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SUBMISSION OF THE
CHRISTIAN ADULT SOCIAL INSTITUTE
(CASI)

TO THE

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

Monday 19 December 2005

Dear Secretary,

In the capacity of president of CASI (Christian Adult Social Institute), I wish to submit to the Inquiry CASI's concerns about the proposal to move authority over RU486 from the Health Minister to the Therapeutic Goods Administration.

I have read a reply from a senator to someone who had written expressing her concerns about moves to legalise RU486. The senator parried off her thoughtful lines by saying the legislation was not about the legalisation of RU486, but rather about shifting control of it. That senator to me seemed to be playing games instead of playing straight with the public.

The legislation is a means to a potential end:

means: **releasing Chemical abortion drugs from ministerial control;**

potential end: **the legalisation of chemical abortions.**

CASI is happy to address itself to both the means and the end.

Sincerely

Michael Casanova
President of the Christian Adult Social Institute.

CASI's concerns over the THERAPEUTIC GOODS AMENDMENT BILL 2005

Summary of CASI's RU486 concerns

1. MEANS – releasing Chemical abortion drugs from ministerial control

CASI believes that the Therapeutic Goods Administration should be dealing only with goods which have an application which is therapeutic, i.e. which support natural physiology or which address distressing illnesses **caused by a departure from normal physiology**.

RU486, in chemical abortion applications, is used not therapeutically, but to disrupt a healthy physiological function. As such authority over RU486 is outside the purpose and focus of the Therapeutic Goods Administration.

2. POTENTIAL END – the legalisation of chemical abortions

CASI is concerned that the use of RU486 for chemical abortions will **compound the health risks of women** to such a degree that RU486, as an abortion drug, should have no place in a first world country like Australia.

A. Physical Health

a) Firstly trials of RU486 excluded such an extraordinary range of women, that it cannot, on the basis of previous trials, be regarded as safe for the target market;

b) Secondly, the health risks of this drug, and its companion drugs

c) Thirdly, compounding these risks is the lack of supervision for up to 50 % of patients (all the more significant for rural women);

B. Emotional Health

CASI is concerned that the frequent occurrence of post abortion syndrome will be compounded for women whose abortion experience is:

a) characterised by more active participation;
b) prolonged; and

c) concluded for many with the sight of their own deceased unborn, which is likely to appear much more developed than expected.

Appendix: one **RU-486 Risks and Dangers**

two **Abortion 'leaves mental legacy', r.e. University of Oslo research 2005**

In greater detail

1. MEANS – releasing Chemical abortion drugs from ministerial control

CASI is against bringing the Chemical abortion use of RU486 away from ministerial control and over to the Therapeutic Goods Administration.

CASI believes that the Therapeutic Goods Administration should be dealing only with goods which have an application which is therapeutic, i.e. which support natural physiology or which address distressing illnesses **caused by a departure from normal physiology**.

RU486, in chemical abortion applications, is used not therapeutically, but to disrupt a healthy physiological function. As such authority over RU486 is outside the purpose and focus of the Therapy.

TGA is for Therapeutic Goods

The Therapeutic Goods Administration should be dealing only with goods which have an application which is **therapeutic.**

The Therapeutic Goods Administration on its website:

What is a therapeutic good?

http://www.tga.gov.au/docs/html/tga/tgaginfo.htm

A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989).

Therapeutic use means use in or in connection with:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; [1]
- influencing inhibiting or modifying a physiological process; [2]
- testing the susceptibility of persons to a disease or ailment;
- influencing, controlling or preventing conception;
- testing for pregnancy; or
- replacement or modification of parts of the anatomy.

Common sense indicates that in order for the use of something to fit the category “therapeutic use”, it must have use in or in connection with:

[1] “preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury”,

and not simply fit the idea of for instance,

[2] “influencing inhibiting or modifying a physiological process”.

Bullets and lethal doses of cyanide influence and inhibit physiological processes, but they are not thereby therapeutic!

Substances used to effect chemical abortions do not have positive medicinal objectives, but rather social objectives of debated merit. The TGA is not the instrument to decide the debate, it was not created for such decision making, but to deal with medicines and the like.

RU486 is counter therapeutic

RU486 is used to disrupt the gestational physiology of a woman, precisely when that process is working naturally and well. In whatever way RU486 works, it is not therapeutic. It does not work by restoring natural processes, but by harshly forcing a woman's body to depart from them. Any claimed benefits are achieved via a non-therapeutic or counter therapeutic effect.

What is the competent authority to judge a counter therapeutic substance or process? An administration designed and authorised specifically to judge therapeutic goods? No.

The competence of the Therapeutic Goods Administration is focused upon assessments of goods which claim to be therapeutic. As such it is incompetent to judge RU486, not because of lack of technical ability, but because it has the wrong focus, at least formally, which is where its legal authority rests.

Assessments of whether or not to approve a substance or medical procedure which claims benefits via counter therapeutic effect, via **causing by a departure from normal physiology**, belongs to an authority which has a focus specific to the task. Since no such **specific** authority exists, the task must move up to the more **general** authority**.**

Therefore the task of approving or prohibiting the Chemical abortion use of RU486 belongs to the general authority under which the Therapeutic Goods Administration operates, ie the Minister for Health.

Extending TGA's mandate to counter therapeutic is counter intuitive, and unwise

To simply amend the Therapeutic Goods Administration legislation to expand its formal tasks to include opposites, therapeutic and counter therapeutic effects, is not wise.

The risks of admixing contrary intentions, of creating competing interests, is well illustrated in the **appendix one** account of ***An Iowa Doctor gives a first hand account: The woman who took RU486... and nearly died***. While the trial at Des Moines was said to be without complications, one of the participants had turned up to a doctor just short of death, having lost more than half her blood. Most pertinent is the response from the sponsors of the trials upon being told of this near fatality:

> ***How did the clinic and the trial sponsor respond?*** [President of Planned Parenthood of Central Iowa Jill] June said "no complications" refers to the trial -- that the trial was conducted successfully – and not to the condition of the participants.
>
> However, Sandra Waldman, a spokeswoman for the New York based Population Council, which sponsored the trial, said the trial resulted in "no deaths or serious complications." When asked whether Louviere's patient's experience qualifies as a serious complication, Waldman said it would be "within the context of what happened before [in France]."

The actual well being of the women involved ended up being lost sight of. When a counter therapeutic effect is the predominating intention, minds may tend to overlook therapeutic or health concerns.

We need the TGA's intentions to be simple, fixed upon health and directly therapeutic goods. Broader matters such as RU486 abortions should be dealt with by the Minister under whom the TGA operates.

2. POTENTIAL END – the legalisation of chemical abortions

CASI is concerned that the use of RU486 for chemical abortions will **compound the health risks of women** to such a degree that RU486, as an abortion drug, should have no place in a first world country like Australia.

A. Physical Health

a) Trials of RU486 excluded women with many common conditions, including those who have used the oral contraceptives in the last 3 months prior to conception!

To avoid dangerous or deadly effects during trials, participants with the following were deselected:

those who had the presence of cardiovascular risks, including high blood pressure, cigarette smoking;

those with asthma;

those under 18 or over 35;

those who had used oral contraceptives less than 3 months prior to conception;

and on and on goes the list!

See **appendix one**, *SAFETY WARNINGS.*

Here it seems was an attempt to validate a drug by picking those who took it, rather than to develop a drug for the actual intended market. If the actual market would naturally include those who favoured the pill, then something safe enough should have been worked on.

But if RU486 is indeed not a drug that should be trialled on women who take the pill etc., etc., then the responsible thing of course for doctors to do would be to avoid any use of it on these women, and those who smoke, and those who have had problem pregnancies, and asthma, and who are over 35, etc., etc. So why on earth would anyone pro woman be captivated by this chemical that just had to have a market, despite being so limited in its responsible use with respect to women's health?

b) Secondly, the health risks of this drug, and its companion drugs,

and of the drugs that women with complications have to take.

RU486 is not a food. It has a toxicity rating and affects multiple body systems, bringing with it many potential side effects. Something that increases blood pressure, for example, should not be taken by women who have the likelihood of high blood pressure already (eg. those who take the pill?!), or who have conditions that are made worse as blood pressure is increased.

There is a large array of nasty side effects: are they the sort of thing that should be hidden from those considering RU486? Side effects have included:

significant pain for 79 to 96 % of participants, half of whom required an opiate or some other injectable pain killer. The pain lasted days and even weeks;

nausea (up to 61%), diarrhea (20%), vomiting (25%);

symptoms of infection (5%);

unknown effect on future fertility and future children;

extra risks for those whose abortions are incomplete and who have to undergo surgical procedures in addition (8 to 23%);

and more side effects.

The potential side effects may be why such an astoundingly wide category of women, including the most natural target demography, were excluded from trials (see a).

c) Thirdly, compounding these risks is the lack of supervision for up to 50 % of patients (all the more significant for rural women) who do not complete the procedure in the presence of health professionals, but rather at home.

Only as few as 50% of women who take RU486 will actually abort at the doctor's clinic, so that 50% or more women may face bleeding and abortion, along with other significant side effects, on their own.

Added to this percentage are those women who do have a "success" as far as termination goes, yet who suffer even severe complications later, and who may be anonymous to RU-486 service providers. How on earth could a woman lose half her blood and nearly die two weeks after participating in an RU-486 trial (Des Moines, USA), and yet for those in charge of the trial to still maintain that the trial was without complications for all the women who participated? The focus of the trial was **NOT on the women involved:** "no complications" referred to the trial and not to the condition of the participants!

B. Emotional Health

CASI is concerned that the frequent occurrence of post abortion syndrome will be compounded for women whose abortion experience is:

a) characterised by more active participation;

b) prolonged; and

c) concluded for many with the sight of their own deceased unborn, which is likely to appear much more developed than expected.

Up to what age of unborn would it be envisaged that RU486 would be used? 64 days from conception is just over 9 weeks.

What might a woman using RU486 see if she expels at home what has been growing in her? Because the facts could not be literally covered over with a cloth before the woman could see. There would be no chance for many to be assured that it was just a blob of formless tissue. Science and the human eye would concur.

An idea of what might be seen can be grasped by reading over a book on 3D / 4D ultrasound technology by Professor Stuart Campbell MD: **Watch me... grow!** *A unique, 3 Dimensional, week-by-week look at baby's behaviour and development in the womb.* Penguin Books, 2004.

> 5 weeks – half a cm long. My brain has divided into distinct segments and my cerebral hemispheres are growing fast. My heart is beating about 150 beats per minute – twice my mother's rate. My internal sex organs are nearing completion.
>
> 6 weeks – up to 2 cm long. My facial features continue to develop. I have a tongue. Most of my internal organs – heart, brain, liver, lungs and kidneys – have developed in a basic form. My hands can bend at the wrist.
>
> 7 weeks – up to 3 cm long. Some movement. Most of my joints have formed, including my wrists and ankles. My fingers and toes are almost complete – and I have touch pads on my fingers. My eyelids almost cover my eyes and I have a nose.
>
> 8 weeks – up to 4 cm long. Twenty tiny tooth buds are forming in my gums. My nervous system is responsive and many of my internal organs have begun to function. My heart has attained its final shape.
>
> 9 weeks – up to 6 cm long. All my vital organs are fully formed and are increasing in volume. In my eyes, the irises are starting to develop. I can swallow, yawn and suck.

It is hard enough for some women who suffer a miscarriage and see nothing. But 6 cm could be well beyond devastating for some women to see. Is this what is wanted by those who support the legalisation of RU486? The deliberateness of abortion brings in time much greater risks of stress than miscarriage. But adding the sight of the deceased unborn would likely compound problems further. See **appendix two**.

appendix one

RU486 *The Abortion Pill* *Risks and Dangers*

Despite heavy publicity by the pill's promoters claiming that the RU486/prostaglandin method is a safe and effective alternative to surgical abortion 1,5 controlled testing has offered a very different picture.

Is it Dangerous?

In France, a woman suffered heart failure and died after taking RU486 in combination with its accompanying prostaglandin.2 In America, one of the women participating in the U.S. trial of RU486 nearly bled to death after taking the abortion drugs (see reverse).

Every RU486 abortion involves at least two drugs, RU486 (also call mifepristone) and a prostaglandin (PG), usually misoprostol. These drugs are dangerous for a number of reasons.
RU486 is a complex chemical molecule affecting mulitple systems of the body. 3 This is why it has effects not only on a woman's reproductive system, but her cardiovascular, digestive, and central nervous sytems as well.3 Misoprostol, the prostaglandin ordinarily used in conjunction with RU486, has its own side effects, triggering the painful, often nauseating, contractions that expel the dead baby. 4

Because of the pain, bleeding, nausea, fevers, and other side effects, these drugs are often further supplemented by additional drugs such as antispasmodics,5 antibiotics, narcotic analgesics, etc.,3 each of which comes with it own attendant risks and side effects and potential interaction problems.
In England, one of the first countries where the drug is allowed, all pills are numbered to ensure that they are not released to untrained personnel.3 In France, the country with the most experience with the drug, the government requires that any facility dispensing the drug have an electrocardiograph and emergency resuscitative equipment nearby. 6

Does it sound safe and simple to you?

SAFETY WARNING

Women with any of the following conditions have been kept out of tests of RU486 for fear that the drug might prove dangerous or deadly for them.

* **Presence of cardiovascular risks, including high blood pressure, obesity, cigarette smoking, and diabetes**. x, 17
* **Asthma and bronchitis** y
* **Age over 35 or under 18** z, 17
* **Menstrual irregularity, fibroids or endometriosis** v
* **Use of IUD or oral contraceptive less than 3 months prior to conception** v, 17
* **History of problem pregnancy, current ectopic pregnancy, or pelvic inflammatory disease** z, 17
* **Allergies, epilepsy, or adrenal insufficiency** y
* **Recent intake of steroid or antiinflammatory medications** y
* **Long term administration of cortisone or similar drugs** y z
* **History of liver, stomach, intestinal, or kidney disease** z, 17

If only women in perfect physical condition can endure the drug... How safe can it be?

x Raymond, RU486: Misconceptions (1991); y Silvestre, NEJM, 3/8/90;
z Couzinet, NEJM, 12/18/86

COMPLICATIONS ?

There are over 1.3 million abortions performed in the U.S. each year. 7 We are told that 20-33% of abortions performed in France are chemical abortions. 8, 18 If U.S. use mirrored French use, and U.S. abortion rates remained stable, one could expect the following numbers of complications based on current clinical data:

Complication 5,17	**Expected U.S. Range**	**Resulting #'s of Complications**
8% failure to complete abortion	X 273,146 - 450,691 =	21,852 - 36,055 "failures" per year
2% hemorrhaging	X 273,146 - 450,691 =	5,463 - 9,014 hemorrhaging per year
2% surgical intervention to stop bleeding	X 273,146 - 450,691 =	5,463 - 9,014 surgical interventions/yr
1% require hospitalization	X 273,146 - 450,691 =	2,731 - 4,507 hospitalizations per year
(4) transfusions	X 273,146 - 450,691 =	515 - 850 transfusions per year

An Iowa Doctor gives a first hand account

The woman who took RU486... and nearly died

Between October of 1994 and Labor Day of 1995, a nationwide trial of RU486 was conducted. A Planned Parenthood clinic in Des Moines was one of the testing sites. News accounts said the trial went well without any problems. One Iowa doctor who saw the story said he knew better.

I could hardly believe my eyes when I read the first paragraph of an article in the Sept.2, Des Moines Register, "The clinical test of the 'abortion pill' has ended in Iowa, with no complications among 238 women who ended unwanted pregnancies without surgery."

This is untrue, and I can only surmise that the reason must have to do with the political volatility of the abortion issue. Regardless, it is imperative from a scientific standpoint that if Planned Parenthood is to be part of a nationwide clinical trial, it must report the facts whether they agree with them or not... (**A**)

In November of 1994, I was called to the Alan Hospital Emergency Room in Waterloo, Iowa, for a woman who was bleeding due to a miscarriage and was in obvious shock. A blood test showed that she had lost between one-half and two-thirds of her blood volume. For those of you who understand this, her hemoglobin was 5.8 and her hematocrit was 17.3. Her blood pressure was 90 over 60, her pulse was 120, she was in obvious shock.

I had thought she was having an incomplete miscarriage, but her husband took me into the hall and told me that she had taken RU486 approximately 2 weeks before. It was my clinical opinion that she would die soon if she did not have an immediate D&C.

Without even doing the routine preparation we normally do for surgery, I realized that I had to take her immediately to surgery to save her life. I took her to the operating toom and removed the contents of her uterus surgically. I gave her two units of packed red blood cells intraoperatively. Even later that evening, 2 hours post-transfusion of those two units, her hemoglobin was still 6.8 and her hematocrit was 20 something. She required two more units of blood because she was still orthostatic and symptomatic...(**B**)

To report to the people of Iowa, the Population Council, and to the FDA that there were "no complications" in Iowa is simply not true...(**A**)

If near death due to the loss of half of one's blood volume, surgery, and a transfusion of four units of blood do not qualify as a complication, I don't know what does. (**A**)
How did the clinic and the trial sponsor respond? [President of Planned Parenthood of Central Iowa Jill] June said "no complications" refers to the trial -- that the trial was conducted successfully – and not to the condition of the participants.

However, Sandra Waldman, a spokeswoman for the New York based Population Council, which sponsored the trial, said the trial resulted in "no deaths or serious complications." When asked whether Louviere's patient's experience qualifies as a serious complication, Waldman said it would be "within the context of what happened before [in France]." (**C**)

"If near death due to the loss of half of one's blood volume, surgery, and a transfusion of four units of blood do not qualify as a complication, I don't know what does." -- Mark Louviere, M.D.

Sources:
A. Dr. Mark Louviere, *Waterloo Courier*, 9/24/95.
B. Statement of Mark Louviere, MD, FDA Mifepristone (RU486) Hearings, 7/19/96.
C. Tom Carney, *Des Moines Register*, 9/21/95.

Nasty Side Effects Part of the Package

Pain
79%-96% of women taking the RU486/PG combination reported pain, 4, 17 so bad that as many as half required some form of analgesia, whether an opiate or some other injectable painkiller. 3, 4, 5, 17
Three researchers who reviewed much of the data on RU486 say "many of the women in these studies experienced pain for several days/weeks until the abortion was complete. Thus we are talking about prolonged, not transient pain, although this is rarely noted." 3

Nausea, Diarrhea, and Vomiting
Between 24% and 61% of RU486/PG patients experience nausea as part of the procedure. About one in five of all women struggle with diarrhea, while 15.3%-26%, or up to a quarter, vomit. 3, 5, 17

Infection
In one trial, as many as 5%, or 1 in 20, showed signs and symptoms of infection. 9 Fevers and chills, often indications of infection, are not unexpected side effects of the process. 5 Antibiotics often must be prescribed for suspected infections. 10

If and when an RU486/PG abortion is unsuccessful (anywhere from 8%-23% of the time 17), and there is an incomplete abortion, the risk of infection is much greater. 13, 14 Whatever supposed benefit chemical abortion has over surgical abortion is lost when a woman undergoes the surgical procedure with its attendant risks.

Other Side Effects
Fatigue, 13 **fainting, skin conditions, anemia, asthenia, hot flashes, heart palpitations, breast conditions,** 5 **mood changes, thirst.** 14

Long Term Consequences
Unknown. Few independent studies. RU486 does cross the blood follicle barrier and get into a woman's ripening eggs.3 Could this affect the reproductive systems of a woman's later children, as DES did?

How Bad is the Bleeding?

Researchers regard heavy, prolonged bleeding as the chief problem and most serious side effect of chemical abortions. 3 The *average* blood loss from an RU486 abortion is reported to be 70ml, nearly four times the average blood loss from a normal suction curettage abortion 15 and very close to the 80ml menstrual blood loss doctors consider "abnormal." 16 This is hardly the "heavy period" spoken of by some of the pill's promoters. 18

In a 1990 British study, five out of 579, or nearly 1%, bled so much that they required both transfusions and curettage to stop the bleeding. 3 In U.S. trials with a new prostaglandin (misoprostol) that was supposed to resolve such problems, "excessive bleeding" was noted in 4 out of 230 women who participated in the Des Moines part of the study. 12 What "excessive bleeding" means is unclear, but we do know that one of those women almost bled to death (see above). Several women in the U.S. trial had to be given uterotonic agents to stop the bleeding. 17

It is not merely the amount of blood lost but how long a woman bleeds that is a medical concern. Normally, the bleeding may last one or two weeks, but there are records of women bleeding as much as two months or more. 3, 5, 17 There is additional concern because only about half of women who take RU486 actually abort at the doctor's office, meaning 50% of more face their bleeding and abortion without medical supervision. 17

NOTES:

1. Baulieu, *The "Abortion Pill"* (1991); Baulieu, in *Clinical Applications of Mifepristone ...* (1993); Lang, *Vogue*, August 1988.

2. Riding, *NY Times* 4/10/91.

3. Raymond, *et al*, *RU486: Misconceptions* (1991).

4. McKinney, *Human Reproduction* (1993), pp. 1502-5.

5. FDA, Mifepristone Hearings, 7/19/96.

6. French Government Letter, April 12, 1990.

7. Henshaw, "Abortion Services in the United States, 1995-1996," *Family Planning Perspectives* (Nov/Dec 1998).

8. Gianelli, *Americal Medical News* 4/12/93.

9. Birth Control Trust, Conference, 4/22/93.

10. WHO Study, *Fertility & Sterility* (1991).

11. Aubeny and Baulieu, *C.R. Acad. Sci. Paris (III)* (1991), pp. 539-545.

12. Jouzaitis, *Chicago Tribune*, 8/30/95.

13. Sitruk-Ware, *Contraception* (1990), pp. 221-243.

14. Li, *Fertility & Sterility* (1988), pp. 732-742.

15. *Ob.Gyn. News* (1989), No. 24, p. 1.

16. Speroff, *Clinical Gynecological Endochrinology & Infertility* , 3rd ed. (1983).

17. Spitz, *NEJM*, 4/30/98.

18. Population Council, Website, **www.popcouncil.org**, 1/98.

appendix two

Abortion 'leaves mental legacy'

Story from BBC NEWS:
http://news.bbc.co.uk/go/pr/fr/-/1/hi/health/4520576.stm

Published: 2005/12/12 10:27:37 GMT

An abortion can cause five years of mental anguish, anxiety, guilt and even shame, a BMC Medicine study suggests.

University of Oslo researchers compared 40 women who had had a miscarriage with 80 who chose to have an abortion.

Miscarriage was associated with more mental distress in the six months after the loss of a baby - but abortion had a much longer lasting negative effect.

Pro-choice campaigners said there was no evidence abortion directly caused psychological trauma.

> **The decision to terminate may bring with it long-standing feelings of anxiety and guilt**
> Richard Warren

The researchers said their work underlined the importance of giving women information about the psychological effects of losing a baby - either through miscarriage or abortion.

The Oslo team found that, after 10 days, 47.5% of women who had miscarried suffered from some degree of mental distress compared with 30% of the abortion group.

The proportion of women who had a miscarriage suffering distress decreased during the study period, to 22.5% at six months and to just 2.6% at two years and five years.

But among the abortion group 25.7% were still experiencing distress after six months, and 20% at five years.

The researchers also said that women who had an abortion had to make an effort to avoid thinking about the event.

Complex response

The researchers, led by Anne Nordal Broen, said the responses of the women in the miscarriage group were similar to those expected after a traumatic life event.

However, the abortion group had more complex responses.

Richard Warren, from the Royal College of Obstetricians and Gynaecologists, said: "It has always been considered, and this study also shows, that the decision to terminate may bring with it long-standing feelings of anxiety and guilt.

"While most women are able to manage and cope with these feelings, when necessary, the need for ongoing support and counselling should be recognised and appropriate help given."

Anna Pringle, from the anti-abortion charity Life, said: "This confirms years of experience with women who come to us for counselling after abortion.

"The emotional suffering can be massive."

Thoughtful decision

However, a spokeswoman for the British Pregnancy Advisory Service - the UK's leading provider of abortion services - said most women weighed up the consequences fully before opting for an abortion.

"We don't see that many women for post-abortion counselling.

"We offer that service but women very rarely come back because they are able to cope with it by themselves."

A spokeswoman for the Family Planning Association, said: "There is no evidence to suggest that abortion directly causes psychological trauma.

"Women can experience mixed feelings after an abortion such as relief or sadness.

"These are natural reactions and few women experience long-term problems."

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