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HEALTH ISSUES

Caution on two contraceptives

Women's groups and activists warn that two injectable contraceptives that will possibly be included in the national family planning programme may not be completely safe.

T.K. RAJALAKSHMI

FEARS about the inclusion of certain injectable contraceptives in the national family planning programme have been raised yet again following the Supreme Court's ruling on August 24 in a case filed by Stree Shakti Sanghatana, Saheli and others in 1986 pleading for a stay on the Phase IV clinical trials of Net-en (Norethisterone Enanthate) and its entry into the programme. Without making a direct reference to a case filed in 1993 against hazardous drugs by the Drug Action Forum, the court assured women's organisations and health activists that neither Net-en nor Depo-Provera (Depo Medroxy Progesterone Acetate), another contraceptive against which a case is pending in court, be permitted for mass use for now. During hearings, the court had asked the Drug Technical Advisory Board (DTAB) to examine its sub-committee's August 1995 recommendations that "the use of Depo-Provera should be restricted to women who would be aware of all the implications of its use".

S. THANTHONI

At a health camp for women. Women's groups oppose providing easy access to injectable-type contraceptives in the name of choice.



While the report pertaining to Depo-Provera was reproduced in the affidavit filed by the government this year, the Union Ministry of Health and Family Welfare proposed to include Net-en in the family planning programme even in places where facilities for follow-up and counselling were not available. Women's and health groups fear that both the injectables would come to be used even in places where the infrastructure does not exist.

Depo-Provera and Net-en, both synthetic derivatives of progesterone, suppress ovulation, make cervical mucous inhospitable to sperm and make the lining of the uterus unsuitable for implantation. Depo-Provera is a three-monthly injectable developed by Upjohn of the United States, while Net-En is a product of Schering AG of Germany.

What has raised the hackles of women's groups and health activists is the manner in which Depo-Provera found its way into the Indian market in 1994 without the mandatory Phase III trials. It was sold across the counter against a medical prescription. According to Schedule Y of the Drugs and Cosmetics Act, "if the drug is already approved and marketed, Phase III trials as required under item 7 of Appendix I are usually required". Since Depo-Provera was already approved in the United States, what remained was the Phase III trials. Item 7 on Appendix I, which is about confirmatory trials, states: "The purpose of these trials is to obtain sufficient

evidence about the efficacy and safety of the drug in a larger number of patients generally in comparison with a standard drug or a placebo. These trials may be carried out by clinicians in the therapeutic areas concerned, having facilities appropriate to the protocol. If the drug is already approved/marketed in other countries, Phase III data should generally be obtained on at least 100 patients distributed over three or four centres primarily to confirm the efficacy and safety of the drug in Indian patients when used as recommended in the product monograph for the claims made."

Dr. C. Sathyamala, an epidemiologist trained at the London School of Hygiene and Tropical Medicine, says the Drugs Controller of India made post-marketing surveillance (PMS) conditional for the sale of Depo-Provera, thereby substituting Phase III trials. In her book *An Epidemiological Review of the Injectable Contraceptive Depo-Provera*, published by Medico Friends Circle and Forum For Women's Health, she points out that Upjohn used Chiang Mai, a remote rural area in Thailand, as its "testing ground" for Depo-Provera. Sathyamala feels that the unlettered women of Chiang Mai were perhaps not informed that they were taking part in clinical trials and that no protection, legal or otherwise, would have been given to them. It is felt that similar tactics may have been deployed in the PMS conducted between June 1994 and December 1997 among Indian women by Professor Rustom P. Soonawala, obstetrician and gynaecologist and Consultant. The PMS study covering 1,079 women was conducted at 10 centres to observe the side-effects and acceptability of Depo-Provera 150 mg. A report submitted in 1999 concluded that no failure of contraception was reported during the survey and no drug-related adversity was found. It said that, "neither pregnancies nor deaths were reported during the study" and that "the results indicate that Depo-Provera 150 mg is a safe and effective contraceptive, and that sufficient pre-treatment counselling on the expected hormonal effects would greatly increase the acceptability of this method of contraception." Interestingly, two of the three authors of the report are from Pharmacia and Upjohn.

During the course of the study, some women were reported to have discontinued the contraceptive. The reasons attributed for this were "non-serious medical events", which, interestingly, included irregular bleeding, in some cases heavy, amenorrhea (absence of menstruation), urinary tract infection, abdominal pain, bloating abdomen, post-coital bleeding, weight gain, abdominal cramps and even viral hepatitis. Women's and health groups were disturbed by the conclusion that was reached that the symptoms were non-serious.

In fact, at a workshop convened by the Institute for Research in Reproduction in Mumbai in December 1998 to review the status of the available injectable contraceptives in the Asian region *vis-a-vis* India and to discuss the inclusion or otherwise of such contraceptives in the national family planning programme, the consensus was that the injectables had side-effects.

Women's and health groups cautioned the government against their inclusion in any form in the family planning programme. Concerned about the "deliberate misrepresentation of information", they urged the government to disallow the use of such hazardous drugs as the existing health infrastructure was not capable of providing the necessary follow-up for such long-acting contraceptives. Further, the non-accountability of pharmaceutical companies, coupled with evidence to the contrary about their efficacy, they said, provided the grounds for a ban on all injectables.

Interestingly, Depo-Provera is more commonly used in developing countries. In developed countries it is not an item of "popular choice".

ORIGINALLY introduced in 1967, Depo-Provera was publicised in India in 1994 by a leading advertising group, which proclaimed it to be the world's most widely used and widely available and largest used preparation of its kind, and that it had been successfully used by over 30 million women in 90-odd countries. Sathyamala says that, even if one concedes that Depo-Provera is the "largest used" preparation, its overall use is low and that except in South Africa it does not appear to be an important contraceptive of choice even in countries with no restriction on its use. There is a stark difference in the share of injectables used among the black and white populations of South Africa. Some 41 per cent of the contraceptive users preferred injectables. A break-up of this figure revealed that persons using injectables constituted only 3 per cent of the 79 per cent of white women, who used modern methods, while users of injectables formed 27 per cent of the 49 per cent of the black women who used modern methods. Quoting various studies and papers, Sathyamala writes that in developed countries, where Depo-Provera is registered as a drug, it is prescribed primarily to mentally challenged women, women with a problem of drug addiction, indigenous populations such as native Americans in the U.S. and Maoris in New Zealand, sexually active adolescents, coloured women and women from low-income groups.

According to Sathyamala, Depo-Provera is a long-term, systemic, invasive contraceptive, which acts at multiple levels. Its potency and the ease with which it can be used have been cited as reasons for its promotion in sections with high birth rates and low "motivation" levels. By not taking the women's experience seriously, it is more than likely that important morbidities are being left out, she argues. When a woman reports a symptom while being on Depo-Provera, the general tendency seems to be to "reassure" her that the reported symptom is not associated with the use of the contraceptive.

Women's groups, such as the All India Democratic Women's Association, Sama and Jagori, and health forums such as the Medico Friends Circle and the Forum for Women's Health, maintain that Depo-Provera has been indicted for causing a climacteric-like syndrome (premature menopause), irreversible atrophy of the ovaries and endometrium (inner lining of the uterus) leading to sterility, deaths due to spontaneous formation of clots inside blood vessels (thrombo-embolism), a 10-fold increase in the birth of Down's Syndrome babies and increased infant deaths. There are heightened chances of breast and cervical cancer as well. Activists of the organisation have accused Upjohn of suppressing and/or underplaying the life-threatening implications of the injectables and in the process misleading the medical community as well as the Drugs Controller of India. Studies on Depo-Provera have been funded by Upjohn or directly carried out by its bio-statistical division. The dissenting groups feel that given the large body of scientific information on the injectable, the conduct of another study that was part of a PMS was nothing but an attempt to mislead and misinform the authorities.

The introduction of the injectables cannot be seen in isolation of the government's population policy. The activists argue that while the National Democratic Alliance government appears to have given up coercive methods of population control, State governments were doing exactly the opposite. While a Bill to debar people with more than two children from contesting elections was still on the national agenda, Haryana and Delhi have passed a legislation debarring persons with more than two children from contesting the local body elections. In Maharashtra, the third child is excluded from the benefit of the Public Distribution System. In Uttar Pradesh, Rajasthan and Madhya Pradesh, the disincentives include the denial of access to government schemes.

Evidently, these disincentives could push women and their families into accepting what they perceive as safe and long-acting contraceptive methods. Women's groups are not against family planning and contraception, but they oppose the easy access to

injec table-type contraceptives in the name of choice, while the truth is that for the majority of Indian women, informed choice about anything, leave alone contraceptives, is a chimera.

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