SUBMISSION TO INQUIRY INTO THERAPEUTIC GOODS AMENDMENT (REPEAL OF MINISTERIAL RESPONSIBILITY FOR APPROVAL OF RU486) BILL 2005

From World Federation of Doctors who respect Human Life (Vic Div) per Dr Philomene Joshua Tenni, Secretary.

This bill seeks to repeal **Subsection 3(1) (definition of restricted goods**) and the related Sections 6AA, 6AB, 23AA and Subsection 57(9).

Subsection 3(1) actually reads

3 Interpretation

(1) In this act, unless the contrary intention appears:
Restricted goods means medicines (including progesterone antagonists and vaccines against human chorionic gonadotrophin) intended for use in women as abortifacients.

The act does not mention RU486 by name, but abortifacients.

The amendment is aimed at extending all abortion by making any and all abortifacients freely available. WE OPPOSE IT.

In medicine, risks are only legitimate, when they are taken to avoid an inevitably worse outcome. Killing the developing individual, and exposing the mother to unnecessary risks, cannot be countenanced in a civilised society.

Fleming and Ewing showed that the vast majority of Australians do not want abortion for themselves and do not approve of it. They also realize, that there are many complex situations behind abortion requests, which need educational, social, financial and medical treatment to fix, and are therefore uncertain of the role of the law. This is reflected in the differing state laws.

While the legislature has the duty to provide optimal social conditions, there are some people who do not have any problems, or if they have them, have no motivation to fix them. The law then has to function as a **motivator**. It is a real developing life that is being terminated, not just an opinion.

Healy's RU486 trial in Melbourne circa 1996, is said only to have attracted about half the 100 candidates advertised for, and most of them bled.

The Australian experience is mainly with accidentally occurring miscarriages. An understanding of this is important as a framework from which to look at the problem.(Appendix 1.)

RU486 or mifepristone, is a synthetic steroid with antiprogesterone properties. It was tried for hormone dependent cancer, but abandoned when it caused severe Addisonian symptoms of adrenal failure. The adrenals implement the body's response to stress with adrenalin, and control fluid and electrolyte and glucose balance with the corticosteroids. They regulate the inflammatory process which fights infection and are needed to check inappropriate auto immune responses. Mifepristone's killing properties are most evident in pregnancy, where the baby dies first.

This was welcomed as an abortifacient, and a massive campaign of trials succeeded in eliminating much of the developing generation and helped cause an aging of western society.

The trials were designed by abortionists to spread abortion. The language used was pure propaganda, where "success" was the killing of the unborn. Any adverse mortality or morbidity of the mother was downplayed as statistically insignificant. The brevity of most large trials makes long term follow-up difficult or impossible.

Medical trials vary enormously both in the amount of detail they give, and the results they obtain. A paucity of detail may indicate a paucity of observation. So may exceptionally "good" results. Nevertheless, information can be gleaned from them.

While FDA gives requirements for surgery as 5-8%, the most reliable trials give serious symptoms- requiring medical treatment - as 23% in the American trials, 22% in New Zealand, and 22% just for parenteral analgesia in Britain. Practically all patients suffer other symptoms as well.

This means one in five will have problems, and without observation, cannot be picked up

Because doctors are reluctant to use it, there is constant pressure around the world, towards nurses, chemists, and alternative practitioners to deliver, and to dilute necessary precautionary protocols(See Appendix 2), . Increased mortality, and increased morbidity, for the patients to suffer, would place extra demands on the medical force. More training in gynaecology would be required in Australia.

RU486 (MIFEPRISTONE)
Early attempts at medical abortion involved mifepristone only.
Birgerson and Odlind showed in 1987 that mifepristone (a progesterone receptor blocking agent) taken 3 times a day for a week, in pregnancies, at or less than 49 days from the last period, caused abortion 61% of the time.[i] Only 2 women had incomplete abortions. The rest failed to abort, and had vacuum aspiration on day 7.
Later, prostaglandin analogues were added.

MISOPROSTOL
Misoprostol is well known in Australia, for its use in oesophagitis and gastritis associated with hiatus hernia. The NHS Pharmaceutical Guide warns against its use in pregnant women.
It may, taken alone, cause abortion 40% of the time. "Doctors have discovered a high rate of birth defects among infants exposed in utero to misoprostol, such as fused joints, growth retardation and a paralysis of the face called Moebius syndrome. In Brazil, where up to 75% of the clandestine abortions involve misoprostol. Studies suggest between a third and a half of infants born with Moebius had been exposed to misoprostol."[ii]

The makers of Cytotec (misoprostol), Searle, (now part of the Pharmacia Corporation) warned all health care practitioners in a letter of August 23, "Serious adverse events reported following off-label use of Cytotec in pregnant women include maternal and fetal death; uterine hyperstimulation, rupture or perforation requiring uterine surgical repair, hysterectomy or salpingo-oophorectomy, amniotic fluid embolism; severe vaginal bleeding, retained placenta, shock, fetal bradycardia and pelvic pain."
Acute allergic reactions involving facial swelling and bronchospasm, and allergic shock may occur in susceptible individuals.

An FDA (U.S. Food and Drug Administration) Alert on misoprostol was issued in May 2005. It is **not** to be used to induce labour nor to decrease blood loss after a baby.[iii]

A review article on "Efficacy and safety of misoprostol in obstetrics"[iv] covering articles from 1999 to 2004, found that the "Efficacy for abortion with mifepristone was superior versus placebo and gemeprost, but misoprostol is **more painful and less effective than dilation and subsequent evacuation."--** In the prevention and treatment of postpartum hemorrhage, misoprostol was **not** any better than oxytocin.
.Used as a labour inducing agent---**no** controlled clinical trials were found.
Use for hysteroscopy facilitates the procedure versus placebo, but entails a **higher frequency of adverse events."**

RU486 COMBINED WITH MISOPROSTOL.

Claims that mifepristone and a prostaglandin had been used successfully to terminate pregnancy in Europe[v] (where they had had serious cardiovascular effects including one myocardial infarct), and China, led to the ground mark experiment "Early pregnancy termination with mifepristone and misoprostol in the United States" by Spitz published in 1998. This was a seventeen centre trial covering 2121 women with pregnancies up to 9 weeks duration. They were given 600mg mifepristone, then 400mcg misoprostol 2 days later, observed for 4 hours and returned on day 15 for final assessment.
Results: 2015 returned . 6 did not.
Of pregnancies of 49 days or less, 762 of 827 (92%) terminated.
50-56 days 563 of 678 (83%) ..
57-63 days 395 of 510 (77%) .. .
This occurred within 4 hrs of the administration of misoprostol in 49% of the women and within 24 hours in 75%, and took longer in the rest.
The largest increase in "failures" represented ongoing pregnancy –from 1% in the early group to 9% in the late. Abdominal pain, nausea vomiting and vaginal bleeding occurred, and 65 women were hospitalised for surgery and IV fluids.

An overview of the US trials found 99% patients had experienced adverse effects. Of these, approximately 23% were judged to be severe

The authors of the trial bemoaned the fact that the "success" rate in this study was lower than that reported by the other researchers (presumably China and Europe). However, since then, there have been deaths in Europe.

The numbers of near death bleeding post-medical abortion cases has caused China to **ban all pharmaceutical sales of RU-486 "to guarantee patients' safety and protect their health."[vi] "Even with doctors prescriptions".** (Unfortunately the ban does not seem to have extended to Hong Kong.)

Chinese hospital staff had been too busy to handle the procedure (more counselling, more visits and observation) and they also had to manage the referred cases with serious side effects and complications.[vii] Patients had been buying their own medication over the counter and doing it themselves.
If you think that could not happen here, think of the **chemists handing out morning after pills regularly on the Gold Coast during schoolies week. One chemist said more than 150 schoolies had asked for the MAP at her store.[viii]**

One case of a woman prone to pre-eclampsia who would have had to go hundreds of km to get a surgical abortion was publicised. If she had had a sudden large bleed after the medical abortion, she was still several hundred kilometres from the nearest public hospital, and might not have been alive at the end of the trip. **American protocol would have excluded this patient** on the grounds of having had severe pre-eclampsia which may have caused previous serious liver and renal disease and left residual hypertension, as well as being more than one hour from the emergency department servicing the abortion facility. Most doctors have never had experience in gynaecological surgery. When my nephew's wife had a miscarriage on arriving in Broome, she was told how lucky she was, because the obstetrician had just arrived on his monthly visit to the town.

Ashok PW, Flett GM, Templeton A, .in their letter to the Lancet on "Termination of pregnancy at 9-13 weeks' amenorrhoea with mifepristone and misoprostol."[ix] described 120 UK abortion patients (median age 22.1 years) who received a single oral dose of 200mg of mifepristone 36-48 hours before admission, at which time 800mcg of misoprostal was administered vaginally. Where indicated, a further 2 doses of 400mcg of misosprostol (vaginal or oral) were provided every 3 hours. All 120 women aborted on the day of prostaglandin. The time range was1.3 –16hours.
6 women (5%) required exploratory curettage for retained placenta
60 women (50%) required oral analgesia
26 women (22%) received parenteral analgesia
38 women (32%) suffered diarrhoea
bleeding ranged from 3-43 days.
They advocated extension of medical abortion to later gestation times to decrease the need for surgery.
Here the women were admitted and observed. The 5% in dire trouble received emergency curettage promptly, (which immediately puts the lie to the claim that medical abortion can replace surgery.) The claim that it can reduce surgery is ***useless****, if you do not know who will or will not need it.*

It has been said "There is no need for the woman to remain under medical observation,
The abortion process can occur at home, but" -and here's the rub- the woman must have access to appropriate and skilled 24 hr emergency help if needed."[x] It is then stated "Analgesia must be offered (pain and bleeding are a normal part of the process), and the woman should be supported emotionally as much as possible."
Just who would be around to give parenteral anaesthesia at home, (for the 1.3 to 16 hours that the process took in these cases) and just how normal this would be, is debatable. Who would dispose of a small body with recognisable head and limbs and provide "emotional support"?

No-one should dispute the direction, that follow-up to confirm that all products of conception have been removed, is necessary.

In this series, 6 women required exploratory curettage for retained placenta, although *one wonders if the women who bled for 43 days or thereabouts perhaps were missed.* Questionnaires were administered to 73 women (*why not 120*) and only 3 (4%) expressed dissatisfaction with medical abortion because of pain and bleeding-*Is this all the questionnaire covered?*
What happened to the other 47 women? Did they vote with their feet?

The total symptoms recorded come to 130, but only 120 women took part. No doubt some women had more than one problem, but it seems there was almost 100% adverse symptom rate.

RECENT FIGURES.

A pubmed search of Mifepristone turned up 3962 references. Among the first 100 references, the most recent posted, were found10 articles of actual clinical trials, 5 articles of allied medical interest, 6 of sociological or psychological interest and 6 on deaths.

DEATHS ASSOCIATED WITH MIFEPRISTONE/MISOPROSTOL & C. SORDELLI

Six articles were found[xi], dealing with 4 deaths in California, 2 in 2003, one in 2004, and one in 2005, and 1 had previously occurred in Canada in 2001. All the women were young and healthy. They had apparently successful medical abortion procedures (there was no evidence on autopsy of retained products of conception), presented with cramping, but no fever, and all died remarkably rapidly with tachycardia, refractory hypotension, multiple effusions, edema, haemoconcentration and profound leukocytosis, within one week of presentation. All had an endometritis.

It has been postulated that the women who developed C.sordellii infection after medical termination might equally well have developed the infection had their pregnancies proceeded to term.

A search for maternal postpartum deaths associated with C.Sordelli revealed five. 3 were reported in 1989[xii], 1 in 1997[xiii], and 1 in 2000[xiv].

Of the first three, only **one** was an endometritis- in the remaining two, **other** loci of infection were found, confined to a retained vaginal sponge, and to an infected caesarian wound respectively.
The 1997 case is the most interesting, in that it was the only one diagnosed before death, by blood culture. Laparotomy revealed a substantial amount of serosanguinous fluid, the peritoneum was lifted by a jelly-like retroperitoneal tissue. The appendiceal apex was hyperaemic and adhered to the rear parietal peritoneum, and the right adnexa appeared oedematous and thickened. Gall bladder, duodenum, stomach, ileum, ascendens and transverse colon appeared thickened and ischaemic. Pancreas, spleen and liver were normal.
She died despite IV cefotaxime1Gramme tds. They suggest antibiotics such as penicillin, tetracycline, metronidazole, clindamycin and imipenem , but antitoxin serum might be more rapid and specific. C sordelli and C difficile sera are known to be effective in preventing illness and death in animal models. It is not available for humans. Her death was appendicitis.
The year 2000 case of postpartum C sordelli was an endometritis, and the first from Sweden, no other details were given.

The tally is **2** cases of C sordelli endometritis for the postpartum patients between 1989 and 2000, and **5** cases of postabortal endometritis between 2001 and 2005.

This indicates postpartum endometritis deaths are falling while postabortal endometritis deaths are rising.
Although the modes of death are similar, medical abortion does appear to leave the uterus more vulnerable to C.sordelli, than pregnancy.
Bleeding and purulent discharge found in 30% medical abortion patients by WHO also indicated an increased susceptiblity to infection.
Miech discusses the immunity loss in “Pathophysiology of mifepristone-induced septic shock due to Clostridium sordellii”[xv].

The impairing of the immune response to infection by mifepristone,[xvi] does have to be considered as contributing to the endometrial spread of C sordelli.

OTHER DEATH ASSOCIATED WITH MEDICAL ABORTION.

A law suit alleges that a 38year old died on September 12, 2001, from a massive infection resulting from a ruptured ectopic pregnancy, five days after she visited the Knoxville abortion clinic and began taking the RU-486 drug combination.[xvii]
While there are increasing hospitalizations[xviii] for ectopic pregnancy in the US-there were 88,400 in 1989-mostly due to past or present infection, or postoperative adhesions, the great majority of these do not result in death.
The mifepristone-misoprostol regimes both counteract the body's attempts at recovery, and give symptoms which mask the diagnosis, or delay treatment, with fatal results.

Other deaths due to delayed bleeding tend not to be reported in trials, because the women go to another hospital, or none at all as in the case of the 16year old Swedish girl who simply bled to death 2003 There have been at least 10 deaths associated with the use of RU-486 overseas.
One in France April 1991-an asthmatic mother of 5 children who bled, and probably had hypotension and asthma as well.
One in Canada 2001 septic C.sordelli shock, the 4 in California between 2003 and 2005 also with septic shock. An American girl who died of ruptured ectopic pregnancy in 2001.There was one death possibly from myocardial infarction and 2 from Britain of unknown origin which have been mentioned in the lay press.

Virtually all deaths could have been predicted from the original cancer findings.

A LOOK AT SOME OF THE LITERATURE.

1. The first of the trials, entitled "Study supports the introduction of early medical abortion in Turkey"[xix], aimed to show that early medical abortion could be introduced safely in Turkey.
This seemed at odds with Professor De Costa's statement in her article that it was already available to women in Turkey.
209 women aged 18-49 years were matched with surgical abortion . They took 200mg mifepristone, followed by 400micg oral misoprostol (75% at home). **There were 1.4% (3) on-going pregnancies in the medical abortion group, and none in the surgical. There was a high incomplete abortion rate** mentioned, but not documented in the abstract.
This did not deter the authors from recommending that it be introduced with a change in dose of misoprostol.
This article cannot be regarded as an endorsement for the practice.

2. From Scandinavia came "An outpatient regimen of combined oral mifepristone 400mg and misoprostol 400micrograms for first trimester legal medical abortion"[xx] (less than 56 days pregnant- *unclear as to whether measured from LMP or gestation* . 660 women participated. "Successful abortion was defined as an endometrial thickness of less than 20mm thickness evaluated by transvaginal ultrasound, and minimal bleeding at a control examination performed 14 days after administration of misoprostol."
After menstruation, the endometrium is desquamated to a thin layer of stroma. By the time of ovulation, the endometrium is approximately 2-3 mm thick. By the end of the secretory phase it is 4-6 mm thick.[xxi] A thickness of 10 to 20 mm would indicate that miscarriage was by no means complete, or at the very least, a great deal of endometrium still to be shed.However, 92% were

deemed to have had successful abortion with **8% vacuum aspiration** mainly for uterine retention (70%), and also for vaginal bleeding (25%) , vomiting (2%), and pelvic infection (2%)
Over a 6 month period 70% completed a questionnaire, and of these 74%would prefer medical abortion again if the need arose. *This means that only 342 of the 660 women reported satisfied, far from satisfaction rates of up to 98% reported.*

3. From Delhi, India[xxii], we learn that medical abortion although legal, is unpopular, presumed due to the longer duration of bleeding compared with surgical abortion. 150 healthy pregnant women, with amenorrhea of less than 63 days, were given mifepristone 200mg orally on day 1, with 0.8 mg misoprostol either orally or vaginally on day 3. Women in the oral group and one of the 2 vaginal groups were given misoprostol 0.4 mg bd from day 4 –10.
"Results: complete abortion rate in each of the groups was 96-100%per cent.(*Why the range, why not a definite figure?)* The addition of misoprostol 0.4mg bd from days 4-10, did not help in increasing successful outcome or shortening duration or amount of bleeding."
*These were the complete results from the free full text. Presumably because they were comparing like with like, they did not feel it necessary to document **any** other side effects, nor was there any follow-up recorded. This cavalier attitude, and apparent lack of any close scrutiny of the women, invalidates their conclusion that* "medical abortion for pregnancy up to 63 days using misoprostol 0.8 mg vaginal/oral after pretreatment with mifepristone 200mg is a safe and successful procedure.

5. Also from India came an "Evaluation of the efficacy of mifepristone/misoprostol and methotrexate/misoprostol for medical abortion"[xxiii] Of 100 women (*no duration of pregnancy given)* 50 were given 50 mg/m2 of methotrexate intramuscularly followed by 800micro gm of intravaginal misoprostol, and 50 patients were given 200mg of mifepristone orally followed by 800 microg of intravaginal misoprostal The rate of expulsion (*of embryo or foetus or placental tissue?)* by first week after initiation of treatment was 58% in methotrexate and 98% in mifepristone group. Conclusion: low dose mifepristone and intravaginal misoprostol is safe, effective, and well tolerated **as compared to methotrexate and misoprostol**. *One cannot accept the bland assurances of 98% "safety" with mifepristone, when there are no records of any ancillary treatment, no side effects, and no mention of whether these were home or hospital procedures in the abstract.*

6. New Zealand required the first 67 patients receiving early medical termination[xxiv] with mifepristone and misoprostol to remain in hospital until the products of conception were passed. If this had not occurred within 8 hours of administration of misoprostol, suction curettage was performed.
Early medical TOP occurred in 63 of 67 cases (94%) Only 4 cases (6%) required completion by suction curettage. Clinical events requiring management, mainly bleeding problems, occurred in 11 patients (16%). *It appears that the New Zealand experience of **22%** requiring follow up medical treatment, is at odds with the Indian claims of 98% success rate. No doses were given in the abstract.*

7. In the UK, [xxv] 49 women up to 56 days gestation, at Aberdeen, were given mifepristone 200mg orally in hospital under nursing supervision, and provided with misoprostol tablets 600microg and advised to take them sublingually 36-48 hours later. Of these 48 aborted at home, while one returned to hospital after receiving misoprostol at home. One woman

underwent **surgical evacuation 5 weeks following abortion for excessive bleeding and retained products of conception**.
What is surprising is that this is the only such case reported in these trials. It also shows that the usual time frame of 2-3 weeks observation in most of these trials is giving a false sense of security. The varying leakage rates of people who do not reply to questionnaires, casts doubt on the figures. The report continues
"A total of 43/44 (98%) women were reported satisfied with having the abortion at home. Side effects experienced by women included nausea 32/40 (80%), vomiting 17/41 (42%), diarrhoea 17/41 (42%), shivering 26/40 (65%), tiredness 32/40 (80%), headache 12/39 (31%), hot flushes 14/40 (35%), dizziness 24/29 (62%) and unpleasant mouth taste 19/38 (50%)
To be more correct, only 43/49 women were reported satisfied with having, or attempting to have, their medical abortion at home which is 87.8 % not 98%. And one wonders at that result, in view of the symptomatology reported. Tiredness can be symptomatic of anaemia due to blood loss (80%), shivering and headache can be due to infection or allergic reaction, and/ or cerebro-vascular spasm. No attempt seems to have been made to observe, diagnose them or look after them properly. The recommended protocol has been completely ignored. Putting all the symptomatology together we could say that there was an adverse reaction rate of 487% which is just as sensible as a satisfaction rate of 98%. The conclusion that this study suggests the feasibility and acceptability of home self administration of misoprostal for medical abortion up to 56 days' gestation is fatuous.

8. From Tunisia came "Mifepristone 100mg for early medical abortion"[xxvi]. This was a retrospective study over 8.5 months of 762 cases of early (up to 56 days gestational age) medical abortion. 100mg of mifepristone was used on day 1 after clinic visit and vaginal ultrasonography. Misoprostol 400microg was administered orally on day 3. Following administration of prostaglandin, women were observed in the ward for 4 hours. A control visit on day 15 was systematic. Success was defined as a complete uterine evacuation without surgical intervention
One woman aborted within 48 hours of mifepristone ingestion. The success rate was given as 94.4% and the failure rate (5.6%) increased with the gestational age. Pain was the predominant side effect. 6 cases of bleeding required a surgical intervention. *It is unclear whether these 6 cases were included in the 43 women who failed to abort medically.* 96% of the women reported at the control visit on day 15. *We would have to regard the fate of the 4% non-attenders as dubious. This would make a 9.6% incident rate.*

9. From France came "Consistency of medical abortion efficacy from 5 through 14 weeks' gestation."[xxvii] This was a retrospective observational study of 512 medical abortions. The protocol combined 400mg of mifepristone orally, followed 48 hrs later by 800mcg misoprostol vaginally, and repeated after 4 hrs, if the patient did not begin to abort. The abortion rate was 98.4%,. The secondary vacuum aspiration rate was 8.2%. The uterine exploration rate was 1.4% -these occurred only at gestations above 13 weeks. 1.6% of patients had complications. Conclusion: Medical abortion was consistently effective through 14 weeks and can be offered as an alternative to the surgical technique. *???*

(8.2% vacuum aspiration rate, 1.4% uterine exploration rate and 1.6% complications adds up to ***11.2%*** *serious incident rate.*

10. In Hong Kong, "A prospective randomized comparison of sublingual and oral misoprostol when combined with mifepristone for medical abortion at 12-20 weeks gestation."[xxviii] *marks the extension of the use of MAP even later into pregnancy .*

120 women at 12-20 weeks gestation were randomized, to receive 200mg oral mifepristone followed by either sublingual or oral misoprostol 400mg every 3h for a maximum of 5 doses 36-48 hrs later. The course of misoprostol was repeated if the woman did not abort within 24hours. Results : Abortion occurred in 91.4% in the sublingual group as compared to 85% in the oral group The median induction-to-abortion interval was significantly shorter in the sublingual group(5.5h) as compared to the oral group(7.5h) .The incidence of fever was higher in the sublingual group. The incidences of other side-effects were similar.
Conclusion: Sublingual misoprostol, when combined with mifepristone, is effective for medical abortion in the second trimester. The induction-to-abortion interval is shorter when sublingual misoprostol use is compared to oral misoprostol.

*This abstract carefully **avoids** documenting the expected side effects of late medical abortion, which is worrying. Only fever gets a mention, as being more in the sublingual group. The failure rates of 15% and 8.6% are high. We are not told whether any babes were born, or what other measures were taken, which could hide an iceberg of clinical incidents. The total doses of misoprostol appear to be high. 1600mcg in divided doses is recommended for 1 day by the makers.*

The most disturbing trends noticed in these studies are the increasing expansion into **later** pregnancies and **home** deliveries of medical abortion.

The 5 sociological studies were all about **how to extend medical abortion** to Turkey, Tamil Nadu, Nepal, and the announcement of a prospective randomised controlled trial comparing same day administration of mifepristone and misoprostal for termination of pregnancy with the standard 36-48 hour protocol . Funding source: none. *May it stay that way. Previous work gives both direct and indirect evidence that reducing the time for involution does increase complications.*

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APPENDIX 1.

NATURAL HISTORY AND MANAGEMENT OF MISCARRIAGE

As students, all doctors learn that the body contains about 11 pints or 2.5 litres of blood, and if bleeding like a tap, as may happen during a miscarriage, can exsanguinate quickly. We were told of women found dead on a toilet in this condition. We learnt that the placenta occupies the whole of the uterine cavity for the first 3 months of pregnancy. If a woman presents with loss pv, urgent assessment is needed to find and remove any placenta in the os and arrange further treatment with surgery, oxytocics, and resuscitation as necessary. **Those who had an opportunity to do a hospital gynaecology term, learnt in practice how to do so. The majority of doctors do not have this experience**. A woman who is pregnant is booked into hospital, and has her blood group taken immediately. Hospitals calculate that a certain percentage will miscarry, and gynaecology wards are available for treatment. She has an obstetrician she can ring, or a hospital with whom she is familiar, and who have her details.
In a normal miscarriage, when the embryo or foetus including its nutrient organ the placenta, dies the white cells start to enter the placenta within 24 hrs, and it starts to separate. This process may take weeks. Bleeding may not occur until separation is complete. Attempting to navigate the os, the placenta may become jammed, reflex atony of the uterus occurs filling it with blood. Oxytocics may then quickly remedy the situation. However, if separation is not complete, parts of

the placenta will remain causing bleeding, and make surgery necessary. Resuscitation will depend on the amount of blood lost.
It also happens that bleeding from miscarriage may be light, or intermittent, and then stop altogether. But later there may be a sudden and profuse bleed, requiring emergency treatment. Approximately 50% of normal miscarriages require emergency treatment.[xxix]
Inducing a miscarriage is extremely dangerous, because you are dealing with a live organism with a surrounding placenta pulsating with blood . There has been no time for any involution, so the capacity for a bleed is much greater. Especially with surgical abortion and speeded up medical abortion.

APPENDIX 2.

CONDITIONS FOR USE OF MEDICAL ABORTION IN OTHER COUNTRIES.

In France, the UK, and the USA, where these drugs are licensed for use, contraindications and protocols have been developed, taking into account untoward incidents to the mothers from the trials, except losing their babies of course.

- In FRANCE, this is regulated by a joint directive (1990) from the Director General of Health, the Director of Hospitals, and the Director of Pharmacy and Medication, which states that whenever prostaglandins are given "in association with RU-486, the following technical conditions ..are **indispensable** and are to be followed:

- The doctor must ensure that diagnostic instruments and machines are close by, such as electrocardiogram equipment and particularly resuscitative cardiopulmonary equipment (including nitrous oxide and injectable calcium antagonists and a defibrillator)
- Clinical observations and blood pressure readings every half hour are indispensable for several hours following the administration of these drugs
- Whenever there is chest pain, an electrocardiogram should be taken on the suspicion of rhythm troubles, and in case of significant lowering of blood pressure."

Roussel-Uclaf recommends that mifepristone plus any prostaglandin not be used in women who smoke over 10 cigarettes a day, who are older than 35, or who have any cardiovascular risks.

France's experience, initially with 16,369 women attending 30 centres in 1988-1989, and a later trial reported in 1992 of 16,173 patients from 300 centres, produced one acute myocardial infarction and 3 cases of marked hypotension after RU486 and prostaglandin analogues. Safety

was only guaranteed **"provided that the recommended protocol is adequately followed and the contraindications to prostaglandin are respected."**[xxx]

In the UNITED KINGDOM, regulations concerning the use of RU-486 state: "The use of mifepristone must be followed, 36 to 48 hours later, by a prostaglandin analogue, (unless the abortion is already completed). ..There is a risk of profound hypotension, related to the administration of prostaglandin occurring during this period. Hence **the patient must be observed in the treatment centre for at least 6 hours, or until any bleeding or pain have diminished to** an acceptable level, whichever is the longer. **It is imperative that suitably experienced medical personnel and resuscitation equipment are available during this period**." (Mifegyne label, U.K.)

In the UNITED STATES, women were excluded from the FDA trials of medical abortion, if they had

asthma, were smoking more than 10 cigarettes a day,
glaucoma, mitral stenosis, arterial hypotension, sickle cell anaemia,
insulin dependent diabetes, anaemia, bleeding problems, or were on anticoagulants,
chronic adrenal failure, (mifepristone failed in attempts to treat cancer because it caused severe Addisonian symptoms)steroid medication, allergies to mifepristone and /or misopristol,
ectopic pregnancy, IUD (must be removed), adnexal masses or tenderness on pelvic examination that suggested pelvic inflammatory disease,
a previous history of severe liver, respiratory or renal disease or thromboembolism
current cardiovascular disease, hypertension or blood pressure over 140/90
if they lived or worked more than one hour from the emergency facility that served the abortion facility conducting the trial.

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[ii] New scientist Sept 1 ,Agencie France Presse quoted http://www.ru486facts.org/index.cfm?page=references

[iii] U.S.Food and Drug Administration http://www.fda.gov/cder/drug/infopage/misoprostol/default.htm

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