospitals Corporation] Wants RU 486 Here, But Won't Boycott Maker*, NEWSDAY, July 24, 1992, at 33; *California: Medical Association Resolves to Import RU 486*, Mar. 20, 1992, available in LEXIS, Nexis Library, AbtrRpt File.

In addition, New York City Mayor David Dinkins wrote to President Bush and thirty mayors nationwide, urging them to formally encourage Roussel-Uclaf to seek an application for the import of RU 486. Lou Fintor, *U.S. Lawmakers and Politicians Formalize Support for RU 486*, 83 J. NAT'L CANCER INST. 816, 818 (1991).

¹⁴⁴ *RU 486 and Medical Research*, *supra* note 26, at 8 (testimony of Eleanor Smeal, President, Feminist Majority Foundation).

also strongly supports the availability of the drug in the United States.¹⁴⁵

State and local advocacy for RU 486 may become a decisive factor in the ongoing debate over the drug. For example, the Center for Reproductive Law and Policy is researching the intra-state mini-FDA in California as a potential mechanism for RU 486 approval.¹⁴⁶ Approval of RU 486 in California would grant millions of women in that state access to the drug, as well as allow constitutional claims for equal protection by women in every other state.¹⁴⁷

III. THE ROLE OF GENDER

The controversy surrounding RU 486 is inextricably linked to the use for which it is currently licensed: abortion.¹⁴⁸ Since abortion is an option available only to women, the debate over RU 486 is inherently related to gender.¹⁴⁹ Gender is thus a factor in current decisions regarding RU 486 and should be considered in conjunction with the regulatory framework and health care systems in the United States and Great Britain.

A. *Gender-Specific Issues and Health Care*

The systematic exclusion of women from health care training until late in this century¹⁵⁰ has adversely affected research and treatment of women's health concerns in the United States and

¹⁴⁵ *Harris Poll: Majority Support Availability of RU 486*, Aug. 13, 1992, available in LEXIS, Nexis Library, AbtrRpt File. In a Harris poll conducted July 17–19, 1992, respondents were asked whether RU 486 should be available in the United States. Of 1,256 adults, 60 percent answered yes, 36 percent replied no, and 4 percent were unsure. Respondents were also asked whether they were aware of the Supreme Court's decision in *Bentley v. Kessler*. Of the 71 percent who had seen or heard of the ruling, 53 percent disapproved of the decision, 41 percent approved, and 6 percent were unsure. *Id.*; see also, e.g., Malcolm Gladwell, *Supporters of Abortion Pill Divided on Court Challenge*, WASH. POST, July 17, 1992, at A4.

¹⁴⁶ *RU 486 and Medical Research*, *supra* note 26, at 7 (testimony of Kathryn Kolbert, Vice President, Center for Reproductive Law and Policy).

¹⁴⁷ *Id.*

¹⁴⁸ See Mariner, *supra* note 45, at 600.

¹⁴⁹ See *infra* notes 174–75 and accompanying text.

¹⁵⁰ Camilla Parham, M.D., Family Practitioner, Address at the 1992 Empowering Women Forum Series: Invasion of the Body Snatchers (Controlling Women's Bodies, Punishing Women's Lives, Freeing Ourselves), at the Boston YWCA (Jan. 27, 1992) [hereinafter 1992 Empowering Women Forum Series].

Great Britain.¹⁵¹ During the nineteenth century, women were often the subjects of medical experimentation.¹⁵² In the twentieth century, hysterectomies are the most frequently performed operation, notwithstanding the fact that this expensive operation is unnecessary approximately 60 percent of the time.¹⁵³ Coronary heart disease is another example of how research conducted by and tailored to the needs of men can be inadequate when it comes to treating women.¹⁵⁴

The political process in the United States also affects a variety of health care decisions, particularly through congressional control over funding. For example, contraceptive research has never been a priority for the federal government.¹⁵⁵ Yet, Medicaid has never stopped paying for the sterilization of women.¹⁵⁶ Likewise, the “ongoing prohibition against federal funding for abortion research [the “Hyde Amendment”¹⁵⁷] . . . implies that our society

¹⁵¹ Eleanor Smeal believes that “exclusion of women from leadership positions has resulted in the exclusion of women from the research agenda.” *RU 486 and Medical Research*, *supra* note 26, at 9 (testimony of Eleanor Smeal, President, Feminist Majority Foundation); *see also supra* notes 118–19.

¹⁵² Ruth Hubbard, Professor Emeritus in Biology at Harvard University, Board Member, Civil Liberties Union of Massachusetts and Council for Responsible Genetics, Address at 1992 Empowering Women Forum Series, *supra* note 150.

¹⁵³ *Id.* Hysterectomies are more common in the United States than in Canada or Great Britain. The American Medical Association recommends that a woman seek at least two opinions before a hysterectomy is performed. *Id.*

¹⁵⁴ Researchers found sex bias in the management of coronary heart disease of women and highlighted the problems of extrapolating male-generated research findings to women. Ayanian and Epstein describe such skewed medical practices as the “Yentl Syndrome.” John Ayanian and Arnold Epstein, *Differences in Use of Procedures Between Women and Men Hospitalized for Coronary Heart Disease*, 325:4 *NEW ENG. J. MED.* 221 (1991); Richard M. Steingart et al., *Sex Difference in Management of Coronary Artery Disease*, 325:4 *NEW ENG. J. MED.* 226 (1991) (physicians pursue less aggressive management approach for coronary disease in women despite greater cardiac disability in women).

¹⁵⁵ “In the United States today, the government spends less on contraceptive research in a single year than the Defense Department spends in 15 minutes.” *NEWSDAY*, Jan. 12, 1989, at 77, *quoted in* Valerie Cotler, *The FDA, Contraception, and RU 486*, 12 *WOMEN’S RTS. L. REP.* 123, 131 n.152 (1990). Worldwide spending for methods of fertility regulation has declined by nearly one-quarter since its peak in 1972. *RU 486 in Foreign Markets*, *supra* note 1, at 5 (testimony of Jacqueline Darroch Forrest, Ph.D., Vice President for Research, Alan Guttmacher Institute).

¹⁵⁶ Dr. Parham stated that while she was a practitioner in North Carolina during the late 1980s, she became aware that many women underwent tubal ligations on their twenty-first birthdays—as soon as they became eligible for Medicaid payments for the operation. Informed consent did not exist: the women mistakenly believed that tubal ligation would be a more permanent form of birth control, rather than irreversible sterilization. She emphasized, however, that this situation is not unique to North Carolina. Camilla Parham, M.D., Address at 1992 Empowering Women Forum Series, *supra* note 150.

¹⁵⁷ The Hyde Amendment specifies that federal funding may not be used for abortions

has no interest in improving the safety of an operation that 1.6 million citizens undergo each year."¹⁵⁸

The Supreme Court upheld the Hyde Amendment in 1980 in *Harris v. McRae*,¹⁵⁹ stating: "it simply does not follow [from *Roe v. Wade*] that a woman's freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices."¹⁶⁰ Herein lies the crucial difference: while the political process which controls Medicaid and Medicare creates a fragmented approach to health care, the British NHS provides the entitlement which *Harris v. McRae* denies—a *comprehensive* medical plan to every citizen.¹⁶¹

The most recent affirmation of this piecemeal approach to health care in the United States is the so-called "gag rule" enunciated in *Rust v. Sullivan*.¹⁶² The "gag rule" is a regulation promulgated by the Department of Health and Human Services that forbids medical personnel in federally funded clinics from advising pregnant women about abortion.¹⁶³ The policy is contrary to the provision of health care in Great Britain, where necessary

except where the life of the pregnant woman is endangered. H.R. 3839, 102d Cong., 1st Sess. (1991). The most recent appropriations rider on the Department of Health and Human Services spending is Sec. 203 of Title II of H.R. 3839.

¹⁵⁸ *RU 486 in Foreign Markets*, *supra* note 1, at 5 (testimony of David Grimes, Professor of Obstetrics and Gynecology and Preventative Medicine at the University of Southern California School of Medicine in Los Angeles).

¹⁵⁹ 448 U.S. 297, 298 (1980).

¹⁶⁰ *Id.* at 316. Many women's advocates believe this decision eliminated any possibility of choice for many women, particularly women of color who are statistically in the lowest socioeconomic groups of U.S. society. Speech by Janet Mitchell, *The Politics of RU-486, Norplant, and Depo-Provera: Expanding Women's Choices or Increasing Social Control?*, Speech at Simmons College (Oct. 5, 1991).

¹⁶¹ See *supra* notes 82–86 and accompanying text.

¹⁶² See 111 S.Ct. 1759, 1762 (1991). The Supreme Court rejected a facial challenge to regulations promulgated by the Department of Health and Human Services (HHS). *Id.* at 1771.

¹⁶³ The relevant provisions specified that any clinic receiving federal funds: (1) may not provide counselling concerning abortion or provide referral for abortion; (2) may not encourage, promote, or advocate abortion; and (3) must be organized so that the clinic's other medical services are physically and financially separated from prohibited abortion activities. *Id.* at 1765–66.

In November 1991 and again on October 2, 1992, the House of Representatives failed to override the presidential veto of legislation preventing the gag rule from taking effect. 137 Cong. Rec. H10856 (daily ed. Nov. 22, 1991); Elizabeth Neuffer, *House Sustains Bush on Abortion*, BOSTON GLOBE, Oct. 3, 1992, at 3. The U.S. Court of Appeals, however, voted 3-0 on November 3, 1992 to prevent the government from enforcing the HHS regulation. The Court of Appeals found a procedural violation in the Bush administration's failure to hold hearings on its modified version of the gag rule. Dick Lehr, *Court Places Hold on Clinic "Gag Rule"*, BOSTON GLOBE, Nov. 4, 1992, at 3.

medications or procedures do not depend on the type of procedure nor on the recipient's financial status.¹⁶⁴ The British provision of comprehensive medical care, including funding for abortion,¹⁶⁵ suggests that—unlike the United States—reproductive decisions in Great Britain are viewed as a part of overall health care.

B. *Gender-Specific Issues and Equal Protection*¹⁶⁶

1. The British Model

The British equivalent of American Equal Protection analysis is natural justice, the requirements of which are essentially unwritten rules of the common law.¹⁶⁷ Although the doctrine is often explained purely in terms of fairness, natural justice is not a natural law philosophy, and is more like administrative law.¹⁶⁸ Natural justice evolved through the control exercised by central courts over courts of inferior jurisdiction and focuses primarily on procedural concerns.¹⁶⁹ The differences between the British approach and that of U.S. courts can be summed up as follows:

The power of constitutional adjudication enjoyed by the Supreme Court and the inferior federal courts both emphasizes their central role in the political process and encourages greater flexibility in handling precedents than is the case in Great Britain. Moreover, the courts are perceived in the U.S. as a major forum for the determination of social standards in regulatory affairs, whereas in the U.K. such matters are

¹⁶⁴ See *supra* notes 82–86 and accompanying text.

¹⁶⁵ Abortion Act of 1967, sec. 1, sched. 3, amended by Health Services Act of 1980, sched. 1, para. 17; National Health Service and Community Care Act 1990, sec. 66(1), sched. 9, para. 8; see also Abortion Regulations of 1991, S.I. 1991, No. 499.

¹⁶⁶ The focus in this section is on the Equal Protection Clause of the Fourteenth Amendment, rather than the right to privacy which has been traditionally linked to reproductive decisions and discussions of health care. It would seem that equal protection jurisprudence is the more forward-looking approach, given the Court's clear retreat from the doctrine of privacy. See, e.g., *Bowers v. Hardwick*, 478 U.S. 186 (1986). Additionally, there has been a marked shift in the Court's ideological perspective since the landmark privacy cases were decided.

¹⁶⁷ EMLYN C.S. WADE AND ANTHONY W. BRADLEY, *CONSTITUTIONAL AND ADMINISTRATIVE LAW* 642 (1985).

¹⁶⁸ See *id.* at 649–50.

¹⁶⁹ *Id.* at 642. The procedures British courts review under natural justice include the right to be heard by an unbiased tribunal, the right to have notice of charges of misconduct, and the right to be heard in answer to charges. *Id.* at 649.

seen as predominantly within the province of statutory control.¹⁷⁰

The licensing of RU 486 reveals the independence of statutory agencies such as the CSM. Members of Parliament did not know of the pending decision on RU 486 until shortly before the Health Secretary made the official announcement that it would be distributed.¹⁷¹ Such a scenario would be unlikely in the United States, given congressional oversight of the FDA.¹⁷² In addition, British courts exercise a higher degree of deference in regards to administrative decision-making than courts in the United States.¹⁷³ Consequently, unlike U.S. reliance on Equal Protection analysis, British jurisprudence has not addressed gender-specific health care issues in relation to natural justice.

2. U.S. Equal Protection and Gender-Specific Issues

In the United States, the Equal Protection clause of the Fourteenth Amendment may be invoked when legislation makes an impermissible classification which causes maldistribution of a particular thing or outright denial of access to a substantive right.¹⁷⁴ Difficulties arise, however, in evaluating legislation which only addresses the experiences or concerns of a single sex.¹⁷⁵ The argument is that legislatures are not imposing a classification when an issue is specific to one gender, because legislatures do not create the gender distinction itself.¹⁷⁶ Indeed, there is a question as to whether the doctrine of Equal Protection is capable of encompassing decisions which affect only women.¹⁷⁷

Catherine MacKinnon, a leading scholar in feminist legal theory, has observed:

¹⁷⁰ Teff, *supra* note 39, at 586–87.

¹⁷¹ On July 1, 1991, Tories in the House of Commons demanded to know what was going on with RU 486 because the only information available was provided by the press and not the government. Rowan Dore, *Abortion Pill Statement Demanded*, July 1, 1991, available in LEXIS, Nexis Library, Intl File.

¹⁷² See text accompanying note 60.

¹⁷³ See *supra* note 56.

¹⁷⁴ See Wendy K. Mariner, *Access to Health Care and Equal Protection of the Law: The Need for a New Heightened Scrutiny*, 12 AM. J.L. & MED. 345, 350 (1986).

¹⁷⁵ See generally Catherine MacKinnon, *Difference and Dominance: On Sex Discrimination*, in FEMINISM UNMODIFIED: DISCOURSES ON LIFE AND LAW 41 (1987).

¹⁷⁶ Susan Estrich and Kathleen Sullivan, *Abortion Politics: Writing for an Audience of One*, 138 U. PA. L. REV. 119, 124 n.10, 145 (1989).

¹⁷⁷ MacKinnon, *supra* note 175, at 37; Susan Atkins, *Women's Rights*, in MOBILIZING LAW THROUGH SOCIAL ACTION 353 (1986).

The legal mandate of equal treatment—which is both a systemic norm and a specific legal doctrine— becomes a matter of treating likes alike and unlikes unlike; and the sexes are defined as such by their mutual unlikeness. . . . A built-in tension exists between this concept of equality, which presupposes sameness, and this concept of sex, which presupposes difference.¹⁷⁸

The concept of Equal Protection is at odds with gender-specific issues because Equal Protection analysis proceeds on the assumption that for some things, women are the same as men, and that for other things, women are different than men.¹⁷⁹ While this appears quite rational, the flaw in the scheme is that men remain the basis for comparison; “unquestioned is how difference is socially created or defined, who sets the point of reference for sameness.”¹⁸⁰

The inherent tension between notions of equality and societal concepts of gender, i.e. the tension within Equal Protection analysis itself, can be addressed only by adopting a more appropriate point of reference.¹⁸¹ MacKinnon describes three possible approaches to Equal Protection analysis: (1) the “difference” doctrine, which grants women special protections to the extent that they are different from men, and values or compensates women for the characteristics which distinguish women from men; (2) the gender neutrality or “sameness” doctrine, which grants women access to what men have to the extent that they are the same as men; and (3) the “dominance” theory which views sex inequality questions as a result of systematic dominance—male supremacy—and perceives social inequality from the standpoint of subordination of women to men.¹⁸²

The difference doctrine underlies standard legal analysis of gender-specific issues such as pregnancy.¹⁸³ Pregnancy presents a difficult case in terms of sex equality because it is a situation where a woman is simply not “equal” to a man, if equal is inter-

¹⁷⁸ MacKinnon, *supra* note 175, at 32–33.

¹⁷⁹ *See id.* at 33–34.

¹⁸⁰ Catherine MacKinnon, *Reflections on Sex Equality Under the Law*, 100 *YALE L.J.* 1281, 1287 (1991).

¹⁸¹ *See* MacKinnon, *supra* note 175, at 40.

¹⁸² *See id.* at 33, 40. MacKinnon explains that the difference approach, implicitly based on Aristotle, misses the fundamental question: “Why should you have to be the same as a man to get what a man gets simply because he is one? Why does maleness provide an original entitlement, not questioned on the basis of *its* gender?” *Id.* at 37.

¹⁸³ *See id.* at 33.

preted as “the equivalent of.” The law formerly treated pregnant women differently than men, and differently than other women, in order to grant or deny special protections or benefits.¹⁸⁴

The Pregnancy Discrimination Act (PDA)¹⁸⁵ amended Title X and “made clear that, for all Title VII purposes, discrimination based on a woman’s pregnancy is, on its face, discrimination because of her sex.”¹⁸⁶ PDA thus brought the treatment of pregnancy, at least by employers, within the analytical scope of the gender neutrality doctrine.¹⁸⁷ PDA essentially compelled the Court’s decision in *UAW v. Johnson Controls, Inc.*,¹⁸⁸ a case which addressed employer decisions involving sex-specific traits.¹⁸⁹ The Court invalidated the company’s sex-specific fetal protection policy,¹⁹⁰ because the policy “classifies on the basis of gender and childbearing capacity, rather than fertility alone.”¹⁹¹ The Court mandated that, in order to effectuate the goal of protecting the offspring of its employees from lead, Johnson Controls place the same constraints or offer the same choices to all fertile individuals.¹⁹²

¹⁸⁴ The first such case, *Geduldig v. Aiello*, upheld a state’s disability insurance system which excluded benefits for disability accompanying normal pregnancy and childbirth. 417 U.S. 484 (1974). The Court held that the exclusion did not constitute “invidious discrimination” because the state’s decision was not based on gender as such. *Id.* at 494, 496 n.20. The Court expanded the rationale of *Geduldig* in *General Electric Co. v. Gilbert*, by rejecting a Title VII challenge to a private employer’s disability plan excluding pregnancy. 429 U.S. 125, 137–38 (1976). The Court specifically held in that case that discrimination on the basis of pregnancy is not discrimination on the basis of sex. *Id.* at 145–46.

¹⁸⁵ Pregnancy Discrimination Act, 42 U.S.C. § 2000e(k) (1978).

¹⁸⁶ *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 684 (1983).

¹⁸⁷ See Pregnancy Discrimination Act, *supra* note 185, § 701(k). By prohibiting discrimination on the basis of pregnancy because it is the same as discrimination on the basis of sex, the Act asserts that pregnant women are the same as all nonpregnant persons in the terms and conditions of employment. See *id.*

¹⁸⁸ 111 S.Ct. 1196 (1991).

¹⁸⁹ *Johnson Controls* is not an Equal Protection case, but a brief analysis of its reasoning will provide an analogy to the denial of RU 486.

¹⁹⁰ *Johnson Controls*, 111 S.Ct. at 1202. Eight employees of Johnson Controls, a battery manufacturer, became pregnant while maintaining blood lead levels exceeding those recommended by the Occupational Safety and Health Administration (OSHA). In response, Johnson Controls barred all women from jobs involving actual or potential exposure to lead, unless the women could medically document their infertility. Men, regardless of whether they were planning a family, were not encompassed by the lead-exposure policy. *Id.* at 1203.

¹⁹¹ *Id.* The majority stated: “The bias in Johnson Controls’ policy is obvious. Fertile men, but not fertile women, are given a choice as to whether they wish to risk their reproductive health for a particular job.” *Id.* at 1202.

¹⁹² *Id.* at 1217. “Our conclusion is bolstered by PDA . . . [under which] such a classification must be regarded as explicit sex discrimination. Respondent has chosen to treat

The opinion suggests that attributes ordinarily defined as sex-specific traits, such as pregnancy, may be recharacterized in ways that emphasize sameness rather than difference. In *Johnson Controls*, the starting point of the analysis is sameness—fertility. Classifying only on the basis of fertility prohibits the distinctions between men and women as well as distinctions between pregnant women and all nonpregnant persons that were evident in pre-PDA holdings. The result reached by the Court by relying on PDA seems identical to one it might have reached by applying heightened scrutiny to the employer's classification.¹⁹³

The holding in *Johnson Controls* is also analogous to the result reached by utilizing MacKinnon's dominance theory to assess the company's fetal protection policy.¹⁹⁴ The dominance theory questions not only the validity of Johnson Controls' classifications, but the dynamics of the decision-making process itself.¹⁹⁵ The dominance theory is critical of reality, and far from the mainstream rules of law.¹⁹⁶ Yet,

[i]f sex inequalities are approached as matters of imposed status, which are in need of change if a legal mandate of equality means anything at all, the question whether women should be treated unequally means simply whether women should be treated as less. When it is exposed as a naked power question, there is no separable question of what ought to be.¹⁹⁷

MacKinnon's view of sex inequality encompasses a variety of societal aspects which cause or contribute to the imposed status of women. In contrast, traditional legal analysis grants presumptive validity to legislative and employment classifications by declining to consider the origins or implications of the classification.

all its female employees as potentially pregnant; that choice evinces discrimination on the basis of sex." *Id.* at 1210.

¹⁹³ See *Johnson Controls*, 111 S.Ct. at 1215 ("The fetal protection policy at issue here reaches too far. . . . There has been no showing that the policy is reasonably necessary to ensure safe and efficient operation of Johnson Controls' battery manufacturing business.").

¹⁹⁴ MacKinnon, *supra* note 175, at 45 ("Seeing sex equality questions as matters of reasonable or unreasonable classification is part of the way male dominance is expressed in law. . . . In the dominance approach, sex discrimination stops being a question of morality and starts being a question of politics.").

¹⁹⁵ MacKinnon's analysis would focus on the "socially situated subjection of women" and the (presumptively) male-dominated power structure of the company. See *id.* at 41.

¹⁹⁶ *Id.* at 40.

¹⁹⁷ *Id.* at 43.

IV. DENIAL OF RU 486 AS GENDER BIAS

A. *RU 486 and Denial of Access*

The denial of RU 486 in the United States, like Johnson Controls' former policy, is an example of a dubious classification. RU 486 is not treated like other drugs the FDA evaluates, and the agency's decisions about RU 486 are made on the basis of different criteria than other unapproved drugs.¹⁹⁸ The Subcommittee on Regulation, Business Opportunities and Energy concluded that the FDA's justification for the Import Ban—the hazardous nature of RU 486—seemed prompted by a shift in policy, rather than an objective evaluation of available information.¹⁹⁹ The FDA did not contact a single researcher or expert actually studying the drug prior to its decision,²⁰⁰ nor did the agency evaluate either RU 486 or the two prostaglandins currently used with it for safety and effectiveness.²⁰¹

Similar to the employer's policy in *Johnson Controls*, the Import Ban reaches too far; there is no showing that it is reasonably necessary to ensure the safety, quality or effectiveness of the drug at issue. An evaluation of RU 486 on the basis of its many proven benefits would mandate a different result than the current Import Ban. Denying access to RU 486 does not further the government's primary objective to preserve and promote the public health.²⁰²

It is thus doubtful whether the FDA decision to ban the importation of RU 486 would pass muster under the minimal scrutiny afforded by the rational relation standard of Equal Protection.

¹⁹⁸ See *Benten v. Kessler*, No. CV-92-3161, 1992 U.S. Dist. LEXIS 10156, at *14–15 (E.D.N.Y. July 14, 1992); see also *supra* notes 104–09 and accompanying text.

¹⁹⁹ See *Import Ban*, *supra* note 7, at 1–2. No studies or other scientific data were cited by officials of the FDA to support its statement that the drug is a health hazard. See *id.* at 39–40. When asked to cite studies that the agency had relied on for its conclusion that RU 486 is a hazardous drug, the Associate Commissioner of Regulatory Affairs responded that the FDA “certainly just felt like the importation of this drug was very serious.” *Id.* at 43.

²⁰⁰ *Id.* at 38.

²⁰¹ *Id.* at 36.

²⁰² “The only way to understand an import alert that has no basis in science for a drug that represents no overall threat to the public's health” is to view it as the message of “the United States government [that it] does not want this substance to enter this country for any reason whatsoever.” *RU 486 and Medical Research*, *supra* note 26, at 6 (testimony of Arthur L. Caplan, Ph.D., Director, Center for Biomedical Ethics).

B. *RU 486 and Equal Protection*

In accordance with the Equal Protection theories described by MacKinnon, RU 486 should be made available in the United States. The difference doctrine of Equal Protection would entitle access to RU 486 as a means of compensating women for the adverse characteristics which distinguish women from men.²⁰³ Even if its use as an abortifacient were to be entirely discounted, the potential benefits of RU 486 accrue disproportionately to women.²⁰⁴ RU 486 has potential for treatment of diseases and disorders which only women suffer as a matter of genetics, and thus would equilibrate women with men when it comes to these gender-specific concerns.

The gender neutrality doctrine mandates that RU 486 be made available to women because they are the same as men in that the government has an equal responsibility to promote public health. If men are granted access to the safest procedures available for the treatment of life-threatening disorders, Equal Protection must mean that women are entitled to equivalent access to medical technology. Under either approach, the potential of RU 486 for women's health care renders its denial a denial of Equal Protection in health care to women.

Moreover, many compelling arguments can be made that the possibility of increased reproductive autonomy with RU 486 is a sex equality right deserving protection under the Fourteenth Amendment.²⁰⁵ Mariner argues:

To permit the withdrawal of RU 486 solely because it terminates pregnancy can be seen as a means of denying women

²⁰³ See *supra* notes 181–82 and accompanying text.

²⁰⁴ This is apparent when one considers the list of diseases and disorders for which RU 486 is a potential treatment. Breast cancer, Cushing's Syndrome, endometriosis, and fibroid tumors, to name just the most well-documented applications of RU 486, disproportionately affect women. It is also intuitive that RU 486 is applicable primarily to women's health concerns because it interacts with progesterone, a female hormone. See *supra* notes 16–30 and accompanying text.

²⁰⁵ Lawrence Tribe asserts that reproductive autonomy plays a fundamental role in the "intensely public question of the subordination of women to men through the exploitation of pregnancy." TRIBE, *supra* note 37 at 2; see also Sara Fuchs, *Women's Quest for Economic Equality*, J. ECON. PERSP. 25, 33–37 (1989) (control over the rate of childbirth as key factor in recent gains in women's wages relative to men's); Michelle Stanworth, *Reproductive Technologies and the Deconstruction of Motherhood*, in REPRODUCTIVE TECHNOLOGIES: GENDER, MOTHERHOOD, AND MEDICINE 10, 15 (Michelle Stanworth ed., 1987) ("fertility control coexists with a powerful ideology of motherhood—the belief that motherhood is the natural, desired and ultimate goal of all 'normal' women").

control over reproduction, thus denying them access to a particular form of care solely because they are women (or at least pregnant women).²⁰⁶

Even if surgical abortion remains legal in the United States, it seems inefficient, if not cruel, to deny women a safer alternative.²⁰⁷

C. *Gender Bias and RU 486*

Both the British and the U.S. legal and medical systems were structured and completely controlled by males until at least the beginning of the twentieth century.²⁰⁸ Women as a class, although never constituting a numerical minority, have been a political minority—if not a non-entity.²⁰⁹ The dominance theory of Equal Protection analysis advocated by MacKinnon suggests that RU 486 should be made available to women to counteract the effects of systematic societal dominance of men over women.²¹⁰

Gender bias in governmental actions may be characterized as either affirmative or negative.²¹¹ The affirmative view is to frame gender bias as a denial of the *freedom to* do something all men are allowed to do. Conversely, a negative definition of gender bias is a denial of *freedom from* government restrictions on access to things all men may receive. The denial of RU 486 in the United States constitutes gender bias under either view. First, men are free to choose when and under what conditions they will assume the responsibilities of becoming a parent. Women do not have this same choice if their reproductive autonomy is denied. If RU 486 is currently being denied in the United States because it is

²⁰⁶ Mariner, *supra* note 45, at 600; *see also* Nahid Toubia, *Perspectives on the 'Abortion Pill' RU 486: Liberation or Nightmare?* L.A. TIMES, June 21, 1991, at B7 (U.S. policy on RU 486 needlessly jeopardizes millions of lives).

²⁰⁷ *Id.*

²⁰⁸ "No woman had a voice in the design of the legal institutions that rule the social order under which women, as well as men live." MacKinnon, *supra* note 180, at 1281.

²⁰⁹ Four women were elected to the Senate in the November 1992 elections, bringing the total number of women to 6. Prior to the election, there were 29 women in the House of Representatives. An unprecedented 108 women ran for seats in the House of Representatives in November 1992. Chris Black, *Four Women, Including First Black, Elected*, BOSTON GLOBE, Nov. 4, 1992, at 1. Despite such impressive gains, women and minorities in the United States remain drastically underrepresented. *See* John Hendren, *Women Lawmakers Try to Make Up for Low Numbers with Combative Stance*, States News Service, Feb. 4, 1992, available in LEXIS, Nexis Library, Omni file.

²¹⁰ *See supra* notes 194–95.

²¹¹ *See generally* FRIED, *supra* note 37.

an abortifacient, then all women are deprived of its other benefits, despite the fact that not all women are or will ever be pregnant.²¹² Thus, analogous to *Johnson Controls*, fertile men are given a choice that is not available to fertile women.²¹³ Secondly, men are free from government restrictions on access to the safest means available for necessary medical procedures.²¹⁴ To the degree that RU 486 is less risky than a surgical abortion or a more effective treatment for breast cancer, women are not free from restrictions on equivalent medical treatment.

Gender bias is so obvious in regard to the treatment of RU 486 that it is almost difficult to recognize.²¹⁵ The class of beneficiaries deprived rights by the denial of RU 486 is primarily women, while the governmental decision-makers denying the rights is virtually all male.²¹⁶ Almost every conceivable benefit of RU 486 will accrue only to women,²¹⁷ and the medical procedure currently at issue, abortion, could only be required by women. To deprive one class of beneficiaries access to particular services is to discriminate on the basis of the medical procedure needed.²¹⁸ The NHS's distribution of RU 486 to any woman who qualifies

²¹² As in *Johnson Controls*, to treat all females as potentially pregnant is explicit sex discrimination. See 111 S.Ct. 1196, 1210 (1991).

²¹³ See *id.* Although U.S. women currently do not receive any benefits from RU 486, researchers at Iowa State University are conducting experiments with RU 486 to ease the birthing process for cattle. *RU 486 Report*, *supra* note 2, at 2.

²¹⁴ It is interesting to note that the FDA gave approval to David Grow to import RU 486 as an experimental treatment for his inoperable brain tumor. The agency's decision came less than a week after the Supreme Court denied Benteen the use of RU 486, and resulted from Mr. Grow's testimony at the third hearing held by Wyden's subcommittee. *RU 486: Brain Cancer Patient Obtains Drug*, Aug. 10, 1992, available in LEXIS, Nexis Library, AbtRpt File; see also *FDA Says a Cancer Patient Can Use RU 486*, BOSTON GLOBE, July 30, 1992, at 11; Samantha Kennedy, *FDA Ruling on Abortion Pill is Shocking, Unfair*, HOUSTON CHRON., Aug. 3, 1992, at 13.

²¹⁵ See MacKinnon, *supra* note 180, at 1296 ("The worse the inequality is, the more like a difference it looks.").

²¹⁶ To ignore gender is to ignore the fact that the overwhelming majority of legislatures are biologically exempt from the restrictions they are imposing. Estrich and Sullivan, *supra* note 176, at 152.

²¹⁷ See *supra* note 204. The potential to improve the quality of life for women with breast cancer is of paramount concern, particularly when there has been no progress in reducing the death rate from breast cancer in the past twenty years. *No Progress Seen in Breast Cancer Prevention*, BOSTON GLOBE, Dec. 12, 1991, at 12 (44,500 women die annually and over 175,000 women are diagnosed every year in the United States alone); see also *Import Ban*, *supra* note 7, at 6 (Dr. Horwitz's testimony that RU 486 could provide a safe and effective alternative for the one in nine women who will develop breast cancer if they live to be 70).

²¹⁸ Mariner, *supra* note 174, at 355.

for it is convincing evidence that in Great Britain equitable access to health care is more important than political pressures brought to bear by a vocal minority.²¹⁹ RU 486 will undeniably augment a woman's ability to decide when or if she will give birth; its denial constitutes restricting access to the safest means available for abortion. Most importantly, aside from its use as an abortifacient, RU 486 should be available in the United States because it constitutes a part of comprehensive health care for women.

CONCLUSION

The interaction of government policy and regulatory decisions in the United States and in Great Britain are indicative of each nation's philosophy regarding health care. Decisions by the FDA and the CSM regarding RU 486 in one sense focus on the question of the legitimate boundaries of federal regulatory power. The FDA's Import Ban on RU 486 is at odds with the U.S. notion of liberty as freedom from government intervention. Further, the FDA's decision creates a political and bureaucratic barrier to the introduction of RU 486 in the United States. The licensing of RU 486 in Great Britain, on the other hand, highlights the autonomy of the British drug approval system.

The structure of the U.S. health care system also affects the potential use of RU 486. In particular, the political climate regarding abortion, and legislative mandates preventing funding for abortion, influence current decisions regarding RU 486 in the United States. The ability to completely sever abortion funding from the provision of other women's health services is evidence that reproductive decisions are not regarded as an essential part of women's health care in the United States. The NHS in Great Britain takes the opposite approach—a comprehensive view of medical care which encompasses treatment with drugs like RU 486.

RU 486 is a potential treatment for a wide range of illnesses, and denial of access to RU 486 in the United States is contrary to the recommendations of virtually every reputable medical organization. It is difficult to justify the denial of potential medical

²¹⁹ Medical decisions are beyond the scope of judicial review in Great Britain. *See R. v. Ethical Comm. of St. Mary's Hosp.*, 1 F.L.R. 512, 524 (Q.B. 1988). The British approach reduces the mingling of politics and science, at least at one level, and thus arguably reduces inappropriate influences in regulatory decision-making.

benefits because of the drug's proven effectiveness. Indeed, the current Import Ban has the effect of discriminating on the basis of one particular medical procedure. The continued denial of potential benefits to all women on the grounds that some pregnant women may use it for one (legal) purpose is nothing less than discrimination on the basis of sex. It is disheartening that the numerous benefits RU 486 will provide for women's health care have not yet eclipsed the political maneuvering which has essentially placed any claims of entitlement beyond the reach of the judicial system.

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