

The Chairperson  
National Human Rights Commission

Dear Sir,

This is to bring to your notice the decision by the Union Health Minister to conduct trials of the injectable contraceptive, Net En, in twelve medical colleges hospitals in the country. For the last two decades concerned scientists, women's groups, and health activists have opposed the introduction of injectable contraceptives in the family planning programme. We consider the trials a violation of the basic principles of right to health of the women on whom the trials are going to be conducted on the following grounds:

1. The side effects of injectable contraceptives like Net En are well known. Severe side-effects of Net-En are well documented, including menstrual disorders, cessation of the monthly cycle or irregular bleeding, general weakness, migraine headaches, and severe abdominal cramps. In a country where a large percentage of women in the reproductive age suffer from anaemia, irregular and heavy bleeding can have catastrophic consequences. Moreover studies have shown that injectable contraceptives like Net En can also lead to reduction of bone density. This is again fraught with grave consequences for poor women who have low bone density due to poor nutritional status. Studies on effects of injectable contraceptives also point to a possible rise in the incidence of cancers. There are also unresolved questions regarding the return of fertility and the health of babies born after cessation of the drug. It should be remembered that the Phase 3 trials being conducted by the ICMR in the early eighties was given up precisely because of the drug's unjustifiable side effects and because it was found unsuitable for Indian women. There is no change in this situation to make the injectable suitable today.
2. Trials of injectable contraceptives like Net En require close monitoring, not just for a few months or years but over long periods, to study the long term impact on both the woman and children born to them. Such monitoring is not possible given the state of public health in the country. Past experiences have exposed the total failure of concerned medical authorities to properly monitor subjects of such trials. In the Norplant (another long acting contraceptive) trials for example there was an unacceptably high percentage of women "lost to follow up." Even today there are thousands of women who had Norplant implanted, about whose health there is no available information. Since it is mainly poor women who visit Government hospitals, once again it is they who will be treated as guinea pigs during the trials. Past experience of contraceptive trials on women in the country have also shown that they are put on contraceptives without being told that they are participating in a trial and that the contraceptive is still being tested. Vital information regarding the safety, and adverse effects of the contraceptive are withheld from women, thereby depriving them of the right to make an informed choice. The proposed trials thus are in violation of the Declaration of Helsinki on trials on human subjects, which states that, "In research on man, the interest of science and society should never take precedence over considerations related to the well being of the subject."
3. The trials are clearly being undertaken in order to clear the way for the introduction of Net En in the government's population control programme. The government is attempting to justify the phased introduction of injectable contraceptives into the family planning system on the specious plea that it would provide women with a wider range of contraceptive "choice". This is making a mockery of the concept of "choice" given that an overwhelming majority of women are denied their basic rights and have no choice as regards access to health, education or employment. But even on the issue of contraceptive choice, why should the Government introduce contraceptives known to have adverse side effects. For the large majority of women using contraceptives

through informed choice. Injectables are definitely not their first choice. On the contrary, it is precisely in third world countries -- where illiteracy rates are high and where governments bow to the pressure of funding agencies and multinational pharmaceutical companies -- that injectable contraceptives are being pushed in family planning programmes.

1. Given the demand record regarding hygienic practices in the country, the introduction of injectables on a mass scale would also serve to expose large populations of women to the potential risk of diseases that can spread through injections, like AIDS and Hepatitis B.
2. The Net En trials are yet another example of the targeting of poor women to push through the government's population control and family planning programmes. These policies have reinforced the unequal gender relations that exist in our country and stand in violation of the Universal Declaration of Human Rights.
3. Since the target population in the trials are going to be poor women who work long hours to ensure the survival of their families, any adverse effect on their health will consequently affect their right to work.

We wish to reiterate our firm belief and demand that women should have the choice to decide the number of children they want and that they should have easy access to safe and affordable contraceptives. There is a big unmet demand for such safe contraceptives which is what any family planning programme should be concerned about. Net En has not been proved to be safe, especially in conditions where monitoring is likely to be poor or virtually nonexistent.

We see the decision to undertake trials of Net En as part of the current efforts by the central and several state governments to control the population at any cost through coercive and dangerous methods that target women. These efforts now extend to the linking of welfare measures and schemes of the government with small family norms, in total disregard of the violation it constitutes of human rights and constitutional guarantees.

In this regard we urge the Commission to intervene and pressurise the government to withdraw their decision to conduct trials on Net En.