

# RU 486/PROSTAGLANDIN THREATS TO SAFE PREGNANCY TERMINATION

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Synopsis—Women’s right to safe and legal abortion is under threat worldwide. News of the French abortion pill, RU 486, which is touted by its promoters as safe, quick, and easy with the control in women’s hands, seems like the much awaited panacea to change the abortion debate. However, in this paper we dispute that chemical abortion is the answer to women’s demand for hassle-free and safe abortion. Instead we posit that RU 486 has been falsely promoted and elaborate on the contrived nature of its administration: (a) 3-5 visits to a licensed abortion clinic spread over 2 weeks; (b) the fact that RU 486 has a 20-40% failure rate that necessitates the addition of a second drug, prostaglandin, to bring it up to a 93-94% success rate (still considerably less than the 99% of conventional abortion); the small number of women who can use it (an extremely large number of contraindications and only usable up to a 49-day pregnancy after a woman’s last period); the many short-term effects (e.g., emergency bleeding, sometimes necessitating blood transfusions, and cardiovascular problems, which have already led to the death of a French woman in April 1991 [Alt-man, 1991]); and the unknown long-term effects due to the drugs’ action on the womb, the ovary, the adrenal glands, the brain, and also the developing embryo. We suggest that RU 486/prostaglan-din abortion is ill conceived and dangerous for women’s health and self determination, and that particularly its introduction into so-called developing countries could have disastrous consequences. We conclude that RU 486/prostaglandin abortion is far from being an abortion “miracle.” In fact, it might lead to a further erosion of existing abortion services because it makes it easier/cheaper for the doctors and the state—but not for women. Promoting chemical abortion may thus unwittingly contribute to closing down women’s abortion choices rather than expanding them.

## INTRODUCTION

“The French Abortion pill,” RU 486, is praised as an alternative abortion procedure to what are termed “surgical” methods, based on claims that it is (a) private and woman controlled, (b) safe and effective, and

(c) superior to conventional abortion methods. The claims are based on a contrived treatment protocol, where RU 486 clinical efficiency is largely dependent on the salvage prostaglandin chemical to reduce its failure rate from 40% to 5% (Klein, Raymond, & Dumble, 1991). Advocates of RU 486 dilute the importance of its short-and long-term biological consequences, together with the acute dangers of prostaglandin medications, maintaining that RU 486-induced abortion is a further “choice”

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for women. We dispute each of these claims and contend that RU 486 has been falsely portrayed as an abortion “miracle.” We contest the claim that chemical abortion will increase women’s choices, and contend that the unethical misconceptions and myths that have accompanied RU 486 research and development have led to its premature acceptance without due consideration of the inherent hazards. We conclude that RU 486/prostaglandin is an ill-conceived abortion approach that endangers women, particularly those from countries where abortion is illegal, and argue that it may actually erode women’s future access to lawful, safe, and women-controlled abortion practice at a global level.

#### THE HISTORY OF RU 486

RU 486, a steroid with the trade name Mifégyne (mifepristone), was first synthesized in April 1980 by Roussel Uclaf scientists. Just 10 years later, the same scientists asserted that the research that led to the synthesis of RU 38486 (later shortened to RU 486) was performed without the intention of discovering an abortifacient. The discovery was asserted to be the by-product of the search for a molecule that would bind strongly with the glucocorticoid receptor (Ulmann, Teutsch, & Philibert, 1990). Subsequent identification that RU 486 was (also) a progesterone antagonist prompted one of its consultants (Emile-Etienne Baulieu) to focus Roussel Uclaf investigations on RU 486’s potential to impede ovulation, act as a “morning-after” pill, and interrupt pregnancy.

Despite scant research on animals and some dubious results from Geneva (Hermann et al., 1982), where the first experiments were conducted on women in 1982, a mere 17 months after the drug was synthesized, clinical trials began in France, Sweden, Holland, the United States, England, Finland, and China. Roussel Uclaf supplied the drug, and its staff and consultants are listed among the authors of

the resulting publications from many of these trials. Andre Ulmann of Roussel Uclaf is even credited with designing a Chinese study of RU 486 (Zheng, 1989). In these trials, reported “success rates,” in terms of women whose pregnancy was completely terminated by RU 486 and who required no further medical intervention, ranged between 60 and 80% (Kovacs et al., 1984). It was concluded that RU 486 was a medical breakthrough and a promising alternative to conventional abortion methods, despite the 99% complete termination rate of those methods.

In order to lessen the RU 486 abortion failure rate, the next step in the development of the abortion pill was to combine RU 486 with prostaglandin. In 1970, prostaglandins, which induce uterine contractions, were introduced globally to initiate labor and to interrupt pregnancies. Prostaglandins have an unacceptable abortion failure rate and are associated with painful gastro-intestinal side-effects and injurious, even fatal, effects in women (Cates, Grimes, Haber, & Tyler, 1977; Euler et al., 1989; Kajanoja, 1983). These serious shortcomings prompted the European Women’s Health Movement to organize against prostaglandin-induced abortion in the late 70s, labelling it medical violence against women (Gruppe Prostaglandine, 1981). Nonetheless, taking their cue from the earlier research of Csapo and colleagues (Csapo, Sauvage, & Weist, 1971), Bygdeman and Swahn (1985) commenced to administer a prostaglandin medication with RU 486. Under the sponsorship of WHO, the 1984 Swedish study included only 34 women, 32 (94%) of whom experienced a complete abortion. RU 486/prostaglandin was rapidly deemed superior to RU 486 alone. Subsequent studies varied the RU 486 dosage while combining it with different prostaglandin analogues that were administered as intramuscular injections, suppositories, or, as first reported in 1990 (Swahn, Gottlieb, Green, & Bygdeman, 1990), an oral medication. There is no evidence in the

medical literature indicating that basic research was undertaken to identify the potential adverse effects from the *interaction* of the two drugs before the clinical trials were conducted, nor to the present time.

The history of RU 486 took a dramatic turn in 1988, following the French Ministry of Health's licensing of Roussel Uclaf to market RU 486 in September. On October 26, Chairman Sakiz of Roussel suspended the distribution of RU 486. It was claimed that this action was due to antiabortionist threats to the company and its employees. Conveniently, the World Congress of Gynecology and Obstetrics in Rio de Janeiro, Brazil, was meeting at that very moment and included a Roussel Uclaf-sponsored Symposium on RU 486, which sent a petition of 2,000 names to Roussel Uclaf protesting the withdrawal of the drug. On October 28, 1988, the media reported that the French Minister of Health, Claude Évin, had ordered Roussel Uclaf to put RU 486 back on the market. He was quoted as saying that RU 486 had become "moralement la propriété des femmes," a slogan that has since become the battle cry of the drug's supporters, including some feminist groups. In February 1989, RU 486 was officially back in France—under tight security—at hospitals and centers licensed to perform abortion.

Two years later, in January 1991, a bizarre twist was added to the "official" story (Vigy, 1991). The French Government Council (Conseil d'État) reprimanded Health Minister Claude Évin for exceeding his power in ordering Roussel Uclaf to return RU 486 to the market in October 1988. Surprisingly, however, Évin claimed that he had not issued such an order because discussions and exchange of arguments with representatives from Roussel Uclaf had made recourse to this procedure unnecessary. Combined with the exceedingly convenient timing of events from the Rio de Janeiro convention, this indicates a contrived history of events operative at all levels.

The decision to put RU 486 back on the market pertained only to France. Roussel Uclaf had decided not to market the drug in other countries. Meanwhile, in November 1988, the U.S.-based Reproductive Health Technologies Project initiated a well-funded international campaign. With the slogan "New Technologies/New Choices," it began a campaign to convince politicians and the community at large to put pressure on Roussel Uclaf to distribute the drug in the U.S. and other countries. The campaign is unequivocal in its assessment that the debate is entirely between the "bad" antiabortionists and the "good" scientists who developed this miracle drug in the service of women. Attempts to identify women's biological and social disadvantages from RU 486/prostaglandin abortifacients, which are directly related to the drugs' advantages for the pharmaceutical industry, medical profession, government health economies, and world population strategies, have generally been dismissed or maligned, as right wing, disguised pro-life criticism (Hoffman, 1991). It has been the rare exception (Duffy, 1991; Moore, 1990) for professional literature to separate the issues of safe abortion services and women's health standards from those that complicate abortion politics; such as institutionalized morality, patriarchal denial of women's reproductive independence, and strategies to limit population growth in developing countries.

#### *The role of the international press*

The early controversies in France over the safety of the two drugs were generally omitted from the lay press, notable exceptions being *Le Monde* and *Le Quotidien du Médecin*, where some of the curious events in France were described (Kami, 1990; Nau & Nouchi, 1988; Nouchi, 1988). The overwhelming majority of articles portray the controversy over RU 486/prostaglandin as a simplistic battle between pro- and antiabortion forces. Newspaper and magazine articles hail chemical abortion as "safe and painless" and

uncritically echo medical claims of “the drug’s reduced rate of complication over surgical abortion.” Further, conventional abortion is reported to be traumatic and dangerous, on the grounds that it is “surgery” that necessitates general anaesthesia (thereby denying the existence of suction curettage with a local anaesthetic). Chemical abortion is presented as superior. Other press reports repeat Baulieu’s claims that there is a moral obligation to provide RU 486 for the “third world” to decrease the death toll from botched abortions. These proposals ignore several important factors. First, abortion mortality and morbidity is directly related to the unsanitary conditions under which illegal abortion is practiced. Second, the provision of chemical abortifacients for Western women has no connection with the prevalence of legal sanctions against abortion procedures in developing countries. Third, within a hostile environment that denies women the right to terminate a pregnancy, abortion-inducing drugs are especially prone to illegal marketing and misuse. Finally, and more critically, when viewed from the ethical considerations of human rights and informed consent, women’s groups within those developing nations have clearly voiced their objection to RU 486-induced abortion, and have condemned its introduction into their countries.<sup>1</sup>

#### MODES OF ACTION OF RU 486

RU 486, according to its French developers, terminates a pregnancy by blocking the uterine progesterone supply and increasing natural prostaglandins to start uterine contractions (Baulieu, 1989). This theory is not uncontested. Elger et al. (1987) postulate that RU 486 inhibits secretion of natural prostaglandin. Sitruk-Ware et al. (1990) contend that RU 486 affects only the superficial layer of the uterine lining and, with traces being detected even 14 days after administration, that its half-life may be more

extensive than first indicated. Both hypotheses may account for the 20-40% failure rate of RU 486 alone, and prolonged bleeding (for up to 54 days) without complete expulsion.

Other research suggests that RU 486 acts as a cell poison (Bardon, Vignon, Chabos, & Rochefort, 1985). Moreover, RU 486 action is in no way confined to the uterus. It also acts directly on the adrenal glands, hypothalamus, cervix, ovaries, and breasts. It has been found to act as a progesterone agonist (Collins & Hodgen, 1986), a property which could induce ectopic pregnancies (it is already recognized that RU 486 does not terminate them), and links it to cardiovascular risk (Kafriksen, 1990).

In addition to being an antiprogestosterone, RU 486 is a strong antiglucocorticoid and a weak antiandrogen (Baulieu, 1989). Gluco-corticoid insufficiency may lead to adrenal insufficiency, with symptoms such as fatigue, abdominal pain, nausea, dizzy spells, and/or fainting—all of which have been noted after RU 486 administration (Sitruk-Ware et al., 1985). Furthermore, because it blocks cortisol action at the hypothalamus-pituitary level (Healy & Hodgen, 1985), women undergoing chemical abortion may be less able to cope with stress, which becomes an important factor for the 5-7% of women who require a conventional abortion once RU 486/prostaglandin termination has failed them.

RU 486 action on the ovary delays ovulation and impairs folliculogenesis, and also affects the next menstrual cycle (Di Mattina et al., 1987). No immature egg within the ovary escapes exposure to RU 486 in abortion procedures, but the effect of that exposure on a woman’s future fertility is undetermined. RU 486 has direct action on the trophoblast/placenta, where there is some evidence that this action retards the embryos in continuing pregnancies (Das & Catt, 1987; Yang & Wu, 1990). Given the multistep nature of RU 486/ prostaglandin abortion, together with the method’s 5-7% failure rate and the

recognized teratogenic effects of prostaglandins (Collins & Mahoney, 1983), in vitro toxicology research into the effects of combined RU 486/prostaglandin exposure is urgently required to ensure that it does not contribute to the birth of children with abnormalities. Overall, many studies indicate that the mechanisms of RU 486 action are poorly understood, but thousands of women have already been exposed to high doses of the drug in what amounts to unethical medical practice.

#### CLAIMS FOR RU 486/ PROSTAGLANDIN ABORTION

##### *Privacy versus control*

RU 486 claims are based on its supposed privatization of the abortion experience, where a woman pops a pill in the privacy of her own home and her pregnancy is over and done with. A different picture is visible within the medical literature, where the degree of medicalization unveils the rhetoric that chemical abortion is a women-controlled procedure. RU 486 is proclaimed to be the prototype of the second generation of abortion methods enabling women to control their fertility, but medical reports repeatedly warn that RU 486/prostaglandin should only be given under strict medical supervision in specialized abortion centres. Moreover, the reality of the medical surveillance is not simply physician supervision from a distance. Rather, chemical abortion is a highly medicalized, multistep, time-consuming procedure. For many women, the procedure considerably extends their anxiety, suffering, and pain. Women who are not excluded by the ever-increasing list of contraindications from RU 486/prostaglandin-induced abortion must first submit to a physical examination to exclude uterine bleeding or pelvic infection. Vaginal ultrasonography and/or a determination of serum human chorionic gonadotropin ( $\beta$ -hCG) confirm and define the

age of a woman's pregnancy. Many centres impose a waiting period of at least 24 hours, after which the woman returns to the clinic or hospital for RU 486. Current protocols contradict the privacy claim for RU 486. Women do not swallow their RU 486 pills at home, but are "watched" by medical personnel as they swallow the medication in the clinic. Promises that women could purchase RU 486/prostaglandin at the local supermarket are unlikely to be fulfilled. Given the acute health hazards chemical abortion presents, this is the only ethical standard that has been applied in the chemical abortion promotion.

Some centres administering RU 486 without prostaglandin require women to return 7 days later to confirm that the embryo has been totally expelled. Most centres, however, now administer prostaglandins in concert with RU 486 to hasten and strengthen the contractions that will ultimately propel the embryo from the uterus. Women return again to the clinic 36-48 hours after the RU 486 for the injection, vaginal suppository, or, more recently, oral prostaglandin medication. During this interval women may not consume alcohol or cigarettes, and, on return to the medical centre for the prostaglandins, are given another pelvic examination, the second in 48 hours. In France, since the cardiovascular accidents, one of which was fatal (Altman, 1991), women are kept prone for 6-8 hours and have their blood pressure and other vital signs measured half-hourly during and after prostaglandin administration. This protocol has been adopted for the U.K. also. Importantly, it specifies medical supervision and confines the procedure to a medical centre equipped with an electrocardiogram, cardio-respirator, and coronary spasm medication.

Following the extremely medicalized treatment at the clinic/hospital, the wait begins, which for many women lasts a week, for others even longer. Any description that this is an at-home abortion is clearly deceptive, with only the final stage of the abortion, the

expulsion of the embryo, likely to occur at home—or outside a medicalized environment—although there is every chance that the woman could be at work, or in the supermarket or on public transport when, and if, the embryo is finally expelled from her uterus. Irrespective of where the event takes place, the reality can be an excruciatingly long waiting period (an interval that exceeds that encountered from a conventional abortion), which is frequently accompanied by pain, bleeding, vomiting, nausea, and other complications.

Finally, the woman must return several days later for her third pelvic examination within a period of 8 days to verify that the abortion is complete. Again, vaginal ultrasound and/or a determination of  $\beta$ -hCG is used. Should the abortion be incomplete, 2-13.4% of women (Gao et al., 1988) have to endure a second (this time conventional) abortion procedure.

The pelvic examinations and vaginal ultrasounds are each internal procedures that invade women's bodies during the chemical abortion process, despite the claim that chemical abortions would avoid inserting medical instruments into the body. Quite misleadingly, curettage is portrayed to be the sole invasive internal or instrumental procedure when, in actual fact, chemical abortion involves greater interventionist instrumentation than conventional abortion.

Finally, the claim that chemical abortion may bypass the antiabortion movement has no foundation. Due to its very nature as an on-the-premise practice administered only at registered clinics (which to comply with the laws in the U.K. must also hold an additional licence to administer RU 486), chemical abortion is no less likely to be the target of antiabortionist threats than conventional abortion clinics. However, because chemical abortion involves multiple visits, it, not conventional abortion, is the procedure that may expose women to multiple episodes of harassment.

*Safety and effectiveness*

There are multiple conditions, contraindications, and complications that expose the fallacy that RU 486/prostaglandin-induced abortion is "safe and effective." Medical facilities are essential to (a) establish the existence and length of pregnancy, (b) monitor blood loss and possibly provide for its replacement, (c) provide analgesics (often narcotic) for pain, (d) determine via ultrasound whether the treatment protocol has been totally successful in expelling the embryonic tissue, and (e) perform a conventional abortion should chemical abortion be incomplete and/or the pregnancy continue. Due to the social stigma attached to abortion, many women are disinclined to seek the prompt medical intervention that is a basic requirement for chemical abortion safety. Those conducting RU 486/prostaglandin studies in white middle-class western women report compliance and follow-up problems (Silvestre et al., 1990). There have been difficulties in getting women to return for sequential treatments of RU 486 and prostaglandins, and for final tests that confirm the completeness of the termination, which again raises the issue of the possible teratogenic effects of RU 486/prostaglandin when the abortion fails and pregnancy continues. Any medical treatment involving multiple steps is fraught with non-compliance, and this is particularly so because abortion has unique psychological, legal, and physical burdens for women.

The situation is increasingly complicated for women from developing countries, where prolonged bleeding as a result of RU 486/prostaglandin-induced abortion has life-threatening implications due to their endemic anaemia. Furthermore, abortion is more likely to be illegal, and these women are further disadvantaged by the absence of a medical infrastructure that could deal with the range of medical disciplines that are vital to RU 486/prostaglandin-induced abortion. Other problems of women in developing nations, such as lack of access to abortion providers

and difficulty in finding transportation to and from authorized clinics, together with scarcity of domestic facilities for storing the prostaglandin at cool temperatures, are equally real for poor, indigenous, and rural women in industrialized countries.

There is evidence already emerging from Brazil confirming that chemicals with abortifacient potential are prone to misuse in the absence of an alternative method that is legal (Schönhöfer, 1991). The availability of RU 486/prostaglandin medications in developing countries where abortion remains taboo is predicted to have even greater catastrophic effects than the abuse of misoprostol in Brazil. Already at two international conferences, women from so-called developing nations have strongly rejected the introduction of chemical abortion into their countries.<sup>1</sup> The goal of their resistance to RU 486 is to avoid replacing statistics that record the number of women who die from "botched curettages" with others that indicate the number of women who die from blood loss or infection following RU 486/prostaglandin (to which could be added women who experienced fatal cardiovascular accidents due to the prostaglandin component) and the number of women who are rendered infertile because of the infections, together with the number of women from a new category, those who give birth to babies with severe deformities when chemical abortion has failed to terminate their pregnancy.

#### *Contraindications*

Numerous criteria exclude large numbers of women from RU 486/prostaglandin treatment. First, the majority of studies recommend that it is only suitable for women whose age is between 18 years and a poorly defined older limit that varies from 35 (Sitruk-Ware et al., 1985) to 40, (Swahn & Bygdeman, 1989) to 42 years (Grimes et al., 1988). In 1991, the French Health Ministry restricted RU 486/prostaglandin abortion to women younger than 35 years of age, as does the World Health

Organization (WHO) in their recent trials. Second, even though the efficacy of RU 486/prostaglandin abortion is limited by the actual age of a woman's pregnancy, the methods of estimating the age of the pregnancy, together with its upper limit, are also poorly defined (Couzinet, Le Strat, Ulmann, Baulieu, & Schaison, 1986; Gao et al., 1988; Somell & Ölund, 1990; Swahn & Bygdeman, 1989; UK Multicentre Trial, 1990; WHO, 1989). Pregnancy age has been measured in some studies as the number of days since the last menstrual period, or less specifically as 42 to 49 days since the last menstrual period. The upper limit of pregnancy age has been cut off at 42 days in some studies or extended to 49 days and, less commonly, to 56 and 63 days in others.

There are a multitude of other contraindications (Couzinet et al., 1986; Maria et al., 1988; Somell & Ölund, 1990; Swahn & Bygdeman, 1989; UK Multicentre Trial, 1990; WHO, 1989). Women with fibroids, abnormal menstrual bleeding, endometriosis, pelvic inflammatory disease (PID), and "cervical incompetence" are excluded from some trials. Other studies exclude women with a previous history of spontaneous or induced abortion and/or a history of "abnormal pregnancies," including multiple and ectopics.

Some studies also rule out women who have used IUDs or hormonal contraception 3 months prior to or during the last cycle in which conception occurred, which, considering the significant number of women this represents on a worldwide base, further diminishes the claim that RU 486/prostaglandin abortion is the safe treatment of choice for *large numbers of women*. However, because only a few studies disqualify contraceptive users from chemical abortion treatment, is chemical abortion a greater hazard for these women? Will their risks be identified, or will there be further tragedies?

Still more women are excluded by their

medical history (Cameron, Michie, & Baird, 1986; Couzinet et al., 1986; Rodger & Baird, 1987; Silvestre et al., 1990; Somell & Ölund, 1990; Swahn & Bygdeman, 1989; UK Multicentre Trial, 1990; Vervest & Haspels, 1985; WHO, 1989): Allergies, including asthma; epilepsy; adrenal insufficiency; kidney, gastrointestinal, liver, and pulmonary disorders; or simply a "history of serious medical disorder" are sufficient grounds for exclusion. The list of contraindications continues. Any woman who has taken steroid medication in the past 12, 6, or 3 months is excluded. This exclusion is related to the antigluccorticosteroid properties of RU 486/prostaglandin. More critically, some nonsteroidal medications may serve to reduce the effectiveness of the prostaglandin component of RU 486/prostaglandin abortion. Anti-inflammatory drugs, including simple aspirin, are known prostaglandin inhibitors (Waltman, Tricorni, & Palay, 1973). Therefore, their simultaneous use with RU 486/prostaglandin almost guarantees that the abortion will be incomplete.

Finally, in light of the documented accidents and death from RU 486/prostaglandin abortions linked to cardiovascular complications, we were appalled to find that only a few studies excluded women on the basis of cardiovascular risk, including hypertension and/or clotting disorders. Smoking is a new contraindication following the April 1991 French woman's death blamed on cardiovascular complications caused by "heavy smoking." Obesity is identified as an additional factor detracting from the RU 486/prostaglandin success rate (Grimes, Berstein, Lacarra, Shoupe, & Mishell, 1990). More conditions will certainly be added in the future, restricting RU 486/prostaglandin to a further diminished population of women.

#### COMPLICATIONS

Incomplete abortions with or without a

continuing pregnancy constitute a major complication. When RU 486 is used without prostaglandin, incomplete abortions/continuing pregnancies range from 44% to 10% (Grimes et al., 1990). Where a combination of RU 486/prostaglandin is used, incomplete abortions/continuing pregnancies range from 13.4% to 2% (Gao et al., 1988). Incomplete abortions and ongoing pregnancies of course necessitate that the products of conception be removed by conventional abortion methods. Incomplete evacuation can be accompanied by severe bleeding due to tissue that remains in the cervical area. One study indicated that a woman who had been classified as a success returned 2 months later because of residual decidual material (Sitruk-Ware et al., 1990). This effect of RU 486/prostaglandin abortion can lead to further complications such as pelvic inflammatory disease from infection, infertility, and possibly uterine cancer. An as yet unpublished study from Roussel Uclaf (Aubeny, 1990) indicates that 4.7% of 1,250 women had incomplete abortions, with or without continuing pregnancies, after RU 486/prostaglandin treatment. This figure of 4.7% constitutes 482 *real* women who, after chemical abortion failed them, had to submit to an additional abortion procedure.

Bleeding is another complication. The largest number of blood transfusions reported so far took place in a U.K. multicentre trial (UK Multicentre Trial, 1990) where 5 out of 579 women required both blood transfusion and curettage. Sometimes, heavy bleeding necessitates an emergency uterine evacuation; other times, when a uterine evacuation is performed because of an incomplete RU 486 abortion, the evacuation itself leads to heavy bleeding. In one study after administration of RU 486, 9% of women experienced heavy bleeding; and when the prostaglandins were subsequently administered as the second medication, an additional 9% bled heavily (Couzinet et al., 1986; Somell & Ölund, 1990; Swahn & Bygdeman, 1989; UK Multicentre



Trial, 1990; WHO, 1989). In many studies, prolonged heavy bleeding is regarded as the chief problem and most serious side effect of chemical abortion.

Some researchers have attempted to make distinctions between the severity of bleeding caused by RU 486 when used alone, and that due to RU 486 in combination with prostaglandins. It has been suggested that the addition of "a small dose of prostaglandin" might be effective in limiting excessive bleeding. However, the WHO multicentre study (1989) cites one centre with an "unacceptably high frequency of heavy bleeding" when combined treatment is used, and concludes that it is questionable whether the risk of heavy bleeding is lessened by using a combination of these two substances.

In some studies, women were prescribed oral contraceptives after completion of the abortion, so the bleeding may have been stopped artificially (Gao et al., 1988). Other studies mention that bleeding was significant enough to cause loss of work, and one notes that although blood loss was not life threatening, it could compromise the health of women in a population where anemia is endemic, as in many developing countries (Rodger & Baird, 1989). Many studies report a significant drop in hemoglobin levels, which can cause low blood pressure and shock, and necessitate a blood transfusion. In one study, 15.3% of women had almost a 10% fall in their hemoglobin level (Sitruk-Ware et al., 1990). Sixteen out of 150 women were prescribed iron therapy to repair the hemoglobin deficit (Maria et al., 1988). Contradictorily, studies reporting bleeding as a significant side effect of the treatment also state that it is not excessive. Other researchers distinguish between moderate and mild bleeding and propose that, with experience, their confidence in disregarding minimum continued vaginal bleeding increased (Cameron, Michie, & Baird, 1986; Rodger & Baird, 1987; Vervest & Haspels, 1985).

Severe pain and other gastrointestinal side effects are frequently reported from RU 486/prostaglandin administration, but these complications are inconsistently assessed, and often attributed to the pregnancy itself. More recent studies compare the pain of combined RU 486/prostaglandin with pain experienced after the use of prostaglandins alone (Silvestre et al., 1990). This is an outrageous comparison because it is acknowledged that pain from prostaglandin-induced abortion is intolerable. A more genuine, and indeed ethical, assessment of pain would be from the comparison between pain from RU 486/prostaglandin with that from conventional abortion. It certainly cannot be made from comparisons with a procedure that has been largely abandoned because of its extremely painful effects.

The unarticulated message about pain in many of these studies is that female pain is expected. Many of the women experienced pain for several days/weeks until the abortion was complete. It therefore is prolonged, rather than transient, pain. This is rarely noted, or is commonly dismissed. Both severe and moderate pain are perceived as normal and natural by the researchers and often by the women themselves. This is also true in the trivialisation of pain from RU 486/prostaglandin abortion when compared with menstrual cramping, and ignores the fact that for many women menstrual cramps are severe enough to interfere with their everyday activities.

The degree of pain experienced by most women undergoing RU 486/prostaglandin abortion can be more reliably assessed from the number of women requesting analgesics. In the 1990 U.K. multicentre trial of 579 women (UK Multicentre Trial, 1990), the percentage of women receiving narcotic analgesia was 50%, and an additional 30% required nonnarcotic analgesia. In the largest published multicentre study to date (Silvestre et al., 1990), which reported on treatment of

2,040 women in France (75 women who did not return for follow-up were excluded from the study), only 1% required opiate analgesia. A novel feature of this study, however, was that, in one sub-group made up of 378 women who were given 0.5 mg of the prostaglandin sulprostone, 76% were premedicated (the study does not specify what the premedication was). This adds a new twist to the recording of pain, since premedication dulls women's perception and experience of pain to follow. One would speculate that pain would be less obvious to these women, yet in spite of the premedication, 51.2% of the 378 women still required further analgesia.

The assessment of gastrointestinal side effects presents another problem. Some studies treat vomiting, nausea, and diarrhea as a single side effect. Some assess them separately. It is generally claimed that the addition of prostaglandins to the treatment regimen leads to vomiting, nausea, and diarrhea, and therefore some studies give figures before and after prostaglandin administration. Where these three gastrointestinal complications are not separated, figures in the combination treatment studies are in the 20% range. A Chinese study reports vomiting and nausea together, citing a 48.3% occurrence in 97 women (Zheng, 1989). When reported separately, figures for vomiting range from 18% out of 116 women (9% after RU 486 administration and 9% after prostaglandin) (Swahn and Bygdeman, 1989) to 15.3% out of 2,040 women (Silvestre et al., 1990). Figures for diarrhea indicate a similar incidence and range (13% of 579 women to 8.2% of 97 women), but nausea is more variable and far more common (57% of 70 women to 25% of 100 women).

For regimens using RU 486 without prostaglandin analogues, gastrointestinal effects remain significant, despite the claims that it is the addition of prostaglandins that promotes these complications. The incidences of nausea and vomiting were combined to

indicate a single side effect in one study where, in fact, 40% out of 95 women experienced both (Zheng, 1989). A U.S. report indicated vomiting in 14% of those women who aborted and in 60% of those who did not (Grimes et al., 1990). Figures for nausea from RU 486 alone range from 27% of 124 women to 24% of 100 women. Diarrhea is not a frequent complication after RU 486 administration unaccompanied by prostaglandin analogues.

Other immediate chemical abortion complications, attributed to RU 486 interference with the functions of the hypothalamus, are fainting, fatigue, and mood changes, which are manifested as irritability and depression (Li et al., 1988). Finally, antibiotics have been administered both before and after vacuum aspiration to women who had incomplete abortions. A French study reports that 25% of the 28 women who had incomplete abortions also developed a fever (Sitruk-Ware et al., 1990). The question needs to be asked how many women who had incomplete abortions in other studies developed infections and fever and required antibiotics.

Promoters of RU 486/prostaglandin abortion emphasize the low percentage of complications. Evidence from the medical literature clearly demonstrates this is untrue. Of more importance, it is critical to realize that 1% of 579 women—the percent of women receiving blood transfusion in the UK Multicentre Trial (1990)—represents 5 women, which is 5 too many. More critically, a larger number of women may require transfusion in places where there is no medical backup to stop the bleeding, nor essential resources to replace the blood loss.

In light of the claims that RU 486 is a simple abortion pill, it is important to highlight how it has evolved, in cumulative fashion, into a complex drug cocktail:

1. In the beginning, there was RU 486.

2. Then, the researchers and clinicians added an ingredient:  
RU 486 + prostaglandin.
3. Then, the studies began to cite  
RU 486 + prostaglandin + narcotic and other analgesics.
4. Then came  
RU 486 + prostaglandin + analgesics + premedication.
5. Finally, we read of  
RU 486 + prostaglandin + analgesics + premedication + antibiotics.

And so it continues. Oral contraceptives have been added to stop bleeding, while some women have been given antidiarrhea and antinausea medications for the gastrointestinal side effects.

The history of the development and application of chemical abortion has been an increasing regimen of drug cocktails. Researchers and minimize the drug cocktail effect, as they minimize other complications. As we evaluated the literature on complications, it became clear to us that the medical acceptance, without comment or criticism, of what have now become “minimal,” “tolerable,” and “acceptable” side effects for women deserves to be highlighted for what it is—unethical medical practice.

#### CHEMICAL ABORTION VERSUS CONVENTIONAL ABORTION

Proponents of RU 486/prostaglandin abortion claim that chemical pregnancy terminations are safer than conventional abortions. However, there have been no systematic comparisons between RU 486/prostaglandin terminations and conventional abortions performed by vacuum aspiration or surgical dilatation, curettage, and evacuation. The category “surgical abortion” is hardly monolithic or, for that matter, always surgical. Often, what are referred to as surgical methods are more appropriately termed suction methods. Routine first-trimester abortions fall

into several categories: abortions performed by dilatation and surgical curettage (usually involving a general anaesthetic), aspiration abortions and other suction methods involving curettage but usually employing a local anaesthetic. Distinguishing between types of conventional abortion is crucial since promoters of RU486/prostaglandin abortions contend that it avoids the trauma and dangers of surgery and anesthesia. But with many conventional abortions, only local anesthesia is administered, so that the so-called risk of general anaesthesia is not an issue.

How comparisons are framed in the medical literature is a fascinating subject. The ideology that abortion is dangerous and has risky complications is *refuted* in the context of assaults from the antiabortionists, but asserted in the context of promoting RLJ 486/prostaglandin. The pro-RU 486/prostaglandin lobby’s “dangers of surgical abortion” strategy and their literature deserve additional comment. The overall impression conveyed is that the monolithic surgical abortion is indeed dangerous and complicated. Yet, undeniably, conventional abortion does not largely involve surgical methods and general anaesthesia, is 99% effective, requires two medical visits as opposed to three or four for chemical abortion, has fewer contraindications and complications, results in less than 1% incomplete abortions, and can be performed over a wider range of time. The length of time for a chemical abortion to “take,” added to the time involved in multiple visits to the centre of administration, is one great omission from the comparative assertions. Often a woman has to wait hours or days, or in some cases weeks, for the embryo to be expelled. This is, at the very least, an unpleasant and unwanted experience. In the meantime, bleeding has begun as well. Does the woman continue her work, or does she wait for the expulsion to happen in the privacy of her home or the “privacy” of the street? Comparatively, conventional abortion has the advantage of being quick and time-

limited, instead of multistep and long drawn out.

RU 486/prostaglandin works best within 49 days after a woman's last period; conventional abortions can be performed safely and effectively within the entire first trimester of pregnancy. The RU 486/prostaglandin method is associated with greater blood loss than is suction curettage. Both, as delivered within the current medicalized setting, require doctor supervision. However, it is generally agreed that physicians are not essential for safe conventional abortion practice. While conventional abortion has a low rate of infection and uterine perforation, this is dependent on the method employed, the skill of the provider, and the context in which it is performed.

The abysmal safety statistics from conventional abortions in third world countries are cited in defense of chemical abortion. But the RU 486/prostaglandin method is as unacceptable in these countries for the same reasons as poorly performed conventional abortions: lack of trained personnel and supervision. Moreover, in many third world countries abortion is illegal. Many promoters of RU 486/prostaglandin are concerned about the effects of infection from conventional abortions done on women in developing countries, but seem unfazed by the possibilities of incomplete abortions, bleeding, and infection of women in these very same countries who do not have access to the medical supervision required by the RU 486/prostaglandin combination treatment.

The benefits and liabilities of chemical and conventional methods—for the medical profession, hospitals, and the state—have not been adequately addressed within the comparative literature. The cost of RU 486/prostaglandin abortion, for example, is not less expensive for women, but appears to be cheaper for the hospitals and clinics. The U.K. Women's Health and Reproductive Rights Information Centre newsletter reports that the

National Health Service in Britain will save £15-20 million per year when England begins to use RU 486/prostaglandin (Women's Health and Reproductive Rights Centre, London, 1990).

In the past, women have received isolated and reluctant support from the medical profession to establish centres where conventional abortion methods are administered. By and large that resentment and resistance remains. It is quite unsurprising, then, that the same profession would prefer chemical to conventional abortion, since it will gain a more humanized abortion experience from RU 486/prostaglandin—but at whose expense? Here too, providers' attitudes toward methods of abortion have a significant influence on the method selected by women. Many of the studies supporting the safety and effectiveness of RU 486/prostaglandin cite women's satisfaction from chemical abortion, with a 60-90% preference towards chemical over the indiscriminately termed "surgical" method. Reasons such as "awareness of what was happening to them," "more natural," "avoidance of general anaesthesia," "more discreet," and "less traumatizing" have all been mentioned. The preference is understandable, given the current abortion climate, and can be due to one of several factors. The most common culprits include a woman's experience of a surgical termination that involved an unnecessary anaesthetic, an abortion provider's punitiveness toward women undergoing abortion (this includes medical ambivalence and/or hostility towards conventional methods), and the manner in which society inflicts guilt on women who undergo abortions. This is not to claim that conventional abortion is a positive and uplifting experience for women, nor that being in the stirrups promotes any version of female control. It is to say that RU 486/prostaglandin does not change this order of things.

An unfortunate effect of the brief comparisons offered in the medical journals

between chemical and conventional abortion is that RU 486 has been pitted against suction and vacuum aspiration. Although many groups promoting RU 486/prostaglandin abortion regard it as a medical alternative for early pregnancy interruption, or as expanding “choices” for women seeking abortion, some groups see it as the treatment of primary choice, or as a *replacement* for conventional abortion. This is a major unexamined consequence of promoting and privileging RU 486/prostaglandin at the expense of conventional abortion methods. Should longterm debilitating consequences eventually result from this drug in later years, as happened with diethylstilbestrol (DBS), women may have reached the point where conventional methods of abortion will no longer be widely or even marginally available. Further, since RU 486/prostaglandin abortion must be done within a 42-49-day time period after the last menstrual period, this may become the accepted upper age limit for legal abortion.

The assault on conventional abortion by the right wing and religious conservatives in the United States and other countries has, of course, increased the fervor for an abortion method that is self-administered, safe, effective, and free from harassment. Unfortunately, RU 486/prostaglandin does not fulfill these criteria. What the present situation seems to have generated is a general system of misconceptions. It is a misconception that chemical abortion is women controlled, rather than medically. It is another misconception that, because RU 486 is a pill, the method is quick and easy; it is a further misconception that it does not involve medical instrumentation; and the greatest misconception is that the new abortion pill will create an abortion alternative for women that is free from the present threat of the right wing. In reality, it may have the very opposite effect of consolidating abortion procedures at even more restricted and controlled medical

centres, and of ultimately diminishing the availability of safe, conventional abortions for women.

#### ENDNOTE

1. Resolutions from the 6th International Women and Health Meeting, Manila, The Philippines, November 1990; “Women, Procreation and the Environment” conference, Rio de Janeiro, Brazil, October 1991.

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