



LifeCanada - VieCanada

376 Churchill Avenue, Suite 310

Ottawa ON K1Z 5C3

www.lifecanada.org

1-866-780-LIFE

THE NATIONAL ORGANIZATION CONNECTING EDUCATIONAL PRO-LIFE GROUPS ACROSS CANADA

July 23, 2004

Re: *Regulations Amending the Food and Drug Regulations (1272 – Levonorgestrel)*
Canada Gazette, Part 1, May 22, 2004

Karen Ash
Policy Division, Bureau of Policy
Therapeutic Products Directorate
Department of Health
Address Locator 3102C5
1600 Scott Street, Holland Cross
Tower B, 2nd. Floor
Ottawa, Ontario
K1A 0K9

Dear Ms. Ash:

We appreciate the opportunity to respond to Health Canada's proposal to make the morning after pill (MAP), levonorgestrel, available for use in Canada without a prescription. LifeCanada has a number of concerns which we would like to share with you and, as a result, request that Health Canada reconsider this proposal.

You may not be familiar with LifeCanada. We are a national educational organization whose membership includes individual members as well as 107 local and provincial pro-life groups from all regions of Canada. We work together to promote respect for all human life from conception to natural death.

Does easier access to MAP reduce the number of abortions?

LifeCanada, a pro-life organization, is deeply concerned about the rising numbers of abortion performed on Canadian women (106,418 in the year 2001). We are often told that any effort to make the MAP more readily available will result in the decrease in the number of surgical abortions. Now that some governments have experimented with selling MAP without a prescription and, in some cases are even paying for it, we can look at their experience to see what impact their efforts have had. The government of Quebec has allowed the sale of MAP without a prescription since January 2002. For the first year women were usually charged a fee of \$30.00 but the fee is now covered by the Quebec medical card. Have these measures reduced the number of abortions in Quebec? Not at all. One year after the morning after pill was made available without a prescription in the province of Quebec, the number of abortions continued to rise as did the number of women using the morning after pill. The number of abortions rose to 29,140 in 2002, up from 28,489 in 2001, even though the morning after pill had been available from pharmacists since January 2002. These figures do not include the number of abortions performed in private clinics which were not covered by health care dollars. The number of women using the morning after pill also continues to rise; 7151 women purchased the morning after pill from a pharmacist in 2002, up from 4415 women in 2001. The morning after pill is now fully covered by Que-

Canadians Embracing Life!

bec's healthcare plan. In 2003, the Quebec government had reimbursed 8717 women for the cost of the morning after pill as of December 18, 2003. The only conclusion which can be drawn based on these findings is that making the morning after pill more readily available does not decrease the number of surgical abortions even though more and more women use it. (Information from *La Presse*, December 18, 2003, article by Louise Leduc entitled *La pilule du lendemain: les beaux jours sont encore à venir...*)

What is the impact on STI's?

A recent study by Dr. David Paton entitled "*Random Behaviour or Rational Choice? Family Planning, Teenage Pregnancy and STIs*" (http://www.loveforlife.org.uk/download_centre/David%20Paton%20-%20Random%20Behaviour%20or%20Rational%20Choice.pdf) raises other serious concerns which need to be considered before making MAP more easily available. Professor Paton's findings show that "the adverse impact on STI rates has increased significantly since emergency birth control has become more widely available." Dr. Paton found that between 1998 and 2001 in England, an increase in family planning services and availability of emergency contraception without a doctor's prescription was associated with an increase in STIs (rate of 93.08 in 1998 to 119.27 in 2001). This seems to confirm the theory that because easier access to emergency contraception enables young people to reduce the risk of pregnancy, it acts as an incentive to engage in risky sexual activity.

Do we know if MAP is safe for women?

Health Canada should also be concerned about the impact of MAP on women's health. Wendy Wright, Senior Policy Director of Concerned Women for America, says there has been a lack or absence of scientific studies on: MAP's long-term effects; repeated usage of the drug; effects on adolescents; and the high hormone dosage. "A drug's safety at one dose or range of doses does not mean that the drug is equally safe at a much higher dose," she said (see Talking Points on the MAP, www.cwfa.org) "Yet proponents stake their arguments on decades of use of the birth control pill, a lower dose – which is not available over-the-counter."

U.S. will not allow sale of MAP over-the-counter.

On May 6, the US Food and Drug Administration rejected a plan to allow MAP to be sold over-the-counter at American pharmacies, citing a concern that it might be unsafe for girls under the age of 16. Ms. Wright says that all studies presented to the FDA were based on unscientific, anecdotal evidence and focused on the drug's efficacy in decreasing birth rate, not on the drug's effect on women. Barr Pharmaceuticals Inc, the manufacturer of the levonorgestrel MAP, Plan B, was unable to provide the FDA with any data on whether girls under 16 could use the drug safely without a doctor's input. Barr has this posted on its website: "Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 as for users 16 years of age and older." (www.go2planb.com/section/prescribing_info/) If such data can be produced, Dr. Steve Galson of the FDA would reconsider the decision, Reuters reported. Is Health Canada also concerned about the safety of MAP for girls under the age of 16?

Canadian Physicians for Life express concern.

It is surprising that Health Canada would even consider selling MAP without a prescription until we have greater assurance that it is safe for women to use. Birth control pills, which contain much lower doses of levonorgestrel, can only be obtained following a medical exam, a prescription and oversight by a physician for the duration of the use. According to Dr. Will Johnston, president of Canadian Physicians for Life, "Physical and clinical examinations by a physician are essential to good healthcare: to counsel patients on how to reliably avoid pregnancy, to determine sexually-transmitted diseases and abusive or coercive relationships, and to discuss health risks. MAP does not protect against STDs and instead of preventing a pregnancy, may terminate it. Such serious issues cannot be adequately addressed at a pharmacist's counter."

The Canadian Paediatric Society offers clinical practice points.

These comments seem to be in keeping with the clinical practice points which appear on the Canadian Paediat-

ric Society's website (<http://www.cps.ca/english/statements/AM/ah03-01.htm#practice>) which offers advice to physicians dealing with girls who request 'emergency contraception'. They say:

"Adolescent girls may come specifically for emergency contraception, or an indication for emergency contraception may be discovered during routine history taking. In either case, the date and nature of the last menstrual period should be elicited, as well as when she has had intercourse since that period. She should also be asked about her history of contraceptive use and history of contraindications to oral contraceptives. Physical examination should include determination of blood pressure. Pelvic examination is indicated if the last menstrual period was unusual and the physician suspects that the patient is pregnant, has concerns about sexually transmitted infections or if an IUD will be inserted. If a pelvic examination is performed, specimens should be taken for chlamydia and gonorrhea cultures, as well as a Pap smear if one has not been done in the past year."

There is also a section which offers advice on what to discuss with the girl during the visit. The physician is to explain that 'emergency contraception' is not 100% effective, what her options are if she does become pregnant, that she may not be protected against sexually transmitted infections, and physicians are told that "An appointment can be scheduled for one week after the next expected menstrual period. This appointment is an opportune time for counseling around the teen's choices about her sexual activity, contraception, sexually transmitted infections and safer sex."

The Australian Medical Association asks the government to reverse it's decision.

It is difficult to imagine a pharmacist in a busy drugstore having the time to discuss all of these issues with an adolescent girl since there is very little privacy and other customers may be waiting for his/her attention. What happens when the adolescent girl does not understand or wants information about related issues? Pharmacists in Australia have already experienced difficulties as a result of having to counsel the young women seeking 'emergency contraception' without first visiting her physician. CNSNews.com (www.cnsnews.com/Culture/Archive/200401/CUL20040102a.html) reported in January that the Australian Medical Association, who initially supported the government's decision to make 'emergency contraception' available without a prescription, is now asking the government to reverse its decision because of concerns raised by pharmacists. "AMA ethics committee chairwoman Dr. Rosanna Capolingua said pharmacists were not prepared to deal with the sensitive matters arising when a customer wants the morning-after pill." Dr. Capolingua said that the idea of a pharmacist being able to have a serious discussion about such sensitive matters as unprotected sex and on the need to use appropriate contraception in future, was "absurd". Pharmacists complained, "We are not prepared to counsel customers appropriately...and we don't understand it well enough, we don't understand the side-effects to be able to do this."

Contraceptive or Abortifacient?

Finally, of grave concern to us is the use of the term 'emergency contraception' which will mislead women and their partners into believing that they are using a contraceptive when in fact they may be using an abortifacient.

We are told that levonorgestrel can prevent pregnancy by acting in one of three ways. "It acts as an EC by preventing the release of an egg from the ovary, preventing fertilization of the egg or preventing the fertilized egg from attaching to the wall of the uterus."(*Canada Gazette Part 1*, page 1633)

When the egg has been fertilized and then prevented from attaching to the wall of the uterus, how can we refer to this drug as a contraceptive? It is a universally accepted fact, in scientific circles, that any one human individual's life, biologically speaking, begins at the completion of the union of one of its father's sperm with its mother's ovum, a process called conception or fertilization.

“It is the penetration of the ovum by a spermatozoa and the resulting mingling of the nuclear material each brings to the union that constitutes the culmination of the process of fertilization and marks the initiation of the life of a new individual.”

Bradley M. Patten, *Human Embryology*, page 43, McGraw-Hill New York, 1968

“Development begins at fertilization when a sperm fuses with an ovum to form a zygote; this cell is the beginning of a new human being.”

Keith Moore, *The Developing Human: Clinically Oriented Embryology*, Page 12, W.B. Saunders, 1974

“A new individual is created when the elements of a potent sperm merge with those of a fertile ovum, or egg.”

Encyclopedia Britannica, 15th edition 1984, page 968

Proof of the beginning of human life has been shown by Steptoe & Edwards with the first successful “test tube” baby and continues to be re-affirmed through in-vitro technology and other genetic research. This reality was eloquently presented by Dr. Jerome Lejeune, world renowned human geneticist and Nobel Prize Nominee, during his presentation to the Canadian Legislative Committee studying Bill C-43 in March 1990. Dr. Lejeune said:

“We know, beyond any possible doubt, that when the sperm enters the ovum all the information required to make a human being...is present. We also know, with the same degree of certainty, that no subsequent genetic information, after fertilization, is passed on to a human being. This is neither the opinion of a moralist nor the hypothesis of a metaphysician, it is a very specific observation made in the course of experiment.

If it were not true that all the information required to define each human being is present at fertilization, in-vitro fertilization would not be possible. If a human being did not exist at fertilization, it would be impossible for a sperm to enter an ovum in a test tube and for the embryo that may result to be transferred to a woman who is not the biological mother. In other words, the fact that in-vitro fertilization exists proves, beyond a doubt, that human life begins at fertilization.”

Dr. J. Lejeune, *Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-43*, House of Commons, march 21, 1990, Issue No. 18, pp 7 & 8

Once fertilization has taken place it is misleading to refer to the newly formed embryo as a fertilized egg because it obscures the fact that a new human being has come into existence. A new human life does not begin at implantation but, from a scientific perspective, from the moment of conception or fertilization. Therefore to refer to the use of levonorgestrel as an emergency “contraceptive” is misleading.

51.8% of Canadians believe that a fetus is a human being at conception.

A 2001 Leger Marketing poll reported that 51.8% of Canadians believe that the fetus is a human being at conception. A young woman, or her partner or parent, who hold this view may be very upset to learn that the use of this “contraceptive” drug could have resulted in the loss of their very young unborn child. At the very least, it is important to change the language used in referring to levonorgestrel or any other morning after pill.

Women deserve the right to be fully informed of all repercussions before agreeing to take any drug.

It is our sincere hope that you will seriously consider all of the issues and concerns which we have raised. On May 20, 2004 the Canadian Physicians for Life press release ended with the following plea:

“On May 6, the US Food and Drug Administration rejected a plan to make MAP available over the counter at American pharmacies, citing a concern that it might be unsafe for girls under 16. Does the Health Minister not

have similar concerns about our Canadian adolescents? We urge the Minister to put the health of Canadian women and girls before political ideology and commercial interests and reject any attempt to distribute this potentially harmful abortifacient in Canada without a doctor's prescription.”

We fully agree with this statement and recommend that levonorgestrel not be made available without a prescription.

Sincerely,

Carroll Rees
Executive Director