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Elton Humphery
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Community Affairs Committee
Department of the Senate
Parliament House
Canberra ACT 2600
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Dear Mr Humphery and Members of the Inquiry,

I appreciate the opportunity to make a written Submission to be considered by you. I would also be prepared to appear before the Committee on either February 3 or 6, 2006. and can best be contacted on 0438 00 29 79 or rklein@netspace.net.au

Recommendation:

My suggestion to Members of the Inquiry into the Therapeutic Goods Amendment (Repeal of Ministerial responsibility for approval of RU486) Bill 2005, is to recommend rejection of this Bill and upholding the categorisation of RU486 (and other progesterone antagonists) as well as vaccines against human chorionic gonadotrophins as restricted goods.

I further suggest that

- a) either the Health Minister of the day should continue to reject evaluations or registrations of these restricted goods by him/herself, or
- b) the Senate Inquiry recommend the establishment of a Committee of Experts consisting of informed community members including social and natural scientists, doctors, pharmacists and ethicists. Such a Committee of Experts would need to be funded independently. Its research should go beyond aspects of quality, safety and effectiveness of these restricted goods and investigate their complex interactions with Australian women's lives. The Committee of Experts would have an important role in aiding the Minister for Health in her/his deliberations.

Indeed I suggest that in the event that Members of the Australian Parliament were to vote to accept this Bill (referred to as Bill 2005 in this Submission) that such an independent Committee of Experts should nevertheless be established immediately, and, parallel to the TGA, conduct its own broader investigation into the question of the availability of RU486 as an abortifacient in Australia. I make this suggestion - and will elaborate on it below - because the brief of the TGA does not enable it to fully canvass the range of social and ethical issues emanating from RU486 abortions. Further, as the TGA is financed on a full cost-recovery basis (user pay basis, see 3. below), it is unreasonable to believe that it has the capacity - and indeed the RU486 licensee who is applying for registration would be willing to pay for it - to perform an in depth inquiry into *all* aspects of chemical abortion.

I suggest that in fact independent of whether the Bill 2005 is rejected or accepted, such a multidisciplinary Committee of Experts may be essential to alleviate community concerns about either the wisdom of an individual's (the Minister for Health) decision, or the narrowness of the TGA's investigation that assesses RU486 as if it were a drug like any other.

Introduction

In the following I will provide a brief summary of my main arguments against the introduction of RU 486 (known as Mifepristone or Mifegyne in Europe, Mifeprex in the USA, Mifegest or Mifeprin in India) as an abortifacient into Australia. They are based on in-depth research I conducted with Prof Janice Raymond and Dr Lynette Dumble into the history, science and ethics of RU486 published as *RU486: Misconceptions, Myths and Morals* (accessible at www.spinifexpress.com.au) and granted a Certificate of Commendation by the Australian Human Rights Commission. I put these arguments to Members of Parliament in 1996 in support of Senator Harradine's Amendment to the Therapeutic Goods Act 1989 that came after RU 486 trials in Melbourne had to be stopped by the then Health Minister Carmen Lawrence for its flawed research protocols. Although published in 1991, I contend that the chemical composition of mifepristone (RU486), its mechanisms and multifold problems remain the same in 2006 as do the many problems with the second component in a chemical abortion, prostaglandins, also discussed in depth in *Misconceptions*. I am a biologist and social scientist and have been an academic and activist in women's health over the past 20 years, most notably as a member of the international network FINRRAGE (feminist international network of resistance to reproductive and genetic engineering) that has unveiled human rights abuses of contraceptives such as Norplant as population control agents in developing countries and has been instrumental in stopping Phase II trials in India on the 'vaccine' against pregnancy: the second drug in the category restricted goods of Bill 2005. I have also worked on the harmful effects of drugs used in IVF, hormone replacement therapy and Creutzfeld-Jakob disease (see short CV at end of Submission). I am in full support of a woman's right to have access to safe and legal abortion if she decides that this is the necessary course of action at a particular point in time and I believe that the well established suction abortion (preferably with a local rather than a general anaesthetic) represents current international best practice.

My remarks in this Submission will by necessity remain brief and I commend *Misconceptions* to the Committee: it makes for interesting reading of the many twists and turns in the torrid saga of introducing two chemicals as abortifacients (RU 486 and a prostaglandin) that some call 'choice' and others call 'coercion' and 'population control.' I put it to Members of this Committee that the worldwide impact of chemical abortion goes well beyond the argument that chemical abortion is simply 'a pill' whose quality, safety and effectiveness can be assessed, and that, for this reason alone, the TGA is an inadequate body to decide whether it should be imported into Australia or not.

1. A brief history of RU 486, problems with drug trials and US FDA approval

After a mere 17 months of animal research, the first human trial took place in Geneva, Switzerland, on 11 pregnant women in 1981 to test RU 38486 (later shortened to RU 486). Of these, in 8 women their pregnancies were terminated in 5 days, in one woman after 9 days. One of the women initially claimed as 'success' later needed a uterine evacuation and in another, heavy bleeding necessitated blood transfusion and emergency surgery¹. Press reports of the time claimed RU 486 was 'no abortion miracle'. In fact, the developers, French pharmaceutical Roussel Uclaf, had discovered the action of RU 486 as an anti-progesterone on the lining of a woman's womb as a *byproduct* of RU 486 action as an *anti-glucocorticoid*. This anti-glucocorticoid property should have been sufficient to stop consideration of RU 486 as an abortifacient as it lowers the ability of a woman to fight infection and to deal with stress (for details see pp. 67-70 in *Misconceptions*). Indeed it haunts the use of RU 486 to this day and is quite likely responsible (or co-responsible with adverse effects from prostaglandin, see below under 2.) for 5 deaths of women who could not fight infections after RU 486/Prostaglandin (PG) abortion. *The anti-glucocorticoid property is one of the reasons why RU 486 can never been termed 'safe' as its action in individual women is unpredictable.*

Nevertheless, with Etienne Beaulieu at the helm - the French scientist who is (wrongly) claimed to be the 'Father of the Abortion Pill' - and his insistence that RU 486 would save the lives of thousands of women in the third world who die from botched abortions because of abortion's illegality - international research progressed although our thorough Literature Review showed that it was rarely independent and that employees of Roussel Uclaf and or funding from this company were omnipresent. It soon became clear that the rates of complete abortion with RU 486 which ranged from 54% to 90% were not only erratic but well below the 99% success rate of conventional suction abortion. As a consequence, in 1984 the next step was to combine RU 486 with a prostaglandin (intramuscular injections, suppositories and, first reported in 1990, orally with Misoprostol [Cytotec] which currently is the most frequently used prostaglandin). However, prostaglandins (PGs) had been used in the 1970s for abortions and due to severe pain, incomplete abortions and toxicity affecting the embryo/foetus should the

¹ Unless otherwise indicated sources can be found in *RU486: Misconceptions, Myths and Morals* by Renate Klein, Janice G Raymond and Lynette J Dumble, Spinifex Press, 1991, now accessible at <http://www.spinifexpress.com.au>

pregnancy continue, had been campaigned against by the Women's Health Movement in the late 70s/early 80s, especially in Germany (*Misconceptions*, pp. 97-101).

The point is that by 1984 the 'simple' abortion pill had become a drug cocktail of two complex medications that both have a host of receptor sites in the human body and do not specifically work towards ending a pregnancy. (Some 1985 and 1990 research we found claimed that RU 486 acts in fact as a cell poison, *Misconceptions* pp. 70-71, but the view that RU 486's cytotoxic nature rather than its anti-progesterone effect might terminate pregnancies, seems to be conveniently overlooked in current discussions.) It must also be pointed out that the chemical interactions between RU 486 and PGs have *not* been studied under laboratory conditions and, importantly, that all manufacturers of PGs used with RU 486 continue to refuse permission to use the prostaglandin with RU 486 (eg Schering and Searle) and in fact explicitly warn that these anti-ulcer drugs should not be given to pregnant women as they may induce miscarriages, lead to incomplete abortions and heavy bleeding. Abnormalities in the developing foetus/child are also known (as happened with regularity in Brazil where Searle's Misoprostol [Cytotec] is used on its own; *Misconceptions*, p. 110 and p. 111). PGs are also associated with cardiovascular events (see Chapter 4 in *Misconceptions*).

The inevitable combination of RU 486 with PG is one reason why RU 486 is not like any other drug and cannot simply be assessed (eg by the TGA) on its quality, safety and efficiency. *RU 486 does not work on its own, it needs the prostaglandin component.* Moreover, the drug cocktail doesn't stop there: because of excessive pain, women are also given pain medication which has to be opiate-based as conventional pain killers such as Aspirin and Panadeine inhibit the effect of the prostaglandin (eg weaken uterine contractions). Anti-nausea medication is often added and in some research studies women were also given prophylactic antibiotics in order to prevent infections.

While more and more problems emerged with chemical abortion and so many multiple regimes are used that it is impossible to reasonably compare them (see 2. for contraindications, adverse reactions, time restrictions and the drawn out abortion time), RU 486/PG abortion became a political football. In France it had a tumultuous history in 1988 where it was put on the market, was taken off again, and ordered back by the government. All of this, proponents of RU 486 claimed, was because of anti-abortionist threats against the manufacturer.² A group of French scientists (based at the Necker Hospital in Paris) who wanted RU 486 withdrawn because of excessive bleeding necessitating emergency curettage and sometimes blood transfusions, and low haemoglobin, were dismissed as anti-abortion.

Roussel Uclaf withdrew RU 486 from a variety of countries including Australia where it was being trialled in 1988 in Melbourne as part of a WHO multi-center study (*Misconceptions* p. 124). Moreover, Roussel Uclaf explicitly refused to lodge a

² Interestingly the relevant health official claimed two years later that it was Roussel Uclaf who had withdrawn RU 486 because of safety concerns, *Misconceptions*, pp. 13-14).

registration for RU 486 in Australia; *in fact to this day no application for RU 486 has been made.*

An Australian visit by Etienne Beaulieu in 1990 sparked a media debate similar to the current discussion: Proponents claimed RU 486 had become ‘the moral property of women’, that Australian women were denied ‘choice’ and anyone critical of it was put in the pro-life camp (or in the case of Lynette Dumble and myself called ‘ill informed’ and not qualified to talk on this subject!; *Misconceptions* p. 126). Beaulieu, in a 1990 media interview in New Zealand conceded that ‘we’ll see a few catastrophes’ (*Misconceptions*, p.22). Indeed in April 1991 a French woman died from chemical abortion. She suffered heart failure shortly after the injection of the prostaglandin. The company’s response - and Beaulieu’s - was simple: blame the type of prostaglandin used (Nalador) and introduce others (Cervagem and Misoprostol) – a sad example of trial and error that puts women’s lives at risk. Roussel Uclaf also added a warning that RU486/PG abortion should not be used by women who smoked and were older than 35 (or younger than 18). The age limit nevertheless continues to be constantly transgressed as can be seen in recent adverse effects and death of a 16 year old woman in the USA.

While RU 486/PG abortion was introduced in a number of European countries during the 1990s (eg UK, Germany, Switzerland, Sweden, Norway), it took until 2000 to introduce it into the USA. Roussel Uclaf had merged with German pharmaceutical Hoechst and wanted nothing more to do with RU 486. Given the considerable monetary gains to be made from its worldwide distribution, the argument that this reluctance was due to pro-life threats, in my view, does not hold. Rather, I suggest Roussel Uclaf/Hoechst knew first hand the many complications with the drug that had surfaced during clinical trials (see 2. for further details). In 1994 the company donated the patent to the Population Council who then established the firm Danco for the sole purpose to gain FDA approval and distribute RU 486 in the USA. (The manufacture of RU 486 takes place in China by Shanghai Hualian Pharmaceutical Co., Ltd. which might raise questions about quality control.) The fact that the Population Council, well known for its population control policies under the guise of furthering women’s rights and ‘reproductive choice,’ now holds the patent on RU 486 is important as it made visible the clear intention that the main users of this drug were to be women in developing countries where abortion remains mostly illegal. (This fact is the perfect excuse to push RU 486 notwithstanding its serious threat to women’s lives; see 4. below for further documentation on current Population Council activities.)

The flawed FDA approval under the Clinton administration has been well documented, and can best be gleaned from the FDA’s own documents. The FDA lowered the expected number of trials, allowed the applicant (the Population Council/Danco) to also use aggregated French data and fast tracked approval for RU 486 under the Accelerated Approval Regulation, normally reserved for drugs that treat life threatening diseases (eg HIV/Aids). *We must remember here that pregnancy is neither a disease or illness, nor normally life threatening and that a time-tested non-chemical method – suction abortion – exists to terminate pregnancies.* In its deliberations, the FDA actually criticised the French data for its many inaccuracies, eg women were lost in the studies, consent forms

were wrongly dated, adverse effects were minimised. These are the exact same problems that we also found in our thorough Review of the Literature and which we deemed to cast serious doubts on the final deliberations of most of these studies that RU 486/PG abortion is 'safe and effective'. The FDA also waived the usual requirement to conduct extra studies if a drug is intended for use by persons under 18 (the French research specified an age limitation from 18 to 35), and commented that the US trials were not gathered from controlled or randomised trials. Moreover evidence emerged from a doctor, Dr Mark Louviere, who was part of the trial and testified that serious adverse effects (life threatening haemorrhage) were not reported by Planned Parenthood who administered the trial. Worryingly also, the FDA did not stipulate use of Ultrasound, as protocols in Europe do, to establish the age of a pregnancy as well as to exclude an ectopic pregnancy. The Agency also did not insist on women staying in a medical clinic for 4 hours both after RU 486 intake and PG administration. Worryingly, this (unsafe) protocol is now also suggested for use in Third World countries (see 4. below).

Crucially, the FDA agreed to the sanction of RU486/PG abortion despite the continued refusal of Searle to file a supplemental New Drug Application (NDA) for Misoprostol [Cytotec] that has to be used with RU 486. I contend this is another reason why the assessment of RU 486 has to be different from other drugs. Indeed, although off label use of drugs is legal, it surely is highly unethical to proclaim that an abortion method is safe and effective when chemicals whose interaction has not been tested, and one of which is prohibited for use in abortions by its manufacturer, are administered to healthy women!

Summary:

- Women's reactions to RU 486 are unpredictable because of its anti-glucocorticoid property. RU 486 can thus never be deemed 'safe.'
- Chemical abortion consists of a dangerous drug cocktail of RU 486 + PG + opiate pain medication (+ anti-nausea medication and prophylactic antibiotics).
- FDA approval deeply flawed.
- Prostaglandin Misoprostol not endorsed by manufacturer Searle for abortions.
- Suction abortion, preferably with a local anaesthetic, is long-term tested best abortion practice.

2. Re-medicalisation instead of de-medicalisation, adverse reactions, contraindications and other sites of RU 486 action

Proponents of chemical abortion RU 486/PG - euphemistically called 'medical' abortion presumably because in an age where people prefer organic products and try to limit the poisons going into our bodies - claim it to be 'more natural' and 'private' than 'surgical' abortion. By using the term 'surgical,' they evoke the horror of a knife cutting through flesh when in reality in a suction abortion no flesh is cut but instead the products of conception are gently sucked out of a women's uterus³. (From a pro-life perspective this

³ The horror of 'cutting' does not seem too worrying to Australian women as the number of elective caesarian sections steadily increases, often on doctors' advice!

is still seen as destroying an unborn child, but most pro-life advocates, except the extremists, would agree that since the majority of Australians agree with a woman's right to abortion, suction abortion is the long established best practice.) However, instead of terminating a pregnancy in 10 minutes with a minimum recovery time of only hours, especially if a local anaesthetic is used⁴, an RU 486/PG abortion is a drawn out multi-step procedure than can last for weeks. After counselling, the woman is given a pelvic examination and an ultrasound to establish the age of the pregnancy (before 49 days for best practice), then she takes 3 tables of RU 486 (600 mgs) in a licensed practitioner's premises and, in the French protocol, is required to stay in the practice for 4 hours in case of instant serious pain, nausea, vomiting and blood loss. Women can get very emotional during these 4 hours – they have time to re-think their often difficult decision to terminate a pregnancy that could have been their (next) child, but they can't stop the abortion now as RU 486 is thought to have a teratogenic effect on the embryo/foetus. In the UK, this has caused doctors to dislike RU 486/PG abortions as more staff are needed and other women present in the surgery can get upset by the witnessed suffering. If no embryo is expelled the woman goes away (with analgesics and, possibly, anti-nausea medication) and has 48 hours to again ponder her decision and wait for the embryo expulsion which could take place anywhere: when she is with her children, on the bus or at work. She is told not to drink alcohol and not to smoke⁵, to have 24 hour telephone access and be no further than an hour away from a medical facility with an emergency room. In other words if something untoward happens, it can be perceived as 'her fault.' Conversely, in a suction abortion, if an accident happens, the woman is already on a doctor's premises and the injury is the doctor's responsibility and usually is kept at bay.

The woman returns 48 hours later to the doctor's premises and is often given another pelvic examination and, in case of ongoing pregnancy or simply uncertainty (blood loss by itself does not equal embryo expulsion), the 'unlicensed' prostaglandin, oral Misoprostol (although in the US some doctors insert these tablets into a women's vagina). Then she is told to wait another 4 hours in the medical rooms during which time

⁴ Suction abortion is not without problems including, but not restricted to, long-term grief and sadness for the woman for whom the abortion was a difficult decision – not a happy 'choice' - because having a(nother) child at this point in time was not possible, or if indeed the pregnancy was due to coercive sex whether in marriage, de-facto or casual relationships, and to continue it would have caused the woman great emotional harm. Much more attention needs to be given to men's role in sexual interactions and to revoke weakening commitment to practising safe sex. See Melinda Tankard Reist, *Giving Sorrow Words* (2000) and Women's Forum Australia (Selena Ewing) *Women and Abortion* (2005). Serious public campaigns are required to reduce women's need for abortions (similar to campaigns against violence against women), and also to offer solid support to women who wish to continue their unintended pregnancies, but discussion of these issues remains outside the scope of this Submission.

⁵ I have not been able to find any research on RU486/PG interaction with recreational drugs such as Ecstasy; an important point to consider since the simplistic public interpretation that RU 486/PG abortion is 'just a pill' could appeal to (young) women who use recreational drugs, say between the RU 486 and the PG part of the abortion.

serious pain, increased bleeding, nausea and vomiting and increased cramping and contractions may occur, as well as cardiovascular problems and the embryo may or may not be expelled. Bleeding and pain may continue for days if not weeks (we found cases of up to six weeks' bleeding) and the woman is requested to return for another ultrasound two weeks later. Five to 8% of women will then need a suction abortion as the RU 486/PG pregnancy termination was incomplete. If we were to assume that half of Australian women's abortions (40 000) were to be done using chemical abortion, this would mean that yearly, between 2000 and 3200 women would have to undergo a second abortion: clearly a medically and socially unacceptable situation. Importantly, recent research has also identified that compared to suction abortion during the same first 7 weeks of pregnancy, RU 486/PG abortion carries with it a *ten times higher risk* of the woman dying from the abortion than conventional suction abortion (MF Green, 2005, *New England Journal of Medicine* 353, pp. 2317-2318).

The claim that this drawn out procedure is safer, more 'private' and more 'de-medicalised' than a conventional suction abortion is plainly wrong. Quite to the contrary, RU 486/PG re-medicalises the abortion procedure and through repeated pelvic examinations, ultrasound and possible suction abortion at the end, is *not* instrument free. The only 'privacy' it affords a woman is that she could literally bleed to death in her own home - or suffer a heart attack - or die from septic shock. And all this, we have to remember, not to combat an illness, but to end an unintended pregnancy for which she is only half-responsible and for which there exists a non-chemical time-tested solution.

I ask the Committee and especially those Members who see RU 486/PG abortion as something Australian women must not be denied, how anyone could wish a woman to suffer days or indeed weeks of pain, emotional upset and possible remorse about her abortion! Seeing the embryo if it is expelled, even if it is small, can add further turmoil for the woman. Promoters of RU 486/PG abortion have argued that it is just like a miscarriage but such a statement devalues the often intense pain and emotional trauma that occur with miscarriage. But even more importantly, it is unreasonable to compare a natural event - miscarriage - with a chemically induced reaction which also affects other parts of the woman's body (see below) and may have as of yet unknown long-term health effects. Moreover, the level of pain is usually much higher in RU 486/PG abortions as is the possibility of heavy blood loss sometimes even necessitating blood transfusions. Life-threatening cardiovascular events (including death) are other unacceptable consequences of this unpredictable practice that reminds me more of an act of medieval punishment than 21st century best practice to quickly and efficiently do what the woman has decided needs to be done: terminate a pregnancy. *Giving women 'choice,' as liberal advocates demand, in my books is deeply unethical when it entails promoting a procedure that is known to be inherently dangerous.*

The events described above represent the recommended best practice protocol with which to avoid catastrophes, and indeed women's lives have been saved when they suffered cardiovascular problems, or heavy blood loss from chemical abortion, but were able to reach a hospital in time. However, in the USA for example these protocols are breached with no ultrasound, no waiting time on the doctor's premises, and having the woman take

home the prostaglandin. Extremist proponents of RU 486/PG abortion want it available over the counter worldwide (see 4. below for more details). It has to be said quite categorically that it is irresponsible to give RU 486/PG to women who live in remote areas – and yet it happens in Third World countries and indeed the claim that women in the bush could avail themselves of RU 486 started the 2005 campaign in Australia!

The series of recent deaths from infections in Canada and the USA present even more serious problems as the symptoms of the responsible bacterium *Clostridium sordelli* that caused a serious infection leading to septic shock mimic exactly the symptoms that women are told to expect from RU 486/PG abortion: uterine bleeding, pain, nausea, back pain, fatigue (and no fever). Because RU 486 dilates the cervix, the bacterium enters the uterus where it starts secreting toxins into the bloodstream. The body's weakened immune system from both the RU 486 (anti-glucocorticoid effect), as well as the PG (which in transplant medicine is used to prevent rejection of an organ), is not able to fight the invasion by *C. sordelli*. The result may be death by fatal toxic shock syndrome. Codeine, wrongly taken to counter the severe pain, increases the action of RU 486 and thus the rate of infection (see Patient Information *Annals of Pharmacotherapy*, September 2005, by Ralph P Miech).

Extremely worrying is a report on 21 year old Vivian Tran's 2003 death in California. The Coroner stipulated cardiac arrest as the cause of death and only when her family insisted on a private autopsy was it discovered that her body was riddled with *C. sordelli* that had led to septic shock (*Los Angeles Times*, October 7, 2005). *The point that Members of the Committee need to remember is that no one knows how any woman will react to these chemicals. RU 486/PG abortion can thus never be declared 'safe': it is inherently unpredictable and should not be used.* Furthermore, it must be assumed that many more deaths have occurred from RU 486/PG abortion which, as in Tran's case, were not recognised as such and thus not notified to Danco/the Population Council.

The nature of, and complications, that occur with RU 486/PG abortions and have been documented in the research studies are staggering. (I urge Members of the Committee to read Chapter 2 in *Misconceptions*, pp. 25-55, to gain an understanding of how serious these adverse effects are, and how ill suited RU 486/PG is for abortion use.) In the interest of space suffice to repeat here that they include, but are not limited to, incomplete abortions with or without continuing pregnancy, heavy, often prolonged bleeding including the need for blood transfusions. The number of women with heavy bleeding doubles in some studies after the administration of the PG, often haemoglobin drops to a critical level. (A Swedish woman bled to death in 2004.) Non fatal and two fatal heart attacks have been recorded; the cause of death of two women in the UK has not been revealed by the British Health Minister (telegraph.co.uk, 18/01/2004). Both RU 486 and PG are known to lead to cardiovascular events.

Mild, moderate and severe pain that lasts for days and even weeks, as well as gastrointestinal effects, are deemed acceptable 'side' effects of RU 486/PG abortion, and often double after PG administration. Unacceptably, many studies in fact dismiss women's pain as insignificant. As we said in *Misconceptions* (p. 43): 'Pain that would be

unnatural/intolerable for men is natural/tolerable for women'. Diarrhoea is mostly linked to the PG whereas nausea and vomiting occur with both drugs. Other adverse effects include fainting, mood changes, fatigue and more recently, as reported in *Contraception* (November 2005), serious pelvic inflammatory disease due to a rare invasive infection with *Streptococcus C* following RU 486/PG abortion. It is important to note, also, how researchers are assessing these adverse effects. A Swedish 1989 study that included 160 women by Swahn and Bygdeman offered the following conclusion (p. 293; in *Misconceptions*, see pp. 47-48):

Six patients had an incomplete abortion and in one the pregnancy continued unaffected. Side effects included intense uterine pain after the prostaglandin administration (16%), vomiting associated with the antiprogesterin [RU486] intake (9%) and after the prostaglandin administration (9%). One woman needed emergency curettage due to heavy bleeding. Six percent of the treated patients had a decrease in hemoglobin exceeding 20 g/l during the first week but no patient needed blood transfusion. *No serious side effects were recorded* (our emphasis).

I leave it to Committee Members to deliberate if the women who suffered these adverse effects would agree with the researchers' assessment!

The significant number of contraindications is another issue that precludes use of RU 486/PG abortions for many women (see pp. 34-37 in *Misconceptions*). Apart from the limited age of pregnancy, women excluded from research studies were those younger than 18 and older than 35, women deemed 'obese,' with menstrual irregularities, fibroids, endometriosis, previous ectopic pregnancies, pelvic inflammatory disease and women who had used an IUD or taken oral contraceptives up to three months prior to their current pregnancy. Non-steroidal anti-inflammatory medications may reduce the effectiveness of the PG component which is serious given how many (young) women suffer from arthritis. Smoking was added as a contraindication after the French woman's death in 1991. Other conditions excluding women from research studies included asthma and other allergies, epilepsy, adrenal insufficiency, kidney disease, gastro intestinal, liver and pulmonary disorders as well as pre-existing clotting disorders and cardiovascular problems.

Since it is unlikely that current administration of RU 486/PG abortion in the US and elsewhere still exclude women with these conditions, and because follow up studies are rare, we do not know how many women may have suffered possibly long-term damage to their health that has not been attributed to their chemical abortion.

Last, but certainly not least, precisely because RU 486 is non-specific as a progesterone receptor blocker in a woman's womb to starve the embryo of nutrients, it has many other sites of action as I will briefly detail (see pp 67-79 in *Misconceptions*). Because RU 486 is described as an anti-progesterone it also acts on a woman's fallopian tubes (hence possibly encouraging ectopic pregnancies as the fertilised egg gets stuck in the tube), the cervix, the vagina, ovaries, breast and hypothalamus. I have already mentioned the anti-glucocorticoid action of RU 486 that appears implicated in the deaths from infection and should be reason alone for not using RU 486 for abortions although it may be used in the

treatment of Cushing's syndrome. Other ongoing research is focussing on glaucoma, meningioma (brain tumour) and breast cancer. In addition, long-term research into effects on women's future fertility including effects on eggs, is also sparse and inconclusive. Direct RU 486 effects on the embryo were shown by Yang and Wu in 1990 (*Misconceptions*, pp. 77-78). Yang and Wu's research presented further worrying data that RU 486 might in fact *cause* ectopic pregnancies in addition to not terminating them.

It is quite ironic that supporters of RU 486 have used these other sites of actions to ask for greater access to this drug in Australia: witness the many claims that the 1996 Amendment 'banned' trials of RU 486 for other potentially life saving treatments for illnesses including this recent statement circulated on an e-mail list on January 7, 2006:

I don't think Australians need to worry about the terrorist threat. In fact, terrorists could just put their feet up and let the c[ommonwealth] Government continue to *destroy thousands of innocent lives by continuing to deny them access to lifesaving medication* (my emphasis) .

Such hyperbole shows the misinformation that circulates in the community. These claims are wrong: the 1996 Amendment did not ban RU 486 and it is indeed being trialled in Australia for other indications including as emergency contraception, and, since 2003 in conjunction with the contraceptive implant Implanon, to counter unacceptable bleeding and study RU486s action on ovulatory function and cervical mucus.⁶ Cancer research is also ongoing. The rejection of Bill 2005 would not jeopardise these projects, nor indeed preclude further research. *However, it is precisely these many other sites of actions of RU 486 that make it eminently unsuitable as an abortifacient as it is not specific enough in its action to stop a developing pregnancy.*

Summary

- RU 486/PG abortion re-medicalises rather than de-medicalises abortion.
- It is myth that it is more natural, private and in women's control.
- RU 486/PG abortion is a multi-step drawn-out procedure that can last for weeks and cause women not only physical pain but considerable mental anguish.
- Nine deaths have been recorded so far but it can be reasonably assumed that many more women have died as a consequence of chemical abortion and that their cause of death was not recognised as related to the abortion.
- Chemical abortion is especially unsafe for women who live in remote areas.
- The 5 to 8% rate of incomplete chemical abortions necessitating a second abortion – via suction – is totally unacceptable.
- Because of its 2-component nature with multiple sites of actions, complications and

⁶ Implanon is the 'new' Norplant after Norplant was withdrawn in the 1990s from US markets because of causing blindness in women (it continues to be available in Third World countries!). It is beyond the scope of this Submission and indeed Bill 2005 but I suggest the Department of Health commission a study into ongoing research on hormonal contraceptives in Australia, some of which submits healthy women to dangerous experimentation which in my view warrant an in-depth review of acceptable research ethics.

contradictions, it can not be evaluated 'just like another drug.'

3. *Inadequacy of the Therapeutic Goods Administration (TGA) to assess the full impact of RU 486/PG abortion and problems with current endorsements by Australian professional bodies.*

As explained by representatives of the TGA and the Department of Health and Ageing, in this Committee's Hearings on December 15th, 2005, the TGAs brief is to evaluate the quality, safety and effectiveness of drugs. It does this by assessing applications that come forward. Such pre-market evaluation is usually based on existing clinical research and international experience, '...all the published evidence. That includes things that are published by the Food and Drug Administration or the corresponding organizations in Europe. ... the TGA takes decisions based on scientific evidence' (Jane Halton, *Senate Hansard*, December 15, 2005, CA 20). The medicine also has to be manufactured by a licensed manufacturer. A product will *not* be approved '... if the risk of the use of a product effectively outweighs its benefit' (Jane Halton, *Senate Hansard*, December 15, 2005, CA 18). Once a drug is approved, the drug's company has to provide the TGA for three years with ongoing reports on their marketplace experience. The TGA has laboratories that carry out post-marketing sampling of these products. Post-market monitoring is becoming more and more important.

The brief of the TGA as explained to the Inquiry Committee seems simple and straight forward. It is clear that drugs are assessed only based on their quality, safety and effectiveness. Interactions of two drugs - Mifepristone and Misoprostol - let alone the myriad of regimens, complications, contradictions, multiple sites of actions, as well as social and ethical components of chemical abortion would be a considerable challenge for the TGA. Of course, long-term research studies, originated in Australia - clinical trials as well as laboratory studies - could be requested by the TGA. However the problem arises as to who would fund the extensive work that is required. *The TGA could not fund it because since 1998-99 the Australian Government has required the TGA to operate on a full cost-recovery basis (in ANAO Audit Report No 18 2004-05, p. 33).* Put differently, for all the registration steps outlined at the beginning of this section, including post-market monitoring, the TGA would have to charge the applicant. The TGA is not funded by the Australian Government on a regular basis and does not expect to receive revenue from the Government in 2005-2006 (see TGA website)⁷.

This 'private' funding arrangement raises some difficult question should the TGA be endorsed by Parliament through acceptance of Bill 2005 to begin evaluating RU 486. In my view it would have two options: via FDA documents use the flawed research from the US trials and accreditation as well as previous data (including the many meta-analyses

⁷ Given how many Australian advocates for RU 486/PG demand the TGA to take over the evaluation, it is clear that the general public believes it to be independent of industry and fully funded by the Australian Government. That this is not the case is clearly worrying, and indeed so in the assessment process of *all* drugs that come into Australia. Even the FDA is US Government funded.

that produce rather meaningless results as they are based on many different trial protocols), or to demand the applying parties - presumably the Population Council/Danco - to sponsor new and long-term Australian research both in the laboratory and through clinical trials. Since the Population Council/Danco would have to pay for this wide-ranging and multidisciplinary body of research, the second option is unlikely to take place as the argument will be made that RU 486/PG abortion has now been used by 'millions of women.' Although there is no hard data for this claim, even if it were true, this is in itself meaningless because other drugs and devices such as the high dose contraceptive pill, Norplant, DES, the Dalkon Shield IUD, and, most recently, HRT (hormone replacement therapy) were also used by millions of women causing serious damage to their health before, in the case of HRT, it was finally exposed by long-term research as increasing the risk of breast cancer as well as cardiovascular events. If the TGA were to treat Mifepristone/Mifeprex as well as Misoprostol *together* as just like any other drug, then chemical abortion might well gain approval just like VIOXX did in spite of already apparent problems that were known to the manufacturer. This is not an indictment of the TGA's work practices, it is simply a down-to-earth assessment of a body that is not Government funded, but works on a full cost recovery basis. I put it to the Committee that given the extremely complex nature of chemical abortion, the TGA's assessment by necessity would not be adequate⁸.

Another interesting question arises from the reported steady progress to merge the TGA with Medsafe (the New Zealand Medicines and Medical Devices Safety Authority to establish the Australia New Zealand Therapeutic Products Authority (December 11, 2005, <http://www.tgamedsafe.org/media/051211tpimc.htm>). Since Medsafe has allowed RU 486/PG abortion into New Zealand, after the merger, could chemical abortion possibly 'slip' into Australia due to a technicality? This possibility too, makes the oversight of the Minister for Health over chemical abortion a necessity. In addition, any developments and changes that might take place due to the Australia-United States Free Trade Agreement (AUSFTA) regarding the importation of drugs need to be closely monitored for possible further relaxation of guidelines.

Furthermore, should chemical abortion be allowed to be administered in Australia, like in the USA, adverse effects would not necessarily come to light. The TGA requires product sponsors to report adverse effects - obviously not always entirely successful as the Vioxx case demonstrates - but for medical professionals and pharmacists the reporting of

⁸ Nevertheless it must be pointed out that in the events in the mid-1990s that led to the 1996 Harradine Amendment now under discussion, the TGA's inadequacy to deal with drug applications was put under the spotlight. It was found out to simply cash the application fee of \$ 90 and issue a receipt rather than assess RU 486 which came into Australia for trials (see Kingston, *The Canberra Times*, October 27, 1994). More recently, in December 2004, the TGA has also been severely criticised by the Australian National Audit Office, eg for its failure to properly check on information presented by drug companies (*ANAO Audit Report No 18 2004-05*). It is claimed that the TGA still does not issue sufficient 'black box warnings' about drugs' adverse effects to Australians (see Pirani, *The Weekend Australian*, December 17-18, 2005, p. 24).

adverse effects is voluntary. Given the distressing events discussed under 2. including the many questions surrounding contradictory study results as well as the recorded 9 deaths from chemical abortion, we could have a situation in which the public would believe that RU 486/PG abortion was working well and without problems because adverse effects were not being reported. In saying this I am not casting a bad light on medical practitioners in Australia; my statement simply reflects the fact reported from many countries, that problems with abortions, whether conventional suction or chemical abortion, are unlikely to be reported by 'pro-choice' people as it is feared that it might play into the hands of anti-abortion groups. Sadly, in such a scenario, who loses out are clearly women whose right to safe abortion is compromised.

It is also noteworthy to look at the evidence that is used in the current Australian debate over chemical abortion in which bodies such as the AMA, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), the Public Health Organisation and the Rural Doctors' Association, endorse RU 486/PG abortion as safe. Interestingly, the November 2005 publication by the RANZCOG which it says is a Guide for Practitioners, and which it appears is relied upon by the other just mentioned organisations for their claim that RU 486 is safe and effective, does not include the US trial, eg a publication by Spitz et al. (1998) who reported a high failure rate in the US clinical trial of only 827 women: 8% before 49 days, 17% at 50-56 days and 23% at 57-63 days gestation; 8% of women required an additional suction abortion and in 1% the pregnancy continued (*New England Journal of Medicine*, 1998, 338, pp. 1241-1247).

By quoting the RANZCOG's endorsement of RU 486/PG abortion, promoters of chemical abortion have the public at large believe that the RANZCOG have conducted their own clinical research into RU 486/PG abortion when, by necessity, they base their endorsement of chemical abortion on reviewing the relevant literature. It would seem plausible that the TGA too might use the RANZCOG's and the AMA's endorsement of RU 486/PG abortion as further reason why new – and expensive – Australian studies may not be necessary to demand from The Population Council/Danco should they submit an application.

For these reasons I would urge the Committee to suggest the appointment of an independent Committee of Experts (see the beginning of this Submission). In the unfortunate event that Bill 2005 will be accepted by Members of the Australian Parliament, such a Committee could counteract limitations by the TGA. Should Bill 2005 be rejected, such a Committee could still advise the Health Minister. I doubt that the RU 486/PG debate will go away for reasons I briefly detail in 4. below.

Summary

- The fact that the TGA operates on a full cost recovery basis renders it unlikely that it could demand of a RU 486/PG sponsor to pay for extensive original research into the multifactorial actions of the two abortifacients under discussion.
- Endorsement of RU 486/PG abortion by professional bodies such as the RANZCOG and the AMA will be understood by the general public as the result of these bodies' own trials which it clearly is not.

- The merging of the TGA with NZ Medsafe as well as possible ramifications from the Australia-United States Free Trade Agreement (AUSFTA) need to be closely monitored.
- The voluntary reporting in Australia of adverse effects by medical professionals and pharmacists would make it unlikely that the public would be fully informed of problems with chemical abortion (due to fear of reprisal from anti-abortion advocates).

4. The role of the international Women's Health Movement, population control ideology, the International Consortium for Medical Abortion (ICMA) and women's compromised safety

The international women's health movement was as divided on chemical abortion in the late 1980s/early 1990s as it remains today. Women's health groups associated with Family Planning and Population Groups campaign in favour of chemical abortion, more radical women's health activists, especially in the Third World, denounce RU486/PG abortion as yet another means of population control. These critics argue that in the conveniently manufactured juxtaposition of pro-life vs pro-choice, and using the illegality of abortion in many countries a convenient pretext, RU 486/PG abortion is an extension of the range of harmful contraceptives such as Depo Provera, the Copper-T IUD and Norplant that were coercively deployed in Third World countries. (For this reason *Misconceptions* was also published in Bangladesh in 1991 where a major study in 1995 revealed the coercive nature of Norplant trials and how it was delivered as part of US AID (Farida Akhter, 1995, *Resisting Norplant*). In 1990, the 6th International Women and Health Meeting in Manila issued a Resolution condemning the trials and introduction of RU 486/PG abortion internationally.

However, some participants were adamant then that RU 486 should become a worldwide alternative to suction abortion and indeed their sustained support of RU 486 researchers and close working relationships with groups such as the Population Council led to the formation of ICMA (International Consortium for Medical Abortion) in 2001⁹ that is now a major player in making RU 486/PG abortion available worldwide, including their current aggressive campaign to have RU 486 available over the counter. Marge Berer, a long time promoter of chemical abortion under the banner of 'choice' and 'rights' for

⁹ Prior to ICMA's existence, in 1998, the Population Council had convened and sponsored a Meeting of Experts in Bellagio, Italy and issued a Consensus Statement in favour of chemical abortion already introducing reduced safety requirements, eg the need for ultrasound and provision of chemical abortion at medical premises. Undoubtedly this Statement would have been tendered to the FDA during the registration approval process. Five of the listed 20 Consensus Statement signatories include employees of the Population Council. Interestingly, one of them is André Ulman, one of the earliest researchers on RU 486 at Roussel Uclaf. Similarly, Dr David Grimes, an early US researcher of RU 486 is listed among the signatories, now as the President of a private company (*Contraception*, 1998. 58, pp. 257-259).

women, and Editor of *Reproductive Health Matters* is the Chair of ICMA.¹⁰ *Reproductive Health Matters* published a *Special Issue* on Medical (sic) Abortion in November 2005 which makes for chilling reading.¹¹

In the Editorial Berer puts forward, and quite bluntly so, that mifepristone and misoprostol are safe and effective, that ‘medical abortion is the use of pills to cause a miscarriage’ (Editorial *Reproductive Health Matters*, Nov 2005, p. 6). She further states:
Medical abortion, with or without the involvement of a health care provider is helping to reduce deaths and morbidity from complications such as sepsis and uterine perforation leading to hysterectomy, arising from unsafe invasive procedures, in places where most abortions are still illegal (*idem*).

The fact that abortion is indeed illegal in many countries is thus implicitly accepted and women’s lives are equally - or more - put at risk through the promotion of chemical abortion available over the counter. *This is a harm minimisation strategy that is not good enough at the beginning of the 21st century when women’s lives are at stake.* Moreover, throughout her Editorial, Berer does not mention the serious adverse effects including any of the documented deaths from RU 486/PG abortion. Indeed she castigates some European countries for ‘overmedicalising’ the procedure and still insisting on ultrasounds, waiting time and administering the PG on clinical premises (*ibid*, p. 8). As I indicated earlier in 3. quite predictably, Berer comments that ‘The US FDA labelling for mifepristone does not require ultrasound to date the pregnancy’ (*idem*) thus using the flawed FDA registration process I described earlier as legitimisation for her claim. The next statement, however beggars belief: ‘For all women, a phone number they can call with 24-hour access in case of questions or concerns is very reassuring, even though experience shows that most women do not feel the need to call’ (*idem*). Anyone who knows the conditions in Third World countries can make up their mind about how feasible such a suggestion is! Or indeed how feasible this is for women living in remote areas in industrialised countries including Australia. Worryingly, even the use of chemical abortion for second trimester abortion is mentioned (*ibid*, p. 9): a recent trend that is also surfacing in the Australian discussion and would put even more women’s lives in grave danger. Interestingly, Berer also writes that ‘...in some places in Norway,

¹⁰ At the September 2005 10th International Meeting on Women and Health in New Delhi, India, Marge Berer/ICMA heavily promoted the over the counter availability of RU 486/PG abortion. However the Meeting with over 800 international women’s health advocates attending, did not endorse this abortion method. Berer is also a long-time supporter of the anti-hCG fertility ‘vaccine’, which is the second drug considered restricted goods under the 1996 Amendment (see Richter, 1996 for a throughout critique of this ill-conceived immunological contraceptive).

¹¹ I urge the Committee to read the papers in this Special Issue. *Reproductive Health Matters* is published by Elsevier (www.rhmjournal.org.uk). As there are connections between *Reproductive Health Matters* and Reproductive Choice in Australia, it could well be that the Committee will receive this Issue, perhaps as supporting evidence how widespread chemical abortion is, and how Australia is ‘lagging behind.’ The evidence I present in this Submission of course does not endorse such claims.

women are only being offered medical (sic) abortion and they must specifically ask for a surgical (sic) procedure if they prefer it' (*idem*). For once I agree with Marge Berer that the relentless push for more 'choice' (chemical abortion) can indeed lead to *a reduction of methods available* (suction abortion).¹² Berer ends her 'battle cry' for RU 486/PG abortion by asking readers to make 'Efforts ... around the world to encourage low-cost, high-quality manufacture of generic mifepristone and misoprostol ...' (*ibid*, p. 9). This is indeed a rallying call to the world – and Australia must not miss out! The final page of the Editorial shows us the lovely picture of a smiling young girl from Trinidad: a sad indictment of how trivialised the issue of (chemical) abortion has become.

Conclusion

As the November 2005 Issue of *Reproductive Health Matters* also includes a fact sheet we can expect to see this circulated widely, including in Australia by 'pro-choice' groups.¹³ Another push that has already started - and could well swell up before the vote in Parliament is taken - is the lodging of applications for the use of RU 486/PG abortion by Australian abortion providers (as has occurred in Queensland and South Australia).

Although common sense would lead one to believe that now was not the best time to push RU 486/PG abortion, given the increasing discussion on the US deaths, the search for explanations of the infections, more warnings from the FDA, further health problems and a planned 2006 US conference to discuss these problems, promoters of RU 486/PG abortion are going full steam ahead. (In fact it seems to me that the World Health Organisation, WHO, should reconsider their recent 2005 inclusion of both Mifepristone and Misoprostol in their list of essential drugs!)

I contend that the current campaign in Australia as well as in Italy is deemed necessary to get these 'wayward' western countries in line so that the forceful push into Third World countries can go ahead unhindered. (And of course more money can also be made whenever another country falls in line.) No one should be under the illusion that chemical abortion is primarily designed to give women in western countries more 'choice.' Instead it was - and remains - an aggressive instrument of population control to contain the number of fertile women in non-western countries. In these countries deaths will be even easier to disguise in maternity mortality figures: indeed if a woman bleeds to death or dies of toxic shock from RU 486/PG abortion, the chemicals that cause her demise can not easily be identified.

¹² Another point not mentioned so far in this Submission is of course that many doctors do, understandably, not 'like' to perform abortions and may indeed see it as easier on themselves to put the full responsibility on the woman to terminate her pregnancy.

¹³ This is reminiscent of a 'women's health' campaign in the late 1980s/early 1990s in which the privately funded US based Reproductive Health Technologies Project was distributing educational packets of articles about chemical abortion that were wholly comprised of studies and statements prepared by the drug researchers (*Misconceptions*, pp. 3-4).

I urge the Committee to seriously consider all these issues in its final deliberations on whether to recommend rejecting or accepting Bill 2005. *It is my strong contention that for all the issues presented in this Submission, Bill 2005 needs to be rejected.* RU 486/PG abortion is a political issue that is outside the TGA's assessment brief.

The sponsors of Bill 2005 say that the 'science' should prove the safety and appropriateness of RU 486/PG but the problem is that the 'science' itself is not beyond reproach and is certainly not conclusive. Because RU 486 has become such a political issue and proponents push its use in Australia (just as they did in the USA) as 'a woman's right to choose,' community knowledge of its multiple problems remains low. It is still mostly seen simply 'as a pill that stops a pregnancy' - and on top of that very frequently confused with the Morning After Pill.

It is my sincere hope that the Committee sees through this rhetoric and its Recommendation will be to reject Bill 2005 and keep the 1996 Amendment.

Dr Renate Klein
January 15, 2006

Selected Bionote

Dr Renate Klein holds an MSc from Zürich University, a BA (Honours) in Women's Studies from the University of California at Berkeley and a PhD in Sociology of Education from the University of London. She also has a college teaching certificate in natural sciences from Zürich University and a postgraduate certificate in interdisciplinary studies concerning developing countries from the Swiss Federal Institute of Technology. She was a Research Associate in the Department of Neurobiology at the University of Zürich and taught biology and chemistry at a number of colleges in Switzerland as well as in an Agricultural College in Paraguay. She is an Associate Professor in Women's Studies at Deakin University where she developed and taught an MA course in Reproductive Medicine and Feminist Ethics. Prior to her appointment at Deakin University in 1991 she was a Distinguished Visiting Professor in Women's Studies at San Diego State University where she lectured on reproductive technologies and genetic engineering. She came to Australia in 1986 as a Georgina Sweet Fellow of the Australian Federation of University Women and conducted the first study on women's experiences of in vitro fertilisation with a focus on fertility drugs used in the procedure. She continued critical feminist research on the new and old reproductive technologies including international population control with an emphasis on fertility drugs, hormonal and immunological contraceptives as a post-doctoral research fellow at Deakin University. She was a member of the international working party on the anti-fertility 'vaccine' from 1995 to 2000.

In 1984 she was co-editor of *Test-Tube Women: What Future for Motherhood?* the first international feminist collection on the pros and cons of the new reproductive technologies. In 1989 she edited *Infertility: Women's Experiences with Reproductive Medicine* (both books translated into German and Japanese) and also published *The Exploitation of a Desire: Women's Experiences with In Vitro Fertilisation*. In 1991 she co-authored *RU 486: Misconceptions, Myths and Morals* with Janice G. Raymond and Lynette J. Dumble, published in Australia, the USA and Bangladesh and translated into German *Die Abtreibungsspielle RU 486: Fortschritt oder Gefahr* (1992). The book received a Certificate of Commendation from the Human Rights Commission. From 1987 to 1996 Dr Klein was the Australian editor of *Issues in Reproductive and Genetic Engineering A Journal of International Feminist Perspectives* (published by Pergamon Press).

Dr Klein has also conducted research on the medicalisation of women, Creutzfeld-Jakob Disease (with Lynette Dumble), hormone replacement therapy, hormonal contraceptives and cloning. She is the author of 21 book chapters on the subject of reproductive medicine and genetic engineering and has 38 journal articles published on this topic in Canada, the USA, Australia, Germany, Switzerland, Bangladesh, amongst them *The Lancet*, *Medical Observer*, *Journal of the Society of International Development*, *Pro Familia Magazin*, *Sexualpaedagogik und Familienplanung*, *ISIS: Women's World*, *Women's Studies International Forum*, *Feministische Studien*, *Feminist Therapy Newsletter*, *Health Care for Women International*, *Australian Medicine*, *Search Magazine*, *On the Level*, *Bioethics News* (Monash), *Deutsche Krankenpflege Zeitschrift*, *Medical Observer*. She has also widely published on this topic in popular magazines including, *Cosmopolitan*, *Emma*, *Annabelle*, *Brigitte* and many feminist publications.

Renate Klein is a frequently invited guest speaker at national and international conferences (with over 100 delivered talks), and recently gave an invited lecture on RU 486 and the anti-fertility 'vaccine' at the 10th International Women and Health Meeting in New Delhi, India, September 2005. She was also one of the Indian Organisers' invited international advisors.

Her other research and publication areas include feminist research methodology, feminist theory, international publishing, cyberfeminism, prostitution and trafficking. Dr Klein is a founding member of FINRRAGE (Feminist International Network of Resistance to Reproductive and Genetic Engineering) and CATWA (The Coalition of Trafficking against Women, Australia).