enough is enough

Injectable contraceptive Net-En : a chronicle of health hazards foretold

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ENOUGH IS ENOUGH

Injectable Contraceptive Net En: A Chronicle of Health Hazards Foretold

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INTRODUCTION

World Population Day, 11th July. It's a day that governments and policy makers rarely forget to observe. A day dedicated to platitudes and the rhetoric of concern for the welfare of the people. A day that is invariably marked by a heightening of the panic about "population explosions". But for decades, women's groups and health activists have believed that this is merely one more occasion on which to seriously reconsider the population control argument in the light of the price people are paying in the game of controlling numbers, and call a halt to development of hazardous contraceptives and coercive, unethical methods of population control.

The injectable contraceptives Net En and Depo Provera have had a chequered history from the time they were developed in the 1950s. Net En was registered by the Drugs Controller of India for use in India (by private practitioners) in 1986, and Depo Provera in 1994. Since then, the government has been wanting to introduce injectables for mass use in the Family Welfare Programme (FWP), but vigorous opposition from women's groups, including two court cases, has thus far stalled these moves.

The latest measures to enforce the "small family norm" in the NCT of Delhi are listed in the Delhi Population Bill, which, by harsh disincentives denying basic rights to the citizens, seeks to reduce the population of Delhi. These draconian measures come as a sharp contrast to the niceties mouthed by the government in international forums. In the recently concluded United Nations General Assembly (30 June - 2 July) to review the implementation of the Programme of Action of the International Conference on Population and Development, the government reiterated its commitment to the guiding principles of the Cairo Conference which uphold the dignity and rights of all citizens. Yet, despite having launched the Reproductive and Child Health Programme in 1997 which avowedly seeks to address women's reproductive health in a holistic manner, the government is seeking to introduce methods of contraception which are potentially hazardous to women's health, and which carry a high potential for abuse.

Recent developments also point to a fresh attempt at bringing these injectables into the FWP. In the 1997 study by the United Nations Population Fund (UNFPA) in collaboration with the Government of India, injectables are one of the contraceptives projected as part of the future FWP. A meeting convened in December 1998 by the Institute for Research in Reproduction, Mumbai, an Indian Council of Medical Research, recommended, amidst stiff opposition from women's groups and health groups, the introduction of injectables into the FWP, albeit in a phased manner.

Net En and Depo Provera are long-acting injectables with a similar mechanism of action; the hazards associated with their use are also similar, and both have had a controversial history in India. In the early eighties, Depo Provera was considered by the ICMR to be unsuitable for introduction in India, and clinical trials were conducted on Net En, which became the focus of the campaign against hazardous contraceptives. In the nineties, when Upjohn Co had succeeded in pushing Depo Provera onto the Indian market, Depo also became a part of the campaign.

This report looks at Net En and Depo Provera and why they are shrouded in controversy but focuses mainly on Net En. Net En is just one of the long-acting, invasive hormonal contraceptives that women's groups have been opposing. As we shall elaborate, use of Net En is associated with many risks and side effects, it's effectiveness is doubtful in field conditions, and its "convenience" contributes to further reinforcing women's powerlessness in matters related to fertility control. The report analyzes how injectables fit into the overall objectives of the Government of India vis a vis population control. The report also traces the campaign against Net En in the context of the critique of the population policy. It then outlines the inter-linkages between pharmaceutical companies, governments, scientific bodies and international funding agencies to understand the impact of hazardous contraceptives on the lives of individual women.

BACKGROUND

The injectable contraceptives Net En and Depo Provera have had a chequered history from the time they were developed in the 1950s. All over the world, questions were raised about the safety of the use of these drugs as contraceptives, since their use was associated with many short-term and long-term adverse-effects and hazards. Net En had been withdrawn from the market in 1971 following the development of tumours in rats, which indicated that the drug could be potentially hazardous in women. Simultaneously, there was much pressure on the authorities in UK and the USA by the world population control establishment to formally licence Depo Provera for contraceptive use so as to circumvent the accusation that a drug banned in the country of manufacture was being promoted elsewhere. Public hearings were held in USA and UK, in which women's groups presented evidence about the health hazards and potential for abuse associated with the use of injectables.

In India, in the early 1980's, women's groups and health activists were aware of the problems associated with injectable contraceptives. However, the hazards became a reality when news about clinical trials on Net En became public. Women's groups soon began to wrestle with the tongue-twisting names of these injectable contraceptives Norethisterone Enanthate (Net En) and Depot Medroxyprogesterone Acetate (DMPA or Depo Provera). Grappling with medical terms and delving into the politics of population control, women's health and the machinations of the pharmaceutical industry, a familiarity with these terms grew. Net En and Depo Provera became oft heard words in these circles. Soon, the campaign against injectables became virtually synonymous with the women's health movement in India.

Following the first ICMR press release in 1983 declaring its intention to introduce Net En into the Family Planning Programme, women's groups and health groups like the Drug Action Network and Medico Friends Circle were trying to gain information about the clinical trials. Information which was systematically denied. In 1983 and 1984, ICMR initiated a Phase IV (Programme Introduction) Study in urban and rural centres to assess the acceptability of Net En in order to introduce injectable contraceptives in the National Family Welfare Programme.

Patancheru in Andhra Pradesh was one of the centres where this study was being conducted. Members of Stree Shakti Sanghatana, a Hyderabad-based women's organisation visited the Primary Health Centre (PHC) at Patancheru near Hyderabad on April 1, 1985. A 'camp' had been organised to introduce the injectable Net En. This PHC had been selected by the Osmania Medical College for the Phase IV trial. The para-medics who talked to the activists said that they had been assigned the task of procuring 20 recruits for the trial from the nearby areas. They said that if they had informed any of these women that they were subjects of an experiment or that there were possible side-effects, no one would have volunteered. The women who had been assembled that day at the PHC were from the poorest class. They told the women activists that the only information they had been given was : "*Injection le lo, bachcha nahin hoga.*" ("Take this injection, you won't get pregnant.")

This blatant flouting of the requirement of informed consent was a clear violation of the Helsinki Declaration on medical ethics, to which India is a signatory. It soon became apparent that this was not an isolated incident, and unethical trials were being conducted all over the country. For instance, in Jaipur, the Sawai Man Singh Medical College issued posters and pamphlets advertising the injectable in a similar way, touting it as a "miracle" solution to unwanted pregnancy. The Stree Shakti Sanghatana, along with Saheli, Chingari and seven concerned individuals proceeded to file a writ petition in the Supreme Court, asking for a stay order on the Phase IV trials. The stay, however, was not granted, and the case is still pending in court.

In our Writ Petition, one of the main points we had stated was that for the safe administration of any invasive spacing method (a method which causes changes in the entire body), women need to be **screened and supervised** carefully by the medical team at regular and frequent intervals. In the case of hormonal

What is Net En?

Net En is a short form of Norethisterone Enanthate. It is a synthetic (artificial) form of the hormone progesterone. Net En, when injected into women, prevents pregnancy. The drug is in an oily solution which is injected deep into the muscle.

How does Net En work?
Synthetic hormones act by imitating the function of naturally occurring hormones. But by being artificially introduced at the wrong times, they disrupt the delicate natural hormone balance. The way in which Net En works (the mechanism of action) is still not fully understood. It is presumed that Net En prevents pregnancy in the following ways:

- It inhibits ovulation (production of the ovum/egg)
- It makes the cervical mucus thick and scant, thus creating a barrier for the sperm
- It makes the endometrium (lining of the uterus) less suitable for implanting a fertilized ovum (egg)
- It slows the rate of ovum transport to the oviduct (Fallopian tube)

Dosage
200mg injection every two months.

Who manufactures Net En?
Net En is manufactured by Schering AG, Germany, and marketed in India by German Remedies under the brand name Noristerat. One dose of 200 mg costs Rs 126.

Current Status in India
Approval granted in April 1986 for only private marketing.

Not approved for introduction in the government Family Welfare Programme.

What is Depo Provera?

Depo Provera is the brand name of Depot Medroxyprogesterone Acetate (DMPA). Like Net En, it is a contraceptive in the injectable form. It is also a progestogen – a synthetic (artificial) form of the hormone progesterone in a microcrystalline suspension.

How does Depo Provera Work?
The mechanism of action of Depo Provera is similar to that of Net En.

Dosage
150 mg injection every three months.

Who manufactures Depo Provera?
Depo Provera is manufactured by Upjohn Co., USA, and marketed in India by Max Pharma, India. One dose of 150 mg costs Rs 150.

Current Status in India
Approval granted in June 1993 for only private marketing.

Not approved for introduction in the government Family Welfare Programme.

supervised carefully by the medical team at regular and frequent intervals. In the case of hormonal contraceptives this kind of screening and supervision needs to be more frequent because of the number of **complications and side effects** that can arise. Given the state of the health services and the socio economic constraints existing specially in rural areas, we had voiced our serious reservations about the feasibility of introducing Net En into the rural health network and the mass Family Planning Programme. Most of these reservations still stand, in addition to new concerns.

In fact, the sustained opposition to Net En and Depo Provera has been for several reasons. They are hazardous, causing irreversible and serious damage to the entire body; they remain in the body even after the contraceptive is stopped; return to fertility is not assured; being provider-controlled, there is tremendous potential for abuse, especially in the context of a government-run population control programme.

INTRODUCTION OF INJECTABLES : IN WHOSE INTEREST?

The question which naturally arises is, why, despite its hazards, are policy makers intent on introducing Net En into the Family Welfare Programme? To understand this, we have to start by taking a look at contraceptive use in India. For the majority of Indian women, contraceptive use occurs within the framework of the government-run Family Welfare Programme, and is directly dependent on official policy decisions. Since the inception of the Family Planning Programme after independence, Indian women have been offered a "Cafeteria" of contraceptives to choose from. The "modern" methods of contraception included sterilisation, and spacing methods like the intra uterine device (IUD), the pill and the condom. Most of these methods have been targeted at women, who are held responsible for uncontrolled breeding. In addition to responsibility, women's need for birth control is also greater than that of men, since it is women who bear the brunt of repeated pregnancy and child rearing. Over the years, sterilisation continues to remain the method which the largest number of couples use. Despite much propaganda and outreach programmes, use of spacing methods is low. According to one estimate (UNFPA 1998), current use of contraceptives methods is as follows:

Percent Users by Method in India (1998)

Sterilisation	71.5
Any traditional method	10.5
Condom	6.3
IUD	6.2
Pill	5.1
Injectable	0.5

As is evident, sterilisation (female sterilisation, since male sterilisation forms only a small percent) is the main "modern" method preferred. While women do desire to space their children, they operate under several compulsions. Marriage is almost universal for Indian women. Although the average age at marriage for females has gone up to 19.6 years, there is tremendous pressure to produce a child immediately after marriage. Delaying the first child is an option exercised only by a minority of urban women with careers. Son preference ensures that she continues to reproduce until at least two sons are born. Fear of damaging or losing fertility in a social situation where fertility is highly valued increases reliance on traditional methods like lactational amenorrhoea (there is less likelihood of conceiving when a woman is breast feeding), periodic abstinence from sex etc. High infant and child mortality contributes to a feeling of insecurity about losing the ability to reproduce. Thus, the majority of women complete the desired family size and then go in for a permanent method like sterilisation. However, sterilisation after achieving a family size of 3-4 children, though it is an effective form of birth control for the individual woman, does not have a demographic impact on reducing birth rates.

For the Government then, the challenge is not only how many couples use contraception, but when. Thus, from a policy maker's point of view, spacing methods have a significant role to play in reducing birth rates. Long-acting contraceptives like injectables are "ideal" from this perspective because they have a high theoretical effectiveness, they are provider controlled, so women need not be relied upon to remember taking the pill, or keeping IUDs in place. Net En is highly unsuitable for women, but suitable for policy makers desirous of bringing down birth rates in a hurry. With population control high on the agenda, women's health and well being becomes low priority.

Population control policy in India

Recent measures like the Delhi Population Bill with harsh disincentives to having more than two children, and Amendments to the Panchayati Raj Act in Rajasthan and Haryana disqualifying those with more than two children from contesting elections, are but extreme manifestations of a systematic population control programme set in motion five decades ago.

In 1951, the Government of India launched, with much fanfare, 'the world's first official Family Planning Programme' with the objective of 'reducing the birth rate to the extent necessary to stabilise the population at a level consistent with the requirement of national economy'. Earlier, in 1941, the Population Sub-Committee of the National Planning Committee had already identified population growth as a *cause* of poverty. This false equation remains the basis of the population ideology of the government. The Programme, with the main focus of reducing birth rates, has been garbed in euphemisms - Family Planning was renamed Family Welfare in the 1970's, Safe Motherhood in the 1980s, and Reproductive Health in the 1990s. What ever the nomenclature, whatever the means, the objective has been to reduce numbers.

The perspective of population control is one that views human beings as a burden on the economy, as responsible for the destruction of the environment. This perspective echoes the dire predictions made by Malthus in 1798 - that man's (sic) propensity to beget would soon outstrip earth's capacity to produce food. However, 200 years later, Malthus has been proved wrong - the earth is producing more than enough food to feed all its inhabitants. In reality, widespread hunger and malnutrition exist due to lack of purchasing power and unequal distribution of resources. However, in its special sitting for the 50th anniversary of Indian independence, the Parliament resolved that, "a vigorous national campaign be launched ...to combat economically unsustainable growth of population, recognising that such growth lies at the root of most of our human, social and economic problems." (MOHFW 1998).

The Population 'Explosion' : Exploding Myths

The reasons for population growth are varied. It is well known that the plunge in mortality rates is also responsible for population growth. Further, for many decades, demographers have shown how birth rates are affected by the means of production i.e. whether it is a subsistence economy or an industrialised society; standard of living, women's status and education, family structures; women's entry into the labour force, etc. With a high infant mortality rate of 72/1000 and about 100 children below 5 years of age dying out of every 1000 (UNFPA 1998), how can families be assured that their children will live? It is well-known that a fall in infant mortality has a direct effect of lowering the birth rate. Contraception is only one of the variables which determines the birth rate. Rather than look at a holistic picture, however, planners have consistently chosen to focus on the provision of more and more effective contraceptives. Such a technological fix ignores the social, economic and cultural causes behind high population growth rate. For governments, population control is a more attractive development option than genuine challenges to the status quo such as land reform, expansion of social services or more equal distribution of resources.

International donor agencies – the International Monetary Fund, World Bank, United Nations Fund for Population Activities (UNFPA), United Stated Agency for International Development (USAID), United Nations Development Programme (UNDP) have identified population growth as one of the main factors for underdevelopment, and have channelled billions of dollars into population control. Besides creating conducive climates for investment in the Third World, population control is seen as a "solution" to the global environmental crisis.

Population growth has been held responsible for poverty, hunger and degradation of the environment. This distorted focus on the symptoms of poverty obscures the real roots of poverty – i.e. inequitable economic and social relations. The 'burgeoning numbers' in the Third World are viewed as rapacious consumers of limited global resources. The resource-heavy lifestyles and unsustainable development of industrial nations are seldom held responsible for depletion of natural resources. The populations of the Third World are blamed for the global environmental crisis. **Yet, each child born in America consumes**

as much energy as 3 Japanese, 6 Mexicans, 12 Chinese, 33 Indians, 147 Bangladeshis, 281 Tanzanians or 422 Ethiopians.

While refusing to acknowledge the impact of these skewed consumption patterns, the poor and marginalised, especially women, are seen as mindless breeders. The focus has been to 'motivate' people to become 'acceptors' of various contraceptives, from condoms and intra-uterine devices to injectables and implants in the 'cafeteria' approach. Planners have consistently chosen to ignore statistics that clearly show that 95% women in India have contraceptive access/knowledge (UNFPA, 1998). When the government propaganda of 'information, education and communication' failed to yield results, incentives and disincentives were marshalled to do the trick. And when this too failed to have any perceptible impact on growth rates, health functionaries, especially at lower levels, were coerced to recruit 'acceptors' by any means possible in order to fulfil targets.

With intensified efforts to bring down the birth rate came a shift towards long-acting, hormonal contraceptives with higher effectiveness rates, like implants (Norplant) and injectables (Net En and Depo Provera). These methods were also more invasive, with serious hazards for the women using them as well as for children conceived accidentally. A more concerning fact was that these methods carried with them a high potential for abuse.

Since policy makers had concluded that leaving the decision to the woman was not 'successful', they (the providers) would have to take control into their own hands. Active intervention of women's groups compelled the government to pay heed to the objections against hazardous contraceptives.

Repeated attempts to include Net En in the Family Welfare Programme

From the very beginning, Net En and Depo Provera have been the subject of much debate and resistance. Following the public attention on the unethical trials in Patancheru in 1986, questions were raised about the advisability of introducing Net En into the Family Welfare Programme. It appeared that Net En was placed on the back burner, while clinical trials on Norplant, the hormonal implant, hormonal vaginal rings and nasal sprays were set in motion. Lower dose injectables, and once-a-month injectables, combined estrogen-progestin preparations which had fewer side-effects, were also being researched. Yet, simultaneously, efforts were on going to register and introduce the injectables in the market. Moreover, the proposal to introduce injectables into the government FWP was not given up completely.

The Drugs Controller of India had given approval for the import and marketing of Net En by private practitioners in 1986. This fact was kept a closely guarded secret, and became known only in 1994, when Net En was officially launched in India for "social marketing". Once the US FDA approved Depo Provera for use as a contraceptive in the US in 1992, the DCI followed suit in 1993. Depo Provera was officially launched for "social marketing" in 1994. Women's groups responded with strong protests since the case against Net En was still pending in court, and the issues raised in the petition had not been satisfactorily answered by the government. Even the report of the Phase IV (Programme Introduction) Study on Net En was not public – and in fact has not been made available till date, despite repeated requests. The findings of this study have a direct bearing on the introduction of Net En into the FWP.

Activists also filed another court case asking for a ban on Depo Provera. The approval for marketing of these drugs led to a situation where indiscriminate over-the-counter sale of these hazardous drugs was rampant. Another disturbing development was the involvement of NGOs in distributing these contraceptives through their health programmes. Yet, the real danger – of mass use of injectables in the FWP was still kept at bay. However, it was apparent that the government was still making moves to include injectables in the FWP.

In 1992, in the light of National Family Health Survey (NFHS) data which showed that only 5.5% couples use reversible modern methods of contraception, the Ministry of Health and Family Welfare in its "Action Plan for Revamping the Family Welfare Programme in India, "decided to place more emphasis on reversible methods, especially "for younger couples with high fertility potential." In total disregard of the serious questions raised

about the safety of Net En, and in the face of a strong national protest against injectables, the Ministry recommended in the Action Plan that injectables "be introduced under the programme, initially under controlled conditions and gradually on a wider scale." In this move, the government was backed by the World Bank, under whose recommendation the Government was launching the revamped Reproductive and Child Health Programme. Says the World Bank, "Given the need for safe, effective, and convenient reversible methods, there seems to be every reason to phase this method into the programme, with the necessary training, surveillance and monitoring by the ICMR and medical colleges." (Measham and Heaver, World Bank, 1996). Such a recommendation is highly irresponsible, since World Bank, should be well aware of the state of the

NET EN AND DEPO PROVERA : SOME SIGNIFICANT DATES

1953 Karl Junkman and colleagues in Germany develop injectable progestins

1957 Schering AG, Germany synthesises Norethisterone Enanthate

1971 Norigest withdrawn from market after pituitary and breast nodules were found in rats injected with Norigest. Investigation reports concluded that findings in rats were not applicable to humans, and after further clinical testing, the drug was reintroduced

1981 Toxicology Review Panel of WHO declares Net En safe for use in FP programmes

1984 Federal Health office of Germany decides to restrict approval to Net En only for use in women who cannot use any other contraceptive

1986 Drugs Controller approves Net En for social marketing. This information withheld from public

1986 Petition filed in Supreme Court for stay on Phase IV trials, by Stree Shakti Sanghatana, Saheli, Chingari and seven concerned individuals

1994 Net En launched in India by German Remedies

1994 Jagori, AIDS Awareness Group and individuals file Intervention application, to include Net En as bannable drug in Drug Action Forum case in Supreme Court

1999 Still not approved for use in FWP in India.

1950s Upjohn Co., USA, developed Depot Medroxyprogesterone Acetate (DMPA) and gave it the trade name Depo Provera

1963 Studies begin of Depo Provera as a "birth control shot"

1967 Upjohn first applies to USFDA for approval to market the drug as a contraceptive in the US. Approval denied

1978 USFDA once again denies approval of DMPA as a contraceptive: Risks outweigh Benefits.

1981 Toxicology Review Panel of WHO declares Net En safe for use in FP programmes

1983 At a special FDA Board of Inquiry Hearing, the National Women's Health Network, USA, opposes the approval of DMPA for contraceptive use in the US

1984 USFDA yet again rejects Upjohn's application for approval of DMPA on safety grounds

1984 Department of Health, UK finally grants license for long-term use of DMPA, as a "last resort".

1985 Women's Centre, Bombay and Medico Friend's Circle become parties to court case against Dr CL Jhaveri, Chairman of Indian Association for Fertility and Sterility, who had applied for license to import Depo Provera from Belgium

1992 USFDA approves DMPA for contraceptive use in the US

1993 Drugs Controller of India approves use of Depo Provera by private practitioners

1994 Depo Provera launched in India

1994 Jagori, AIDS Awareness Group and individuals file intervention application, to include Depo Provera as a bannable drug in Drug Action Forum case in Supreme Court

1999 Still not approved for use in FWP in India.

government health services in India, and the complete lack of monitoring and follow up.

In a recent workshop held in Mumbai from Dec. 17-18, 1998 on "Improving Contraceptive Choices in the National Family Welfare Programme" by the Institute for Research in Reproduction, an ICMR Institute, it became apparent that the government is once again eager to introduce Net En into the National Family Welfare Programme. Minutes of the workshop clearly note that Forum for Women's Health, CEHAT and other women's groups and health groups in Mumbai strongly protested against this proposal. The groups raised issues about potential hazards, as well as the potential for abuse. Their letter of protest states, "There has been a long struggle of women activists and health activists to bring accountability, transparency and sensitivity into this Programme in order to protect women from coercion and deception.....Inspite of this, we find that the objective of the workshop is to *recommend* or otherwise, the introduction of injectable contraceptives in a state-run national programme."

The recommendations of this meeting state: "Taking into consideration the available infrastructure at Primary Health Centres; the need for counselling; screening and appropriate back-up for medical interventions; injectable contraceptives should preferably be introduced **selectively in suitably equipped centres and hospitals.** It is stressed that the introduction should be **gradual** with emphasis on **good clinical practice and rigorous post-introduction surveillance of the side effects and patient care."**

This time round, it appears that the Government is following the precepts recommended by the World Health Organisation (WHO). In 1993, the WHO presented a three-stage strategy for the introduction of contraceptive methods. Stage I – the assessment of user and programme needs; Stage II – service delivery and introductory research; and Stage III – the use of the findings of the research for decision-making, policy, and planning.

The WHO has apparently been affected by the world-wide campaign against injectables, and is determined to take a lesson from history. According to the WHO, "There are sufficient lessons which suggest that without a systematic approach to introduction, expensive mistakes may be may which may be difficult to correct later. For example, a method may earn a bad name and a persistent negative image. A significant initial investment is essential for the long-term viability of a method."

In what seems to be Stage I of the WHO strategy, the Government of India and the UNFPA in August 1996 undertook a Programme Review and Strategy Development (PRSD) exercise to "facilitate Government efforts to broaden its approach to health care and to bring population issues and concerns into overall development initiatives, with special emphasis on the needs of women." One projection predicts that there will be a clear shift towards spacing methods, among which 5.5% users of contraceptives will be using injectable contraceptives. The basis of the prediction of the shift is unclear. Whether user perception, or forces other than the women concerned – drug companies and international funding agencies. It must not be forgotten that vast sums of money are involved.

Use of Injectables : Obviously no world favourite!

Although the first injectables were developed soon after oral contraceptives, "except in a handful of countries, few women use injectable contraceptives compared with other methods." (Population Reports, 1995). In **developing countries**, about 3% of married contraceptive users use injectables (DMPA, Net En, monthly injection). By comparison, 36% of married contraceptive users rely on voluntary female sterilisation, 25% on IUDs, 12% on oral contraceptives, 9% on vasectomy, and 6% on condoms.

A few countries offer a contrast to the world pattern. In the countries with the greatest use of injectables – Indonesia at 15% of married women of reproductive age; and Thailand at 12% - injectables have been widely available for more than 15 years (p.5)

Among the **developed countries** the highest prevalence of injectable use is in South Africa and New Zealand (at 23% in South Africa – as a whole, but is 27% among blacks and only 3% among whites; while for New Zealand, figures are not given.) Surveys in other developed countries do not mention injectables, or else include them among the "other" methods, indicating a very low percentage of usage (Pop Reports 1995).

HEALTH HAZARDS DUE TO NET EN: SUFFICIENT EVIDENCE

Net En, a progestogen (synthetic progesterone) is administered in a high dose injection. Since it acts on the higher brain centres, the action of Net En is not localised to the reproductive system. The effect on the hypothalamus and pituitary gland also results in a disruption of several other bodily systems.

Another point to be kept in mind is that very **high doses** of the hormone are given. The contraceptive effect of one injection of Net En 200mg lasts for approximately 2 months.

Earlier studies by ICMR, however, have found that 20mg Net En given monthly is adequate for contraceptive effect. The WHO multicentre study suggests that Net En 200mg given every 84 days is as effective and has fewer side-effects than the 60-day regimen. However, since it is not possible to predict how an individual woman responds to the drug, from the health provider's point of view, it is more convenient to raise the threshold level and give a higher dose to all women. Giving a higher dose than necessary is especially worrisome in the light of the fact that **drug accumulation** in the body occurs with Net En.

Reported studies of clinical trials on Net En in India and other countries show a high incidence of potential hazards which have been detailed in the following section:

1. Menstrual Disturbances

Menstrual disturbances are the most common side-effect of Net En. High doses of progesterone such as the Net En injectable inhibit the secretion of estrogen and other hormones necessary to maintain the normal menstrual cycle. Therefore, it can cause a major disruption in the menstrual cycle. This is exhibited in the form of what is termed **menstrual chaos,** i.e. irregular bleeding, spotting, changes in the frequency, duration and amount of blood loss, heavy and prolonged bleeding or a total absence of bleeding (amenorrhoea). According to the WHO, with Net En "approximately one half of the users report at least one normal cycle during the first year." (WHO 1982) In other words, with Net En users, approximately **one half of the women did not have even one normal menstrual cycle** during the first year.

In India, the ICMR Phase III trial found that as high a percentage as **90% had either excessive bleeding or amenorrhoea** (absence of bleeding). It is important to note that the incidence of menstrual abnormality increases with each successive dose of the injection.

In 1982, the WHO, admitted that, "Little is known about the basic mechanisms of bleeding distrubances, especially those related to steroidal contraception." The situation has not changed much in the intervening years. As recently as 1992, the WHO continues to admit that unpredictable bleeding - a major side-effect of progestogen-only contraceptives - is poorly understood. Till now, there has been no effective treatment worked out to manage the bleeding problems. Scientific bodies recognise only the effect of unpredictable bleeding vis a vis the social and cultural nuisance, but dismiss lightly the effect of such disturbances on the health of women users, which ought to be the fundamental concern. Yet, in a country like India, where 70% women are reported to be anaemic, even a minor increase in blood loss can be a life and death issue.

Bleeding disturbances associated with Net En are not mere changes of normal menstrual physiology. In other words, they are not a mere increase or decrease of a normal menstrual pattern. Rather, they indicate alterations that are taking place at several other levels in the body. A few hypotheses put forward to explain the menstrual abnormalities arising with progestin-only contraceptives indicate the serious disturbances that could be arising in other body mechanisms.

Lipschutz (1950), Danforth (1964), Irey et al (1970) and Irey, Norris (1973) have shown that such contraceptives cause important changes in the lining of the blood vessels in both animals and humans, not only in the endometrium, but in other organs as well. The significance of this explanation is that this will make women **prone to thrombo-embolisms** (blood clots) which could lead to stroke and heart attack.

Another hypothesis put forward by Paton et al (WHO Symposium on Endometrial Bleeding and Steroidal Contraception, Geneva, 1979) is that the bleeding abnormality may be due to a **disruption in the ability of blood to coagulate**. This means that women suffering from heavy and prolonged bleeding could continue to bleed for a very long time. In fact, one of the studies mentioned by ICMR in the report on Return of Fertility (Dhall et al 1979) shows that in one of the two study subjects "following the injections of Net En the menstrual pattern was grossly disrupted. She had excessive bleeding which could be brought under control only by repeated dilatation and curettage " (Indian Journal of Medical Research, Vol. 69 Jan 1979). It is significant to note that this extreme measure had to be taken after the woman had been given only 3 injections of Net En, whereas women wanting to use Net En as a spacing method would be receiving 12-18 injections.

Yet another explanation (Contraception, Vol 25 No 1, 1982) offered is that the bleeding disturbances could be due to histamine release as occurs in **allergic reactions** which result in gaps forming in the inner lining of the blood vessels, leading to leakage of blood cells into the tissue. That women do suffer from allergic reaction to Net En is admitted by the manufacturer, Schering, who list it as a side-effect. **Anaphylactic shock**, is in fact a life-threatening situation necessitating emergency medical care.

Thus, the heavy and prolonged bleeding which could be experienced during the first few months on Net En use can definitely produce both life-threatening complications and long-term irreversible effects for women users.

Another serious menstrual disturbance arising from Net En use is **amenorrhoea**. According to Goodman and Gilman, a standard textbook of pharmacology, "Continuous administration of a progestin in sufficient doses abolishes the cycle for as long as it is given and leads to ovarian and **endometrial atrophy**." There is no evidence to show whether or not these changes will be reversed naturally or not. Studies in India have shown that women who experience amenorrhoea also experience a greater delay in return of fertility.

Hence, it is apparent that menstrual chaos cannot be regarded merely as a "minor side-effect" or inconvenience. It could be a serious health hazard for women.

2. Atherosclerosis (thickening of blood vessels) and Cardiovascular Diseases.

Atherosclerosis is a major cause of heart attack, stroke and other vascular disease. Progestin-only injectables change cholesterol metabolism in ways that are suspected to increase user's risk of atherosclerosis (thickening and hardening of arterial walls). Most studies find that DMPA and Net En increase levels of low-density lipoprotein (LDL) cholesterol and decrease levels of high-density (HDL) cholesterol. LDL cholesterol has been linked to atherosclerosis, while HDL cholesterol reduces the risk of atherosclerosis." (Pop Reports 1995)

Other studies (Fahny K et al 1991; and Kongsayreepong R et al, 1993) also indicate a correlation between progestin-only injectables and the potential increase in the risk of atherosclerosis.

Another study by Enk et al (1992) on effect of Net En and DMPA on serum and lipoprotein lipids declared, "Thus our findings might indicate an adverse effect in this respect of long term treatment with these progestins, particularly with NET."

It is to be noted that under the sub heading "Clinical Implications", Population Reports K Series, 1995 states: "Because of the effect of progestin-only injectables on cholesterol levels, a group of experts assembled by WHO recommends that women with severe vascular disease (such as severe hypertension, a history of stroke, or ischemic heart disease) or with diabetes involving vascular complications should not use these injectables unless other methods are not available, or, in a provider's careful clinical judgement, other methods would not be acceptable. Women who develop these conditions while using progestin-only injectables or who develop recurrent headaches with focal neurologic symptoms should see a doctor or nurse and switch to a non-hormonal contraceptive method because there is some concern that such headaches sometimes progress to strokes."

3. Thromboembolism

(Development of a blood clot at unexpected sites resulting in damage to heart, lungs, brain, etc.)

There are some data indicating that use of Net En affects blood coagulation, and therefore the risk of thromboembolism which could cause life threatening emergencies such as stroke and heart attack.

A clinical investigation was undertaken by Derham RJ and Buchan PC (1989) on the effects of short-term administration of synthetic sex hormones on blood viscosity and clotting. Estrogens and progestogens, singly or in combination, were found to cause a rise in blood viscosity, which can make a women prone to thromboembolism.

The National Institute of Nutrition, Hyderabad, an ICMR institution, initiated and abandoned a study of Net EN in women volunteers because one of the recipients developed thromboembolism (Annual Report 1992-93, NIN, Hyderabad) at even a low dose (20mg). And yet, the contraceptive dose in the present Net En formulation is ten times that amount.

4. Osteoporosis/Loss of Bone Density

Osteoporosis results in bone fractures, weakening and bending of bones and hence is associated with extensive morbidity (illness).

A New Zealand study (Pop Reports K series 1995) found a significant difference in the bone density of users of progestogen-only injectables (DMPA). The USFDA considered the findings of this study serious enough to take a number of steps including asking Upjohn, the manufacturer of DMPA, to collect more information on this issue and to provide an informed consent document outlining the possible link between DMPA and loss of bone density (Contraceptive Technology Update 1993).

Since Net En is also a progestogen-only injectable, it is clear that the risk of potential needs to be specifically ruled out, and yet, there are no specific studies on the effect of Net En on bone density. The fact that drug accumulation takes place with Net En use is of special concern with regard to loss of bone density, raising a question mark about the extent of reversibility of this side-effect.

This issue is of great significance in India where the bone density among women is likely to be low, and therefore a 7-10% decrease (as reported in the New Zealand study) may increase the incidence of bone fractures. In fact, according to a hospital-based study in Hyderabad on incidence of osteoporotic fractures in women (Shatrughna V, 1998), the frequency of osteoporosis leading to fracture was significantly higher in Indian women as compared to reported figures in the US. This incidence was higher in women who had delivered their first child at an earlier age. In the Indian context, the loss of bone density and the USFDA warning need to be taken seriously because nutritional deficiencies, including calcium deficiency, which contributes significantly to osteoporosis, are widespread in women, and early pregnancy and childbirth are the norm, hence prolonged Net En use may contribute to the development of osteoporosis.

5. Weight Change

Most users of injectables gain weight. While this pattern was found in Indian women as well, Indian studies have found that a significant 2-4% of women have lost 5 kg or more of weight.

Most of these studies give an average weight of women at the time of enrolment in the study, and this is usually around 45 kg. According to ICMR, this is the average weight of Indian women from the low income group (ICMR Bulletin Vol.11 No.12 Dec 1981).

Two studies mention the range of weight: In one study the recruited women weighed 30-60 kg; and in the other 36-73 kg. In ICMR's Phase III trial, almost one-third of the 2388 women recruited weighed 40 kg and below.

Hence, for the average weight of 45 kg, a loss of 5 kg is a loss of more than 10% of a woman's body weight. For a woman of 35 kg, this would be a loss of about 14% of her body weight. Such a drastic loss of weight in women who are underweight and malnourished to begin with can have disastrous consequences like:

* Increased vulnerability to infections
* More fatigue, decreased ability to work
* If pregnancy is desired, not only the mother, but even the infant is affected.

6. Other Metabolic Changes

Changes in Carbohydrate Metabolism

Chowdhary et al reported a rise in blood sugar level which was significant and which remained elevated throughout (International Journal of Fertility, 1987, May-June 32(3).

Changes in Tryptophan Metabolism

The ICMR study using 20 mg monthly injectable Net En (Contraception Vol. 23 No.1) found aberrations in the tryptophan niacin pathway. Changes in tryptophan metabolism have been considered to be of importance in explaining a few of the neuro-psychiatric symptoms experienced by some women while taking oral contraceptives. The physiological implications of the altered tryptophan metabolism are : depression, headache, loss of libido (sexual desire), changes in mood and sleep disturbances.

Decreased sexual desire, painful sexual intercourse, headaches, dizziness, depression, fatigue and abdominal distension are some of the effects of Net En. These are dismissed as being of no serious medical significance. However, from the woman's point of view, these effects can affect quality of daily life adversely. Information that Net En could possibly cause these effects may lead many more women to make a conscious choice against the injectable.

7. Return of Fertility

According to the package insert of Net En, " Following discontinuation, normal ability to conceive usually returns about 4-5 months after the last injection. If a physiologic cycle pattern fails to develop within this period of time, appropriate treatment is indicated in women who want children." (emphasis added)

In other words, as per the manufacturer, such long delays are not usual, and such women are in need of treatment to restore fertility. This amounts to a ridiculous situation of first giving women a contraceptive and then treating them for impaired fertility created by the contraceptive.

ICMR acknowledges that, "Adequate information about the return of fertility following discontinuation of a method is crucial for promoting a particular contraceptive as a spacing method." (Contraception 1986 Vol. 34). Yet the 'Return of Fertility' study by ICMR published in 1986 did not produce very reassuring results. Significant findings of this study were:

1. Of 69 women who had stopped using Net En because they wanted to get pregnant, only 72.5% had conceived at the end of I year, the median time for conception being 7.8 months.
2. Fertility returned faster and in more women who discontinued IUDs even after 3 years of use, than it did in women who discontinued Net En after a minimum use of 6 months.
3. In the sub-group of ex-Net En users who had stopped using the injectable due to amenorrhoea (stoppage of bleeding), 49% had failed to conceive at the end of 1 year. This is a startlingly high figure especially when we consider that most women tend to become amenorrhoeic over a period of time with Net En use.

In the above mentioned study, ICMR did not follow up women for 2 years, so we will never know whether they ever conceived or not.

The delay in return of fertility in ICMR's study is borne out by other data as well. The largest study of return to fertility among users of DMPA conducted in Thailand, found that women conceived 9 months on an average after the last injection, or 5.5 months after discontinuing. By comparison, OC (oral pill) users conceived on an average 3 months after discontinuing and IUD users 4.5 months after discontinuing. (Population Reports, 1995).

This information is highly significant from the point of view of a woman wanting another child. After using Net En for 6-8 months, a woman is hardly likely to find a delay in return to fertility of 1.5 - 2 years acceptable. One of the reasons women do not like using spacing methods is because they fear it will impair fertility. In the context of a very high infant mortality rate of 72 per 1000, return to fertility is one of the most crucial criteria used by women to judge the acceptability of a spacing method. Moreover, the long delay in return of fertility can have disastrous consequences for women, especially younger women, who are under tremendous pressure to bear children, especially sons.

8. Cancer Risk

The risk of developing cancer with the use of DMPA and Net En has been a highly controversial issue for several years.

These questions have arisen because two species of laboratory animals – beagle dogs and rhesus monkeys – given large doses of DMPA or Net EN, usually for long periods, have developed benign and malignant tumours of the breast or endometrium (lining of the uterus). It is worth remembering that Net En was withdrawn from the market in 1971 because of the finding that Net En caused pituitary and breast tumours in rats.

Toxicological studies which involve use of large doses of the drug, had shown that Net En is a definite carcinogen in animals. The findings were as follows:

In rats: Mammary tumours, pituitary tumours and benign and malignant hepatic (liver) tumours.

In beagles dogs: Benign and malignant mammary tumours.

In monkeys: Mammary lesions and endometrial tumours.

Mammary lesions (benign and malignant) were found in all three types of animals.

Since then, according to Population Reports, several studies have been done in humans to assess the risk of cancer. The largest was the WHO Collaborative Study of Neoplasia and Steroid Contraceptives, conducted from 1979 to 1988 in 10 countries mainly focussing on DMPA. It examined the risk of cancer of the breast, cervix, endometrium, ovary and liver among users of various hormonal contraceptives in Kenya, Mexico, and Thailand among other countries. The results of the WHO study show a somewhat increased risk of cervical cancer, liver cancer and breast cancer in young women and also in women in the first few years after they started to use DMPA.

Both the WHO study as well as a well-controlled study in New Zealand found that "Young women faced an increased risk (of breast cancer), as did women in the first few years after they started to use DMPA. An analysis of combined data from the two studies found that the increased risk was mainly among women in the first five years after they started DMPA (a statistically significant relative risk of 2.0). Most of these recent users were young women." (Population Reports, Series K, 1995.)

While ICMR interprets these findings of the WHO study to mean no risk of cancer, other researchers believe that the controversy over cancer risk is still not over. An analysis of the WHO data by Skegg DC et al (1995) concluded that there are still unresolved issues about the relation between DMPA and risk of breast cancer, and pointed out that the relative-risk estimates were higher in certain sub-groups, notable a Relative Risk of 2.0 in women who had started use of DMPA in previous five years.

Staffa JA et al, in their epidemiologic review conclude that, "Since no clear evidence of a relationship between progestins and breast cancer exists, scientists need to conduct further studies. These studies should concentrate

on women in potentially high risk groups which include those who have been exposed extensively to hormones before 25 years of age.

Perhaps the controversy over cancer risk will not be over for a long time to come. According to Population Reports K series 1983: "Studies in humans can gauge risks directly. For a number of reasons, however, epidemiologic studies may not always produce conclusive results, especially when sex hormones and cancers of the reproductive organs are being studied:

- Many behavioural and genetic factors influence the risk of reproductive cancers. For example, age at first birth affects the risk of breast cancer. These factors need to be accounted for. This may require a large population and a complex experimental design.
- For many cancer-causing agents, years or even decades may elapse between exposure to agent and detection of the cancer. Therefore studies may need to focus on people exposed to the drug many years ago.
- Risks might be undetectable after short-term exposure but substantial after long-term exposure. If there are few long-term users, studying their risks is difficult.
- With rare forms of cancer, it may take decades to gather enough cases for adequate epidemiological analysis.
- Even with more common cancers, such as breast cancer, large, long-term, prospective studies that could determine the incidence of cancer in those who have used hormonal contraceptives and those who have not are extremely difficult and expensive to conduct.

Yet, despite decades of use of Net En on women, little information is available on possible cancer risks.

9. Adverse effects on the foetus

The foetus can be exposed to contraceptive hormones (Net En, DMPA etc) in the event that:

- The injectable fails to prevent pregnancy
- A woman receives an injection(s) while pregnant
- A woman becomes pregnant after discontinuing the injectable but hormones (Net En or DMPA) are still in her bloodstream (Pop Reports K Series, 1995 pg. 13)

Animal studies conducted show that synthetic progestins (NET would be included in this category) appear to be teratogenic (i.e. causing malformations in the foetus) in mice, rats, rabbits and rhesus monkeys..... Norethindrone (parent compound of Net En) alone is teratogenic in mice, rat, dog and monkey. The teratogenicity was primarily manifested as masculinization of the female foetus. (Teratology 27:215-222, 1983)

With respect to teratogenic potential in human beings, "Gynecologic Endocrinology" 1980 and "Drugs in Pregnancy and Lactation: A Reference Guide to Foetal and Neonatal risk," 1983, both state that there was masculinization of the female genitalia. The latter reference also cited increased risk of congenital malformation.

A Thai study found, "Children of former users of DMPA were 2 times more likely to have peripheral limb defects than children of women who had used no contraception." (Pop Reports K Series 1987).

Another Thai study found a link between DMPA exposure during gestation and the outcome of pregnancy. Exposure to DMPA within one month before or after conception almost doubled the risk of low birth-weight and, perhaps partly as a result, more than doubled the risk of neonatal death. (Pop Reports K Series 1995)

A Chilean study found that a higher percentage of 4-year old children of DMPA users weighed below average than did non users' children." (Pop Reports K series 1987).

In the face of insufficient information on the possible teratogenic effects of Net En, the possibility of risk to the foetus cannot be ruled out.

The package insert of Net En states, "individual cases of virilization of the external sex characteristics of female neonates were also described following administration of preparations containing norethisterone. Since it cannot be stated unequivocally that such a situation will not occur under Noristerat, injection during pregnancy – and particularly in the sensitive phase after the first month of pregnancy – is contraindicated."

The complacency regarding risk of foetal exposure to injectables stems from two arguments : (a) that contraceptive failure with injectables is low and (b) the risk can be minimised by ensuring that the woman is not pregnant when given an injection. Both these premises do not hold true in Indian conditions. Indian studies have shown higher contraceptive failure rates and the difficulty/inability in ruling out pregnancy at the time of giving the injectable contraceptive. Indian studies have also shown the possibility of women deliberately taking the injection in the belief that it will cause an abortion.

The difficulties in diagnosing early pregnancy have already been stated. The high possibility of women getting pregnant between injections has also been described. With the possibility of serious adverse effects on the foetus, the necessity to prevent such an occurrence cannot be over-emphasised. These factors combine to greatly increase the risks of foetal exposure in the Indian situation.

The potential hazards of injectables should be considered in the light of the fact that contraceptives are used by healthy young women in the prime of their lives. Thus, risk-benefit assessments of the kind carried out for drugs to treat diseases, cannot be applied to contraceptives. Pregnancy is not a disease, and contraception not a cure. Hence, we have to keep in mind that when a healthy woman uses a contraceptive, the degree to which side-effects and potential hazards are acceptable varies from a situation where she is taking a drug to cure an illness. When large numbers of the female population are ill due to morbidity induced by a contraceptive drug, the cost to society in terms of human resources is immense. This factor needs to be given serious consideration while promoting Net En as an "ideal" contraceptive.

"Claims" of Net En : The True Story

Net En is safe

Net En has many short-term and long-term hazards – some of them life threatening.

Net En is effective

Effectiveness depends on the timing of the injection, and timing of repeat injection. If women drop out, or miss out one or two injections, the effectiveness will be lower.

The body weight of the woman user also affects the effectiveness. An ICMR study found that thinner women had more chances of becoming pregnant even with the injection.

The mode of delivery i.e. injection is convenient. No hospitalisation necessary

Great skill needed to ensure effectiveness.In context of HIV/AIDS, "convenience" may be dangerous, with unsterilised needles and multiple use of syringes the norm in most public health set-ups.

To ensure safety of Net En, very close monitoring is necessary. It is not sufficient to give the injection and forget about the woman for the next two months. Detailed records of medical history and regular monitoring to check for danger signals like headaches and blurred vision, is mandatory.

Net En is not related to coitus, and therefore more acceptable

The clinical approach of popping pills or giving injections, and the total separation of contraception from sexual activity alienates a woman further from her body. The women's movement has attempted to evolve a closer understanding of the body in order to gain more control over our bodies, and our fertility.

Net En is private. The husband or family need not know that a woman is using a contraceptive.

While it is true that many husbands and families object to a woman using a contraceptive, Net En is no solution to the unequal power balance within the family. Only genuine changes in relationships will contribute to women having greater control over their fertility.

Net En is cost effective and hence, ideally suited to Third World health programes

The cost of each injection being Rs 126, is prohibitive - for individual women, as well as for the government. When infrastructure costs are factored in – of personnel and equipment for ruling out contraindications, administering the injection, monitoring and follow-up, the costs shoot up further. The cash-strapped government can ill afford injectables, if it is going to do a satisfactory job of administering them properly.

SAFE DELIVERY: IS IT POSSIBLE?

At the outset, it should be noted that Net En is a Schedule H drug which can be prescribed only by a Registered Medical Practitioner. Net En is not a contraceptive of first choice for the majority of women. It cannot be presented as a contraceptive of first choice, on par with other spacing methods such as OCs or IUDs as is being done by the ICMR and MOHFW. ("Choices for Spacing" MOHFW 1993).

1. Indications for Use : Only limited to some

In the first place, it is essential to establish who can use Net En.

- According to the German Health Authority, the Federal Institute for Drugs and Medical Devices (BfArM), Noristerat is licensed in Germany as a contraceptive agent for "Long-term prevention of conception (2-3 months) only in women with normal bi-phasic cycles for whom other methods are unsuited, e.g. due to disturbed gastrointestinal absorption, oestrogen intolerance or unreliable administration."

- According to the package insert of Noristerat issued by German Remedies Limited, India, "Noristerat is particularly suitable for women who cannot take oral contraceptives regularly or who do not tolerate them well. Noristerat should only be administered to women with a history of normal (menstrual) cycles."

- According to the document presented by German Remedies at the IRR meeting held in Mumbai, Net En is suitable for women who forget and cannot take pills (Ocs) regularly; have frequent gastro-intestinal tract disturbances; cannot take estrogen and so combined Ocs; cannot tolerate IUDs; and have a partner undergoing vasectomy."

- According to WHO, "a large proportion of the clients in many family planning clinics are breast feeding women. The non-hormonal methods of contraception should be the first choice for them." (Contraception 1994: Vol.50 July pg.36). In India, about 50% of women seeking contraception are breast feeding.

Several gynaecologists interviewed by Saheli Women's Resource Centre, are of the opinion that women do not ask for a particular contraceptive but need to be advised about a suitable method. ICMR needs to unequivocally clarify that Net En is not a method of first choice for certain categories of women failing which, it could lead to an abuse of the drug. It will also militate against all concepts of informed choice by women.

2. Contraindications : Careful ruling out essential

The definitions given above are only broad indicators. Before recommending the use of Net En, enrolling a subject for a trial or administering it, it is crucial to identify those women for whom Net En is **not** suited for. The widely accepted contraindications for use of Net En are presented in the table given alongside.

Most of the above are serious conditions which are difficult to diagnose in the absence of sophisticated medical equipment and skilled personnel. In the absence of these facilities, in a country like India, the diagnosis of the above is left to the clinical acumen of the examining doctor. In the absence of a physician, health workers are expected to use a checklist to screen women.

Each level of dilution in the ability to screen for contraindications only places women at greater risk.

Therefore, it is clear that the administration of Net En by health personnel who are not Registered Medical Practitioners is a clear case of medical malpractice and violation of basic human rights.

(c) Injection Technique

Careful injection technique ensures that the full dose is absorbed at the right rate and thus is fully effective. Because the drug is in the form of a thick, viscous fluid, injection requires more skill on the part of the provider, and is more painful for the woman user, thus reducing acceptability.

With Net En, warming the vials to body temperature thins the viscous solution and makes it easier to draw completely into the syringe. With all injectables the injection should be given in the muscle because absorption may be too slow if the provider injects into fat. In contrast, massaging the injection site accelerates absorption and thus also should be avoided.

Moreover, deep intra-muscular injections require more skill on the part of the provider, because the drug has to be injected into the muscle and not into the layer of fat. The necessity to use a longer, thicker needle gives rise to a higher possibility of injection abscess.

In addition, the package insert of German Remedies states, "it is advisable to place a plaster over the injection site after the injection to prevent any reflux of the Noristerat solution." Further it states, "Experience shows that the short-lasting reactions (urge to cough, coughing fits, respiratory distress) which occur in rare cases during or immediately after the injection of oily solutions can be avoided by injecting the solution extremely slowly." Since it is not possible to predict such "rare cases", it would be essential to administer the Net En injection extremely slowly to every user.

It is to be noted that in ICMRs Phase III trial, there was a high failure rate in the first 6 months of use. ICMR states, "Certain difficulties in administering the drug, such as the leakage of Net En solution from the syringes was reported in general and specifically from the centres where maximum pregnancies were reported."

(d) Prevention of Infection

Increasing use of injectables challenges programmes to prevent transmission of the AIDS-causing HIV virus, hepatitis B, and other blood-borne infections to women users, clinic staff, and the public through contaminated needles and syringes.

According to the Population Report 1995, "Training must address common mistakes that providers make – for example giving several clients injections with the same needle and syringe without sterilising or disinfecting the equipment. Infections may also be transmitted through improper storage of vials containing several doses of injectable".

The stupendous costs of using disposable needles and syringes in a health service system like India cannot be overemphasised. The apprehension that short cuts to reduce costs (for eg. reusing needles etc.) are likely to be taken, is a very real one. In fact, according to Pop Reports K series 1995, "Without close supervision, however, some (health workers) may be tempted to sell the equipment or else reuse it or dispose of it inappropriately." Needless to say, the impact of such actions on public health could be absolutely disastrous.

4. Counselling : Additional care called for

The USAID Technical Guidance Working Group to device screening procedures considered counselling essential and mandatory for safe use of progestin-only injectables.

According to Population Reports K Series, 1995, counselling for injectables is crucial in order to make an informed choice of the method. Injectables pose a number of difficult counselling issues:

The range of side-effects

Providers must make time to discuss the range of side-effects with the potential users. Minor side-effects as well as risks of serious side-effects must be communicated to the user in a simple language which she is able to understand. Time and space must be created to answer any queries

that the user may have.

- Changes in bleeding patterns

Women considering injectables must be informed that their menstrual patterns could be affected in different ways – frequent bleeding/spotting, irregular bleeding, or absence of bleeding (amenorrhoea). Women may need extra counselling support to get through the first few months, and need to understand that it may take up to six months for bleeding to return to normal after stopping Net En.

- Cancer Risk

Women must be informed that the risk of cancer with Net En use has not been ruled out.

- Delay in Return of fertility

No woman should use DMPA or Net En without knowing that she may have to wait to become pregnant after stopping. Providers need to make it clear that time to conception cannot be predicted with certainty for any woman.

- Returning early or late for injections

To ensure informed choice, providers should tell clients that they may return a little early or a little late for an injection and still be protected against pregnancy.

The possibility of getting pregnant if injections are not taken on time must be stressed, especially the fact that the risk to the foetus if it is exposed to Net En is not fully known. Women must also be told that Net En will not cause an abortion.

Aside from counselling on all these aspects of injectables, service providers also need to know how to take detailed history to rule out contraindications, and also monitor serious side-effects.

In the Indian situation, it is clear that service providers like ANMs, social workers, and para-medics do not have the time or training to carry out detailed counselling sessions with each potential user. Yet, the importance of adequate counselling cannot be over-stressed.

According to a Report by the UNFPA (1997), "Contraceptives are less popular because of lack of knowledge about them; a fear of side-effects; the service providers' failure to inform clients of alternative choices (due to pressure to meet targets); near absence of male involvement in family planning; son preference (this applies to any family planning method); and inadequate attention to the quality of care, resulting in minimal efforts at pre-acceptance counselling and post-acceptance follow-up."

5. Training : A necessary qualification

Programmes that are introducing injectables have devoted one or two weeks to training about injectables. To train providers who do not know how to give injections may require two weeks. As we have seen earlier, the technique of injecting Net En is particularly linked to its effectiveness. Providers should know how to manage two rare but dangerous side-effects of injectables: anaphylactic shock, a potentially fatal reaction to an injected drug, and heavy bleeding. Training programmes must require trainees to demonstrate the skills needed to provide injectables – for example, counselling and giving the injection. Such competency-based training improves on training programmes that simply measure increases in knowledge. (Pop Reports 1995).

Training health workers should necessarily include:

- The manual skills to deliver the services i.e. administering the injection
- Sterile technique
- All characteristics of the method – indications, contraindications, side-effects, effectiveness, and duration of action, so that health workers can help users make informed choices

- Risks and benefits of the method compared with other methods
- Knowledge about drug interactions, and history
- Counselling techniques
- Management of complications, especially heavy bleeding
- Management of medical emergencies
- Care of equipment and storage of supplies
- Follow-up of clients
- Record keeping

The important question is: Can the existing Family Welfare Programme (FWP) meet these needs? Several independent analyses indicate that the FWP is not in a position to meet these requirements for safe and ethical, and medically sound delivery of Net En.

The Government itself identifies lack of adequate health delivery infrastructure as a severe problem. The Eighth Five Year Plan states, "The FP programme has also suffered on account of centralised planning and target setting from the top. Regional variations and diversities have not been generally taken into consideration..... Monitoring mechanism under the programme has been reduced to a routine target reporting exercise incapable of identifying roadblocks and applying timely correctives." Yet, in the Ninth Five Year Plan, the Government admits that there is a "shrinking share of public investible resources," and further that "This slippage of 2 percentage points has fallen disproportionately on infrastructure, both economic and social."

The Government of India and the United Nations Population Fund (UNFPA) in August 1996 undertook a Programme Review and Strategy Development (PRSD) exercise to facilitate Government efforts to broaden its approach to health care and to bring population issues and concerns into overall development initiatives, with special emphasis on the needs of women.

According to this Report, "most health care providers are not well prepared to handle all aspects of their work." The short comings include: inadequacy of skill-based materials, and the fact that the methods used are pedagogical rather than participatory. Moreover, there is little opportunity for trainers to evolve need-based programmes. (UNFPA 1997)

"The FWP is Centrally managed and financed. As a result, the Centre plays a crucial role in the following areas: budgeting, developing norms for service delivery, monitoring and evaluation activities, and the design of training programmes. The Programme operates under a vertical, bureaucratic chain of command. This hierarchical structure has all the problems of such structures – **lack of sensitivity to people's needs, limited flexibility, and weak accountability**. It is generally accepted that while the health and family infrastructure has expanded impressively, its services have not been fully utilised. The staffing pattern is intended to allow for doorstep services, but in practice a full team is not always available. A large number of sub-centres function without Auxiliary Nurse Midwives (ANMs) and many Primary Health Centres (PHCs) do not have qualified doctors.

Even where staff is in position, their **training is often sorely inadequate** for the tasks they must perform. In addition, there are problems of unrealistic work load, irregular supplies of medicines, sub-standard buildings and equipment, poor sanitation and hygiene and inadequate pain management.

There is a **deficit in all categories of manpower, equipment, supplies, and finances** for recurrent costs, including salaries. There is also a distinct lack of facilities for emergency obstetric care, including the provision of medical termination of pregnancy, and the diagnosis and management of reproductive tract infections and other reproductive health conditions." (UNFPA, 1997)

The Report goes on to point out, "Too much time is spent on record keeping. Because of the large number of registers, ANMs spend as much as 30% of their time on record keeping and meetings to discuss records. This limits the time available for home visits, other services, and follow-up activities." **Despite the inordinate**

A GLIMPSE AT SOME GROUND REALITIES

Infant Mortality	72/1000	
Mortality of children under 5 years	171 (M)	149(F)
Maternal Mortality Ratio	570/100,000	
Percent illiterate	34% (M)	62.7 %(F)
Mean age at marriage (females)	19.6 years	
Sex Ratio	927 females/1000 males	
Contraceptive Prevalence		
Any method	41%	
Modern methods	36%	
Percent access to basic health care	85%	
Percent births with trained attendants	35%	
Percent with access to safe water	58%	
Percent households with no toilet facility	69.7%	
Percent Central Govt. Expenditures:		
Education	2.1%	
Health	1.6 %	

Source: UNFPA 1998

proportion of time spent, the Report states that "Service registers are incomplete, incorrect or inflated. The ICMR reports that in a national sample survey of sub-centres, one-third of the registers were not filled out correctly." (UNFPA 1997)

In this scenario, maintaining accurate records to monitor serious adverse effects like cancer risk and loss of bone density, seems near impossible, thus putting the potential user in a vulnerable position.

In fact, the Report of the Independent Commission on Health in India (1997) cautions against the use of hormonal injectables because of the inadequate facilities in the health infrastructure. (VHAI, 1997).

6. Management and Supervision

The FWP is not utilised fully because of a shortage of trained manpower and a lack of adequate management, supervision, and logistic support. There are a large number of vacant posts because doctors are unwilling to be posted to rural areas. The ones who go are permitted private practice in some states. As a result, they seem less concerned about the needs of patients at the Government health Centres.

The field staff at the sub-centre level is supposed to be supervised by LHVs, PHC doctor, and male supervisors. In reality, the lack of funds for petrol, oil, and lubricants limits the supervisor's mobility. There are no clear guidelines for supervision. Many of the major constraints in the system are attributed to the lack of a proper work plan and perfunctory monitoring (UNFPA 1997).

ACCEPTABILITY: DO WOMEN WANT INJECTABLES?

a) Overall Discontinuation Rates

Net En 200mg given at 2 or 3 monthly intervals has also been extensively evaluated for its efficacy. The method is as effective as DMPA. The **discontinuation rates for bleeding disturbances and due to other medical and personal reasons were very high in Net En users** and seemed comparable to those with the use of DMPA. (ICMR Bulletin, 1998 pg. Pg.92.)

In ICMR's Phase III trial with Net En 200mg given in two schedules 2 months and 3 months 2388 subjects were observed for 2 years:

This clinical trial represents the largest clinical trial undertaken on Net EN. Disrupted menstrual pattern was the major reason for discontinuation, ranging between 42-43 per 100 users at the end of 2 years. Amongst these, amenorrhoea was the commonest reason for discontinuation....The overall continuation rates with Net En were lower than those observed in similar conditions with the IUD.

The overall continuation rates at the end of one year were 58.5 (2 month schedule) and 59.8 (3 month schedule) per 100 users. Out of a total of 1181 subjects recruited for the 2 month schedule, only 73 were continuing in the trial at 2 years of drug use. Out of 1207 subjects recruited for the 3 month schedule, only 72 were continuing at 2 years. (Contraception Vol.30 1984).

In India, studies have been undertaken to assess its utility in the FWP. However, the discontinuation rates due to **severe menstrual disturbances** were very high. Almost 32% of women discontinued after the first injection and another 38.8% before receiving the third dose.

Similar observations were made in a multi-centric study conducted by WHO in 13 countries. The discontinuation rate in the 13 participating countries ranged between 33.3 and 75.0 and 49.5 and 91.3 per 100 women at the end of one and two years respectively. **The major reasons for discontinuation were menstrual irregularities, weight gain and headache.**

A recent survey of first users of DMPA from USA reported a continuation rate of 28.6% at one year of use. It seems that women who have a wider choice of alternative contraception do not prefer to continue using DMPA. The Ministry of Health and Family Welfare, GOI has not yet approved DMPA for the National FWP, but has approved its use by private physicians.

Discontinuation due to menstrual disturbances

Discontinuation due to menstrual disturbances which consisted of amenorrhoea, excessive bleeding and irregular cycles/spotting were the major reasons for drop-outs. (Contraception Vol.30 1984)

In an attempt to reduce the bleeding disturbances, ICMR added estrogen, and also reduced the dose of progestogen.

The efficacy of injectable contraceptives containing synthetic progestogens-only is well established; however, one of the major side-effects associated with this treatment is the disruption of menstrual cycles. Attempts have been made to improve the bleeding pattern by addition of different esters of estrogens in varying doses in combination with the progestogen preparations.(Contraception Vol.30 1984).

ICMR carried out Phase II multi-centre study of a fixed dose of 50mg Net En administered either alone or in combination with varying doses of different types of estrogens at monthly intervals (monthly injectables) (Contraception Vol. 32 1985).

As far back as 1981, the ICMR concluded that the 20 mg dose regimen "may not only result in reduction of menstrual side-effects but also ensure rapid return of fertility after withdrawal of contraceptive therapy." They go on to say, "Compared to currently available injectable progestational contraceptives Norethisterone Enanthate

200 mg 3monthly and DMPA 150 mg 3 monthly, the disruptions in the menstrual cycle are less with Net En 20 mg. Unlike these two injectables, the disruption of the menstrual cycle does not progressively increase with increasing duration of use of the drug (Contraception Vol.23 No.1 Jan 1981).

ICMR has also recently done a study to compare vaginal bleeding patterns in women using different contraceptive methods. The results of this study show that bleeding disturbances were highest with Net En 200 mg (in 80% users) compared to Norplant, hormonal IUDs, oral pills or IUDs. An earlier ICMR study had reported bleeding disturbances in 90% of women users, and there was no improvement with prolonged use, unlike in Norplant users.(Datey S Contraception 1995 March 51(3))

When these are the results with ICMRs own trials, why do they want to introduce Net En 200 mg, the dose which causes the most disruption in menstrual cycles and that which is most unacceptable to women, judging from the poor continuation rates?

b) Return of Fertility

As discussed earlier, return of fertility is of crucial importance in a spacing method, and has a direct bearing on acceptability.

c) Loss of Libido and Other Effects of Net En

The mechanism of action of Net En is not localised to the ovary. Both the hypothalamus and pituitary gland are equally affected, therefore a disruption is experienced in several other bodily systems controlled by these centres such as : regulation of body temperature, hunger, thirst, sexual function and emotional changes. That such bodily changes do take place with Net EN is apparent from the manifestation of symptoms such as headache, dizziness, weight gain, anxiety/depression, fatigue, hypertension, decreased libido and abdominal distension.

Although only 1 woman dropped out from ICMR's Phase III trial due to decreased libido, and this aspect is rarely mentioned in review articles on injectables (DMPA and Net EN), an Australian study (Fraser and Dennerstein 1994) found that 8% DMPA users experienced loss of libido and painful/difficult sexual intercourse. (Medical Journal of Australia 1994 Vol.160).

Due to cultural reasons, Indian women may not mention problems related to sexual function. Mostly, they are not in a position to refuse having sex with their husbands/partners. To do so in conditions where, due to contraceptive use, they experience a lack of desire and find intercourse painful, is tantamount to experiencing sexual abuse.

There is a definite gender bias in this aspect of contraceptive research wherein male contraceptives are quickly abandoned if they impair sexual function whereas this is not considered serious enough to abandon any particular female method with such a side-effect. If women knew that injectables could cause loss of libido/painful intercourse, many more of them may well reject this contraceptive rather than bear these painful effects in silence.

d) Survey of use of injectables among gynaecologists

A random survey among 19 gynaecologists in private practice in Delhi and Bhopal, was conducted by Saheli in order to determine:

- the extent of use of the injectable Net En among private practitioners
- the preferences of women with regard to spacing methods
- the factors in favour of the injectable Net En, as well as the factors against it
- the experiences of women with the use of the injectable Net En

The survey revealed:

- women patients who come to them do not have any particular preference and usually left it to the doctor to prescribe a method
- most of the women in their practice preferred oral contraceptives and IUDs
- 4 of 19 gynaecologists currently prescribe injectables, and only 1 was unequivocally in favour of injectables
- The reasons for not prescribing injectables were:
  - Too many side-effects like bleeding disturbances and amenorrhoea
  - Cost Factor
  - Intensive Follow-up and monitoring essential, therefore too time consuming

From the responses of these private practitioners, it can be concluded that injectables have many unacceptable side-effects and require close monitoring and follow-up. It can be concluded that if this is the situation with doctors who have a middle-class and upper-class clientele, the scenario of introducing Net En in the government set-up with its poor infrastructure, will be highly unacceptable.

POTENTIAL FOR ABUSE : INHERENT IN INJECTABLES

Contraceptive methods in India have had a long history of coercion. Although women had been routinely forced to "accept" contraceptive methods under the target-oriented Family Planning Programme, it was the excesses of male sterilisation during the Emergency which brought the issue into the public eye. Coercion of other spacing methods has also been rampant, some instance of which were highlighted, for instance the case of forced insertion of IUDs in a "health camp" in Bangalore in 1981. Instances of forced insertion of Norplant were documented in the film More recently, the case of quinacrine sterilisation was publicised by women's groups asking for a ban.

A contraceptive method can be said to have a potential for abuse is several ways:

- The very nature of the injectable carries with it the potential for abuse. This is because once the injectable is administered, the action cannot be reversed. Thus, even a woman has serious side-effects, or wants to conceive, she cannot stop using the contraceptive at will. She has to wait until the contraceptive effect wears off. Thus, she has **no control** over the contraceptive.
- When the contraceptive is administered **without the knowledge** of the woman i.e. she is unaware that she is being injected.
- When the woman is aware that she is being injected, but is **unaware that she is being administered a contraceptive**. For eg. She may think it is a tetanus shot, or vitamin injection. Ina culture which is particularly pro-injection, such a possibility is highly likely.
- When a woman is aware that she is being injected with a contraceptive, but she is unaware of the risks and hazards involved. Such abuse arises from an **absence of informed consent.**
- When a contraceptive method is not fully tested, and a woman **does not know she is being recruited as part of a trial**. This practice is very common in the Indian situation, where contraceptives under trial are "offered" in the cafeteria along with tried and tested methods, thus confusing the woman, who is not in a position to give informed consent. Such unethical delivery of Net EN in a camp in a village in Andhra Pradesh formed the basis of our 1986 petition. Unfortunately, the ground reality has not changed since then.
- When Net En is presented as a method of "first choice" along with other spacing methods, this is another dimension of abuse, since Net En is **not** meant as a method of first choice, but as a method to be used by **women who cannot use any other method.**

- Where the provision of contraceptive methods is within the framework of a **target-driven approach**, health providers, in their desperation to fulfil targets, may use unethical from downright coercion to false promises, incentives and disincentives, to "recruit" users. The history of sterilisation, especially male sterilisation, bears witness to this occurrence. The mode of administration i.e. injection, in the Indian situation, is very popular, and hence even more open to the potential for abuse.

- Due to a lack of information about the possible side-effects, women may not correlate certain side-effects with the use of Net En eg. Swelling of the calves (sign of thromboembolism – a serious adverse effect). Moreover, they may not be able to self-monitor their own health in order to report any changes, especially keeping in mind that the next visit to the health provider is as long as 2-3 months later.

- In a situation where health providers themselves misuse government supplies of drugs, and where unqualified private practitioners are rife, Net EN may be misused as an abortifacient (Pop Reports K series 1995 pg. 28). In fact, an Indian study by Ram et al (1976) states, "Because of the modesty of Indian women to undergo P.V. examination, it was not possible to determine if the women was pregnant. The patient's word about her LMP was accepted to be true. As such 7 pregnancies went undetected. This way, 2 pregnant patients even received 2 injections each. (**Upon close questioning later on they revealed that secretly they had hoped that the injection might induce abortion**. To their surprise it didn't)." This is an instance of medical malpractice justified by "cultural reasons", which is totally unacceptable.

Instances of denial of basic human rights and rampant misuse of the injectable abound. In 1990, a controversy raged over the alleged coercion of female Vietnamese refugees into Hong Kong. "It was reported that women were threatened with the loss of food, tickets, or sanitary supplies if they refused the injection." (Berer 1990).

In a developing country like India, health providers are under compulsions set by the National Family Welfare Programme. Studies have revealed that the same **stringent criteria** mandatory in the West, are **not used in developing countries**. "The developing world is precisely where women are least likely to be healthy, have the least opportunity to freely make choices about their own bodies, and have the least education by which to understand chemically induced changes to their bodies." The author concluded that, "The **highest use** of DMPA is **among the least well-selected, least well-informed, and least well-monitored populations.** This despite the fact that its long-term safety record is unestablished "(Parsons 1990)

The study further found that women may readily consent to the administration of long-acting injectables into their bodies as a result of

(a) Lack of knowledge of contraindications and reactions to the injectables

(b) Lack of knowledge of how to compare available contraceptive methods

(c) As a result of coercion by husbands and relatives.

Certain populations in the West are more vulnerable to abuse by the health system. A study in the US in 1992 found that 61.1% physicians had prescribed DMPA to female **teenagers** for family planning even though it had not been approved for use by the US FDA. 68% of physicians reported **mental retardation** as a strong potential indication for DMPA.

Similarly, a study in France (Thebaud 1982) found that "It (DMPA) is used on a long-term basis primarily for **psychiatric patients** deemed incapable of managing their own contraception and **immigrant women** with whom communication is difficult. In both situations, true communication is impossible and the choice of contraception is made by the physician, whose prescription is made in total ignorance of the psychological, cultural, and social effects that its use may entail for the woman."

In Western countries, if figures for use of injectables are interpreted, the **ethnic and racial discrimination** becomes apparent. A study conducted in France documented a highly disproportionate pattern of use. Only 4% of French-born women using contraceptives used Depo Provera, compared to 15% of Algerian women living in France and 20% of sub-Saharan women, researchers found. "These results cannot be explained as

merely the choice of the women involved. A review of the records revealed that African women initially requested a method other than Depo Provera more than twice as often than French women."

Another study in France by Herschkorn et al (1990) found that, "The criteria under which injectable contraceptives are prescribed are not mainly medical but are narrowly linked to **socio-cultural factors** and the socio-economic factors of the women for whom it is prescribed: and this is in comparison with other methods of contraception. Prescribing this substance has a degree of urgency about it."

The problem is compounded because women in developing countries generally do not have any system of **redressal**. In contrast, as far back as 1980, a woman in the United Kingdom was awarded a settlement of 3,750 pounds for damages because she was prescribed the injectable contraceptive DMPA without warning her about the likely side-effects. Similarly, another case in 1983 was settled at 3,000 pounds. The judge proclaimed, "To deprive her of the right to choose is to deprive her of a basic human right to do with her body as she chooses." Another case in 1985 was similarly settled at 3,600 pounds as damages for the woman "not being warned by doctors of the possible adverse effects." (Chorlton P, The Guardian, 1980).

After the FDA approved Depo Provera for use as a contraceptive in the US in 1992, several women's health organisations in the US, including the National Latina Health Organization, the Native American Women's Health Education Resource Center and the National Women's Health Network, documented the disproportionate use of DMPA in low-income women and women of colour. (Our Bodies Ourselves, 1998).

WHY DO WOMEN' S GROUPS OPPOSE LONG-ACTING CONTRACEPTIVES LIKE NET EN?

Women's groups the world over have been opposing long-acting, hormonal, invasive contraceptives like injectables (Net EN, Depo Provera, Cyclofem etc), implants (Norplant, Capronor). What is it that makes these contraceptives so unsuitable for women, especially in the Third World?

- **They are invasive,** meaning that they act on the entire body system for the one purpose of contraceptive effect. They affect several organs in the body – the hypothalamus and pituitary in the brain, the liver, the heart etc. in addition to the reproductive organs.
- **They are hazardous.** Studies so far have shown that these contraceptives have several short-term side-effects such as menstrual disturbances, headaches, fatigue, depression etc. and possible hazards like thromboembolism (formation of blood clots), cardiovascular problems, osteoporosis and cancer risk. Risks to the foetus, and future children have not been satisfactorily ruled out.
- **They are long-acting.** By their inherent nature, the effect of these contraceptives cannot be withdrawn before a given period of time. So, even a woman experiences a serious problem, she has to wait till the effect wears off, in about 12-15 weeks in the case of injectables. In India, where health care services are inadequate or absent, this can be a serious problem.
- **Return of Fertility** is not assured. Although these methods are promoted as spacing methods i.e. to ensure a gap between one child and the next, many women have experienced delay, or difficulty in conceiving. For instance, some women could not concevie even a year after stopping the use of Net En.
- **The risks to breast-feeding infants** whose mothers are injected with Net En or implanted with Norplant, have not been satisfactorily ruled out. This is a grave concern, since as a spacing method, a majority of women targeted for injectables will be breast feeding.
- **Risks to children** conceived by accident during use of injectables or Norplant, or conceived before the effect of the drug has worn off, have not been satisfactorily ruled out.
- **They are provider controlled,** which means that the health service provider (Auxiliary Nurse Midwife, doctor, paramedic) is the one who controls when to administer the contraceptive. With Norplant, the provider even has to remove it, and there is documented evidence that women were denied removal of Norplant even though they experienced problems with it.

- **The health care infrastructure is inadequate** to ensure safe delivery of long-acting hormonal contraceptives. Ruling out contraindications, monitoring the woman during use, responding to emergencies like anaphylactic shock, ectopic pregnancy, stroke (possible hazards of these contraceptives) needs well-equipped health facilities with well-trained personnel – a far cry from the present dilapidated health centres and absence of medical staff especially in rural areas.

- **Unethical testing** has been a hallmark of clinical trials of long-acting contraceptives in India. From lack of informed consent to outright coercion, scientific investigation on contraceptives have fallen short of meeting universally accepted ethical norms. It is our contention that the inherent nature of these contraceptives contributes to their misuse.

- **Potential for Abuse** given the nature of long-acting hormonal contraceptives – long-term effect and easy to administer – there is a high chance that they will be indiscriminately used in the population control programme. Women may be given injections without them knowing it is a contraceptive. Women's need for contraception may be misused, and they "agree" to take an injection or implant without being fully aware of the side-effects and hazards. Misinformation, lack of informed consent and "persuasion" through incentives have been women's experience in the past 5 decades in the Family Welfare Programme in India. In the West, injectables have had a history of abuse on Hispanic, Black, immigrants and women incarcerated in mental asylums and jails.

- **They offer no protection against HIV/AIDS. T**he spread of HIV/AIDS is a very real threat for all sexually active persons (in India, 75% spread is due to heterosexual sexual contact). A method which offers protection against HIV/AIDS and sexually transmitted diseases would be a more suitable method in this situation.

- **Profit making by pharmaceutical companies** takes precedence over women's health. In the rush to win over the market, especially Third World governments, research norms are violated, and ethics take a back seat in the race to complete trials, get approval and apply for patents.

Contrary to the official perception of women as mindless breeder of babies, women do desire to control their fertility. We have been campaigning for safe, effective, reversible contraceptives which women are able to control. Barrier methods which do not interfere with the entire body system, but are effective contraceptives are the condom, diaphragm, cervical cap, female condom. It is no coincidence that safe and effective barrier methods for women like the diaphragm and cervical cap are not available in India. Since they are reusable for 2-3 years, they are also cheap (and obviously, no pharmaceutical company can make huge profits, as with injectables and implants). Alongside, we have been campaigning for increased male responsibility in contraception, and development of safe and effective male methods.

WHAT DO WOMEN CONSIDER A GOOD SPACING METHOD?

- The method should not have uncomfortable side-effects i.e. itshould be acceptable/tolerable as a contraceptive for 2-3 years
- After discontinuing the method, a woman, if she so desires, should be able to become pregnant and bear a normal child
- The method should be safe for breast feeding mothers and their infants
- The method should not have serious contraindications which would need specialised skills to diagnose
- The method should not cause long-term irreversible damage to the health of the woman or her future children

Injectables like Net En and Depo Provera do not fulfil <u>any</u> of the above criteria.

THE CAMPAIGN IN INDIA AGAINST INJECTABLES

The campaign against injectable contraceptives has been vigorous and visible. Women's groups in India were aware of the controversy surrounding injectables in the US and UK, where women's organisations and health activists had been raising questions about the health risks associated with injectables, and the potential for abuse. Though there was extreme secrecy surrounding the clinical trials in India, women's groups have struggled to gather data and highlight instances of abuse of hazardous contraceptives. However, such attempts were stonewalled, and a complete lack of transparency was exhibited in "official" matters. When reason and logic met with little success, protests took on more vigour. Anger at the abuse of women's bodies fuelled the campaign. Protesting against unethical trials and misuse of contraceptives has been a significant part of the women's movement in India. Initiated by city-based autonomous women's groups and health action groups, the campaign widened to include a wide spectrum of progressive organisations including women's wings of left parties, democratic rights groups etc.

The methods of protest have been forceful as well as innovative. From dharnas, sit-ins and demonstrations targeted at the Ministry of Health and Family Welfare, ICMR and other official bodies, to gheraoing the Drugs Controller in his own office to gate-crashing into meetings, the voices of resistance have been loud and clear. And the reactions have been as strong – the local press termed as "unladylike" the action of jumping over the wall to storm the meeting organised by Max Pharma in Delhi to launch Depo Provera in India!

The legal avenue, in the form of public interest litigations have also formed part of our strategy to prevent the introduction of injectables in India. The earliest legal action in Bombay to stall the import of Depo Provera was followed by cases in the Supreme Court against Net En and Depo Provera.

Reaching out to the public has been an important part of the campaign. Producing easy to understand material --booklets, posters, hand-outs and pamphlets and leafleting in crowded localities, we have tried to take the debate out on to the streets. Songs about the hazards of injectables were composed and sung, skits were performed, and slogans coined. Several video films were produced documenting the misuse of hazardous contraceptives – "Something Like a War" etc. Following are some of the significant events of the campaign:

1984 Dec	Five women's organisations of Bombay along with the Medico Friends Circle stage a demonstration outside a closed-door meeting organised by the Family Planning Association of India (FPAI) to discuss the introduction of Net En.
1985	Women's Centre, Bombay and Medico Friends Circle became parties to court case against Dr CL Jhaveri, Chairman of Indian Association for Fertility and Sterility, who had applied for license to import Depo Provera
1985 Mar	Focus on Injectables on International Women's Day in Bombay
1985 April	Activists of Stree Shakti Sanghatana, Hyderabad, expose unethical use of Net En without informed consent, in Family Planning camp in Patancheru
1986 April	Petition filed in Supreme Court for stay on Phase IV trials, by Stree Shakti Sanghatana, Saheli, Chingari and seven concerned individuals
1986 Aug	Saheli Seminar on "Population Policy and Implications for Women: Special Focus on Injectables."
1986	Medico Friends Circle meeting in Dungarpur, Rajasthan discusses injectables
1989	Women and Health meeting in Jaipur discusses injectables
1992 Mar	International Women's Day Rally in Delhi against the New Economic Policy and Population Control

1992 Sep	News about German Remedies intention to market Net En (Brand name: Noristerat). Women's groups take up matter with Ministry of Health and Family Welfare and National Commission for Women. Promotional literature of government included Net En as a desirable method for spacing children, though it was not officially part of the National Family Welfare Programme. Women's groups take up the matter with the Ministry, demanding that such literature should be destroyed.
1993 May	Protest letters by women's organisations to the Ministry of Health and Family Welfare regarding entry of injectables.
1993 Jun	Meeting of women's groups in Delhi with Secretary, Ministry of Health and Family Welfare, regarding Population Policy and entry of hazardous contraceptives.
1993 Aug	Women's groups send memorandum to the Ministry regarding social marketing of injectables.
1994 April	Forum for Women's Health and other groups in Mumbai protest launch of Depo Provera
1994 April	Women's groups in Delhi storm into Max Pharma launch of Depo Provera in Delhi
1994 May	Saheli initiates a chain letter warning women about the hazards of injectables like Net En and Depo Provera.
1994 June	Meeting with the Drugs Controller of India taking up the matter of package insert in injectables to conform to international standards. It is also brought to the notice of the Drugs Controller that Net En, a hazardous drug, was being sold Over-the-Counter in an indiscriminate manner.
1994 Aug	Public meeting organised by women's groups to confront the DCI and ICMR regarding granting permission for entry of injectables.
1994 Nov	Campaign Tour in Madhya Pradesh by Forum for Women's Health, Mumbai, and Saheli to spread awareness about hazardous contraceptives.
1994 Dec	A week long public awareness raising leafleting campaign about the hazards of injectables at several busy intersections all over Delhi.
1995 May	Saheli organises workshop on "Concepts in Fertility, Contraception and Healthcare" using ten years experience in resisting hazardous contraceptives beginning with Net En.
1995 Jul	On World Population Day, women's groups organise protest demonstration outside Ministry of Health and Family Welfare opposing hazardous contraceptives.
1995 Mar	Declaration against hazardous contraception by women's organisations at the National Convention of Women, in preparation for the World Conference on Women, Beijing.
1997 Feb	Seminar organised by the National Commission for Women to discuss the Draft Statement on National Population Policy, and raised the issue of banning hazardous contraceptives. These recommendations were forwarded to the Joint Parliamentary Committee.
1998 Jul	On World Population Day, Saheli submits memorandum to the Minister for Health and Family Welfare, raising the issue of hazardous contraceptives.
1998 Dec	Forum for Women's Health, CEHAT, ACASH and other groups protest at IRR meeting convened to recommend the introduction of injectables

REPRODUCTIVE HEALTH POLICY : RHETORIC VERSUS REALITY

In some measure, pressure on the government did result in some changes, but modifications were more cosmetic than real. The early 1990's saw a shift in the language of the population control policy, if not its substantive aspects. The United Nations International Conference on Population and Development (ICPD) held in Cairo in September 1994 has come to represent a watershed of sorts for health planners and women's health advocates alike. A much touted 'paradigm shift' was said to have been set in motion by the Government of India, which reflected a departure from its 'population control' policy to one of 'holistic reproductive health'.

The Government of India from 1992 had begun to recognise that the top-down target approach to family planning should change, "Targets based on micro-level planning suiting the local specific needs be fixed for monitoring the program." Going further, a Child Survival and Safe Motherhood Program (CSSM) was also launched in 1992.

In the years preceding the Cairo Conference, women's groups were networking to reshape population agendas, especially in Third World countries. Development issues were sought to be placed at priority. Governments were pressurised to depart from the 'demographic imperative language' and accommodate women's perspectives on sexual and reproductive health; link population and consumption patterns and address the issue of male responsibility in reproduction and contraception.

The Programme of Action of the ICPD 1994, endorsed by the Government of India proclaims, "States should take all appropriate measures to ensure, on a basis of equality of men and women, universal access to health care services, including those related to reproductive health care, which includes family planning and sexual health... and provide the widest range of reproductive health-care services without any form of coercion. All couples and individuals have the basic right to decide freely and responsibly the number and spacing of their children and to have the information, education and means to do so." At various international forums, the Government of India is constrained to demonstrate its commitment to women's rights. The Beijing Declaration ratified by the Government of India, states that governments were "Determined to advance the goals of equality, development and peace for all women everywhere in the interest of all humanity." Such rhetoric came to assume a permanent place in government policies henceforth.

In November 1994, a joint mission of the Government of India and the World Bank was set up to undertake a sectoral review. In 1995, the World Bank submitted a report entitled, "India's Family Welfare Program: Toward a Reproductive and Child Health Approach" to the Government of India. The government adopted the policy, and as a first step, in April 1996 abolished method-specific contraceptive targets nation-wide. The 'Target Free Approach' (TFA) was thus launched in 1997, followed by the 'Community Needs Assessment Approach' (CNAA). The concept of RCH, according to the Government was "to provide to the beneficiaries need-based, client centred, demand driven, high quality and integrated Reproductive Health Services." The estimated cost of the RCH Programme was Rs 5112.53 crore during the 9th Plan starting 1997-98. International Development Agency (IDA) assistance of about $ 250 million in the form of RCH II will be available after the "satisfactory implementation" of the first two years of the RCH Programme.

An official commitment was made towards a reorientation to the client-centred approach with an emphasis on 'quality of care'. However, these seem to be mere exercises in semantics, rather than a change in the real situation. The sudden removal of method-specific targets in April 1996 was an abrupt change which the 250,000 family welfare staff could not cope with. Because targets had driven the FPP for many decades, and all policy and programme efforts had been focussed on the achievement of targets, their sudden withdrawal without preparation caused considerable confusion at the field level. Since no alternate monitoring system had been put in place, there was no way to evaluate performance of programme staff, which had hitherto been measured by achievement of targets. Not surprisingly, reported use of all contraceptive methods fell in the year following the TFA. Moreover, the RCH Programme itself seems to be more a means to the end of population control rather than an end in itself. Evaluations of the Programme still focus on the number of contraceptive users and percentage of "protected" couples. The MOHFW Progress Report of the RCH Programme (1998) goes out of the way in its assurances that despite the Target Free Approach, contraceptive use was not dropping, and in most states there was an all-round upswing.

The abysmal condition of primary health services inspires little hope that things will change. With basic equipment like instruments to measure blood-pressure and supplies of iron and folic acid tablets being unavailable and routine ante-natal care not made possible, 'Safe Motherhood' is a far cry. This does not prevent planners from justifying the use of hazardous contraception with the specious argument that the risk from hazardous contraception is lower than that from maternal mortality. The government is increasingly shrugging off its responsibility for health. With liberalisation of the economy following Structural Adjustment in the early '90's, health services are becoming increasingly privatised. The cutbacks in the social sector are apparent in the budget allocation for health which has been steadily shrinking, while that for 'Family Welfare' continues to grow. For instance, in 1997, the budget for 'Family Welfare' is almost double that of health.

National Population Policy : The Carrot and Sticks Game Continues

In 1993, the Ministry of Health and Family Welfare set up an Expert Group under the chairmanship of MS Swaminathan to prepare a draft National Population Policy (NPP). Women's organisations in Delhi played a critical role in publicising the proposals of the Expert Group, and initiating a public debate on the whole issue of population control. Despite mouthing a commitment to women's rights and appearing pro-people, the Policy, when finally submitted in 1994, contained several objectionable items. The same draft is still pending for debate in the Parliament. The Policy states that, "the unsustainable lifestyle of the wealthy nations and persons in our country are responsible for using far more than a fair share of natural resources and causing grave threats to the environment." However, the Expert Group, reverting to Malthusian thinking, puts the blame for environmental degradation on "population and poverty" and states that access to food, education, health and work for all will "remain illusory" without limiting population growth. Its recommendations contain many measures to curtail the numbers of the poor.

The perspective of the NPP is clearly revealed in its position on 'Contraceptive Methods', "India has an efficient scientific set-up for testing for safety, efficacy, reliability and acceptability of contraceptive methods before introducing them into the Family Welfare Programme." The scientific bodies mentioned, however, have not been following strictly scientific guidelines with regard to long-acting hormonal contraception. Although the NPP admits that "controversies are raised from time to time", it does not see it fit to resolve these controversies before proceeding with development and introduction of these methods.

It is clear that mere lip service is being paid to the 'Target Free Approach'. It is well accepted by now that pressure to fulfil targets contributes to imposing coercive measures on people. However, the NPP continues to adhere to the goal of achieving a national average of Total Fertility Rate (TFR) of 2.1 by the year 2010. With a present TFR of 3.07, the achievement of such an unrealistic target of 2.1 can only be achieved by coercive measures. At every step, the true objective of the NPP is plainly visible: "The emergence of grassroots level democratic structures provides opportunities for correcting the prevailing gender imbalance in the acceptance of contraception."

Despite proposing such anti-people measures to deny the basic rights of people, the NPP mouths its supposed concern for 'empowerment of women'. Yet, it even views education for girls in terms of its impact on adoption of contraception and the 'small family norm'.

Recent Trends : Draconian Laws

Notwithstanding claims to the contrary, disincentives remain a hallmark of the population policy in India. In 1992, in a direct attack on the democratic right to contest elections, the Government of Rajasthan, amended the Panchayati Raj, Co-operatives and Municipalities Act. Anyone with more than two children was disqualified from contesting elections to local self-governing bodies. Haryana too followed suit with a similar Act. While it is acknowledged that women have little control over their own fertility, undemocratic laws such as these doubly victimise women.

The Expert Group on Population not only upholds these undemocratic and unconstitutional Acts, it recommends their extension to the whole country. The proposal to enact the 79th Amendment to the Constitution, to

Whither Goes WHO?

From a scientific advisory body with supposedly no vested interests, the World Health Organisation (WHO) has travelled a long way. The WHO has been a a reference point for governments as well as health and consumer groups the world over. The recommendations and guidelines emanating from the WHO have been treated as almost sacrosanct and inviolable – a standard to aspire to. Recent trends within this body, however, are disturbing, and have deep implications for policies on health and population. It is worth remembering that the Special Programme of the WHO was launched in collaboration with the United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), and the World Bank – all major players in the global population control scene. The varying impacts of these agencies also needs to be analysed in order understand the shifts within the WHO.

Fall in the standards of safety requirements for contraceptives benefited the multinational drug companies of the industrialised nations. Stringent pre-marketing testing requirements of contraceptives in these countries had led to a situation where patents would be near expiry by the time the product came into the market. These companies, therefore had to look for global markets to maintain their profitability. It was not a coincidence that a green signal from WHO led to contraceptives being registered for sale in Third World countries. Net En, for instance, was put on the essential drugs list of WHO for developing countries. In contrast, for most of the industrialised countries, including Germany, the country of origin, the drug was listed as a contraceptive of second choice. The close collaboration of the WHO with the pharmaceutical industry is a cause for concern.

Linking the Public and Private Sectors

When the WHO Special Programme of Research, Development and Research Training in Human Reproduction was launched in 1972, it was expected that industry would take over the production, marketing, and other introduction activities, once publicly funded clinical trials on contraceptives had been completed. Since this has not occurred, for various reasons, the WHO has taken upon itself the task of manufacturing and marketing contraceptives. The **Concept Foundation** was created in 1992 by the Program for Appropriate Technology in Health with assistance from the WHO Special Programme.

Located in Bangkok, Thailand, the Foundation, according to the WHO, "facilitates the transfer of manufacturing technology, providing technical assistance and independent quality assurance, undertaking selection of suitable manufacturers and distributors, arranging license agreements and ensuring that liability issues are addressed." Cyclofem, the once-a-month injectable is being manufactured and marketed through the Foundation in Indonesia, Mexico and Thailand. Though garbed in noble objectives like "helping to make the much needed health products available to all," the Foundation admits that it "works with companies to assure reasonable profits. The Foundation believes that only through competitive return on investment would it be possible to mobilize the private sector."

The marketing of products capitalising on the "good" name of WHO is highly questionable. The WHO says that since, "The products made available by the Foundation emanate from *highly regarded public sector research institutions*, such as the Programme," this will be an advantage to pharmaceutical companies.

WHO's Partnership with the Pharmaceutical Industry

The growing partnerships between the WHO – a public interest scientific and research body- and the pharmaceutical industry- whose main aim is to maximize profits – is another disturbing trend. Drug industry sponsorships will directly affect the role that the WHO will play in the area of public health. The pharmaceutical company MSD (Merck, Sharp and Dohme) has succeeded in seconding a senior staff member to the staff of the WHO Tobacco Free Initiative (TFI). According to an internal MSD announcement, this is a "pioneering arrangement", "a marvelous opportunity to continue to build bridges", and the Corporation expects the person to be an "effective ambassador". This close association is alarming, to say the least.

The recent controversy over guidelines for drugs for hypertension is another case in point. The WHO/ International Society of Hypertension (ISH) Working Group prepared new Guidelines for the Management of Hypertension. Several critics have pointed out that the Task Force ignored ground rules of clinical assessment and placed a great deal of weight on the results of two trials funded by pharmaceutical companies. The industrial sponsor of one of the trials funded the press conference, and the company's logo appears on the welcome page of the ISH web site. WHO's endorsement of the recommendations will no doubt be used to encourage an increased use of hypertensive drugs, at great expense, and for little public health benefit.

In 1996, the WHO evolved a Draft Guidelines on the Acceptability of Donations from Commercial Enterprises. However, while the Guidelines have not been thrown open for consultations before finalizing, the WHO has been operating on the basis of this Draft. This throws up a major question about how, and whether, WHO tackles the conflict of interest between public interest and commercial enterprises. Advocacy groups such as the Health Action International have been raising these concerns, and demanding greater accountability and transparency by WHO in all of its decision making involving industry partnerships.

disqualify those with more than two children from contesting elections, once more displays the government's faith in disincentives. In fact, the MOHFW states, "This (the proposed Bill) seeks to incorporate promotion of population control and small family norm within the framework of Article 47 dealing with the Directive Principles of State Policy and including in the list of Fundamental Duties (Article 51-A), a clause enjoining the citizens of India to promote and adopt the small family norm." (MOHFW Annual Report 1996-97). Thus, being subjected to coercive population control is equated to a national duty!

In 1996, the Minister of Health and Family Welfare in the ruling BJP government, Harsh Vardhan, introduced the Delhi Local Self-governing Bodies (Disqualification for Membership) (Small Family) Bill (Bill No.6 of 1996). The proposed Bill aimed to disqualify persons with more than two children from contesting elections. The Bill, however, was not passed. Protests from women's groups, and the subsequent fall of the BJP government sidelined the Bill.

However, the Delhi Population Bill (Bill No.1 of 1999) to be introduced in the Legislative Assembly of the National Capital Territory of Delhi by Congress MLA Kiran Choudhry is another attack on democratic rights. Notwithstanding the supposed shift to reproductive health, this Bill clearly states its aim "to provide for measures for the control of population in the NCT of Delhi." While the "benefits" for voluntary sterilisation proposed under the Bill include a cash reward of Rs 120 and free education for the existing children upto senior secondary level in a Government school, the disincentives outlined are reminiscent of the coercive measures widely used during the Emergency:

"Every person and his spouse who, after a period of one year from the date of the coming into force of this Act procreates more than two living children, he:

a) shall not be eligible to contest elections to the Legislative Assembly (or Municipal Corporation of Delhi) or to be nominated to the New Delhi Municipal Council;

b) shall not be allotted any house under any housing scheme launched either by the Government or any local authority;

c) shall not be entitled to become a member of any society under the Delhi Co-operative Societies Act, 1972 for the purposes of allotment of a house or a plot or a piece of land for construction of a house;

d) shall not be entitled to avail of any loan or facility of any kind from the Delhi Financial Corporation or any other financial institution under the control of the Government;

e) shall not be entitled to draw ration from any Fair Price Shop under the Public Distribution System, or Liquefied Petroleum Gas from any agency owned or controlled by the Government;

f) shall not be eligible for appointment in any Government establishment or office or public sector undertaking or an autonomous body owned or controlled by the Government or any local authority.

Special provisions for Government Employees:

1) No employee of the Government or of a public sector undertaking under the control of the Government or of any local authority shall be entitled to any increment or promotion in service if, after the commencement of this act, he procreates more than two living children.

2) If any employee of the Government or any local authority undergoes an operation for birth control after having two living children, he will be entitled to an increment equivalent to his on month's basic salary.

The rationale for these harsh measures is stated to be because "Delhi has the highest rate of population growth in the country." Yet, a large percentage of the high growth rate in Delhi can be attributed to migration from rural areas, and not due to high fertility. The Bill completely ignores this aspect of demography.

The Bill is a direct attack on women, in a context where women do not have the right to control their own fertility. Moreover, with the strong preference for sons, coercive policies limiting family size, would encourage

the use of sex determination followed by selective abortion of female foetuses. The sex-ratio, already unbalanced at 927 females per 1000 males, is likely to get further skewed.

Instead of working towards resolving root causes of social problems, the State is choosing retrogressive measures like the enactment of such undemocratic laws. On the other, it is also actively withdrawing from its responsibilities towards its people.

Privatization, the World Bank and NGOs: Dwindling Role of the State

"The rapid growth of population is one of the greatest barriers to the economic growth and well-being of our member states....The control of population growth is yet another area where the Bank needs to take new initiatives," declared Robert McNamara in his first speech to the board of governors as President of the World Bank, and launched the Bank into the field of population. The Population Projects Department was formed in 1969. While recognising that the relationship between population growth and socio-economic development is complex, the Bank has remained firm in its belief that intervention to reduce the rate of population growth is both a desirable and a feasible component of national development policy. The World Bank's population activities have been focussed on "increasing government commitment to developing a policy framework for fertility decline as a national development objective, and providing loans and credits for implementing population programs." In other words, the World Bank has made population control a conditionality for loans and grants-in-aid to Third World governments.

Recent statements by US officials make it amply clear that aid for population control comes not from altruism, but clear business interests and fear of being overrun by burgeoning Third World populations. Says Secretary of State, Madeleine Albright (USIS, September 1998), "International family planning also serves important U.S. foreign policy interests : elevating the status of women, reducing the flow of refugees, protecting the global environment, and promoting sustainable development which lead to greater economic growth and trade opportunities for our businesses."

The World Bank thrust towards the private sector in health was enunciated in the 1993 World Development Report, 'Investing in Health'. Following the economic reforms in the early 1990s, the World Bank advocated a strategy of relying more on the private sector, and 'encouraging' clients to pay for health services. From a basic right of a citizen, health was now to be viewed as a consumer item which only the rich can afford. The World Bank proposes that what it terms the initial wave of reforms of the State often includes a divestiture of State assets, or privatization, which is concentrated on commercial enterprises. This leads to a second wave – the divestiture of public infrastructure and utilities. Finally, divestiture of state assets continues, and a focus on non-government and private management and investment in health, education and pensions systems comprises the third wave. It is clear that the Government of India is closely following these unhealthy prescriptions in the health sector.

The Reproductive and Child Health Programme launched following the sectoral review undertaken by the Government of India and the World Bank envisages a significant role for both the private health sector as well as Non Government Organisations (NGOs). According to the Progress Report of the RCH programme (MOHFW 1998), "Small NGOs all over the country are being involved in counselling, advocacy and for increasing awareness about the RCH Programme. Assistance to them is being channelised through 'mother NGOs' at the regional level, who will also be the monitoring and reporting agencies on their behalf. This will ensure that small NGOs will neither need to make applications to the GOI, nor will have to come to GOI for funds or to report about their work." Such a free-for-all can only be viewed with great alarm. National level NGOs are expected to evaluate the functioning of the 'mother NGOs' at the regional level. In short, the government appears to have contracted out the health sector, with no attempt even to monitor and regulate the functioning of NGOs. Accountability, thus, is a major casualty in this process of NGO-ization.

The increasing reliance on NGOs to implement government schemes can be seen in several fields – health, education, employment schemes, rural development etc. NGOs, with their flexible structure and closer outreach to people, appear to have more credibility and sincerity in implementing programmes. The government has sought to utilise this factor to the fullest extent. Many NGOs are little more than implementing agencies for the government with funding from foreign donor agencies. Depending on funding for their very existence leaves little scope to critique the donor driven agenda – be it family planning or the new catch all concept of "reproductive health". NGOs such as DKT International, Mumbai, the Family Planning Association of India (FPAI) and Marie Stopes Clinics/Parivar Sewa Sansthan, with branches all over the country, have included Depo Provera in their "reproductive health package" supposedly in an attempt to 'increase choices in spacing methods'. The experience of NGOs in West Bengal and Karnataka carrying out "trials" on quinacrine, the hazardous female sterilisation method, indicates that there is a dire need for regulation of NGOs by a non- NGO body. Women's health cannot be compromised in this era of deregulation.

Post Marketing Surveillance. No surveillance at all.

"Experience with oral contraceptives and IUDs has shown that some side-effects and some benefits of contraceptives are not discovered immediately. The animal and clinical trials required in most countries before contraceptives are introduced, ensure that contraceptives are safe and effective in the short run. Only continued Post Marketing Surveillance (PMS) of larger numbers of women, however, can detect side-effects that are rare or appear only after a long period." (Population Reports, Series K, 1987).

Rigorous PMS is also necessary because there are wide differences in the way in which different populations react to injectables. In India, no study has followed up Net En users for more than 2 years. On the recommendation of the ICMR, the Drugs Controller approved the marketing of Net En in 1986, and Depo Provera in 1993 for the private market. In both instances, this approval was granted with the "advice" to the drug company that PMS be conducted. In the case of Depo Provera, this "advice" to conduct PMS was limited to "selected centres". The fact that PMS was not made a mandatory requirement for the licensing of injectables makes a mockery of the entire exercise.

Even though one of the objectives of the PMS study was to monitor the incidence of side-effects and the acceptability of the drug as a contraceptive and to follow up side-effects until they are resolved, very little information is actually being made available about the results. Repeated requests to the Drugs Controller by women's groups in Delhi and Mumbai for information on the protocol of the PMS as well as the results obtained have been repeatedly stonewalled. After a lot of persistence, the Forum for Women's Health, Mumbai, was given a very short and sketchy report on the PMS study on Depo Provera. In the case of Net EN, even 6 years after the PMS was ordered, the results have not been made public as yet.

The PMS study was being conducted on Depo Provera by Max Pharma in 10 centres all over India. Out of a total of 469 women enrolled for the study only 77 remained after 4 doses of the injectable i.e. after one year. However, the reasons for drop-out are not clearly stated. The fact that only 16.4% women continued with Depo Provera after a one year period, raises serious doubts about the suitability of the injectable. Yet, reporting on side-effects is scanty and the absence of measurement is taken to mean absence of incidence.

PMS handed over to the pharmaceutical company which directly stands to gain removes any pretence of "scientific objectivity" of the research. In a situation where PMS is not mandatory, the drug company is not accountable for the quality of its "research". The companies are merely fulfilling formalities, which casts serious doubts about the authenticity of the data generated.When even women recruited for closely monitored clinical trials are not adequately followed up, the situation for PMS conducted by drug companies can be well imagined. The fate of individual women who suffer side-effects or life-threatening emergencies after use of injectables is not even likely to come to the notice of the company, for whom each human life is merely yet another statistic.

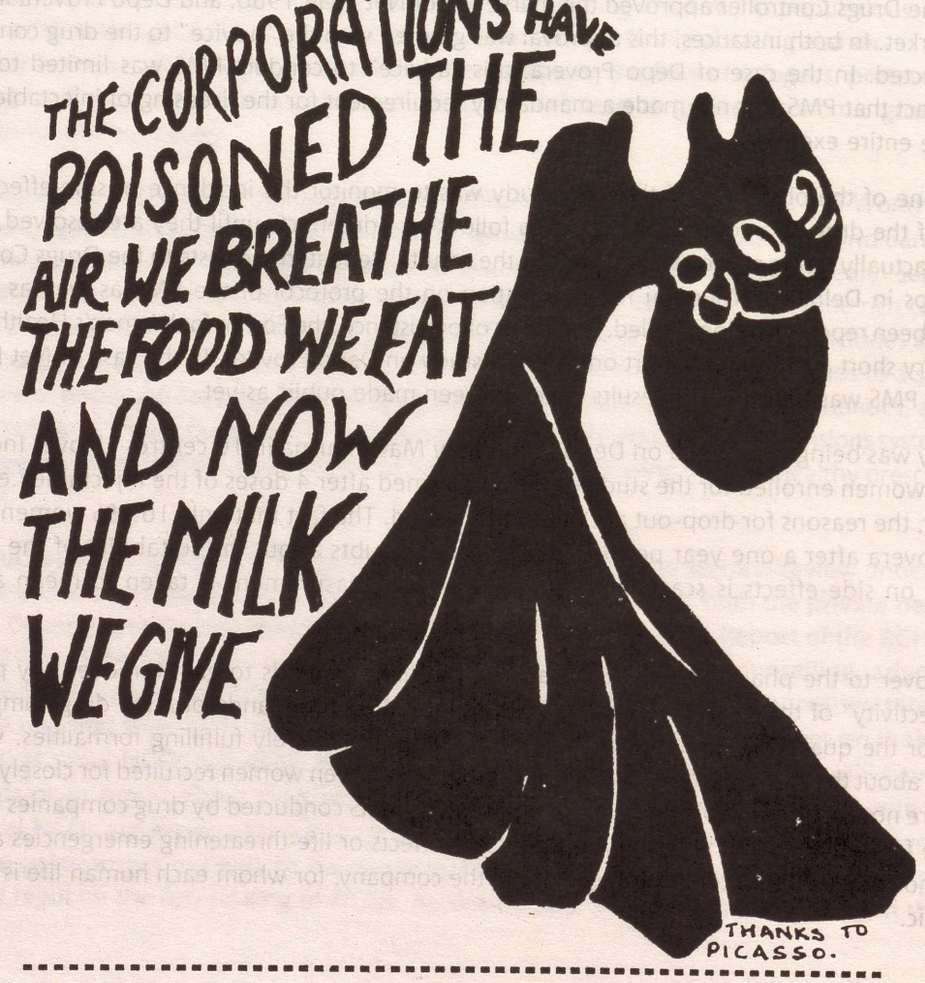
IN CLOSURE

The population "explosion" theory has many proponents, as has been touched upon in the preceding pages, there are several vested interests involved.

From eugenic and racial concerns, to concerns for the environment, from concerns of political instability to a concern for the maldistribution of resources, the answer seems to be – population control. And this, of course, means contraceptives.

In addition, the financial stakes in this pursuit are also very high. Since those whose population is to be "controlled" reside mainly in the Third World which is highly populated, vast sums of money naturally accrue to any manufacturer – be it a pharmaceutical company or the WHO - that can come up with a contraceptive that is "acceptable" and "effective" by standards set by them, and not the women who use them. Not surprisingly, from injectable contraceptives like Net En or Depo, implants like Norplant, anti fertility vaccines or even hazardous sterilisations and IUD insertions, no list of side effects or the suffering of women subjected to them seems to be reason enough to call for reconsideration of the issues at stake. Thus far, the battle for achieving effectiveness has been won many times, but not the war of finding a contraceptive that is "acceptable" to women.

If contraceptive manufacturers were like the manufacturers of refrigerators, they might heed the advise of potential clients and meet their needs. There may be no need for coercion and stern disincentives against childbearing. But in the matter of contraception, the demographic sword hangs too heavy to allow room for user controlled contraception.



BIBLIOGRAPHY

American Health Consultants Contraceptive Technology Update, 1993

Ananthasubramaniam et al, "A Muti-centre Phase III Comparative study of two hormonal Contraceptive Preparations Net Oen 50 mg + E2 Valerate 5 mg given every month and Net Oen 200 mg given every two months as intramuscular injection- A Report of a 12 month Study", Contraception Vol. 42 (2) 1990)

Balasubrahmanyan V, "Contraception As If Women Mattered," Centre for Education and Documentation, Bombay, 1986

Banerjee SK et al, "Comparative Evaluation of contraceptive efficacy of Norethisterone Enanthate 20 mg injectable contraceptive given every two or three months", Contraception Vol.30. No. 6 Dec 1984

Baweja et al, "Phase II Randomized Clinical Trial with Norethisterone Oenanthate 50 mg alone or in combination with 5 mg or 2.5 mg Estradiol Valerate or Cypionate as a monthly injectable Contraceptive," Contraception Vol. 32 Vo.4 Oct 1985

Berer M 1990 "Controversy over use of Depo Provera by asylum seekers in Hong Kong" Newsletter of the Women's Global Network of Reproductive Rights, 1990 (32) 10-2

Boston Women's Health Book Collective, "Our Bodies Ourselves," 1998

Centre for Education and Documentation, "Injectables: Immaculate Contraception?", A CED Health Cell Feature, CED, Bombay, 1983

Centre of Social Medicine and Community Health, "Reproductive Health in India's Primary Health Care," Jawaharlal Nehru University, New Delhi, 1998

Chayanika, Swatija, Kamaxi, "We and our Fertility: The Politics of Technological Intervention," Mumbai, 1998

Chorlton P 1980, "Hospital settles claim over drug's side-effects" The Guardian, London, 29th May 1980

Chowdhary et al, "Alterations in blood sugar, protein and lipid levels in Indian women by Norethisterone Enanthate "International Journal of Fertility, May-June 32(3) 1987

Datey S, Gaur LN, Saxena BN, "Vaginal bleeding patterns of women using different contraceptive methods – an Indian experience", ICMR Task Force study, Contraception March 51(3) 1995

Delhi Science Forum, The Indian Economy 1997-1998: An Alternative Survey

Department of Family Welfare, Ministry of Health and Family Welfare, Government of India, June 1993

Derham RJ and Buchan PC, (1989) "Haemorheological Consequences of Osetrogen Progestogen Therapy" Eur.J.Obstet.Gynecol.Reprod.Biol; Vol 32 ISS 2, 1989

Eighth Five Year Plan Chapter 12, GOI

Enk L et al (1992) "A prospective one year study on the effects of two long acting injectable contraceptives (depot-medroxyprogesterone acetate and noresthisterone oenanthate) on serum and lipoprotein lipids" Horm. Metab. Res 1992 Feb; 24 (2)

Fahny K et al., (1991) "Effect of depo-medroxyprogesterone acetate on coagulation factors and serum lipids in Egyptian women" Contraception, 1991 Oct. Vol 44 (4)

Forum for Women's Health, "Some Thoughts on Clinical Trials", Paper presented at the Conference of Indian Association of Women's Studies, Mysore, May 1993

Fraser IS and GJ Dennerstein, 1994, "Depo Provera use in an Australian metropolitan practice" Med J Aust 1994 May 2, Vol.160 (9)

Health Action International, "Re. WHO's Partnership with the Pharmaceutical industry," letter to WHO, Amsterdam, May 18 1999

Herschkorn P et al 1990, "Doctors and injectable Contraception. Analysis of the logistics of prescribing in accordance with the views expressed by doctors" J Gynecol Obstet Biol Reprod (Paris) 1990; 19(2)

ICMR Bulletin Vol.11 No.12 Dec 1981

ICMR Bulletin Vol.28 No.10. October 1998.

Isart F et al 1992 "Use of injectable progestin (DMPA) in adolescent health care" University of Florida. (Unpublished)

Kongsayreepong R et al, (1993) "A multi-centre comparative study of serum lipids and apoliprotiens in long-term users of DMPA and a control group" Contraception 1993 Feb. Vol. 47 (2)

Measham AR and Richard A Heaver, "India's Family Welfare Programme: Moving to a Reproductive and Child Health Approach," The World Bank, 1996

Ministry of Health and Family Welfare, "Choices for Spacing" (booklet), NOHFW, New Delhi 1993

Ministry of Health and Family Welfare, "Statement on National Population Policy, " MOHFW, New Delhi, 1996

Ministry of Health and Family Welfare, Annual Report 1996-97, MOHFW, New Delhi, 1997

Ministry of Health and Family Welfare, "Reproductive and Child Health Programme: Schemes for Implementation," Department of Family Welfare, GOI, Oct 1997.

Ministry of Health and Family Welfare, Annual Report 1997-98, MOHFW, New Delhi 1998

Ministry of Health and Family Welfare, "Reproductive and Child Health – Progress Report up to March 31st," MOHFW, New Delhi 1998

Ministry of Health and Family Welfare, "India's Progress Towards Reproductive Health Goals," Country Paper presented at ICPD + 5 Conference, The Hague, 8-12 February 1999.

National Institute of Nutrition, Annual Report 1992-93, NIN, Hyderabad, 1993

Ninth Five Year Plan 1997-2002, Vol. I, GOI

Pachauri S (Ed), "Implementing a Reproductive Health Agenda in India: The Beginning," Population Council, 1999.

Parsons CDF 1990,"Drugs, Science and Ethics: Lessons from the Depo Provera Story", Issues in Reproductive and Genetic Engineering, Vol.3, No. 2 pg.101-110 1990

Population Reports, Series K Number 2 1983

Population Reports, Series K Number 3 1987

Population Reports, Series K Number 5 1995

Prema K et al, "Low dose injectable contraceptive Norethisterone Enanthate 20 mg monthly – I clinical trials, Contraception Vol.23 No.1 Jan 1981

Ram e et al 1976, "Control of Fertility by Three Month contraceptive Injection of Depo Provera," J of the Christian Medical Association of India, Vol. LI Nos. 9-10 Sept-Oct.1976

Ravinder P et al, "Pharmacokineticks of Orally administered Norethisterone Enanthat in Rabitt, Monkey and Women ", Contraception Vol.55 1997

Sai Fred T and Lauren Chester, "The Role of the World Bank in Shaping Third World Population Policy," in Godfrey Roberts (ed), "Populaiton Policy : Contemporary Issues," New York, 1990

Savara, M, "Injecting Net En into India" Centre for Education and Documentation, Bomaby, 1986

Shatrughna V, "Hospital-based study on incidence of osteoporotic fractures in women, Aug 1997 – Aug 1998, National Institute of Nutrition Annual Report

Skegg DC et al (1995), "Depot Medroxyprogesterone Acetate and breast cancer," JAMA 1995 Mar 8, Vol: 273 (10)

Staffa JA et al (1992), "Progestins and breast cancer: an epidemiologic review" Fertility and Sterility, 1992 Mar;57 (3)

The World Bank Group, "Health, Nutrition and Population: The Human Development Network," World Bank, 1997

Thebaud A, 1982, "Depo Provera: Who chooses?" Colloque International sur la contraception vue du cote des femmes organise par le MFPF, Paris 1982

United Nations Population Fund, "Programme Review and Strategy Development: India", UNFPA, undated

United Nations Population Fund, "The State of World Population," UNFPA, 1998

United States Information Service, "Population at the Millenium," USIS, 1998

Veltch A 1983 "Damages for birth-control injection" The Guardian, London, 23rd July 1983

Voluntary Health Association of India, "Report of the Independent Commission on Health in India," VHAI, 1997

Women's Voice "Letter to Health Minister of Karnataka" 16th October 1981

World Health Organisation, "Facts About Injectable Contraceptives: Memorandum from a WHO Meeting," Bulletin of the World Health Organisation, 1982.

World Health Organisation, "Progress in Human Reproduction Research," No.22, 1992

World Health Organisation, "Progress in Human Reproduction Research," No.28, 1993