PRESS RELEASE

For the first time in India, the attempts of the Health Ministry and the ICMR, to push a hazardous contraceptive for women, has been challenged, through a writ petition filed in the Supreme Court on the 7th. of April 1986.

The Court today, (1st. May 1986) issued notice to the respondents to show cause as to why the petition should not be admitted and stay order granted on further trials of the contraceptive. In addition to the Health Ministry, the ICMR, and the State of Andhra Pradesh, the Drug Controller of India was also impleaded as a respondent. The notice is returnable on July 15th. 1986.

The contraceptive in question is Norethisterone Oenanthate (Net-Oen), an injectable form of the female hormone, progesterone, similar to the controversial drug Depo-Provera. Produced by Schering, a West German firm, it was first marketed in Peru in 1967. In 1971, it was withdrawn, as rats tested with this drug developed pituitary and breast nodules. Thereafter, it was put back on the market and is now being propagated as the ideal contraceptive for third world women.

The ICMR is currently engaged in the last stage of trials and the government plans to introduce it into the mass Family Planning programme in a big way. Far from sharing the optimism of the government and the ICMR, the petitioners contend that ther are several reasons for grave concern.

The drug is a definite hazard to women's health and a potential hazard to their progeny. The high dose of Net-Oen which is to be infected every two months, causes a complete disruption of the hormonal balance maintaining the reproductive system of women. Menstrual CHAOS, which is experienced by 90% of Indian women administered the drug, is just one of the ways in which this is manifested. Neither has the cause of this menstrual chaos been understood, nor has an effective treatment

WHO, ~~xxxxxx~~ though a proponent of Net-Oen, admits that the safety of the drug is yet to be established with regard to asp ects such as: effect on lactation and progeny, cancer risk, long-term sequelea, effocts on lipid metabolism and endometrial bleeding.

The drug has a long list of contraindications ranging from breast feeding in the initial 6 months since delivery, liver disease including jaundice, breast or genital cancer, undiagnosed vaginal bleeding, to suspected pregnancy. Women suffering from several other conditions such as diabetes and hypertension, need to be monitored closely. Given the present state of health in India, the Primary Health Centres (through which the drug will be primar ily be administered) are not equipped to screen women with these conditions, administer the injection in a carefil and safe manner and deal with complica tions as and when they arise. Hence, under Indian conditions , the potential hazards of this drug do not justify its introduction into the mass Family Planning programme.

All the same, in their eagerness to complete the trials on the drug, the centres chosen by the ICMR have been recruiting women through unethical publicity campaigns. Women are being lured by incomplete and biased information which is designed to conceal the experimental nature of the exercise and are led to believe that the drug is already tried and tested.

One of the major fears of the petitioners is that, once introduced, this contraceptive has a high potential for misuse and can recreate the Family Planning scene of the Emergency era. Unlike then, the unwitting victims may not even be aware that they have become acceptors of this method of contraception because an injection can always be administered under false pretexts.

The petitioners therefore, contend that all further experiments wo men with this drug must be stopped and the drug be banned for use in India.

...

From
SAHELI,
WOMEN'S RESOURCE CENTRE,
UNIT ABOVE SHOP 105 to 108
SHOPPING CENTRE,
DEFENCE COLONY BRIDGE (SOUTH SIDE)
NEW DELHI 110 024.

DATE: MAY 1, 1986.

PRESS RELEASE

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/..2/

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PETITIONERS

Stree Shakti Sanghatana — Women's organisation, Hyderabad
Saheli — " " Delhi
Chingari — " " Ahmedabad
Dr. Shyama Narang, Dr. Kamala S.Jaya Rao, Dr. Davayani Dangoria, Dr. A.K.Vasudevan, Dr. Ramana Dhara, Ms. Vimal Balasubramaniam.

RESPONDENTS:
Union of India through its Secretary, Ministry of Health.
Indian Council of Medical Research through its Director General.
State of Andhra Pradesh through its Secretary, Department of Health and Family Welfare, Drug Controller of India.

ADVOCATES
Petition filed by Mr. Venkataramani;
Appeared before Court: Mr. M.S. Ganesh.

Saheli

Women's Resource Center

Date 22.12.90

FOR: CHIEF REPORTER / NEWS EDITOR.

We are circulating the enclosed press release concerning a forthcoming hearing in the Supreme Court (next month) against the use of hazardous contraceptives being tested on Indian women. In particular the injectible NET-EN and other similar contraceptive drugs like Norplant, the anti-fertility vaccine and vaginal hormone releasing rings. We hope you will publish this material in the public interest.

for SAHELI

(Sathyamala.

(DR SATHYAMALA)

Unit above Shop. 105, to 108, Shopping Centre, Defence Colony, Bridge (South Side),
New Delhi-110024 PHONE : 61 6485

22.12.90

PRESS RELEASE

WOMEN DEMAND BAN ON HAZARDOUS CONTRACEPTIVES

The injectible contraceptive NET-EN once again being pushed by family planning centres in urban areas like Delhi , is still not out of the controversy dogging itm, ever since pressure from women's groups caused clinical trials to be stopped in Andhra Pradesh five years ago.

The Supreme Court case asking for a comprehensive stay on all such long-acting hazardous hormonal contraceptives is due to come up for hearing in the middle of next month.

A petition had been filed in 1986 by women's groups comprising the Stree Shakti Sangathana, Saheli, Chingari and several individual petitioners including doctors and journalists. They have now widened the scope ~~of~~ through an application filed on the 15th of December 1990 asking for additional reliefs.

The women are asking for a stay on the introduction of not just the injectible contraceptive NET-EN but are calling for a halt on the clinical trials and use of SIMILAR hazardous long-acting contraceptives, specifically sub-dermal implants (popularly known as Norplant), anti-fertility vaccines and hormone releasing vaginal rings.

Originally, the petition filed against the Ministry of Health & Family Welfare, the Drugs Controller, and the Indian Council of Medical Research (ICMR) had averred that the injectible contraceptive NET-EN caused irreparable damage to the health of women, caused infertility, and was likely to result in long-ter health effects such as cancer, apart from having a high possibility of causing congenital deformities in children exposed to these drugs in the womb.

The earlier contention of the petitioners that the Government held the life of Indian women in callous disregard since without their informed consent they were being reduced to guinea pigs by the ICMR, HAS NOW BEEN BORNE OUT BY The fact that today NET-EN is freely being adminstered to unsuspecting women in the OPD's of major hospitals and slum clinics in Delhi and other metropolitan centres.

Over the last two decades more than 10,000 women from the deprived sectors of society have been willfully subjected to dangerous levels of these hazardous contraceptive drugs. Taking advantage of the ignorance and illiteracy of women who come from urban slums and rural areas, the ICMR has pursued its unholy goal of population control at a definite cost to the health of women and their progeny.

The expanded application in the Supreme Court strongly urges them to award compensation to women who have suffered ill health as a consequence to the intake of these dangerous contraceptive. And furthermore to award exemplary damages to all women forced to participate in such clinical trials on these poorly researched contraceptives, without their specific "informed consent".

But beyond this, the petition centres around women's fundamental rights to life, health and dignity, when it comes to making reproductive choices.

Women have a right to be informed of such choices. It is not an idle formality. This petition goes one step forward in pressing the government to fulfill its social and constitutional obligations towards women who constitue fifty percent of the population of this country.

R Ghanandani & Sathyamala

(RUKHMANI ANANDANI & SATHYAMALA).

for SAHELI,
Women's Resource Centre,
Unit above Shop No. 105 to 108,
Shopping centre
Defence Colony x Bridge,
New Delhi -110024.

ph No: 616485.

Date 22.12.90.

PRESS RELEASE

The Drugs Controller of India forced to Retreat

The campaign against Depo Provera and NET-EN contraceptive injections has finally started moving. Based on the evidence presented by women's organizations, the Drugs Controller of India has stated that he will take stern action against chemists found selling Depo Provera and NET-EN without proper prescriptions.

He has also asked Max Pharma to change the package insert for Depo Provera which at present provides very sketchy information. In future the package insert will conform to that in the US.

He has also ordered German Remedies to carry out a post marketing surveillance for NET-EN.

In the meanwhile he is actively considering that the sale of these injections is limited to restricted outlets.

While these changes are welcome they constitute only the tip of the iceberg. Women's organizations have raised a number of questions about the short and long term hazards associated with these contraceptive injections. These patch work measures of the Drugs Controller do not justify his decision of approving the marketing of these injections in any way.

Women's organizations, health groups, and human rights groups opposed to these injectable contraceptives are concerned with the long list of 78 adverse reactions which include many life threatening conditions and inadequate research on long term safety, return of fertility, effect on children exposed in utero or through breast milk. In a country like India there is every chance of extensive misuse of these drugs. Their concern also stems from the fact that there is no anti-dote for these drugs and the side effects last far longer than their contraceptive

effect.

We have demanded that the Drugs Controller pass an order suspending the sales of these drugs till such time that at least the remedial measures ordered by him are implemented.

Saheli, AIDS Awareness Group, Jagori, Purogami Mahilla Sangathan
Centre for Women's Development Studies, National Federation of
Indian Women, MARG. Brinda Karat., Joint Women's Programme

Asha Ramesh, Kamala, Kalpana Mehta.
Pimla Kapoor for the AIFW

Dt. 3rd May'1994.

PRESS RELEASE

WOMEN'S ORGANIZATIONS DEMAND WITHDRAWAL OF CONTRACEPTIVE INJECTIONS

All India Democratic Weomen's Association, National Federation of Indian Women, Purogami Mahila Sangathan, Jagori and Saheli gheraoed the Drugs Controller of India to day, demanding that the licences given to the contraceptive injections Depo-Provera and Noresterat be withdrawn. The approval of these injectable contraceptives in India is a clear example of the havoc multinationals can play with the lives and health of the Indian people.

Depo-Provera is a product of the Upjohn Ltd. USA which is known to be unsafe and was not approved as a contraceptive in US for more than 25 years. This preparation has not even undergone the necessary clinical trials in India which would establish its safety.

Noresterat has undergone fifteen years of clical trials in India which have demonstrated its hazardous nature and the fact that it is not acceptable to most Indian women. In the court case against it the Government has failed to provide evidence of its safety. Noresterat is an invention of Schering AG.

Both these injections have been available for more than thirty years and have been used extensively on poor women, on ethnic minorities, inmates of mental asylums and other vulnerable sections in the first world and in repressive population control programmes in the third world. No where in the first world are these considered contraceptives of first choice by the medical system.

In order to induce a long acting effect these drugs are injected in large quantities in the body far in excess of what is needed to achieve contraceptive effect. This results in complete disruption of the cyclical processes in the women's body. Common side effects are, menstrual chaos, ranging from complete amenorrhoea to very heavy bleeding requiring hospitalization, mood changes and depression, head aches, heart disease,

14 July 1993.

Badri forwarded a copy of protocol for PMS sent by Upjohn to ICMR - for approval by DCI.

Joint Sec, Min. of H & FW wrote to DCI to speed up approval.

19/7/93

DCI approval given to Saxena.

19/10/93 Ref #: LO/No/DEPR/4.

FPAI — DCI

Expedite Test licese to import from Upjohn NV, Belgium (5500 vials)

6/Dec No 12-48/91-DC

DCI - ICMR : FPAI will undertake study with Upjohn NV, Belgium (Ref. to discon 28/9/93 & in continuation of letter dt. 29/9/93.

18/2/94.

ICMR - DCI : PMS is not with ICMR. (nothing to do with FPAI study).

25 Nov 1992 DCI - Upj.

Ref. to 16.9.91 — Clinical trials are reqd in selected women - design of trial to be dev. with ICMR - & approved by DCI.

Upjohn - DCI. Dec 11/92. Seven (4) studies done in India - 878 women

(Kaur, 4379, Lukherjea 138, Vivkar, 277, WHO (1977) - 78) (KEM, GS sethi med. Col., PGI, before 1977) Ref: Contraception Accepted for pub. 25 March '77)

clotting disorders, hypertension, extreme weight gain, hirsuitism, acne etc.

The drugs ~~press~~ pass through breast milk and if a women accidentally becomes pregnant or is pregnant when she recieves the injection she is likely to give birth to a baby with low birth weight and a high chance of mortality. In addition the child thus born may have congenital malformation affecting its genitalia.

There are enough doubts to suggest that these drugs are carcinogenic. Schering AG and Up John have left no stone unturned to invalidate the research findings in this regard.

Women who use these contraceptives find their fertility impaired.

In its country of origin, Noresterat is meant to be used only by women who are unable to use any other contraceptive. Although in October 1992, USFDA has approved Depo-Provera, this is specifically with the stipulation that UP John collects more data on Osteoporosis among Depo users. USFDA has also recognized that Depo-Provera causes birth defects.

The marketing of these contraceptives in India is completely untenable given the lack of a monitoring system and the refusal of the medical community to be held accountable for its deeds. The health status of Indian women is already low and they do not need additional illnesses induced by hazardous contraceptives.

Ranjit Roy Ch, Texy. Review Panel on post MS.

References: IRR; Bombay - Study
war 27
4/5/93 (Mtg. held on 22/4/93) - Approval etc, Before considering
73/1/A/4/INS intro into RWP, Dept of FW in coll. with ICMR may conduct
DM/M/93-HR pre programme logistic studies involving no. of Couple & a
limit of 1500 ₹.

Upjohn app. 16 Sep '91.

27 Nov 1991 — ~~Asked~~ Sent to ICMR to assess the desirability of ~~not~~ using DMPA.

~~Draw~~ letter - (Keep note ready - addressed to Dr. Tripathi, Sept 18 '92.

~~Dr~~

No obj. given on 11 June 1993 to Upjohn

But, you are advised to contact ICMR (dev. in consultation with ICMR) for PMS. Your counterpart shld. also apply for permission to manufacture formulation.

~~Dy. ICMR - No obj.~~

May 27, '93 - ICMR applied to know when DMPA is to be introduced so that they can through a 'A' type post partum centres

Also, can they have contingency funds — for this

29.6.93 No obj. to pre-prog. studies from DCI.

Upjohn to Saxena (met on May 26 '93)

Read June 16th / letter encloses a draft protocol for PMS and Draft Case Report forms for follow-up of outcome of pregnancy.

..."will also be glad to assist you in dev. ing your training material & programme for intro. in the FP of Tab

(Sd/- RJ Garceau (Director)

Saheli
Women's Resource Centre
ABOVE SHOP NOS. 105-108, DEFENCE COLONY FLYOVER MARKET (SOUTH SIDE), NEW DELHI 110 024. TEL: 4616485

9 July 1999

PRESS NOTE

Release of Report:

ENOUGH IS ENOUGH : Injectable Contraceptive Net En: A Chronicle of Health Hazards Foretold

World Population Day, 11th July . A day that is marked by a heightening of the panic about "population explosions". In Saheli, as part of a 15 year long campaign against hazardous contraceptives and coercive, unethical population control, we take this opportunity to encourage a **reconsideration of the "over" population argument** in the light of the price people, especially women, are paying in the game of controlling numbers.

Recent developments also point to a **fresh attempt at bringing 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 ICMR institution, recommended, amidst stiff opposition from women's groups and health groups, the introduction of injectables into the FWP, albeit in a phased manner.

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 potential short-term and long-term side-effects and hazards. In 1986, Net En was registered for use in India, and Depo Provera in 1993. Both were launched in India in 1994 for "social marketing" by private practitioners and NGOs. Since then, the government has been attempting 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 cases are still pending, and the issues raised have not yet been addressed.

The **health hazards** associated with use of Net en include:

- Menstrual disturbances ranging from prolonged spotting, excessive bleeding to complete absence of bleeding
- Atherosclerosis – thickening of blood vessels and cardiovascular disease
- Thromboembolism – development of blood clots at unexpected sites, resulting in damage to heart, lungs and brain etc.
- Osteoporosis/loss of bone density, resulting in higher incidence of fractures

सहेली वुमेन्स रिसोर्स सेन्टर, दुकान 105-108 के ऊपर, डीफेन्स कालोनी फ्लैओवर मार्केट (दक्षिण),
नई दिल्ली - 110 024. फोन : 461 6485

- Weight changes
- Other metabolic changes resulting in changes in sugar levels, depression, fatigue, loss of libido etc.
- Return of fertility is not predictable(a serious limitation in a spacing method)
- Cancer risk – an unresolved issue
- Adverse effects on the foetus (in case of accidental pregnancy) have not been ruled out

That the public health system is in shambles is common knowledge. We have been stressing the fact that the **Family Welfare Programme is not equipped** to introduce long-acting injectables on a mass scale. Ruling out contraindications, skill while injecting, timing of the first injection and subsequent injections, are of crucial importance. Lack of monitoring and follow up of users, and inability to deal with medical emergencies make the introduction of injectables even more dangerous. **Lack of informed consent** and enforcement of disincentives imbue injectables, with a **high potential for abuse**. The apparent "convenience" of Net En further reinforces women's powerlessness in matters of fertility control.

The latest measures to enforce the "small family norm" in the NCT of Delhi come in the shape of the **Delhi Population Bill**, which, by **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, especially women.

The Saheli report looks at Net En and Depo Provera and why they are **shrouded in controversy,** but focuses mainly on Net En, and the **campaign** against it. We analyze how long-acting, invasive hormonal contraceptives like the injectable Net En fit into the overall objectives of the Government of India vis a vis population control. The report also 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.

The **financial stakes** in contraceptive development are stupendous. 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, rather than the women who use contraceptives. 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.**

Drugs Con

PRESS RELEASE

Ever since April this year, ~~there has been a lot of~~ controversy has surrounded the introduction of DP in India. Women's grps. have raised questions on the safety of Depo Provera. The groups which had called meeting were (*) — — and — . The Drugs Controller of India, Sec. DGHS, Sec. Min of Health & FW, D.G.; ICMR, ~~Max Pharma~~, Mudra were invited to present their views. The ~~manufacturers~~ marketers of Depo Provera Max Pharma & Mudra Diversified, the ~~promoters~~ publicity agency, as well as prominent ~~gynecs~~ gynecs. of Delhi Dr Hingorani & Dr Sushela Mehra were also invited.

The ~~issues involved~~ women representatives of women's groups had met with the DCI & other officials of the Min. of H & FW on May 30th & were assured of a 2nd mtg to clarify points raised by women's groups. This meeting has not taken place till date.

Among the imp. issues to be involved:

(1) Changing the present package insert of Depo Provera that provides sketchy information to doctors to conform to US FDA standards set by the Drug Controller of India.

(2) Providing a number of Do's and Don'ts in a language comprehensible to the public.

(3) Restricting sales ~~at~~ outlets

(4) Monitoring Over the Counter sales without prescriptions.

(X) Jagori
(X) Saheli
(X) Aids Awareness group
(X) Parayagini Mahila Sangathan
(*) Centre for women's development studies
- All India Democratic Women's Assn
- National Federation of Indian Women
- All India Progressing Women Assn
- Joint Women's Programme
- Aids Bhed Bhav Virodhi Andolan

Women's groups demanded to know how the above would be operationalised. Further, although an assurance has been given regarding Post Marketing Surveillance, the protocol is still not forthcoming. A clarification was also sought on the validity of the license granted to Depo-P.

The meeting was attended only by Mr. S.M. Sharma from the DCI's office and Dr. Prema Ramachandran, ICMR. On behalf of the DCI, Mr. Sharma absolved the DCI's office, stating that the responsibility for monitoring sales lay solely with the State Drug Controllers while he said that Max Pharma has agreed to change the package insert, he gave no time schedule for withdrawal of stocks already in the market or inclusion of the new inserts. Nor did he make a commitment towards restricting sales outlets, or monitoring sales without prescriptions. He claimed that none of this was under the jurisdiction of the DCI.

Women's groups were also shocked to learn that the draft protocol that the DCI had promised to share with the women's groups, was 'Confidential' between the DCI, Max Pharma, ICMR, and several institutes all over the country that Max Pharma has 'selected' to conduct PMS.

On her part, Dr. P.R. made light of all scientific evidence that pointed towards the hazards of DP. In fact, she went so far as to say that women like

→ and choose to have serious medical problems like anemia for the sake of birth control. Women's organisations like DP hazardous contraceptives like DP they will continue to use them. Also stressed that

Resolution to be adopted on pop