Norplant: Contraceptive Freedom?

by Marie Cocking

Norplant, le contraceptif récemment approuvé par le Canada serait apparemment une nouvelle libération contraceptive pour les femmes. Cependant, cette méthode contraceptive n'est peut-être pas aussi saine et pratique que les manufacturiers le prétendent. De plus, les conditions d'approbation de Norplant qui sont tenues dans le plus grand secret font qu'il est difficile pour les femmes de faire un choix averti concernant l'utilisation de cette méthode contraceptive.

The fact is, it's impossible to know exactly what effect any hormonal drug will have on women's health until it has been used by thousands of women, outside a clinical setting, for a long time.

The banner above Wyeth-Ayerst's Norplant booth at the end of the Ottawa Civic Convention Center exhibition hall confidently announced: "pending approval in Canada." The display promoting the contraceptive implant dominated the June 1993 meeting of the Canadian Society of Obstetricians and Gynaecologists. And inside the lecture hall—doctors only, please—doctors could watch a Wyeth-Ayerst employee insert the six small silicone hormone-filled rods into a plastic arm.

The marketing extravaganza was a hit. At the closing of the meeting, Society President Dr. Kenneth Milne issued a communiqué saying the Society hoped that under then-Prime Minister Kim Campbell "Canadian women's right to choose the best [contraceptive] option for them will be respected" (Rafuse 467). The Society urged the government to immediately approve Norplant and another injectable hormonal contraceptive, Depo Provera, in the name of Canadian women's contraceptive freedom.

But do Norplant and Depo Provera really offer women contraceptive freedom? And if this is freedom, why is it so hard to find out who decided Norplant was safe and what information they considered in that decision?

Representatives of Health Canada's Health Protection Branch would say nothing except that Norplant was "under review" and Depo Provera, made by Upjohn Canada, was "under appeal." Although this information is technically "public," they would not say who was on the committee (or committees) considering these drugs, besides Dr. Paul Roufail, a division chief in Health Protection's Drug Directorate, nor what studies the manufacturers had submitted supporting the drugs' safety.

Wyeth-Ayerst and Upjohn have this information, of course, but as private, profit-driven companies they have no legal obligation to release it and a good reason not to. In 1986, when UpJohn previously applied to have Depo Provera approved as a contraceptive in Canada, the Canadian Coalition on Depo Provera successfully lobbied the government to block its approval, citing concerns about the drug's long-term safety. Since then, drug companies have learned the value of secrecy. Neither Wyeth-Ayerst nor Upjohn was prepared to lose the Canadian contraceptive market again.

On January 13, 1994, Health Canada approved Norplant. Wyeth-Ayerst, a Canadian subsidiary of a huge U.S. pharmaceutical company, announced the news in media conferences across the country, complete with doctors paid to sing the implant's praises (Mickleburgh). With this announcement, Health Canada and Wyeth-Ayerst heralded the biggest contraceptive "revolution" in Canada since the birth control pill. For better or for worse, when Norplant was released on to the market on March 5, 1994, Canada entered the era of injectable contraceptives.

Norplant: Now that it's here, what is it?

Norplant consists of six small silicone rods filled with enough synthetic progesterone, a progestin called levonorgestrol, to provide contraception for five years. Like the IUD, however, it takes a short operation to activate Norplant. A doctor must make a small incision on the inside of a woman's upper arm and implant the rods in a fan shape under her skin. The levonorgestrol immediately begins to slowly leak through the pourous rods into the woman's bloodstream, at first in a higher dose, then leveling off to a lower dose by about the end of the first year. The progestin works by stopping a woman's ovulation about half the time and by thickening her cervical mucus so sperm cannot reach any eggs that may be released to fertilize them. Over five years, only about four out of one hundred users will get pregnant, making Norplant one of the most effective contraceptives available. (McCauley and Geller)

The implant's active ingredient is not new. Levongestrol has been used is some progesterone-only birth control pills for almost three decades. Norplant, itself, was developed 20 years ago by the Population Council, a U.S. based, non-profit organization concerned with population control. It has been clinically tested in the arms of 55,000 women around the world and it came onto the market first in Finland in 1983. Because it uses a progestin, not an estrogen, some researchers believe it's less likely to put women at risk for breast cancer and cardiovascular disease—risks associated with estrogen.

What makes Norplant "revolutionary" is not so much its active ingredient, but the way the levonorgestrol is released into a woman's body. Unlike the birth control pill, women must depend on doctors for Norplant's implantation and removal.

It sounds safe and convenient—no estrogen, and only a ten to 15 minute investment for five years of worry-free sex. Surely, women should rush to their doctors' offices. But take a longer look and Norplant may not be so safe or convenient.

Like every hormonal drug, Norplant affects a woman's entire body. And like every other hormonal contraceptive on the market, Norplant has been made available before research into the long-term effects of the drug have been evaluated. The fact is, it's impossible to know exactly what effect any hormonal drug will have on women's health until it has been used by thousands of women, outside a clinical setting, for a long time. The World Health Organization (WHO) only started to study Norplant users in 1988 and results won't be available for years. And although the technology was developed 20 years ago, it's hard to find a study that follows women after the implant's removal. Norplant has only been approved for nonclinical use for ten years, not necessarily enough time for long-term effects like cancer to arise. And long-term effects do sometimes arise from hormonal drugs long after they have been used.

Some poor women using subsidized implants report having had their requests for removal denied by doctors who told them to wait and see if the side effects would subside.

Diethylstilbestrol, DES, was a synthetic estrogen given to women until 1971 to prevent miscarriage. At the time, women trusted their doctors and doctors trusted the pharmaceutical companies. But DES is now known as the first human transplacental carcinogen; the women who took it are now at increased risk for breast cancer, their children have increased risk for reproductive system cancers and infertility. DES was a precursor for other widely prescribed inadequately tested drugs and medical devices, such as the Dalkon Shield and Meme breast implants, that have injured or killed thousands of women.

The World Health Organization, in 1985 and again in 1990 supported Norplant. But, based on clinical findings, the WHO advises doctors *not* to prescribe Norplant to women with cardiovascular disease, abnormal vaginal bleeding, benign or malignant liver tumours, or known or suspected breast cancer—all contraindications associated with combined birth control pills. The WHO also advises doctors to closely monitor users with diabetes, anemia, or high blood pressure. In a few women, Norplant can cause tubal pregnancies—life-threatening, if undiagnosed—and ovarian cysts. All of which suggests some women who want to try Norplant to avoid the estrogen-related risks of the birth control pill may still find Norplant too risky.

Beyond unanswered questions about long-term risks, studies show that Norplant's immediate side effects are enough to make anywhere between 17 and 50 per cent of women with the implant ask to have it removed before the full five years (Darney). According to the Population Council's own studies, women use the Norplant an average of 3.5 years (McCauley and Geller).

Dozens of acceptability studies document that up to *95 per cent* of women on Norplant experience menstrual irregularities (Hardon 1993). The first six months tc a year, when the progestin dose is highest, can be a menstrual nightmare. Some women bleed for several weeks straight as the progestin signals their bodies to continually flush out their wombs. Some women then stop bleeding altogether. Other women report feeling like they have continual premenstrual syndrome: headachy, tired, irritable, bloated, hungry, with tender breasts, bad skin, and low sex drives. Some women gain considerable weight, which is significant because Norplant's contraceptive effect is lowered in women who weigh 70 kg (about 154 lbs.) or more, raising the risk of tubal pregnancies. There are well-documented problems with Norplant's removal: several women in the U.S. and hundreds in the developing world have had prolonged infection at the implantation site, broken rods, rods lost under scar tissue, and muscle damage. This is sexual freedom?

Indeed, Norplant's hormonal and surgical side effects are so bad for some women in the U.S. that they've filed lawsuits against Wyeth-Ayerst. Among the four lawsuits that have been put before the courts in the three years since Norplant was approved in the U.S., one is a class action involving 50 women. According to their lawyer, Jewel Klein, the women claim the company did not adequately inform them of potential problems with Norplant's removal or of its side effects. One woman in the lawsuit lost use of her arm due to muscle damage when the implant was poorly inserted. Four others needed the implants removed because they were pregnant, raising concerns about the hormone's affect on babies.

And because women depend on doctors for Norplant's removal, there is potential for abuse. Some poor women using subsidized implants in the U.S. and in parts of the developing world report having had their requests for removal denied by doctors who told them to wait and see if the side effects would subside (Hardon 1990). In 1991 in California, a mother convicted of child abuse was ordered to have Norplant implanted or go to jail, although a higher court overturned that sentence. And at $450 for an implant, Norplant is priced out-of-reach for most lower income women in the United States. However, any woman in Canada can now have Norplant free in exchange for allowing a doctor to "practice" implanting the rods in a live arm. According to Steve King, in charge of

marketing Norplant for Wyeth Ayerst Canada, Canadian doctors are not required to take any special training before offering Norplant to their patients, but Wyeth Ayerst "strongly encourages" doctors to do so. Training entails instruction in the implantation and removal techniques, practice on a fake arm, and then on a live arm with each participating doctor offered one Norplant set to give free to the woman in his or her practice who would most benefit from Norplant. Consent forms are not required, but Wyeth Ayerst suggests doctors use them. So far, according to King, about 1,000 doctors in Canada have taken the training and just over 1,000 women have had Norplant implanted, including those who received it free.

Even if a drug is not approved for a certain use, nothing prevents doctors from prescribing that drug in any circumstance they deem fit.

The potential long-term risks, side effects, and removal problems hardly sound convenient, much less like contraceptive freedom. Women with Norplant, it seems, are asked to ignore their bodies and trust their doctors. And most doctors don't have much more information about new drugs than do consumers. They learn about new drugs through highly massaged events, like the Society of Obstetricians and Gynaecologists' (CPS) annual meeting in Ottawa. Or they learn about them through promotional information sent by drug company "detail" men, hired to promote specific drugs to doctors. Some read about new drugs in medical journals.

Most doctors rely on the information in the Compendium of Pharmaceuticals and Specialties (CPS) which is based on the product monograph prepared by the manufacturer. But, according to Dr. Joel Lexchin of the Medical Reform Group, Health Canada's Health Protection Branch does not systematically monitor information in product monographs to ensure it is correct and up-to-date. Dr. Lexchin writes: "One member of the Canadian Medical Association's subcommittee on drugs and pharmacotherapy suggested that 70 per cent to 75 per cent of monographs published to date are now inaccurate, according to an informal university pharmacology study" (1259). This is probably not the case with the Norplant monograph but it illustrates the need for all patients to be informed consumers.

Even if a drug is not approved for a certain use, nothing prevents doctors from prescribing that drug in any circumstance they deem fit. Depo Provera, for example, is available in Canada to treat endometriosis. It is not approved for use as a contraceptive. But, doctors at the Bay Centre for Birth Control in Toronto, openly prescribe Depo Provera as a birth control (Toronto Women's Health Network Newsletter). These doctors are not even obliged to tell the women whom they inject with this controversial drug that the government has not approved its use as a birth control.

Freedom of choice requires freedom of information

What did Health Canada's Special Advisory Committee on Reproductive Physiology, the group of doctors and health experts who judged Norplant safe, make of the foregoing concerns? It is impossible to say, even now that Norplant is approved in Canada. According to Dr. Roufail, the information in Wyeth-Ayerst's application as well as the names of the researchers who made the decision are not revealed "as a matter of policy." He said he advises callers to apply to get the information through the Access to Information Act. "Why do you need to know? They are all experts in their fields."

According to information obtained by the Women's Health Clinic in Manitoba, through Access to Information, Dr. Albert Yuzpe, chief of gyneacology and reproductive medicine at University Hospital in London, Ontario, is a member of this Special Advisory Committee. And he is no doubt an expert in his field. According the *Globe and Mail*, he was also employed by Wyeth-Ayerst to praise Norplant at its Toronto media conference announcing the drug's approval (Mickleburgh). But this is not a conflict of interest according to the Special Committee's guidelines. According to the minutes of a meeting of the Special Advisory Committee:

> The acceptance of grants from pharmaceutical companies to carry out clinical or basic research should not be considered a source of conflict of interest.
>
> A member of the Committee who *feels in conflict* of interest concerning a subject discussed by the Committee should notify the Chairman and stay way from the discussion.
>
> It is not necessary for members of the Committee to submit a written statement for disclosure of any involvement or share in the pharmaceutical industry.

Even if the Committees does not feel these kinds of situations create conflicts of interest, many Canadians probably would.

Dr. Roufail justifies the secrecy surrounding the drug approval system as necessary both to protect drug companies' patent rights and to protect drug reviewers from undue influence. Influence from whom? Surely not drug companies, because the doors are open to them. Representatives of the Pharmaceutical Manufacturers' Association of Canada meet regularly with representatives from the Health Protection Branch to discuss policy directions (Lexchin). And minutes from a 1992 meeting of Health Canada's Special Advisory Committee on Reproductive Physiology, the group of researchers looking at Depo

Provera for the government, show that a representative of Upjohn was invited to listen to the committee's reasons for rejecting the company's application to have Depo Provera approved for contraception (Lexchin).

Extreme secrecy is unnecessary and benefits no one but drug companies. In the U.S., the Food and Drug Administration's (FDA) review committee meetings are open to the public, so observers can see what information drug companies have submitted to prove to safety and efficacy of their products and who is involved in judging their applications. When a drug is approved, the FDA releases a summary of the information they considered in approval. And U.S. drug companies still manage to turn healthy profits. At the very least, opening up Health Protection Branch's review committee meetings would allow consumer groups to monitor the drug approval process and inform government of their concerns and needs. With high-tech reproductive technologies such as Norplant, informed concent is imposible without informed consumers. Every women needs to know and understand what long-term risks and side effects she may be exposing herself to—especially because Norplant, as a contraceptive, will be used in healthy, young women. Until there is more freedom of information about Norplant, it is difficult to believe the implant offers women contraceptive freedom.

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MICHELE BIRCH-CONERY

Adoption

The first picture ever taken
of her (July, 1944) discovers

her in her plaid skirt and white
blouse, the thin white socks,

white unpolished shoes worn
when she came from the foster

home. Always I see
her arriving crystalline

bright, her childhood innocence
intact. I remember

the walk from the CPR station
(a short half block) to the Wilson

Street apartments. She would act
grownup although embarrassed

by her child's suitcase, its cardboard
handle broken already from the train

ride, Vancouver to Trail. They
can hardly wait to capture

this moment. Alone
against the drab stucco

of her new home she appears
bewildered, small for her age.

How is it that so immediately
and without warning

she is becoming their dream?

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