or you Lavani Mutthy / Rakesh <grade % dol6...sin.net.in> Sobject: Net En Case Update

Dear Friends,

This is to inform you of what is definitely a historic event. On 24th August was the final hearing after which the Net En case has finally come to a close. Yes - the historic case against the injectable contraceptives Net En filed by Stree Shakti Sanghatana, Saheli and others in 1986.

Although we feel as petitioners we have come out of this long-drawn out case honourably, we find it a bit difficult to say we have "won" the case because the order can be interpreted as a "victory" by both sides. However, as our counsel Murlidhar and Ganesh point out (and we concur) given the fact that there have been major changes in the economic, social and political climate since the case was filed 14 years ago, this is the best order we could have got. At that time, the plea was to obtain a stay on the Phase IV clinical trial of Net En, and prevent its entry into the Family Planning programme. Subsequently, Net en became available in the private market, raising other issues - over-the-counter availability, misuse, indiscriminate use by NGOs etc, which were outside the scope of the case.

The case was closed after we as petitioners accepted the following 2 paragraphs of the GOI affidavit:

"Para 4. That perusal of the report* shows that interim recommendations with regard to (DMPA) are that it should not be allowed to mass use in National Family Planning programme and its use should be restricted to women who would be aware of all the implications of its use. It is submitted that the said drug and also Net-oen although available in the market against prescription but they are not included in the family planning programme.

Para 5. That as directed by this Hon'ble court Net En was under examination for clinical trials with ICMR and a Technical report had already been filed before the court after finalizing their trials. Thereafter the Department of Family Welfare have also filed an affidavit indicating that the Ministry of Health and Family Welfare is proposing to introduce Net En injectable as a new contraceptive in National Family Welfare Programme in such places only where adequate facilities for follow-up and counselling are available."

This statement clearly shows that a restriction is recommended, and mass use of injectables is not advisable.

[* Report of the special meeting of the Drugs Technical Advisory Board held on 16th February, 1995. The objective of this meeting ordered by the Supreme Court was to examine the recommendations of the technical sub-committee on certain issues raised by the Drug Action Forum in their petition. The recommendation relevant to DMPA is in Para 7: "The members had agreed for continued private marketing of Depo Provera injection. The drug, however, is not recommended for inclusion in the Family Planning Programme."]

The GOI appears to be following the strategy outlined at the IRR meeting last year - the phased entry of injectables. We have been hearing strong rumours that injectables (some say only Depo) is soon to be introduced in the FP programme. The word going round is "Now that the case is finally over, we can peacefully introduce injectables." However, the order clearly states some kind of restraint, and cautions against mass use. We need to emphasise this fact. It is also important to remember that the Drug Action Forum case (in which Depo Provera is one of the drugs) is still pending. The recommendation of the DTAB in this regard (quoted above) is clearly against mass use.

It may one of you aim any new information about introduction of injectables, please let disseminating this information. Please pass on this information to others.

Vinceta, Vani and Laxmi

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