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International Reproductive Rights: The RU 486 Question†

INTRODUCTION

United Nations authority supporting women's reproductive rights is evidenced by the numerous references to men's and women's equal rights;¹ the right to life;² the right to an education;³ the right to self-determination;⁴ the right to plan a family;⁵ the right to health;⁶ the right to privacy;⁷ and the right to share in scientific advancement and its benefits.⁸ The United Nations International Conference on Population and Development held in Cairo September 5–13, 1994 (Conference in Cairo), stated that although "[i]n no case should [abortion] be promoted as a method of family planning . . . [and] all attempts should be made to eliminate the need for abortion . . . [i]n circumstances in which abortion is not against the law, such abortion should be safe."⁹ International documents nowhere explicate that reproductive rights include the right to an abortion. Silence on the matter of abortion permits ratifying states to self-determine whether or not to extend reproductive rights to encompass the right of access to legal abortion.

Prior to the development of RU 486, most legal abortions required anesthesia and surgery. RU 486, a medical alternative to surgical abortion, was invented by Etienne-Emile Baulieu for Roussel

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¹ U.N. CHARTER pmbl., art. 55; Universal Declaration of Human Rights, pmbl., art. 1, U.N. Doc. A/811 (1948).

² Universal Declaration of Human Rights, *supra* note 1, art. 3.

³ *Id.* art. 26.

⁴ U.N. CHARTER art. 1, ¶ 2; Convention on the Elimination of All Forms of Discrimination Against Women, pmbl. (1967) [hereinafter CEDAW].

⁵ Final Act of the International Conference on Human Rights II, Proclamation at Tehran, ¶ 16, U.N. Doc. A/Conf.32/41 (1968) [hereinafter Tehran].

⁶ Universal Declaration of Human Rights, *supra* note 1, art. 25, ¶ 1.

⁷ *Id.* art. 12.

⁸ Universal Declaration on Human Rights, *supra* note 1, art. 17, ¶ 1.

⁹ *Programme of Action of the United Nations International Conference on Population and Development*, at 8.25, U.N. Doc. A/Conf.171/L.1 (1994) [hereinafter Cairo].

Uclaf, a French subsidiary of the German parent company Hoechst, and was first licensed for use in France in 1988.¹⁰ RU 486 is a pill which, when taken with another drug, prostaglandin, acts to interrupt pregnancy.¹¹ As of August 1994, only four countries, France, Britain, Sweden, and China had approved the use of RU 486.¹²

While early abortion is available simply on request in forty countries, fifty additional countries sanction abortion for women who exhibit a range of health or social indicators.¹³ Thus, although legal abortion is available in ninety separate nations, only four of these nations offer women the choice of terminating their pregnancies through use of RU 486. Undoubtedly some number of the remaining eighty-six surely have in place an existing medical infrastructure which would allow the safe use of RU 486 as an alternative to surgical abortion. It is puzzling that these nations endorsing the multitude of United Nations documents enumerating reproductive rights, where abortion is legal, have not taken the necessary steps to ensure that their own citizens have access to the full range of modern methods of abortion.

Part I of this Note identifies some of the many United Nations instruments which define and support women's reproductive rights. Part II introduces the history of RU 486 and discusses its present and potential uses. Part III explores interpretations of United Nations instruments applied to uncontroverted reproductive rights and the specific right to legal abortion. Part IV analyzes international protection of a woman's right to choose between RU 486 and other available methods of abortion in countries where abortion is legal. This Note concludes with the proposal that in countries offering access to abortion as a legal right, international instruments safeguard a woman's right to pick the method of abortion best suited to her. In countries where it is medically feasible RU 486 ought to be among the choices.¹⁴

¹⁰ Susan Jenkins, "Hurry Up and Wait" Characterizes RU 486 Status Today, 85 J. NATL. CANCER INST., July 21, 1993, at 1110.

¹¹ Michael Klitsch, *RU 486: The Science and Politics*, The Alan Guttmacher Institute 1989, at 3 [hereinafter Klitsch, *Science and Politics*].

¹² E.g., Tania Ewing, *Australia: RU 486 Ready for This?*, Reuters, Aug. 20, 1994, available in LEXIS, News Library, Wires File; Charles Petit, *Academy of Sciences Wants Abortion Pill Put on Fast Track*, S.F. CHRON., Sept. 9, 1993, at A1.

¹³ *Expanding Access to Abortion: Key Policy Issues*, at first chart entitled Abortion Laws Worldwide, (Population Action International, Washington, D.C.) Sept. 1993 [hereinafter *Expanding Access*]. Early abortion ranges from an onset of gestation to a low limit of 10 weeks to a high limit of 18 weeks with a prevalent mean of 12 weeks. *Id.*

¹⁴ Because RU 486 has been tested under strictly scrutinized medical conditions and is

I. REPRODUCTIVE RIGHTS ADVANCED IN UNITED NATIONS DOCUMENTS

A. *Overview of Early United Nations Documents: the Right to Self-Determination, Equal Rights of Women and Men*

The League of Nations first drew attention to the issue of the status of women in 1935.¹⁵ Two years later a committee of experts was appointed to examine "the legal status enjoyed by women in various countries of the world."¹⁶ Although this inquiry was discontinued as a result of the dissolution of the committee at the onset of World War II, it served to awaken the international community to the issue of women's rights.¹⁷ In 1942, under the ominous shadow of war, a general international organization entitled the United Nations proclaimed its commitment to guard and uphold human rights and justice as a conditional prerequisite to international peace and progress.¹⁸ This declaration functioned as the foundation for the United Nations Charter which was prepared and opened for signature and ratification in San Francisco in 1945.¹⁹ The United Nations Charter intended to further "equal rights of men and women . . . self-determination of peoples . . . respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language or religion."²⁰

Unanimously approved at the San Francisco Conference on June 25, 1945,²¹ the Charter's emphasis on equal rights was prompted by the unrelenting efforts of a number of self-proclaimed feminists toiling under the umbrella of the Inter-American Commission on

carefully monitored in the countries where it is licensed, this proposal applies only to those countries where the existing medical infrastructure would offer the close supervision necessary for safe use. See *The Case for Antiprogestins*, A Report of the Reproductive Health Technologies Project (Reproductive Health Technologies Project, Washington, D.C.) 1992, at 5-6 [hereinafter *The Case*].

¹⁵ Laura Reanda, *The Commission on the Status of Women, in THE UNITED NATIONS AND HUMAN RIGHTS: A CRITICAL APPRAISAL*, 265 (Philip Alston, ed. 1992).

¹⁶ *Id.*

¹⁷ See generally *id.*

¹⁸ The United Nations and Human Rights, 1978, at 2, U.N. Sales No. E.78.I.18 (1978) [hereinafter U.N. & Human Rights]. The decision was signed on January 1, 1942, by 26 nations at war, and subsequently adhered to by 21 other nations. *Id.* These nations drew up the Dunbarton Oaks proposals in 1944 thereby providing the groundwork for the United Nations Conference on International Organization which met in San Francisco in 1945. *Id.*

¹⁹ *Id.*

²⁰ U.N. CHARTER pmbl., art. 1, ¶ 2-3.

²¹ U.N. & Human Rights, *supra* note 18, at 2.

the Status of Women.²² The United Nations Charter refers to equal rights as a human right in the preamble and in four articles; most notably articles 1 and 55.²³ These articles repeatedly link equality with self-determination as fundamental rights of women, men, and nations.

The Charter of the United Nations granted authority to the Economic and Social Council to "set up commissions in the economic and social fields [and] for the protection of human rights" which, in turn, established the Commission on the Status of Women on June 21, 1946.²⁴ A year and a half later, on December 10, 1948, the General Assembly of the United Nations adopted the Universal Declaration of Human Rights which "reaffirmed faith in fundamental human rights, in the dignity and worth of the human person and in equal rights for men and women."²⁵ The Universal Declaration of Human Rights expanded the previously enumerated cluster of fundamental human rights to include the rights to life, liberty, and security of person;²⁶ protection against arbitrary interference with privacy;²⁷ the right to a standard of living adequate for health and well-being including medical care and necessary social services;²⁸ and the right to share in any scientific advancement and its benefits.²⁹

B. *Family Planning Rights*

In 1966, motivated by reports from the Commission on the Status of Women, the United Nations General Assembly officially recognized the "sovereignty of nations in formulating and promoting their own population policies, with due regard to the principle that

²² Reanda, *supra* note 15, at 266.

²³ See generally United Nations Action in the Field of Human Rights, at I-13-23, U.N. Doc. ST/HR/2/Rev.2, U.N. Sales No. E.83.XIV.2 (1983) [hereinafter U.N. Action]. The goal of article 1 is "to develop friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples." *Id.* ¶ 15. Article 55 provides that: "the creation of conditions of stability and well-being which are necessary for peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples." *Id.* ¶ 16.

²⁴ U.N. CHARTER art. 68; see also U.N. Action, *supra* note 23, at 81. The Commission consisted of one member from each of the 32 United Nations member states brought together to prepare recommendations championing women's rights. U.N. Action, *supra* note 23, at 81.

²⁵ Universal Declaration of Human Rights, *supra* note 1, at pmb1.

²⁶ *Id.* art. 3.

²⁷ *Id.* art. 12.

²⁸ *Id.* art. 25.

²⁹ *Id.* art. 27.

the size of the family should be the free choice of each individual family."³⁰ The following year, the Commission on the Status of Women drafted the "Woman Charter," entitled The Declaration on the Elimination of Discrimination Against Women.³¹ While not binding on ratifying states, this charter has been appreciated as a moral force invoked to urge states to take action to end legislation and practices that discriminate against women.³² Commitment to promoting equality between the sexes is clearly articulated in article 9(e), which sets out the principle that "girls and women, married and unmarried, shall be ensured equal rights with men."³³

The first formal declaration of specific family planning rights appeared in the International Conference on Human Rights held in Tehran in 1968.³⁴ The objective of the Tehran Conference was to "review the progress made in the twenty years since the adoption of the Universal Declaration of Human Rights and to formulate a program for the future."³⁵ Article 16 of the Proclamation of Tehran declared: "[p]arents have a basic human right to determine freely and responsibly the number and spacing of their children and a right to adequate education and information in this respect."³⁶ Members of the conference recognized that a slowing of the existing population growth rate would offer "greater opportunities for the

³⁰ U.N. & Human Rights, *supra* note 18, at 131.

³¹ See Reanda, *supra* note 15, at 281, 284; see also U.N. Action, *supra* note 23, at 83. After four years of debate and drafting, The Declaration on the Elimination of Discrimination Against Women was adopted unanimously by the General Assembly in resolution 2263 (XXII) on November 7, 1967. U.N. Action, *supra* note 23, at 83.

³² U.N. Action, *supra* note 23, at 83.

³³ U.N. & Human Rights, *supra* note 18, at 131.

³⁴ See Tehran, *supra* note 5, at II Proclamation of Tehran, pmb1.

³⁵ *Id.* It further stated that because

[a]n inferior status for women is contrary to the Charter of the United Nations as well as the provisions of the Universal Declaration of Human Rights . . . the full implementation of the Declaration on the Elimination of All Forms of Discrimination against Women is a necessity for the progress of mankind.

Id. art. 15.

³⁶ *Id.* art. 16. The Preamble cites the Universal Declaration of Human Rights and, (1) states: "that men and women have the right to marry and found a family and that the family is the fundamental group of society;" (2) recalls the General Assembly's 1966 resolution [that recognizes] the sovereignty of nations in formulating and promoting their own population policies, with due regard to the principle that the size of the family should be the individual choice of each family; (3) recalls UNESCO and the World Health Assembly's resolutions on the subject of family planning; (4) and notes that the Commission on the Status of Women had begun to study the relationship between family planning and the status of women. *Id.*

enjoyment of human rights and the improvement of living conditions” for each person.³⁷

In 1969, one year after the conference at Tehran, the General Assembly’s Declaration on Social Progress and Development reiterated the fundamental importance of family planning rights, asserting that “[p]arents have the exclusive right to determine freely and responsibly the number and spacing of their children.”³⁸ Rather than holding this out as a hollow right, the Declaration demanded the provision of information and the means necessary to enable individuals to exercise these rights.³⁹ In 1970, the General Assembly endorsed minimum targets for ensuring the availability of family planning information and services.⁴⁰

The 1975 World Conference of the International Women’s Year in Mexico adopted The World Plan, which identified fourteen objectives directed toward demarcating a society in which women would participate in every aspect of economic, social, and political life.⁴¹ This plan enumerated women’s family planning rights in a number of objectives including those entitled: Health and Nutrition,⁴² The Family,⁴³ and Population.⁴⁴ Whereas, prior to this plan reproductive

³⁷ *Id.* art. 2.

³⁸ U.N. & Human Rights, *supra* note 18, at 131.

³⁹ *See id.*

⁴⁰ *Id.* at 131–32. The 1970 General Assembly explicitly stated its goal to:

[m]ak[e] available to all persons who so desire the necessary information and advice to enable them to decide freely and responsibly on the number and spacing of their children [,] and to prepare them for responsible parenthood, including information on the ways women can benefit from family planning. Such information and advice should be based on valid and proven scientific expertise with due regard to the risks that may be involved.

Id. at 131.

⁴¹ *Id.* at 139.

⁴² *Id.* at 140. This objective seeks to ensure access to health care, provide gynecological and family planning services, reduce maternal mortality, and involve women in all phases and levels of health planning and decision making. *Id.*

⁴³ U.N. & Human Rights, *supra* note 18, at 140. Provision 6 protects the rights of women in all forms of family (nuclear, extended, consensual union or single-parent), ensures joint decision-making on matters affecting family and children, and seeks to establish adequate family counselling services. *Id.*

⁴⁴ *Id.* at 141. The population provision proposes to:

ensure individuals and couples the right to determine freely and responsibly the number and spacing of their children; [ensure that] governmental population policies and programs should pay particular attention to improving the situation of women; remove all legal, social, or financial obstacles to the dissemination of family planning information, means, and services.

Id.

decision making rights were reserved for "parents," the new plan enlarged the scope to include "couples and individuals."⁴⁵ Following the enthusiastic endorsement of proposals emanating from The World Plan in 1975, The United Nations General Assembly called for international, national, and regional action proclaiming the period from 1976 to 1985 the "United Nations Decade for Women: Equality, Development, and Peace."⁴⁶

On December 15, 1975, the General Assembly requested that the Commission on the Status of Women draft the Convention on the Elimination of Discrimination Against Women (CEDAW).⁴⁷ Four years and several drafts later, the General Assembly adopted CEDAW on December 18, 1979.⁴⁸ On September 28, 1994, the United States announced that it was considering joining the one hundred and thirty-six countries that have ratified CEDAW.⁴⁹ CEDAW describes discrimination as conduct that is intentionally designed to exclude or restrict women on the basis of sex.⁵⁰ The heart of the Convention is found in article 2, which embodies the agreement to "pursue by all appropriate means and without delay a policy of eliminating discrimination against women."⁵¹ CEDAW is the only specialist body in the United Nations system with direct responsibility for supervising member states' compliance with treaty obligations with respect to women's rights.⁵²

⁴⁵ See Lynn P. Freedman & Stephen L. Isaacs, *Human Rights and Reproductive Choice*, 24 *STUD. IN FAM. PLAN.* 22 (1993).

⁴⁶ U.N. & Human Rights, *supra* note 18, at 142.

⁴⁷ U.N. Action, *supra* note 23, at 84.

⁴⁸ *Id.* CEDAW was opened for signature, ratification and accession on March 1, 1980. See Margaret E. Galey, *International Enforcement of Women's Rights*, 6 *HUM. RTS. Q.* 463, 475 (Nov. 1984). CEDAW entered into force on September 3, 1981. U.N. CEDAW/SP/1992/4 (92-05062 2854c (e)) 240292, at 4.

⁴⁹ *Vote Nears on Treaty for Women*, *BOSTON GLOBE*, Sept. 28, 1994, at 15.

⁵⁰ CEDAW, *supra* note 4, art. 1. Article 1 defines discrimination against women as "any distinction, exclusion, or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by women" based on the equality of men and women, and on human rights and fundamental freedoms in political, economic, social, cultural, civil, and any other field. *Id.*

⁵¹ *Id.* art. 2. Paragraph (a) ensures practical realization of this principle; (b) includes appropriate legislative measures including sanctions; (c) establishes legal protection; (d) ensures that authorities and institutions act in conformity; (e) eliminates discrimination by any person, organization, or enterprise; (f) and (g) require that countries modify or abolish existing discriminatory laws, customs, or practices and repeal discriminatory penal provisions. *Id.*

⁵² Roberta Jacobson, *The Committee on the Elimination of Discrimination Against Women*, in *THE UNITED NATIONS AND HUMAN RIGHTS: A CRITICAL APPRAISAL* 462 (Philip Alston, ed. 1992). Serviced from Vienna, CEDAW remains relatively isolated from other U.N. human rights organs. *Id.*

CEDAW addresses women's access to health care, family planning,⁵³ and the equality of women and men in deciding the number and spacing of their children.⁵⁴ The United Nations wrote in accountability measures requiring ratifying countries to provide reports including "information on the legal regulation regarding abortion, its legality and enforcement under the law, . . . how many abortions are performed annually, . . . under what conditions, and what the country's policy is on this matter."⁵⁵

The report from the World Conference to Review and Appraise the Achievements of the United Nations Decade for Women: Equality, Development and Peace held in Nairobi, Kenya on July 15–26, 1985, stressed that women's access to information concerning available methods of family planning was essential to the guarantee of women's health generally.⁵⁶ It recapitulated the right of individuals to decide "freely and informedly" the number and spacing of children and explained that "[t]he ability of women to control their own fertility forms an important basis for the enjoyment of other rights."⁵⁷ The report urges nations to provide "means [which] should include all medically approved and appropriate methods of family planning."⁵⁸

C. *The Right to Health*

The World Health Organization (WHO) officially came into being on April 7, 1948, when twenty-six members of the United Na-

⁵³ CEDAW, *supra* note 4, art. 12. Article 12 requires states to "take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning." *Id.* Article 14 requires states to "take all appropriate measures to eliminate discrimination against women . . . ensur[ing] to such women the right . . . [t]o have access to adequate health care facilities, including information, counselling, and family planning." *Id.* art. 14.

⁵⁴ *Id.* art. 16. Article 16 mandates that states take all appropriate measures to eliminate discrimination against women in "all matters relating to marriage and family relations." *Id.* In particular, this article seeks to ensure equality of men and women in respect to "the same rights to decide freely and responsibly on the number and spacing of their children," and access to the information, education, and means to enable them to exercise these rights. *Id.*

⁵⁵ UNITED NATIONS MANUAL ON HUMAN RIGHTS REPORTING, at 168, U.N. Doc. HR/PUB/91/1, U.N. Sales No. E.91.XVI.1 (1991). The reporting mandate continues: "The committee seeks information on the availability of family planning advice, its cost and accessibility, whether any obstacles exist for women in using such services, and whether women alone can decide on the spacing of births." *Id.*

⁵⁶ *Report of the World Conference to Review and Appraise the Achievements of the United Nations Decade for Women: Equality, Development and Peace*, A/Conf.116/28 15, Sept., 1985, ¶ 156.

⁵⁷ *Id.* ¶ 156.

⁵⁸ *Id.* ¶ 157.

tions accepted its constitution.⁵⁹ On November 15, 1948, the United Nations General Assembly appointed WHO as the authority on international health.⁶⁰ WHO's self-stated objective is to promote "the attainment by all peoples of the highest possible level of health."⁶¹ WHO determined that health is a "fundamental right of every human being,"⁶² and defined health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."⁶³

D. *Rights to the Benefits of Advances in Science and Technology*

Although the Universal Declaration of Human Rights contains a provision peripherally touching on the effect of scientific and technological developments upon the enjoyment of human rights and fundamental freedoms,⁶⁴ this issue was not fully considered until the International Conference on Human Rights in Tehran.⁶⁵ The Proclamation of Tehran addressed both the beneficial opportunities and the potential endangerment of rights and freedoms resulting from the rapid progress of science and technology.⁶⁶ This proclamation noted the unprecedented changes resulting from the new opportunities made available by the rapid progress of science and technologies and found that access to these advances was "indispensable to the full realization of human rights and fundamental freedoms."⁶⁷

In the same year as the Proclamation of Tehran, the General Assembly dispatched the Advisory Committee on the Application of Science and Technology to study "the balance which should be established between scientific and technological progress and the intellectual, spiritual, cultural and moral advancement of humanity."⁶⁸ Three years later, on March 18, 1971, the Commission on Human Rights reaffirmed its position that an appropriate use of scientific and technological developments would foster respect for

⁵⁹ U.N. Action, *supra* note 23, at 309.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ The Universal Declaration of Human Rights, *supra* note 1, art. 27. Article 27 states: "[e]veryone has the right to freely participate in cultural life of the community . . . and to share in scientific advancement and its benefits." *Id.*

⁶⁵ U.N. Action, *supra* note 23, at 253.

⁶⁶ Tehran, *supra* note 5, pmbl., art. 18.

⁶⁷ *Id.* pmbl.

⁶⁸ See U.N. Action, *supra* note 23, at 253.

human rights.⁶⁹ The United Nations General Assembly sought to protect the “human personality” from potential damaging effects of biological and medical advances.⁷⁰ The General Assembly cautioned advising member states to pay particular attention to the transfer of knowledge and technology to developing countries.⁷¹

E. *The 1994 International Conference on Population and Development*

Between September 5–13, 1994, one hundred and eighty-four United Nations delegates at the International Conference on Population and Development in Cairo struggled to complete a blueprint for the next twenty years of population control.⁷² Unlike a treaty or convention, the consensus document developed by these delegates leaves it up to the individual nations to determine whether or not to adopt and implement its objectives.⁷³ This document incorporates sexual health into reproductive health and describes reproductive health as a “state of complete physical, mental and social well-being . . . in matters relating to the reproductive system and to its functions and processes.”⁷⁴ The definition of reproductive health has two implications delineated as follows: (1) “that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so,” and (2) that men and women “[have the right] to be informed and to have access to safe, effective, affordable and acceptable methods of family planning of their choice for regulation of fertility which are not against the law.”⁷⁵

The Cairo document suggests that access to “reliable information and compassionate counselling” should be available to women who have unwanted pregnancies and that “[i]n circumstances in which abortion is not against the law, such abortion should be safe.”⁷⁶ The delegates agreed that reproductive health-care programs and family-planning services “must provide that widest possible freedom of choice,” and condemned physical, economic, and psychological coercion in programs as a “breach of human rights that can never be

⁶⁹ *Id.*

⁷⁰ *See id.* at 254–55.

⁷¹ *Id.* at 255.

⁷² *See* Cairo, *supra* note 9.

⁷³ *Id.*

⁷⁴ *Id.* at 7.2.

⁷⁵ *Id.*

⁷⁶ *Id.* at 8.25.

acceptable."⁷⁷ The conference advocated expedition of new and improved methods of regulating fertility through increased involvement of industry suggesting that research on new products must adhere to internationally accepted ethical and technical standards.⁷⁸

II. OVERVIEW OF RU 486

A. *Introduction to Roussel Uclaf and RU 486*

RU 486, or Mifepristone,⁷⁹ is a synthetic drug with antisteroidal hormone properties which, when taken in combination with another drug, prostaglandin, serves to induce abortion.⁸⁰ In 1970, researchers headed by Dr. Etienne-Emile Baulieu at Roussel Uclaf, a French pharmaceutical company, discovered that receptors within the uterus interacting with the hormone progesterone might lead to new methods of fertility control.⁸¹ In 1980, after concentrating on this discovery for a decade, the Baulieu research team developed a drug labeled Roussel Uclaf 38486 which was reported to have induced abortion in nine out of eleven women at its initial trial in 1982.⁸²

As of Spring, 1994, RU 486 had been utilized by roughly 200,000 European women in France, Britain, and Sweden.⁸³ RU 486 is registered and synthesized in China, and is in the registration process in several Scandinavian countries,⁸⁴ Israel,⁸⁵ and India.⁸⁶ Testing on

⁷⁷ Cairo, *supra* note 9, at princ. 8.

⁷⁸ *Id.* ¶ 12.15–12.17.

⁷⁹ See *Round Table on RU 486*, 2 WOMEN'S HEALTH J. 29, 40 (1993) [hereinafter *Round Table*]. RU 486, the generic name of Mifepristone, is the abbreviated name for Roussel-Uclaf 486, the antiprogesterin compound which acts to block cells receptive to progesterone (hence the term antiprogesterin), thereby provoking an abortion. *Id.*

⁸⁰ Etienne-Emile Baulieu, *Updating RU 486 Development*, 20 LAW, MED. & HEALTH CARE 154 (1992).

⁸¹ *The Case*, *supra* note 14, at 23.

⁸² *Id.* Shortly after release of this report, Roussel Uclaf chairman Edourd Sakiz signed the landmark scientific papers for Roussel to begin clinical tests. *Id.* In 1983, the United States Food and Drug Administration (FDA) issued a testing permit to the Population Council for testing RU 486 on 300 women in California; in 1984 WHO conducted a study on 34 women in Sweden; in 1985 the United States National Institute for Health began research on RU 486 for non-abortifacient applications. *Id.*

⁸³ See *Abortion Pill Secretly Used Here: Drug Firm Won't Sell RU 486 in Canada*, CALGARY HERALD, May 30, 1994, at A3.

⁸⁴ Baulieu, *supra* note 80, at 154–55.

⁸⁵ Judy Siegel, *Bill to Legalize Abortion Pill Passes First Reading*, JERUSALEM POST, Dec. 2, 1993, at 1. This article notes that "[o]nly women who meet the criteria of the existing Abortion Law would use the pill—under strict medical supervision." *Id.*

⁸⁶ *Science and Technology; Domestically Produced Abortion Pill to Go on Market*, Brit. Broadcasting Corp., Dec. 2, 1992, available in LEXIS, News Library, Non-US File. The Indian

2,000 women in the United States is planned for Fall of 1994.⁸⁷ The Roussel Uclaf Company, located in Paris, owns the world-wide patent on RU 486.⁸⁸ Germany's Hoechst AG owns just over fifty-four percent of Roussel Uclaf with an additional thirty-five percent owned by French government.⁸⁹

In response to well-orchestrated efforts on the part of various anti-abortion groups exerting, or threatening to exert, overt political and economic pressures, Roussel Uclaf stipulated that five criteria be satisfied before it would consider introduction of RU 486 to a new country.⁹⁰ First, abortion must be legal and the country's abortion law cannot have provisions that would constrain the availability of RU 486.⁹¹ Second, public opinion, medical opinion, and the political climate must be accepting of legal abortion.⁹² Third, an appropriate prostaglandin must be available.⁹³ Fourth, the medical service systems must have the capability to carefully monitor the patients and strictly control the drug distribution networks and supply.⁹⁴ Lastly, Roussel Uclaf requires that professionals involved in the distribution of RU 486 follow strict informed consent procedures which include the patient's signature on a detailed consent form.⁹⁵

B. *Medical Aspects of RU 486*

1. How RU 486 Terminates Pregnancy

RU 486 is a steroid hormone in pill form related in structure to the natural human hormone progesterone.⁹⁶ Yet, unlike progester-

Institute of Chemical Technology (IICT) independently produced RU 486, thus breaking the French monopoly on the drug. *Id.* Although the IICT announced that it would release RU 486 technology to a drug firm for commercial production within a month, this remains to be seen. *India Reports More Than 1.8 Million Abortions*, UPI, Mar. 24, 1993, available in LEXIS, News Library, Curnws File.

⁸⁷ *Abortion Foes Plan to Boycott French Pill Maker*, N.Y. TIMES, June 2, 1994, at A1.

⁸⁸ Baulieu, *supra* note 80, at 154.

⁸⁹ *France: Roussel Paid East Germany 76,000 Marks for Abortion Pill Trial*, Reuters, Dec. 9, 1991, available in LEXIS, News Library, Wires File.

⁹⁰ Renee Holt, *RU 486/Prostaglandin: Considerations for Appropriate Use in Low Resource Settings*, 20 LAW, MED. & HEALTH CARE 169, 174 (1992); Michael Klitsch, *Antiproggestins and the Abortion Controversy: A Progress Report*, 23 FAM. PLAN. PERSP. 275, 279 (Nov./Dec. 1991) [hereinafter Klitsch, *Abortion Controversy*].

⁹¹ See Klitsch, *Abortion Controversy*, *supra* note 90, at 276.

⁹² See Holt, *supra* note 90, at 174.

⁹³ See *The Case*, *supra* note 14, at 14.

⁹⁴ See Holt, *supra* note 90, at 174.

⁹⁵ See *id.*; *The Case*, *supra* note 14, at 14.

⁹⁶ *Round Table*, *supra* note 79, at 41.

one⁹⁷ which causes pregnancy to develop, RU 486 acts as an antiprogesterin inhibiting the production and effectiveness of the progesterone.⁹⁸ Although the actual chemical effect of RU 486 is not yet clear, researchers believe that the drug “tricks” progesterone receptors by attaching to them in place of the real hormone, thus causing the uterine lining to break down and be expelled.⁹⁹

Taken by itself, a large dose of prostaglandin is highly effective in terminating first trimester pregnancies.¹⁰⁰ Yet, the numerous side effects of prostaglandin include nausea, abdominal cramping, gastrointestinal side effects, and extreme uterine pain.¹⁰¹ Like prostaglandin taken alone, RU 486 has been shown to be about eighty-five percent effective as an abortifacient when taken by itself during the first eight weeks of pregnancy.¹⁰² Yet, also similar to prostaglandin, when taken alone RU 486 has potentially dangerous side effects including severe bleeding, incomplete abortions, and risk of infection.¹⁰³ Administration of a small dose of prostaglandin with RU 486 decreases side effects, elevates efficiency by hastening the process, and increases the likelihood of complete expulsion.¹⁰⁴

⁹⁷ Klitsch, *Science and Politics*, *supra* note 11, at 2. Progesterone is so named from the Latin words “pro,” for, and “gestare,” to carry. *Id.* Progesterone works as follows:

Blood levels of progesterone increase greatly after ovulation, when fertilization can occur. If fertilization does not take place, the end of the menstrual cycle brings about a sudden decline in the progesterone levels, the lining of the uterus dissolves and menstruation results. On the other hand, if fertilization occurs, progesterone production continues and the embryo lodges in the lining of the uterus. The high levels of progesterone produced thereafter promote the development of the placenta, decrease the likelihood of uterine contractions that might dislodge the developing embryo . . . and prevent ovulation and the initiation of the next menstrual cycle.

Id.

⁹⁸ See *Round Table*, *supra* note 79, at 40–41. Dr. Etienne-Emile Baulieu coined the term “contragestin” to describe the blocking effect of RU 486 because it counteracts gestation at a very early stage. *Id.* The egg, which is fertilized in the fallopian tube, takes about six days to reach a place in the uterus where it begins the process of implantation, which takes another six to eight days to complete and thus marks the medically defined onset of pregnancy. *Id.* The embryo develops into a fetus at about eight weeks after fertilization, or 10 weeks after the last menstrual period. *Id.* Described as “last chance” contraception, antiprogesterin drugs, such as RU 486, prevent implantation if fertilization has occurred. Rebecca J. Cook, *Antiprogesterin Drugs: Medical and Legal Issues*, 21 *FAM. PLAN. PERSP.* 267 (Nov./Dec. 1989) [hereinafter Cook, *Antiprogesterin Drugs*]. If implantation is complete, antiprogesterins will prevent gestation of an early embryo, causing its abortion. *Id.*

⁹⁹ Csilla Muhl, Commentary, *RU-486: Legal and Policy Issues Confronting the Food and Drug Administration*, 14 *J. OF LEGAL MED.* 319, 327 (1993).

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 327–28.

¹⁰² *Id.* at 329–30.

¹⁰³ *Id.*

¹⁰⁴ Baulieu, *supra* note 80, at 154. Dr. Baulieu notes that the prostaglandin (Sulprostone)

When taken together during the first seven to nine weeks of pregnancy, clinical studies have shown RU 486 and prostaglandin are roughly ninety-six percent effective at inducing abortion.¹⁰⁵ Most of the side effects of the prostaglandin are eliminated due to the substantially decreased dose necessary when taken in conjunction with RU 486.¹⁰⁶ Based on safety, efficiency, and cost, the prostaglandin of choice is Misoprostol.¹⁰⁷ Misoprostol is marketed world wide by Searle, the United States producer and patent-holder.¹⁰⁸ Although RU 486 and the accompanying prostaglandin are presently taken as separate pills, one goal of future research is to develop a single pill which combines RU 486 with a slow release form of prostaglandin.¹⁰⁹

2. French Requirements for Use of RU 486

In France, the use of RU 486, or medical abortion, requires four medical visits with the first three occurring within the seven week gestation limit.¹¹⁰ Because French law mandates a one-week thinking or reflection period, only women less than six weeks pregnant are candidates for RU 486.¹¹¹

originally used in conjunction with RU 486 required intramuscular injection. *Id.* Use of Sulprostone demanded a staff trained to perform the necessary injection. *Id.* As a result of its increased safety, convenience, availability, and low cost, orally taken Misoprostol has replaced Sulprostone as the prostaglandin of choice. *Id.* Studies of Misoprostol taken with RU 486 demonstrate an effectiveness in excess of 99%. *Id.* Gemeprost, a PG-E derivative of Misoprostol, offers another alternative form of prostaglandin given as a vaginal suppository and has been tested in roughly 2,500 cases in France and the United Kingdom. *Id.* at 155.

¹⁰⁵ See Muhl, *supra* note 99, at 329.

¹⁰⁶ *Id.* at 330. Long term effects of RU 486 are unlikely since 75% of the RU 486 is metabolized within 48 hours. *Id.*

¹⁰⁷ Henry P. David, *Acceptability of Mifepristone for Early Pregnancy Termination*, 20 LAW, MED. & HEALTH CARE 188, 189 (1992). In France, the cost of Sulprostone is about \$20 compared to less than \$1 for Misoprostol. *Id.* Unlike Sulprostone and Gemeprost, because Misoprostol does not require refrigeration, its cost is further reduced. *Id.* Research indicates that it may be possible to reduce the dosage of RU 486 when taken with Misoprostol and thereby eliminate one clinic visit by authorizing ingestion of two Misoprostol tablets at home when medical emergency services are readily accessible. *Id.*

¹⁰⁸ *Id.* Searle has not authorized, and has not been requested to authorize, the use of Misoprostol (generic name, Cytotec) in combination with RU 486, and considers "such an application a 'misuse' of its product." *Id.* Searle's label for Misoprostol cautions against its use by pregnant women. *Id.*

¹⁰⁹ See *id.*

¹¹⁰ *Round Table, supra* note 79, at 31. Medical abortion "[r]efers to an induced abortion using drug treatment (specifically RU 486/PG) in contrast to surgical techniques." *Id.* at 40. Surgical abortion "[r]efers to abortions performed by such mechanical techniques as vacuum aspiration, dilation and curettage (D & C), dilation and evacuation (D & E), etc." *Id.* at 31.

¹¹¹ See Klitsch, *Abortion Controversy, supra* note 90, at 276.

At the first medical visit a woman choosing RU 486 registers, has a pregnancy test and ultrasound to confirm that she is pregnant, and signs a thorough consent form.¹¹² The consent form contains an agreement to undergo a surgical abortion should the RU 486 fail to be effective.¹¹³ At the second visit, which occurs after the week of reflection, a woman is given 600 mg of RU 486 in the form of three pills.¹¹⁴ At the third visit, forty-eight hours after the second visit, a woman receives prostaglandin and must remain at the facility for four to six hours, during which time nearly nine out of ten abortions are completed.¹¹⁵ The final visit, seven to ten days later, serves as a control measure to verify the completeness of the process.¹¹⁶

Dr. Etienne-Emile Baulieu espouses a "two-visit" plan for future administration of RU 486 outside of the clinic environment.¹¹⁷ The first visit would entail a medical appointment for an examination to confirm pregnancy, the ingestion of the RU 486 pills, and the dispensation of the prostaglandin pills to take at home two days later.¹¹⁸ The second visit would occur seven to ten days later to ensure that the process had been completely effective.¹¹⁹

Although most women do not have any physical discomfort after taking RU 486, a few experience light bleeding, nausea, headaches, fatigue, and symptoms similar to "morning sickness."¹²⁰ The side effects of the prostaglandin mentioned above occasionally cause a woman to request a pain killer.¹²¹ Prior to the use of prostaglandin in tablet form, there were three incidents of reaction to the injectable prostaglandin; one of which included the death, from cardiac arrest, of an obese, thirty-one year old heavy smoker in her thirteenth pregnancy.¹²² Consequently, the French Ministry of Health mandated that women over thirty-five, heavy smokers, and women with a history of heart or circulatory difficulties be restricted from the use of RU 486.¹²³

¹¹² *Id.*

¹¹³ MARY JOE FRUG, *WOMEN AND THE LAW* 498 (1992).

¹¹⁴ See Baulieu, *supra* note 80, at 54.

¹¹⁵ *Round Table*, *supra* note 79, at 32. In France, the woman remains in her own clothes; she can walk about or lie down; and painkillers are administered if required. *Id.*

¹¹⁶ Baulieu, *supra* note 80, at 154.

¹¹⁷ Jill Smolowe, *New, Improved, and Ready For Battle*, *TIME*, June 14, 1993, at 54.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *The Case*, *supra* note 14, at 7.

¹²¹ *Id.*

¹²² *Id.* The other two incidents involved two women who were heavy smokers over the age of thirty-five both of whom completely recovered from their resulting cardiac problems. *Id.*

¹²³ *Id.*

Studies are presently being conducted by WHO to determine the optimal dosage of RU 486.¹²⁴ Other studies are testing the optimal prostaglandin dose, and the risk of fetal injury if a pregnancy is carried to term after the embryo is exposed to RU 486 in utero.¹²⁵ RU 486 is also being tested for possible nonpregnancy medical applications for the following uses: for pain control in the treatment of endometriosis, for its inhibition of the growth of brain tumors (meningiomas), for its effectiveness in controlling Cushing's Syndrome,¹²⁶ for combating breast cancer, for a once-a-month contraceptive,¹²⁷ and for use in the development of a male contraceptive pill.¹²⁸

C. *Current World Use of RU 486*

1. French Approval of RU 486

On September 23, 1988, after six years of clinical study,¹²⁹ the French Ministry of Solidarity, Health, and Social Welfare registered RU 486 in combination with progestin for use as an abortifacient.¹³⁰ The 1988 announcement of registration and approval by the Health Ministry of France marked the beginning of French availability of RU 486.¹³¹ As a result of threats of boycott and antiabortion protests,

¹²⁴ See Klitsch, *Abortion Controversy*, *supra* note 90, at 277. Results from a comparative study involving 1,200 women have shown that abortions remain at 95% effectiveness whether the women have been given 200, 400, or 600 mg. of RU 486. *Id.*

¹²⁵ *Id.* Roussel Uclaf is presently conducting a study which seeks to detect and track the appearance of any birth defects in children born to women who carried their babies to term after receiving RU 486. *Id.* at 277-78.

¹²⁶ *Id.* at 278. Mifepristone may be used to induce preterm labor late in pregnancy (in the case of fetal death); it is being studied as a cervical dilator; it may be used as a postcoital "emergency" contraceptive or as a contraceptive taken before or after ovulation. *Id.*

¹²⁷ *French Abortion Pill May Have Other Uses*, ST. LOUIS POST-DISPATCH, May 20, 1991, at 3D.

¹²⁸ *Roussel Uclaf's RU 486 Could Be Used in Male Pill: American Academy of Sciences*, AFX News, Dec. 13, 1993, available in LEXIS, News Library, Wires File.

¹²⁹ Rebecca K. Kramnick, Note, *RU 486 and the Politics of Drug Regulation in the United States and France*, 25 CORNELL INT'L L. J. 677, 686 (1992).

¹³⁰ Cook, *Antiprogestin Drugs*, *supra* note 98, at 268. RU 486 was approved for marketing and distribution under strict protective conditions requiring that each package of the drug be assigned a specific number to track its distribution and use. *Id.* Distribution patterns require that the amount of the drug and physician name be recorded in a register, and be limited to public and private hospitals authorized to perform abortions. *Id.*

¹³¹ *The Case*, *supra* note 14, at 23. RU 486 was also approved for use in China at this time. *Id.*

Roussel Uclaf announced its suspension of distribution of RU 486 on October 25, 1988.¹³²

At the time of Roussel's withdrawal, thousands of the 9,000 delegates from eighty-three countries attending the Twelfth World Congress of Gynecology and Obstetrics in Rio de Janeiro immediately signed a petition calling on Roussel Uclaf to surrender its world patent if it remained unwilling to market the drug.¹³³ On October 28, 1988, in response to the wave of indignation raised by the Twelfth World Congress, the French government wielded its power as a stock holder and ordered the company to resume distribution or face the potential transfer to another party of the license to distribute RU 486.¹³⁴ Claude Evin, the French Minister of Health explained this governmental action, stating: "I considered that if this progress existed, it had become the moral property of women, and that it was therefore my responsibility to say so to Roussel Uclaf."¹³⁵ RU 486 has been available in France since Evin's declaration.

2. Approval of RU 486 in Britain

On July 3, 1991, only ten months after Roussel Uclaf first applied for licensing in Britain, the Committee on the Safety of Medicines approved RU 486 for immediate distribution in Britain.¹³⁶ In November 1990, the British government passed the Human Fertilization and Embryology Act, which authorized the government to approve various hospitals or clinics "in relation to treatment consisting primarily in the use of such medicines as may be specified."¹³⁷ Passage

¹³² *Id.*

¹³³ Douglas Hamilton, *Abortion Pill Back on Sale but Still Controversial*, Reuters, Oct. 30, 1988, available in LEXIS, News Library, Wires File. One advocate of RU 486 remarked "there are thousands and thousands of clandestine abortions, and I do not see how this drug could add to that." *Id.* Others added: "In India we have thousands of women dying each year from surgical abortion. Doctors and patients would prefer a safer method, such as this drug." *Id.* A gynecologist in China, where the drug was already in daily use, commented that "this is the most effective and efficient way of performing [abortions]. Banning this drug would be unfortunate for both doctors and patients." *Id.*

¹³⁴ Reed Boland, *RU 486 in France and England: Corporate Ethics and Compulsory Licensing*, 20 LAW, MED. & HEALTH CARE 226, 227 (1992).

¹³⁵ Edward Cody, *France Orders Sale of New Pill: Abortion Drug Had Been Shelved After Angry Protests*, WASH. POST, Oct. 29, 1988, at A1.

¹³⁶ Denise Chicone, Note, *RU 486 in the United States and Great Britain: A Case Study in Gender Bias*, 16 B.C. INT'L & COMP. L. R. 81, 81 (1993).

¹³⁷ Boland, *supra* note 134, at 229. The author reports that: "[b]y inclusion of this provision in the Act, the government took account of the fact that, because abortions using RU 486 do not involve surgery or anesthesia, they can be performed in settings that are less fully medically equipped than hospitals." *Id.*

of this act anticipated and paved the way for approval of the “medicine” RU 486.¹³⁸ The British Birth Control Trust advocated for expedient licensing through its encouragement of the Medicines Control Agency’s “fast-tracking” procedure usually reserved only for urgently needed drugs or for those drugs with a proven safety record.¹³⁹ A spokeswoman for the Birth Control Trust stated: “[t]here is no logical reason for [the licensing of RU 486] to be held up. It has been tested extensively in France [and there] is no intrusive surgical procedure.”¹⁴⁰

The regimen of medical visits for use of RU 486 in Britain is similar to that in France, except that the British require approval by two doctors and allow use up until nine weeks of pregnancy.¹⁴¹ During 1991, the first year of its availability in Great Britain, of the total of 167,400 abortions, RU 486 was used in less than 3,000 cases.¹⁴² One possible explanation for the small number of RU 486 abortions could be the fact that the July 1991 approval for use of RU 486 applied only to abortions performed in National Health Service public hospitals.¹⁴³ Another factor contributing to this small number is that of timing. Although forty-one percent of all abortions in England and Wales took place in National Health Service public hospitals, only one-fifth of that forty-one percent would have been eligible for use of RU 486 with its nine week limitation.¹⁴⁴

Because of the public hospital requirement, RU 486 was unavailable to the fifty-nine percent women who sought abortions through private means.¹⁴⁵ Absent the availability of RU 486 to women seeking abortions through the private sector, one-half of this fifty-nine percent (nearly thirty percent of all women seeking abortions) who sought abortions within the nine week limitation were denied RU 486 as an alternative means of terminating their pregnancies.¹⁴⁶ In

¹³⁸ *Id.*

¹³⁹ Chris Mihill, *UK: Clearance Near for Roussel's RU 486 Abortion Pill*, Reuters, Jan. 3, 1991, available in LEXIS, News Library, Wires File.

¹⁴⁰ *Id.*

¹⁴¹ Boland, *supra* note 134, at 228–29.

¹⁴² *UK: The Contraception Revolution*, Reuters, Dec. 12, 1992, available in LEXIS, News Library, Wires File.

¹⁴³ Boland, *supra* note 134, at 229. This selective licensing was both deliberate and significant since almost 70% of early pregnancy terminations are performed in private clinics where RU 486 was not available. *Id.*

¹⁴⁴ *UK: Speeding Up the Right to Choose on Abortion*, Reuters, July 22, 1991, available in LEXIS, News Library, Wires File.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

December 1991, licensing was extended to private clinics.¹⁴⁷ As of the summer of 1994, RU 486 had been used to terminate "at least" 12,000 pregnancies in Britain.¹⁴⁸

3. RU 486 in Sweden

Swedish research on the clinical use of RU 486 for terminating pregnancies began in Stockholm in 1983.¹⁴⁹ Sweden licensed the use of RU 486 in November 1992.¹⁵⁰ Approximately seventy-five percent of Swedish women make the decision to abort early enough in their pregnancies to fit within the time frame necessary for successful medical abortion.¹⁵¹ Because of the large percent of Swedish women who seek early abortions, Swedish medical authorities agreed that it would be unlikely that the mere availability of a safer and "simpler" early use method would influence greater numbers of women to obtain abortions that they might later regret.¹⁵²

4. China as a Special Case

Shortly before the drug was introduced in France in 1988, the Health Ministry of China announced its approval of RU 486.¹⁵³ China's state run media reported that birth control rules were being ignored by bribed officials and, despite the ten million abortions performed in 1987, China reported at least fourteen million "black children" (children born in breach of the rules).¹⁵⁴ Because conven-

¹⁴⁷ *Id.*

¹⁴⁸ Peter Pallot, *Women Test "Five Days After" Pill*, DAILY TELEGRAPH, June 25, 1994, available in LEXIS, News Library, Curnws File.

¹⁴⁹ Marc Bygdeman & Marja-Lisa Swahn, *Antiprogesterin Drugs: Research and Clinical Use in Sweden*, 20 LAW, MED. & HEALTH CARE 157, 158 (1992).

¹⁵⁰ *Roussel Chief Sees Obstacles for Abortion Pill*, Reuters, June 21, 1993, available in LEXIS, News Library, Wires File.

¹⁵¹ Bygdeman, *supra* note 149, at 158.

¹⁵² *Id.*

¹⁵³ *China Approves Use of French-Made Abortion Pill*, Reuters, Nov. 3, 1988, available in LEXIS, News Library, Wires File; see also Klitsch, *Science and Politics*, *supra* note 11, at 11.

¹⁵⁴ Andrew Roche, *China: China Revises Population Forecast, Says Figures Forged*, Reuters, Nov. 1, 1988, available in LEXIS, News Library, Wires File. The Chinese government endorsed abortion as a means of birth control permitting it on request within six months of gestation, providing services free of charge, and allowing the woman 14 days of paid sick leave for first-trimester abortion with 30 days for abortions after the first trimester. ABORTION POLICIES: *Global Review*, U.N., DEP'T ECON. & SOC. DEV., U.N. Doc. ST/ESA/SER.A/129/85 (1992). In 1979, the Chinese government introduced the one child policy stipulating that women with "unplanned" (unauthorized) pregnancies should seek an abortion. *Id.* In 1983 a national campaign was begun which included mandatory sterilization for couples with two

tional abortions were performed at a low cost by comparison to the expense of RU 486, the government anticipated that RU 486 would not enjoy widespread use.¹⁵⁵

When Roussel Uclaf withdrew RU 486 from the French market on October 25, 1988, the simultaneous discontinuance of distribution outside France ended further Chinese use of RU 486.¹⁵⁶ Later, when marketing of RU 486 resumed in France, China was not bound to respect Roussel Uclaf's RU 486 patent because the Chinese are not members of the International Convention on Patents.¹⁵⁷ Subsequently, China developed and began production of their own generic form of RU 486.¹⁵⁸ Despite China's ongoing production and use of its generic version of RU 486, in 1992, when the Chinese embarked on a national study of the termination of early pregnancies of 1,572 healthy women, it used RU 486 provided and funded by Roussel Uclaf.¹⁵⁹

D. *Potential Global Use of RU 486*

In October 1988, doctors at the conference in Rio de Janeiro who supported the government-backed re-launch of RU 486 in France voiced their belief that medical abortion could reduce abortion risks and save lives of thousands of Third World women.¹⁶⁰ At this time, RU 486 was being considered for approval in Great Britain, Sweden, the Netherlands, Spain, and Belgium, but was not being considered for approval by any Third World country.¹⁶¹ In November 1989, an official from the Italian Health Ministry reported that Roussel Uclaf

or more children, abortions for "unplanned" pregnancies, and IUD (interuterine device) insertions for women with one child. *Id.*

¹⁵⁵ Roche, *supra* note 154.

¹⁵⁶ Klitsch, *Science and Politics*, *supra* note 11, at 10.

¹⁵⁷ *Id.* Although China is still not a signatory to the convention, were China to change its position and ratify the convention, this act would not disallow their continued production and distribution of their replicated version of RU 486 as long as they did not export their drug. *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ See *Clinical Trial on Termination of Early Pregnancy with RU 486 in Combination with Prostaglandin*, 46 *CONTRACEPTION* 203, 203 (1992). Taking the same dose as women in France, complete abortion was accomplished in 91.2% of Chinese women participating in the study, an incomplete abortion in 4.8%, and continued pregnancy in 3.9% of the women. *Id.* Within the cases of complete abortion, 81% were accomplished within 6 hours of administration of the prostaglandin. *Id.* at 207. Used without prostaglandin, RU 486 resulted in a continuing pregnancy rate of 9.3%. *Id.* at 209.

¹⁶⁰ Hamilton, *supra* note 133.

¹⁶¹ *Id.*

had plans to apply for licenses in every nation which made a direct request for distribution within the following year.¹⁶² Given that as of the fall of 1994, RU 486 is licensed for use only in France, Britain, Sweden, with China using a cloned version, the Italian report was either misstated or misunderstood.

In Germany, where the parent company of Roussel Uclaf, Hoechst, is located, the Hoechst Group cites both business and ideological reasons for its refusal to apply to the German Federal Health Office for licensing.¹⁶³ If the availability of RU 486 is found to be in the "public's interest," under German patent law it is possible that either a compulsory license could be forced upon the Germans,¹⁶⁴ or another pharmaceutical producer might acquire the RU 486 patent from Roussel Uclaf and pursue licensing of the drug in Germany.¹⁶⁵

While Spain and New Zealand have voiced their interest in making RU 486 available, introduction has been stymied by Roussel Uclaf's announcement that it has no plans to request licensing in either country.¹⁶⁶ Although over one thousand doctors signed petitions calling on medical authorities to license RU 486 in Switzerland and appealed to Roussel Uclaf to submit an application for approval to the Swiss licensing authority, again Roussel Uclaf has made no move toward introduction of RU 486 in Switzerland.¹⁶⁷

In March 1994, researchers at the Sydney Center for Reproductive Health Research in Australia joined the other eleven reproductive health research centers around the world to participate in WHO's

¹⁶² *Italy: French Firm to Seek Abortion Pill Licenses in Other Countries*, Reuters, Nov. 9, 1989, available in LEXIS, News Library, Wires File.

¹⁶³ *Germany: Hoechst's Refusal to Seek License for Abortion Pill May Open Doors for Other Companies*, Reuters, June 24, 1993, available in LEXIS, News Library, Wires File. This article reports that: "Hoechst is supported by the Health Minister of Health, Iris Blaul, who said that it was not up to a pharmaceutical company to act as guardian of morals." *Id.*

¹⁶⁴ *Roussel-Uclaf Discusses Possible RU-486 Launch with FDA*, FIN. TIMES, Mar. 5, 1993, available in LEXIS, News Library, Non-US File.

¹⁶⁵ *Germany: Hoechst's Refusal to Seek License for Abortion Pill May Open Doors for Other Companies*, Reuters, June 24, 1993, available in LEXIS, News Library, Wires File.

¹⁶⁶ *France: Roussel Uclaf Spain—RU 486 Will Not be Marketed for the Time Being*, Reuters, Sept. 17, 1993, available in LEXIS, News Library, Wires File. Spanish authorities, although supporting the marketing of RU 486, will not take the initiative of approving use of RU 486 due in part to the incompleteness of the clinical trials designed to evaluate the side effects, and also because "Roussel Uclaf should first put in a registration request." *Id.*; see also *New Zealand: Abortion Pill Unlikely to Become Available*, Reuters, July 5, 1991, available in LEXIS, News Library, Wires File.

¹⁶⁷ *Switzerland: Doctors Call for Legalization of Abortion Pill*, Reuters, Aug. 13 1992, available in LEXIS, News Library, Wires File.

clinical trials of RU 486.¹⁶⁸ Five months later these trials were halted due in large part to the papal directive of Catholic bishops anticipating the Cairo conference and calling for the Australian government to stop the trials.¹⁶⁹ Roussel Uclaf has no plans to market the drug in Australia.¹⁷⁰ In Canada, one Toronto doctor, "standing on what she believes to be principle," is said to be illegally offering RU 486 to her patients.¹⁷¹

In the United States, within days of his 1993 election, President Clinton signed executive orders ending a series of Reagan-Bush era abortion rules,¹⁷² in addition to an order to determine whether the previous administration's ban on RU 486 was justified.¹⁷³ In President Clinton's words: "We must free science and medicine from the grasp of politics, and give all Americans access to the very latest and best medical treatment."¹⁷⁴

Although in April 1993 Roussel Uclaf and Hoechst announced that they would not pursue approval of RU 486 in the United States, these companies conceded to allow a nonprofit New York research organization, The Population Council, to sponsor clinical trials of RU 486 in the United States.¹⁷⁵ Under Roussel's agreement with The Population Council, the first United States clinical trials of RU 486 were initially intended to begin in May 1993.¹⁷⁶

¹⁶⁸ See Helen Signy, *Australians Test Abortion Pill*, Reuters, Mar. 14, 1994, available in LEXIS, News Library, Wires File; Tania Ewing, *Australia: RU 486 Ready For This?*, Reuters, Aug. 20, 1994, available in LEXIS, News Library, Wires File.

¹⁶⁹ *Id.* See Ewing, *supra* note 168.

¹⁷⁰ Ewing, *supra* note 168.

¹⁷¹ Daniel Sanger, *Abortion Pill Secretly Used Here: Drug Firm Won't Sell RU 486 in Canada*, CALGARY HERALD, May 30, 1994, available in LEXIS, News Library, Non-US File.

¹⁷² *Clinton Signs Order on Abortion, Fetal Tissue*, Reuters, Jan. 22, 1993, available in LEXIS, News Library, Wires File. The day after entering office, President Clinton lifted restrictions on funding for United Nations population programs. *Id.*

¹⁷³ See *Abortion Ruling's 20th Year Marked in New Political Era: Abortion Rights Supporters Draft Plans for a Broadened Agenda and Opponents Prepare for a Tougher Fight*, ORLANDO SENTINEL TRIB., Jan. 23, 1993, at B5.

¹⁷⁴ *Clinton Signs Order On Abortion*, *supra* note 172.

¹⁷⁵ See Jenkins, *supra* note 10, at 1110; Smolowe, *supra* note 117, at 49. The Oregon and New Hampshire legislatures volunteered their states as test sites prompting the Food and Drug Administration's Commissioner, David Kessler, to respond: "If there is a safe and effective medical alternative to a surgical procedure, then we believe it should be available in this country." Smolowe, *supra* note 117, at 49.

¹⁷⁶ *USA: Roussel Uclaf Abortion Pill to go on Trial in Oregon*, Reuters, May 4, 1993, available in LEXIS, News Library, Wires File; see also *Mifepristone to be Licensed in USA*, MARKETLETTER, May 3, 1993, available in LEXIS, News Library, Curnws File. Abortion rights supporters in the United States welcomed the agreement but expressed concern regarding the hunt for an American manufacturer. *Mifepristone to be Licensed in USA*, *supra*. In the wake of the shooting of a doctor at an abortion clinic in Florida, the National Right to Life Committee stated that

When these trials did not materialize because of Roussel Uclaf's reluctance to risk potential repercussions, frustrated abortion rights groups in the United States announced that they were conducting tests on the Chinese version of RU 486 donated by the Chinese.¹⁷⁷ In an agreement with Peking Union Medical College, proabortion groups defended procurement of the Chinese version as not amounting to an infringement on Roussel's patent, since under patent law an illegal violation occurs only if an unauthorized maker attempts to *sell* a patented drug.¹⁷⁸ In another attempt to circumvent Roussel Uclaf, scientists at the University of California at San Francisco conducted tests on fifty pregnant women using two inexpensive drugs similar to RU 486 and already approved by the Food and Drug Administration for uses other than to terminate early pregnancies.¹⁷⁹

On May 17, 1994, Roussel Uclaf announced an agreement to turn over the RU 486 patent rights and all technology free of charge to the Population Council to find an American company to produce the pill to be used within the first nine weeks of pregnancy.¹⁸⁰ In exchange for giving up its patent rights, Roussel will effectively shield itself from product liability claims and threats made by anti-abortion groups to boycott other products made by its parent company.¹⁸¹

With RU 486 expected to be available in the United States by 1996, a spokesperson for The Population Council, Sandra Waldman, estimated that RU 486 could potentially be used in twenty-five to

it would hold Hoechst and Roussel responsible if any organization applies for a license, and threatened to boycott. *Id.*

¹⁷⁷ Philip J. Hiltz, *Abortion Rights Group Uses Chinese Pill to Goad French*, N.Y. TIMES, Feb. 18, 1993, at A9.

¹⁷⁸ *Id.* The College supervises distribution of the pill in China and has supplied pills for studies on more than 10,000 Chinese patients. *Id.* "The abortion-rights groups hope to show that the compounds are nearly identical chemically so that they can take advantage of the scientific data from the French monitoring of 150,000 women who have used the pill. They could then use this information to get F.D.A. approval of human tests." *Id.*

¹⁷⁹ *New Abortion Drug Cited: Two Substances Already Approved for Other Uses*, NEWSDAY, Oct. 22, 1993, at 8. Methotrexate and Misoprostol were shown to have a rate of induced abortion greater than 80%. See *Two Drugs Available in the U.S. Appear Safe and Effective for Early Termination of Pregnancy*, Bus. Wire, Oct. 18, 1993, available in LEXIS, News Library, Wires File. The principle author of the study stated: "[t]he primary benefit of these drugs is that they are both already approved for use in this country and they are safe They are also cheap. Methotrexate costs less than \$4 per dose and Misoprostol is less than \$2." *Id.* In comparison, the potential cost of RU 486 in the U.S. may be more than \$200. *Id.*

¹⁸⁰ Katherine Q. Seelye, *Accord Opens Way For Abortion Pill in U.S. in Two Years*, N.Y. TIMES, May 17, 1994, at A2.

¹⁸¹ *Id.*

forty percent of the more than one and one half million abortions performed annually in the United States.¹⁸² It is anticipated that turnover of RU 486 in the United States could reach well past the predicted fifty million dollars annual profit margin.¹⁸³ Dr. Baulieu, the inventor of RU 486, has expressed his belief that acceptance of RU 486 by the United States will act as a way station “en route to the pill’s most important destination—the Third World.”¹⁸⁴

III. INTERPRETATION OF INTERNATIONAL DOCUMENTS SUPPORTING REPRODUCTIVE RIGHTS

Scholars from a wide range of disciplines and nationalities have acknowledged that reproductive health, which includes the availability of family planning facilities, information, and the opportunity to exercise one’s voluntary choice regarding the number and spacing of one’s children, are fundamental rights within the scope of binding international human rights treaties and conventions.¹⁸⁵ Ratifying states both endorse and assent to abide by articles advancing equal rights, protecting life, safeguarding access to health care, ensuring privacy and security of person, and enabling citizens to share the benefits of scientific progress.¹⁸⁶ While the concept of each of these principles providing a distinct reproductive right echoes through the pre-1968 United Nations documents, it was not until the conference in Tehran in 1968 that any single document clearly articulated the “basic human right to decide freely and responsibly on the number and spacing of . . . children and a right to adequate education and information in this respect.”¹⁸⁷ A second milestone was achieved in 1994 in Cairo, when the United Nations further recognized that “[a]lthough in no case should abortion be promoted as a method of family planning . . . [i]n circumstances in which abortion is not against the law, such abortion should be safe.”¹⁸⁸

¹⁸² *Id.*

¹⁸³ *France: Roussel Uclaf to Give Its U.S. Patent Rights in RU 486 To The Population Council*, Reuters, June 12, 1994, available in LEXIS, News Library, Wires File.

¹⁸⁴ Joannie Schrof, *Reproduction Showdown*, U.S. NEWS & WORLD REP., Mar. 22, 1993, at 32.

¹⁸⁵ See generally Rachael N. Pine, *Statement of Rachael Pine: United Nations Fund for Population and Development Preparatory Committee II: United Nations International Conference on Population and Development, Cairo, 1994*, Reproductive Freedom Around The World (Center for Reprod. L. & Pol’y, New York, N.Y.), 1993.

¹⁸⁶ See *id.*

¹⁸⁷ Tehran, *supra* note 5, at pmb1.

¹⁸⁸ Cairo, *supra* note 9, at 8.25.

A. *Binding Rights and Fundamental Freedoms*

The phrase "human rights" as defined in *The Restatement of the Law of the Foreign Relations Law of the United States* includes "freedoms, immunities, and benefits which, according to widely accepted contemporary values, every human being should enjoy in the society in which he or she lives."¹⁸⁹ Although almost every existing nation is a party to the United Nations Charter and is thereby bound by human rights obligations, there is no authoritative determination of what these obligations actually entail.¹⁹⁰ Albeit the breadth of these obligations remains largely untested, it is increasingly accepted that parties to the Charter are legally bound to respect most of the human rights enumerated by the Universal Declaration of Human Rights.¹⁹¹

While international law governs relations between a state and its inhabitants, most states have chosen to incorporate international human rights provisions into their own constitutions or laws either directly or by reference.¹⁹² Thus, any binding human rights protection stemming from international instruments derives primary legal force from domestic incorporation of these principles.¹⁹³ By shouldering the legal obligation of compliance, the ratifying state joins a world community where individual human rights are no longer exclusively within the jurisdiction of sovereign states, but are within the purview of international concern.¹⁹⁴

The United Nations Charter begins with a declaration of purpose to promote and encourage "respect for human rights and for fundamental freedoms."¹⁹⁵ Although the text delineates broad guidelines for application, a precise definition of "human rights and

¹⁸⁹ RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 701, cmt. a (1987). The Restatement continues:

A state is obligated to respect the human rights of persons subject to its jurisdiction: (a) that it has undertaken to respect by international agreement; (b) that states generally are bound to respect as a matter of customary international law; and (c) that it is required to respect under general principles of law common to the major legal systems of the world.

Id.

¹⁹⁰ *Id.* at cmt. d.

¹⁹¹ *Id.*

¹⁹² *Id.* at § 701 (reporter's notes 2).

¹⁹³ See Rebecca Cook, *International Human Rights and Women's Reproductive Health*, 24 *STUD. IN FAM. PLAN.* 73, 77 (1993) [hereinafter Cook, *Women's Reproductive Health*].

¹⁹⁴ See Freedman & Isaacs, *supra* note 45, at 20.

¹⁹⁵ See generally Cynthia Price Cohen, *International Fora for the Vindication of Human Rights*

fundamental freedoms” is markedly absent.¹⁹⁶ Neither the United Nations Charter nor the Universal Declaration of Human Rights explicitly states that each human being has a right of control over his or her body. Yet, given that these documents protect bodily integrity one could argue that the right of control over one’s body is implicated by provisions supportive of self-determination, privacy, and life.¹⁹⁷ These international documents provide the analytical framework for examination of the “penumbral zone of enumerated and existing human rights,” inclusive of freedom from all forms of discrimination, privacy in family planning decisions, the nexus between life, health, education and access to family planning information, and access to new reproductive technologies as a benefit of scientific progress.¹⁹⁸

1. Freedom from All Forms of Discrimination

When CEDAW addressed the disadvantaged position of women, it surpassed the limited nondiscrimination mandate of the United Nations Charter and Universal Declaration.¹⁹⁹ CEDAW developed a legal norm as distinct from nondiscrimination and directed at eliminating the subtle practices deeply ingrained in cultural and familial patterns which disadvantage, exploit, and generally constrain the advancement of women.²⁰⁰ A woman’s status within her community generally depends on her right to act as an independent adult. This status is also determined by her ability to safeguard both her own health and life, and that of her offspring. In order for her to exercise these rights and maintain her status in the community, a woman must have control over decisions concerning the number and spacing of her children.²⁰¹

A woman’s status is determined not only by her ability to participate in the community, to earn a living, and to exercise control over her person and property, but is equally dependent on freedom from discrimination in the exercise of these rights. If she is denied the

Violated by the U.S. International Population Policy, 20 N.Y.U. J. OF INT’L L. & POL. 241, 255 (1987), citing U.N. CHARTER art. 1, ¶ 3.

¹⁹⁶ Freedman & Isaacs, *supra* note 45, at 20.

¹⁹⁷ See generally U.N. CHARTER; Universal Declaration of Human Rights, *supra* note 1.

¹⁹⁸ Berta E. Hernandez, *To Bear or Not to Bear: Reproductive Freedom as an International Human Right*, 17 BROOK. J. OF INT’L L. 309, 311–12 (1991).

¹⁹⁹ See Rebecca J. Cook, *International Protection of Women’s Reproductive Rights*, 24 N.Y.U. J. OF INT’L L. & POL. 645, 678–79 (1992) [HEREINAFTER COOK, *International Protection*].

²⁰⁰ See *id.* at 678–80.

²⁰¹ See Freedman & Issacs, *supra* note 45, at 19.

right to choose when to reproduce, and whether or not to reproduce, each of these other social and economic rights has limited power to advance her well-being.²⁰² It is only within the context of a full constellation of rights that the specific right of reproductive choice is made meaningful.²⁰³

2. Privacy in Family Planning

The individual right to privacy as a basic human right has been interpreted to mean that each individual has a right to a private life.²⁰⁴ This broadly defined notion of privacy encompasses interpersonal and intrafamilial relations, and acts of individual autonomy in reproductive choice within the bounds of the law.²⁰⁵ When read in conjunction with the right to freely and responsibly plan a family, effective exercise of one's right to a private life demands adequate access to family planning information, education, and health services.²⁰⁶

Citing various United Nations documents in her United Nations Population Fund 1991 publication, Executive Director Nafis Sadik reports that the emerging governmental consensus accepts that in order for women to directly contribute to social and economic development "[women] must be able to control their fertility."²⁰⁷ That women should be in control of their fertility is a concept different from the concept of private fertility control being "parents" rights, an idea first expressed in Tehran and included in virtually every international statement since 1968, because a joint parental decision does not recognize that women as individuals must have this decision-making right.²⁰⁸ It was not until 1979 and CEDAW that reproductive decisions became individual decisions.²⁰⁹ The concept of free and responsible private reproductive decision-making runs counter to any form of coercive population control whether it be pressure from a partner or state compulsion.²¹⁰

²⁰² *Id.*

²⁰³ *See id.*

²⁰⁴ *See* Hernandez, *supra* note 198, at 328.

²⁰⁵ *See id.*

²⁰⁶ *See* NAFIS SADIK, UNITED NATIONS POPULATION FUND, POPULATION POLICIES AND PROGRAMS: LESSONS LEARNED FROM TWO DECADES OF EXPERIENCE 57-58 (1991).

²⁰⁷ *Id.* at 58.

²⁰⁸ *See* Freedman & Isaacs, *supra* note 45, at 20.

²⁰⁹ *See supra* notes 50-55 and accompanying text; CEDAW, *supra* note 4, art. 16.

²¹⁰ *See* Freedman & Isaacs, *supra* note 45, at 21.

The individual's right to found a family necessarily includes the right to conceive, bear, and rear children.²¹¹ As noted by the renowned international reproductive rights scholar Rebecca J. Cook, a mother must be guaranteed the right to "found a family of her preferred size without the burden of repeated pregnancies to replace lost children."²¹² Cook comments on the tendency to interpret rights claims by focusing on the positive right (a right of noninterference, or freedom to do something, for example, to reproduce), and ignoring its counterbalance, or negative right (for example, to choose not to reproduce).²¹³ Whereas human rights treaties are promulgated to bind parties to refrain from governmental interference with private exercise of rights, a state incorporation of these rights into its own laws becomes equally violative when it precludes individuals from the freedom to choose to reproduce as when it forces individuals to reproduce against their wills.²¹⁴

Free access to contraceptive measures is far less controversial in the international community than is a woman's right to an abortion. Until the Cairo conference in September 1994, nowhere in any United Nations document was the right to an abortion directly addressed or sanctioned as a reproductive right by any United Nations branch. Yet, due to inevitable contraceptive failure, without access to abortion a woman will never have total control over her own fertility.²¹⁵ Hence, the separation of abortion from family planning abrogates a woman's fundamental right to private decision-making and complete reproductive self-determination.

3. Life, Health, and Reproductive Rights

In the arena of reproductive rights, a right to life concerns the human right to live violated by avoidable death during pregnancy or childbirth.²¹⁶ Setting aside the controversial argument holding

²¹¹ Rebecca J. Cook, *U.S. Population Policy, Sex Discrimination, and Principles of Equality Under International Law*, 20 N.Y.U. J. OF INT'L L. & POL. 93, 121 (1987) [hereinafter Cook, *Population Policy*].

²¹² *Id.*

²¹³ See Cook, *International Protection*, *supra* note 199, at 659.

²¹⁴ See Sheila McLean, *The Right to Reproduce*, in HUMAN RIGHTS: FROM RHETORIC TO REALITY 99, 101 (Tom Campbell et al. eds., 1986).

²¹⁵ See JODI L. JACOBSON, *THE GLOBAL POLITICS OF ABORTION*, Worldwatch Paper 97 (Worldwatch Institute, Washington, D.C.), July 1990, at 49. Statistics show that seven out of 10 women using a 95% effective contraceptive would still require a minimum of one abortion in their lifetime to achieve a two-child family. *Id.*

²¹⁶ See generally Cook, *Women's Reproductive Health*, *supra* note 193, at 78-79. See also

that international tribunals "uniformly have concluded that the unborn are not 'persons' and thus do not enjoy rights, in particular the right to life, under international law," within a reproductive rights arena the right to life pertains to the life of the pregnant woman.²¹⁷ This right to life exists for all born persons and is embedded within the right of all peoples to enjoy the highest attainable standard of physical and mental health.²¹⁸

Unlike the right to life which has no contingencies, the right to health remains qualified by the material resources of each signatory state.²¹⁹ These contingencies are dependent on the nation's medical resources. Thus, if a ratifying state's citizens suffer from a preventable illness where the resources are, or could be, available to cure the illness, that state would be in violation of the good faith effort necessary to preserve its citizens' right to achieve full realization of the highest attainable level of health standard.²²⁰

The scope and breadth of "health" as described by WHO encompasses a holistic vision of the individual, inclusive of physical, mental, and social well-being.²²¹ It follows, then, that an unwanted pregnancy that endangers a woman's physical, mental, or social well-being could therefore threaten that woman's realization of health.²²² In its discussions regarding the protection of women's health in countries where access to abortion is restricted, the United Nations has concluded:

If the state is to do all in its power to protect the health of its citizens . . . then it would be appropriate to repeal all laws impeding access to medical termination of pregnancy, leaving abortion subject only to those regulations surrounding other medical procedures of a similar nature. In this

Universal Declaration of Human Rights, *supra* note 1, art. 3. Article 3 states: "[e]veryone has the right to life, liberty, and security of person." *Id.*

²¹⁷ Hernandez, *supra* note 198, at 332 n.98-99 (citing American Convention, art. 1; European Convention, art. 2(1); Universal Declaration, art. 3; Civil Covenant, art. 6). Hernandez argues that no fetal right could compete with, let alone be the basis to deny, reproductive freedoms as included in the right to privacy and health. *Id.* at 332.

²¹⁸ See U.N. Action, *supra* note 23, at 309.

²¹⁹ See Joan Fitzpatrick Hartman, *The Impact of the Reagan Administration's International Population Policy on Human Rights Relating to Health and the Family*, 20 N.Y.U. J. OF INT'L L. & POL. 169, 174 (1987).

²²⁰ See *id.*

²²¹ See U.N. Action, *supra* note 23, at 309.

²²² See Cook, *International Protection*, *supra* note 199, at 720.

way, a safe, legal abortion would become part of the general medical care to which all persons are entitled.²²³

In countries where abortion is legal, and when the goal and outcome of a woman's abortion serves to protect her life and well-being, be it social, physical, or mental, the international right to health suggests that she may claim the right to access to physicians capable of undertaking the abortion procedure safely.²²⁴ These countries must continue to improve access to safe abortion services within the existing constraints of prevailing laws.

4. Education, Information, and the Benefits of Science and Technology

Under international law, women and men are guaranteed equal rights of access to education,²²⁵ family planning information, and any benefits of scientific advances in reproductive technology.²²⁶ Rebecca J. Cook draws attention to the fact that denying women access to information concerning methods of family planning and the actual benefits of scientific progress in reproductive health care deprives women of increased and improved choice, and thus constitutes a form of discrimination.²²⁷

To avoid noncompliance with international law, states offering lawful abortion must inform citizens of new techniques of fertility control and take necessary steps to provide access to these benefits.²²⁸ Women throughout the world have procured both "nontechnological" abortions (for example, through infusions or massages) and technological abortions since time immemorial.²²⁹ International law safeguards equal access of men and women to information concern-

²²³ RUTH DIXON-MUELLER, *POPULATION POLICY & WOMEN'S RIGHTS* 185 (1993) (citing United Nations 1975:89).

²²⁴ See Cook, *Women's Reproductive Health*, *supra* note 193, at 82.

²²⁵ See THEODORE MERON, *HUMAN RIGHTS LAW-MAKING IN THE UNITED NATIONS: A CRITIQUE OF INSTRUMENTS AND PROCESS* 69 (1986).

²²⁶ See Cook, *Population Policy*, *supra* note 211, at 116. Cook notes that "general awareness of the possibility of achieving 'progress' in reproductive health care has arisen in the fields of epidemiology and public health and has led to a greater appreciation of the health benefits and relative savings that result from reproductive health programs." *Id.*

²²⁷ See *id.*

²²⁸ See generally Cook, *Women's Reproductive Health*, *supra* note 193, at 82.

²²⁹ See Margrit Eichler, *Human Rights and the New Reproductive Technologies—Individual or Collective Choices*, in *HUMAN RIGHTS IN THE TWENTY-FIRST CENTURY: A GLOBAL CHALLENGE* 875, 881 (Kathleen Mahoney, Paul Mahoney eds., 1993).

ing the benefits of scientific advances and access to all safe, available, and legal abortion alternatives.²³⁰

IV. ANALYSIS OF RU 486 AND INTERNATIONAL RIGHTS

Ratifying states, by virtue of their endorsement, agree to protect and promote the ideals enumerated within the signed document. Yet, with regard to RU 486, apart from France, Britain, and Sweden (leaving China as a special case), states which offer lawful abortion and where medical infrastructures to support safe use of RU 486 already exist have fallen short on these international pledges. Although responsibility for this failure lands somewhat on the shoulders of Roussel Uclaf, it must also be borne by those nations which refuse to distribute RU 486 to their citizens. Even though RU 486 has been used to terminate approximately 200,000 pregnancies and has passed tests of safety, efficacy, and acceptability, RU 486 still remains curiously unavailable to most of the world's women.

To some people, RU 486 presents a technology with the potential to blur the distinction between contraception and abortion.²³¹ As a result of this near-melding, "[t]his drug has become so politicized that [even] working with it can have damaging professional repercussions."²³² Researchers in the field of reproduction and contraception hailed RU 486 as the most substantial advance since the birth control pill in the 1950s.²³³ Yet, for others, the storm of controversy triggered in France on September 23, 1988, continues to provoke heated debate six years later.

²³⁰ See Cook, *International Protection*, *supra* note 199, at 724-25.

²³¹ See, e.g., Ruth Dixon-Mueller, *Abortion Is a Method of Family Planning*, in *FOUR ESSAYS ON BIRTH CONTROL NEEDS AND RISKS* 15, 16 (Ruth Dixon-Mueller, Adrienne Germain eds., 1993); David G. Savage & Karen Tumulty, *French "Abortion Pill" Stirs Behind-the-Scenes Battle*, *L.A. TIMES*, May 14, 1989, at 1. This article quotes Sharon Camp, vice president of the Population Crisis Committee, as stating:

This pill blurs the distinction between contraception and abortion. Most Americans, even if they are concerned about the surgical abortion of a fetus that looks like a miniature baby, are not so troubled by the idea of a woman taking a pill at home when the embryo is the size of a pea.

See Savage & Tumulty, *supra*.

²³² See Michael Unger, *Women Urge Drop on RU 486 Ban; Abortion Pill Backers Call for Research*, *NEWSDAY*, July 29, 1992, at 15. The Democratic Representative of Oregon, Ron Wyden, further stated: "We cannot afford to have one of our strong cards, developing new drugs, medical technology and scientific research weakened because of a disturbing trend or medical McCarthyism." *Id.*

²³³ See Savage & Tumulty *supra* note 231.

Claude Evin's 1988 declaration that RU 486 "had become the moral property of women,"²³⁴ reverberated in the British actions taken to expedite, or "fast-track," RU 486.²³⁵ Britain and France offer blazing examples of countries that stood resolute in their pledges to support women's rights to reproductive self-determination and access to the benefits of scientific advances.²³⁶

Three-quarters of all the countries in the world have some form of legal abortion.²³⁷ Experts estimate that nearly one-half of the fifty million induced abortions occurring globally each year are illegal and lead to the roughly two hundred thousand deaths from unsafe abortions.²³⁸ Nafis Sadik, Executive Director of the United Nations Population Fund (UNPFA), confronted the issue of unsafe abortions, writing that while UNPFA "does not take a position either for or against [abortion] . . . [w]herever abortion is legal . . . good quality abortion services should be made easily accessible to all women."²³⁹ In a statement that women's rights groups consider a victory, the Cairo conference similarly urged that unsafe abortion be treated as a "major public health concern."²⁴⁰

Reproductive rights, as a broad class of legally protected rights and inclusive of the subcategory of access to a safe abortion, begins and ends with the principle that each woman and man is entitled to control her or his respective reproductive life. Yet, because it is the woman's body which endures first the pregnancy and then the abortion, an analysis of reproductive rights requires a woman-centered application of international rights. A woman-centered analysis respects women's autonomy and entrusts women's abilities to make responsible decisions when provided with adequate information and access to appropriate services. Both UNPFA and WHO agree that both women and men in an ideal world "should have the freedom to choose any method, the right to change methods, and the ability to afford any method."²⁴¹ Within the limitations of legality, one could

²³⁴ Cody, *supra* note 135.

²³⁵ Mihill, *supra* note 139.

²³⁶ Unlike France, which had the leverage of owning a 35% market share of Roussel Uclaf and utilized this weight to strong-arm the company to continue to market RU 486, British government forces set the stage for and expedited approval and licensing processes. *See* Mihill, *supra* note 139 and accompanying text.

²³⁷ *See generally* Catherine Arnst, *French Abortion Pill Gaining Support From World's Doctors*, Reuters, Nov. 7, 1989, available in LEXIS, News Library, Wires File.

²³⁸ JACOBSON, *THE GLOBAL POLITICS OF ABORTION*, *supra* note 215, at 8, 38.

²³⁹ SADIK, *supra* note 206, at 136-37.

²⁴⁰ Cairo, *supra* note 9, at 8.25.

²⁴¹ *Creating Common Ground: Women's Perspectives on the Selection and Introduction of Fertility*

extend this ideal to infer that if abortion is lawful, the range of choice should permit access to the full range of medically safe methods.

A. *A Woman's View of Protected Rights and RU 486*

In a world where abortion has an extensive history, in the words of the inventor of RU 486: “[i]t’s simply an additional scientific method—an extra choice in a situation that’s always difficult.”²⁴² RU 486 should be viewed as “an essential therapeutic advance . . . promis[ing] to offer women around the world a much more humane and safe way to terminate unwanted pregnancies.”²⁴³ RU 486 represents a medical advance with potential to save lives and increase a woman’s autonomy and control over her body. Because this alternative to invasive medical procedure exists, nations offering legal abortion and nations that have agreed to keep pace with medical and scientific technology have a reciprocal duty to ensure access to RU 486.

Reproductive rights discussions focusing on women’s fertility raise the specter of equal rights regarding women’s and men’s control over reproductive decision-making. Since responsibility for the risk of failed birth control is ultimately the woman’s problem, it naturally follows that any right to abortion belongs solely to the pregnant woman. Because it is her right, it must, therefore, be her decision. When women’s health advocates throughout the world drafted the “Woman’s Declaration on Population Policies” in anticipation of the 1994 Cairo conference, they stated that “[w]omen have the individual right and social responsibility to decide whether, how, and when to have children.”²⁴⁴ This statement unequivocally supports women’s uninhibited right to reproductive self-determination. From a historical perspective, political statements in the arena of gender conflict exhibit an ongoing competition between women and men for the control of women’s bodies.²⁴⁵ In the past, and continuing to the

Regulation Technologies, World Health Organization, WHO/HRP/ITT/91 (Feb. 20–22, 1991), at 16, 21, 24 [hereinafter *Creating Common Ground*].

²⁴² David Israelson, *Abortion Pill Sparks New Debate: Manufacturer Says Canada’s Proposed Law May Prevent Product’s Sale Here*, TORONTO STAR, Dec. 15, 1990, at A2.

²⁴³ Edward Cody, *French Delay Marketing of Abortion Pill*, WASH. POST, Oct. 26, 1988, at A61 (quoting Dr. Joseph Speidel, president of the Population Crisis Committee).

²⁴⁴ *Women’s Voices ’94: Women’s Declaration on Population Policies*, (available from International Women’s Health Coalition, New York, NY).

²⁴⁵ See Sheilah Martin, *A Women Centered Approach to Laws on Human Reproduction*, in HUMAN RIGHTS IN THE TWENTY-FIRST CENTURY 905, 907–08 (1993).

present, reproductive technologies have sought to interfere with women's reproductive capacities by directing little effort toward exploration of either noninvasive forms of fertility control for use by women or alternative methods designed for use by men.²⁴⁶

A woman caught in the uncomfortable position of deciding what path to take regarding an unwanted pregnancy should not be subjected to third-party review of her decision. She should, however, be able to choose the method of pregnancy termination that she feels will best preserve her social, physical, and mental health and well-being. Individual control is integral to a woman's self-determination and ensures privacy and dignity in decision-making.²⁴⁷

Privacy is a fundamental element in the ethics of human reproduction and reproductive choice. RU 486 is a drug prescribed by a physician, ingested at home or in a clinic, and taken without anesthesia or invasive surgery. When compared with traditional surgical methods of abortion, women may find that RU 486 offers increased privacy simply because it does not entail surgical invasion.

The threshold issue for analyzing whether a country could consider introduction of RU 486 mandates that abortion be lawful. Where abortion is lawful, the second question then becomes whether or not that country has a medical infrastructure through which RU 486 could be safely administered. Finally, from an international perspective, one must determine whether the country has agreed to promote equal rights with respect to access to benefits of medical progress, and to the pursuit of the highest level of attainable health, life, self-determination and privacy.

B. *Life and Health: Safety, Efficacy, Acceptability, and Availability of RU 486*²⁴⁸

RU 486 is neither a magic potion, nor a panacea. Setting aside its other potential medical applications, within the context of abortion RU 486 is simply an alternative method of fertility control entangled in a web of politics. Any inquiry into whether the availability of RU

²⁴⁶ Sarah Ricks, Note, *The New French Abortion Pill: the Moral Property of Women*, 75 YALE J. L. & FEMINISM 75, 76 (1989).

²⁴⁷ Baulieu, the inventor of RU 486, advocating the right to self-determination, stated: "[i]t's the duty of the doctor to intervene when there's a medical problem . . . the choice to have or not to have a child should be the decision of the women individually." Israelson, *supra* note 242.

²⁴⁸ See *Creating Common Ground*, *supra* note 241, at 17. This meeting of women's health advocates and scientists delineated their discussion using these headings. *Id.*

486 would serve the ideals of life and optimal health requires an examination of the range of alternative methods of fertility control coupled with a glance at global abortion statistics.

The nearly fifty million induced abortions globally each year roughly translates into the termination of one-in-four pregnancies annually.²⁴⁹ History shows that women who are determined to exercise reproductive control often resort to dangerous and illegal abortions.²⁵⁰ In addition to the ten to twenty-two million illegal abortions in 1987, women underwent between twenty-six to thirty-one million legal abortions.²⁵¹ Although abortion-related mortality of women is lower when abortion is legal, because anesthesia and surgery are involved the risk of death is present even with legal abortion.²⁵² While mortality is often used as a measure of the impact of unsafe abortion, another devastating consequence of these women's deaths is the half million young children who become motherless each year.²⁵³

In addition to the twenty-one percent of the world's population living in states permissive of early abortion for sociomedical or socioeconomic reasons, another forty percent of the world's population resides in nations permissive of early abortion simply on request.²⁵⁴ Given RU 486's potential cost and safety advantage over

²⁴⁹ *Expanding Access*, *supra* note 13, at 1.

²⁵⁰ See JACOBSON, *supra* note 215, at 6-7. In addition to the 200,000 abortion-related deaths annually from an unskilled attendant, unsanitary conditions or self-infliction (with hangers, knitting needles, toxic herbal teas, drinking detergents or gasoline, inserting roots or plants into the cervix, or intensive abdominal massage), for every woman who dies, 30 to 40 more suffer serious lifelong health problems (hemorrhaging, infection, abdominal or intestinal perforation, kidney failure or permanent infertility). *Id.* at 38-39; see also *Expanding Access*, *supra* note 13, at 1. Anthropologists believe that historically, abortion is the oldest, and is likely to be the most widely practiced, method of birth control. *Id.*

²⁵¹ *Expanding Access*, *supra* note 13, at 1.

²⁵² See Leslie A. Rubin, Note, *Confronting a New Obstacle to Reproductive Choice: Encouraging the Development of RU-486 Through Products Liability Law*, 18 N.Y.U. REV. L. & SOC. CHANGE 131, 138 (1990-91). In the United States, where roughly 1.5 million abortions are performed annually, there were 14,000 abortion-related deaths reported in 1985. *Id.*; see also *Expanding Access*, *supra* note 13, at third poster, *Modern Methods of Abortion*. Vacuum Aspiration, 99% effective through the first 12 weeks, requires anesthesia and when performed by a trained provider under aseptic conditions is extremely safe. *Id.* Dilation and Curettage (D & C), which can be used through 14 weeks requires local or general anesthesia and sometimes heavy sedation. *Id.* Major complications are twice as frequent in D & C abortions as compared with Vacuum Aspiration. *Id.* Dilation and Evacuation (D&E) performed between 14-20 weeks takes two to three days and requires local or general anesthesia often accompanied by pain medication and sometimes causes surgical trauma and excessive blood loss. *Id.* Methods used for later-term abortions, defined as later than 20 weeks, require more hospitalization, increased pain medication, greater risk, and are more difficult and traumatic for women. *Id.*

²⁵³ See *Expanding Access*, *supra* note 13, at 3.

²⁵⁴ *Id.* Additionally, 16% of the world's population resides in countries which permit abor-

cent preferred RU 486.²⁶⁹ Dilys Cossey, chair of the British Planning Association, explained women's choice of RU 486 over surgical abortion to a subcommittee of the United States Congress: "[w]hen you give a woman three tablets of RU 486, she's standing up, in her clothes, and can talk. With [surgical] abortion, she's on her back, got her feet in stirrups, and, in Britain, she's unconscious."²⁷⁰ Test results support Cossey's assessment of women's selection of RU 486 for reasons of autonomy, control, and privacy.

In short, as between medical and surgical abortion, RU 486 was the self-determined choice of the majority of experienced women. As a general presumption, the highest level of attainable psychological and physical health is likely to be achieved when the methods of abortion are safe and the choice of abortion is self-determined. In nations where abortion is legal and RU 486 is available, whether a woman chooses RU 486 to avoid the physical risks of surgery, or because of a perceived increase in privacy, in nations where abortion is legal and RU 486 is available, international law protects this choice.

Availability of RU 486 is a multifaceted issue reliant on regulations governing access and delivery in international and intranational markets. As with the advent of any new drug, domestic and international decisions regarding licensing and approval of RU 486 must take into account issues of priority, allocation of medical resources, and the political climate. Licensing and approval decisions are not made without consent of the patent holder.

The governments of France and Britain took active steps to override the political obstacles to RU 486's availability. Not only did these countries confront internal impediments, but each made an extra effort to ensure its citizen's access to RU 486 and leapt over Roussel Uclaf's hurdles. Still, Roussel Uclaf continues to exercise its patent holder's prerogative to withhold RU 486 elsewhere in the world. By setting out stringent requirements for introduction and marketing of RU 486, Roussel Uclaf and Hoechst have effectively created a barrier to entry into countries where abortion is legally available but the antiabortion sentiment threatens potential profits.

²⁶⁹ *Id.* The results of other studies have shown that in the U.K. 84% of 94 women found RU 486 acceptable, and of the 13 experienced women 77% preferred RU 486 and would choose it again. David, *supra* note 107, at 192. In China 80% of a total of 89 experienced women preferred medical abortion. *Id.* Testing of experienced women in the Netherlands showed a 90% satisfaction rate using RU 486 with the remaining 10% preferring surgical abortion because "it would be over more quickly." *Id.*

²⁷⁰ Sarah Glazer, *Controversy Persists on French Abortion Pill; Efforts to Study the Drug for Other Uses Are Stymied in the U.S.*, WASH. POST, Dec. 10, 1991, at A7.

Rebecca J. Cook suggests that where limited access to a patent exists, states can enact a "use it or lose it" patent provision governing health care products.²⁷¹ This provision allows the government to monitor the patent holder's failure to market the product, and gives the government power to ensure that citizens receive the health benefit of the product.²⁷² Thus, the government retains the power to transfer the patent to a new holder to market the product.²⁷³

Vocal antiabortion groups, expressing alarm at the potential of increased privacy offered by RU 486's seemingly decentralized method of abortion, fear that introduction of RU 486 might erode the strength of their movement.²⁷⁴ During the Bush administration in the United States, antiabortion tactics contributed to the denial of access to RU 486 for United States citizens.²⁷⁵ A posture of approval or disapproval of RU 486 within the United States, however, will continue to influence decisions made by other nations because the United States is viewed as the main source of development funds and the leader of advanced research.²⁷⁶

In a May 11, 1993, press release, Timothy E. Wirth addressed President Clinton's "comprehensive and far-reaching new approach to international population issues."²⁷⁷ He remarked that several key elements of this approach include "ensuring that couples and individuals have the ability to exercise their right to determine freely and responsibly the size of their families; promoting access to the full range of quality reproductive health care, [and] including woman-centered . . . services."²⁷⁸ In supporting reproductive choice, Wirth suggested that the "abortion issue should be addressed directly with tolerance and compassion rather than officially ignored while women,

²⁷¹ See Cook, *Women's Reproductive Health*, *supra* note 193, at 83.

²⁷² See *id.*

²⁷³ *Id.*

²⁷⁴ See Jay Mathews, *NOW Leaders Threaten Boycott Over Abortion Pill; German Parent of French Drug Firm Markets Several Popular Products in United States*, WASH. POST, July 1, 1990, at A22. The National Right to Life Committee President, Dr. John Willke, expressed concern that picketing abortion clinics would be less productive not only because fewer women would choose surgical abortions, but also because the gruesome posters used to picket clinics would be inaccurate since "an embryo at, say, four to six weeks looks more like a tiny new tadpole than a tiny new human being." Muhl, *supra* note 99, at 338-39.

²⁷⁵ See generally Smolowe, *supra* note 117, at 48-49.

²⁷⁶ *Id.* at 50. Etienne-Emile Baulieu went on to explain that other countries, most notably Canada, are waiting for the U.S. to take the lead. *Id.*

²⁷⁷ *Statement by The Honorable Timothy E. Wirth*, United States Representative to the Second Preparatory Committee for the International Conference on Population and Development, at the Preparatory Meeting, May 11, 1993, USUN Press Release 63-(93), at 2 (the United States Representative to the United States Mission to the United Nations).

²⁷⁸ *Id.*

especially poor women, and their families suffer."²⁷⁹ Wirth's statements echo the United Nations' global and encompassing protections of reproductive rights. In nations like the United States where the laws condone legal abortion and a strong medical service delivery system exists, international rights to self-determination, health, a private life, and the benefits of technological advances support availability of the full range of pregnancy termination methods, including RU 486.

CONCLUSION

International documents delineate fundamental rights and freedoms guaranteed to peoples within states that are parties to these instruments. These enumerated rights include the rights of self-determination, equality, privacy, education and information, family planning, health, life, and access to the benefits of technological advances and scientific progress. In order to objectively assess the potential harms and benefits of a technological advance, states offering legal abortion must sweep aside the hotly-contested abortion debate. If political issues no longer ran interference and internationally protected rights occupied center stage, one might assume that RU 486 would be offered to a substantially larger segment of the world's women.

Although international instruments do not explicitly guarantee self-control over one's own body, the protected rights to equality, self-determination, and privacy imply self-control. A woman must not be questioned regarding the basis of her reproductive decision-making. It is immaterial whether she made her choice for health, economic, social, or cultural reasons. If legal abortion is one option available to a woman seeking to freely and responsibly control the number and spacing of her children, then she should be allowed to choose freely between all safe alternatives.

Tests have shown that the large majority of experienced women prefer medical over surgical abortion. Actual use of RU 486 has shown its safety and effectiveness. Because international reproductive rights now explicitly state that "[i]n circumstances in which abortion is not against the law, such abortion should be safe"²⁸⁰ politics should step aside and allow women access to this alternative method of abortion.

²⁷⁹ *Id.* at 5.

²⁸⁰ Cairo, *supra* note 9, at 8.25.

ADDENDUM

As this Note is being sent to the publisher, fervor in the United States concerning access to medical abortion, and more specifically to RU 486, is being chronicled by the near daily flurry of newspaper articles. The press has drawn attention to the doctors who, rather than wait for availability of RU 486, have offered nonsurgical abortions through the combination of two drugs already approved by the Food and Drug Administration for other uses.²⁸¹ Researchers are beginning to study these drugs as an alternative to RU 486 even though the side effects of this drug combination are more severe and the success rate is lower than with RU 486.²⁸² Doctors offering the two alternative drugs charge five hundred dollars for medical abortions using pills costing less than six dollars.²⁹³

While doctors in the United States are responding with creative solutions to the present inaccessibility of RU 486, The Population Council has begun trials of RU 486 through distribution at twelve to twenty clinics.²⁸⁴ RU 486 will be given free of charge to a total of two thousand one hundred women on an experimental basis.²⁸⁵ If it is approved in the United States, RU 486 is expected to cost about four hundred dollars (as much as a surgical abortion).²⁸⁶

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²⁸¹ Vivienne Walt, *Not Just One Doctor's Secret; Other M.D.'s May Be Quietly Using Drug-Induced Abortions*, NEWSDAY, Oct. 11, 1994, at A14. The women are given an injection of Methotrexate, a drug commonly used to abort tubal pregnancies; four days later these women are given vaginal inserts of Misoprostol, sometimes used to induce labor. *Id.*

²⁸² *Drug Package Found to Be Good for Abortions*, N.Y. TIMES, Oct. 20, 1994, at A21.

²⁸³ *Id.*

²⁸⁴ Philip J. Hilts, *Clinic Trials of French Abortion Pill Begin in U.S.*, N.Y. TIMES, Oct. 28, 1994, at A28. Six of the Planned Parenthood clinics participating in the study are in the following locations: Des Moines, Iowa; Houston, Texas; San Diego, California; Aurora, Colorado; Williston, Vermont; and Cambridge, Massachusetts. *Id.*

²⁸⁵ Dolores Kong, *Abortion Pill to Get Test in Brookline*, BOSTON GLOBE, Oct. 28, 1994, at 29.

²⁸⁶ *Id.*