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Receipt

18/9/92
Jagori Copy

Dr. S.P. Tripathi
Director General
ICMR
New Delhi.

Dear Sir,

We were appalled to read the news item titled "ICMR clears another contraceptive for sale", which appeared in the Pioneer dated 12.9.92, copy enclosed for your perusal.

We have been following up on research being carried out into new contraceptives by ICMR by reading various ICMR publications and we are not aware of any trials involving Depo Provera. In fact, we were quite satisfied that the women of India had been spared from this contro versial preparation after ICMR did no follow up studies after 1972.

We have been quite distressed that ICMR has maintained a silence in the matter despite a telephonic conversation with you asking you to publish a denial. We therefore have enough reason to believe that the above report is true.

If indeed plans are afoot to introduce Depo Provera please let us know the following :

1. Results of various clinical trials conducted with Depo Provera on the basis of which the decision has been taken, side effects, continuation rates included.
2. Dosage and regimen.
3. WHO post-surveillance research reports.
4. List of countries where it has been approved and the nature of use for which it has been approved.
5. ICMR recommendation regarding the nature of use.
6. Screening, follow-up and after-care arrangement.

We have at our disposal a goldmine of data which indicates that Depo Provera is a hazardous drug. Acting on the higher brain centres it disrupts the entire functioning of the body. Common side effects reported elsewhere have been menstrual chaos, depression, thrombosis, ovarian atrophy, headaches, weight gain, dizziness, irritability, fatigue, cramps and discomfort in the abdominal region. *hormones*

Available research also points out carcinogenic and teratogenic potential of this drug. There is a definite delay in return of fertility and a substantial number of women have been unable to conceive at all, following treatment with Depo Provera.

This drug has not been approved for general contraceptive use in most advanced countries because it is not viewed as having any advantage over other contraceptives available in comparison to the risks it poses to the user. It is largely used in the First World on mentally deficient women who have been institutionalised.

In addition to the above, in the context of our country, this drug poses additional hazards.

1. Potential for misuse : In a family planning programme such as the one run by the Indian government, injections can be administered without a woman's knowledge and consent. Particularly, advantage can be taken of the fact that the poor and illiterate in our country see injections to be a panacea for all ills.

2. Lack of screening poor logistics and risk to progeny : As the drug causes amenorrhoea in a large number of users along with other pregnancy like symptoms, there is a large likelihood of women receiving this injection in early pregnancy and not being able to abort in time. Also, given the poor logistics of contact with health workers as well as the family planning supplies, injections may not be given at the desired interval rendering the contraceptive ineffect and prone to failure. In both events, birth defects will be caused due to long term fetal exposure to Depo Provera.

3. Heavy bleeding in an aneamic population : The other common side effect is of heavy bleeding in a substantial number of users. How will this problem be taken care of. It would compromise the health of poor women even further.

The above is only an indication of what may happen to millions of women given the nature of the drug and is by no means comprehensive.

In view of the above we request you to reconsider your decision.

We may like to point out that even in the case of NORPLANT^(R), ICMR had planned on violating the laws of the land and thus by-passed the Phase III trials. This approach is completely untenable and we oppose the foisting of hazardous untested contraceptives on Indian women.

We would like to point out that provider controlled methods which do not rely on users, are unacceptable and have to be replaced by safe methods which users would like to continue with.

We reiterate that the ground reality of medical and health infrastructure is poor in our country and contraceptives such as NORPLANT^(R) or Depo Provera which require a good delivery system and a sophisticated monitoring system can only create new health hazards in our country.

At the end we would like to mention that such contraceptives can not be approved even for limited use because there exists no system in our country to monitor misuse of prescription drugs.

We urge upon you to immediately withdraw your recommendations in the interest of the life and health of Indian women.

Thanking you,

Sincerely

1. A.B.V.A. (Aids Bhedbhav Virodhi Aandolan), Delhi

3. Centre for Women Development Studies, Delhi
4. Indian Social Institute, Delhi
5. Jagori, Delhi
6. Joint Women's Programme, Delhi
7. Kali for Women, Delhi
8. Karmika, Delhi
9. Mahilla Dakshata Samiti, Delhi
10. MARG, Delhi
11. National Federation of Indian Women, Delhi
12. Purogami Mahilla Sangathan, Delhi
13. Sabla Sangh, Delhi
14. Saheli
15. Janwadi Mahilla Samiti, Delhi

AIDWA

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Under Defence Colony Flyover
Above shop no. 105-108
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