

PRESS STATEMENT

The Indian government has once again decided to throw the laws of the land to the winds by announcing its decision to pursue an aggressive programme of population control in Uttar Pradesh in which a new and as yet inadequately tested contraceptive NORPLANT<sup>(R)</sup> will be pushed as a spacing method especially among low parity couples. This programme will receive financial assistance to the tune of a staggering Rs. 800 crore from the USA. Social marketing of the contraceptives will also be actively pursued in the programme.

In a simultaneous move, the Indian Council of Medical Research (ICMR) which carries out contraceptive research on behalf of the government has recently announced a pre-programme introduction trial to assess the logistical problems likely to be encountered with NORPLANT<sup>(R)</sup> on 20,000 women in urban centres throughout the country, despite the fact that it has not yet carried out the mandatory trials to assess the safety and efficacy of the same contraceptive.

India is one of the few third world countries which have a history of taking an independent stand on the introduction of new contraceptives. Our laws make it mandatory to conduct clinical trials to establish the safety of a drug, and its suitability to an Indian population before it can be promoted in the Family Planning Programme. Although inadequate in themselves these laws are designed to protect the health and interests of our citizens against the adventurism of foreign multinational companies. However, in the case of NORPLANT<sup>(R)</sup> we are shocked to find that the trials to establish that the drug is safe and non-hazardous, have been completely ignored.

It is absurd and inconceivable that clinical trials with a contraceptive drug should go hand in hand with its widespread distribution through the health system. This unprecedented move on the part of the Indian government is completely violative of the laws of the land and indicates clearly the lengths to which it is prepared to go to meet the dictates of foreign aid agencies.

We are opposed to the introduction of NORPLANT<sup>(R)</sup> on many counts. NORPLANT<sup>(R)</sup> is a long-acting, invasive and hormonal contraceptive. Being a subdermal implant, its insertion and removal require surgical operation. Its active ingredient is a hormone-livonorgestrel, which acts on the brain centres of women as also on their reproductive system. Its use is associated with a complete disruption of the menstrual cycle in most women users. Continuous use of hormones in the short run is associated with clotting of blood which may lead to thrombo-embolism and heart disease, formation of ovarian cysts and depression. The long term risks are unknown but it is suspected that cancer, infertility and adverse effects on the children born to women users are some of the possible consequences. We are opposed to the promotion of such contraceptive methods which interfere with the entire body of a woman in order for small gains in contraceptive effect.

Since the removal of NORPLANT<sup>(R)</sup> can be done only by specially trained Doctors, women have to be at the mercy of these Doctors who are the main stay of an extremely coercive and callous Family Planning Programme. In doing so, a contraceptive like NORPLANT<sup>(R)</sup> takes control away from women. NORPLANT<sup>(R)</sup> is not alone in this but is only a representative of a series of new contraceptives which do not rely on user motivation. Infact, today trials are going on for a number of methods such as anti-fertility vaccines, nasal sprays, etc. where the user does not even have to be aware that he/she is using a contraceptive. We are opposed to this entire trend in contraceptive research which assumes that men and women are irresponsible and produces contraceptives which have a great potential for misuse in a Family Planning Programme like the one being run in our country.

NORPLANT<sup>(R)</sup> is being promoted as a spacing method. Spacing method implies that the contraceptive under consideration should be useable by women post partum and their reproductive health should be fully restored once they stop using the contraceptive, making return of fertility a vital attribute.

No study has been carried out in India to show that women are able to conceive, bear and produce healthy children after using NORPLANT<sup>(R)</sup>. Further NORPLANT<sup>(R)</sup> is contra-indicated for use in lactating women, at least for the first six months of breastfeeding. NORPLANT<sup>(R)</sup> once inserted has contraceptive efficacy of five years and due to its high cost (approximately US\$34 per device) health providers are very reluctant to remove it from women before this period is over. Even if one takes the word of researchers that return of fertility is prompt after discontinuation, it still means that a woman would have a birth interval of somewhere in the order of seven years between two children assuming that she will be able to conceive within six months to a year after discontinuing use. Is such a large gap between two children in the interest of women when all along the medical community has advocated a gap of 2-3 years?

There is yet another area of concern. The findings of a recent study with a similar implant carried out by ICMR and conducted at Medical Colleges, reveal that out of the women recruited for the trial, 12% (about 300) women could not be followed up during even the 3 year study period and remain untraceable to date. The use of NORPLANT<sup>(R)</sup> requires that an extremely efficient medical system be available to deal with complications arising from its use and to monitor the health status of these women to prevent medical emergencies. If such a high rate of loss of follow up is reported under experimental conditions where best medical services are available and where greater attempts are made to keep track of women for research purposes, one can easily imagine the fate of the large number of women to whom this drug will be recommended in the Family Planning Programme. We need to mention here that just one result of not keeping track of these women would be that their devices are not removed at the end of five years. In other words then the women will face the possibility of conceiving with the ineffective implant still in the body - a situation which can lead to an ectopic pregnancy (when the embryo implants in the fallopian tubes). Ectopic pregnancy can give rise to a life threatening situation, which can cause infertility if not death.

Yet another alarming component of the government's new population policy is the move to introduce social marketing of contraceptives. Social marketing of contraceptives implies outreach of the population control system in areas where there are no health services available through grocers, paan shops and similar retail outlets. The government's proposal indicates that hormonal contraceptives will now be made available through these channels. While we are not opposed to the social marketing of barrier methods like condoms, in the case of hormonal methods like the oral pill, the consequences of such a move will be disastrous. Several third world countries which have attempted such a strategy have reported an increase in fertility rates.

Social marketing implies absence of screening for contra-indications which is essential in the case of hormonal methods. There is also no mechanism to deal with the adverse effects due to the contraceptive, contraceptive failure and the increased possibility of congenital malformations, etc. Fertile ground is thus laid for the creation of a large scale public health hazard. The government's new policy is a clear indication of its unwillingness to upgrade the general health services in the country.

The government is now trying to cash in on the good-will of the NGOs and is making them a party to a coercive and callous population control programme. Most NGOs do not have any expertise to even comprehend the consequences of these dangerous contraceptives, leave alone the capability of coping with health hazards created by them.

We believe that any scientifically designed study on contraception has to have a long term follow-up built into it. In most instances of disasters with hormonal drugs it is not only women but the entire future generation is at stake. Why are we ready to sacrifice the future of our country? Whose interests are we serving? Why do we need ever new methods of contraception whose only advantage lies in ease of service delivery? Strangely, we can not find an answer to this in our own country. Instead some top security documents of US government provide us with a clue. These documents unequivocally

view the population of the third world as a security threat to the developed world. The same US government which at present is busy twisting our arm over matters related to trade is the biggest funder of contraceptive research as well as programmes. It funds the Human Reproduction Programme of WHO, the UNFPA as well as the Population Council which has developed NORPLANT<sup>(R)</sup>. It must be remembered that the concern of all these agencies is not the health of the third world women but to somehow contain the population of the third world. Research is carried out with the primary objective of finding newer contraceptives which require little effort in service delivery and motivating users but not at the cost of their contraceptive effect - cost in terms of the health of the users is totally immaterial. Whatever research is done in respect of safety is primarily for the first world.

While under the diktat of the IMF and the World Bank our government is cutting down expenditure on health services, it is even more snocking that it is ready to swallow first world adventurism by subjecting millions of Indian women to life threatening hazards from contraceptives developed without an iota of concern for women's health.

WE CALL UPON ALL TO SAVE OUR WOMEN FROM THE DANGERS OF INDISCRIMINATE TESTING.

1. ACTION INDIA
2. AIDS BHED BHAV VIRODHI AANDOLAN
3. ALL INDIA DEMOCRATIC WOMEN'S ASSOCIATION
4. ANKUR
5. INDIAN SOCIAL STUDIES TRUST
6. JAGORI
7. KALI for Women

8. KARMIKA
9. NATIONAL FEDERATION OF INDIAN WOMEN
10. PEOPLE'S UNION FOR DEMOCRATIC RIGHTS
11. SAHELI
12. SABLA SANGH

Contact Address :

SAHELI  
Women's Resource Centre  
Under Defence Colony Flyover (South side)  
Above snop no. 105-103  
New Delhi-110024.

Telephone no. 616485 (Wed. & Sat.)

## प्रेस विज्ञापित

भारत सरकार द्वारा नारप्लांट-आर नामक गर्भ निरोधक के परिवार नियोजन में शामिल करने का निर्णय लाखों औरतों के साथ एक खतरनाक खिलवाड़ है।

नारप्लांट-आर के बावत सबसे ज्यादा महत्वपूर्ण बात यह है कि अमेरिका में विकसित इस भयंकर व हानि करने की क्षमता रखने वाले गर्भ निरोधक को भारत में बगैर स्वतंत्र परीक्षण के प्रचलित किया जा रहा है। सिर्फ यहीं नहीं हमारी सरकार दौंगली बात कहकर एक ओर तो इसे परिवार कल्याण कार्यक्रम में प्रचलित कर रही है और दूसरी ओर उसकी विशिष्ट शोध संस्था इंडियन काउंसिल ऑफ मेडिकल रिसर्च खाना पूर्ति के लिए परीक्षण की योजना बनाने में लगी हुई है।

अर्थात् नायदे-मानून को पूरी तरह से ताक पर रख देना भारत सरकार के लिए इतना आसान नहीं है। हमारे देश में परीक्षण करवाने के दो मुख्य कारण हैं - पहला यह कि हर रासायनिक गर्भनिरोधक का असर हर देश में अलग अलग होता है क्योंकि वहाँ के निवासियों की नस्ल, खानपान, वृष्ट पर व्याप्त रोग इत्यादि अलग-अलग होते हैं। दूसरे इन गर्भनिरोधकों को लगाने - निचालने, उसके रहते औरतों के स्वास्थ्य की देखभाल करने इत्यादि के सवाल देश की स्वास्थ्य व्यवस्था पर निर्भर करते हैं जिसका विनास ही वास्तव में यह तय करता है कि कोई मिश्रण गर्भनिरोधक किसी देश विशेष में सफल हो पाएगा अथवा नहीं।

नारप्लांट-आर एक हॉर्मोन से बना चमड़ी के अंदर आरोपित किया जाने वाला गर्भनिरोधक है। इसमें निहित रसायन लगातार खून में रिसता रहता है व इसी जरिए शरीर व दिमाग के हर हिस्से पर असर करता है जिससे अन्य प्रक्रियाओं के साथ-साथ पुजनन प्रक्रिया भी गड़बड़ जाती है और गर्भ निरोधक भी नहीं ठहरता है। यह बात हमारी समझ के बाहर है कि सिर्फ पुजनन शक्ति पर सबूत पाने के लिए औरतों के पूरे शरीर व दिमाग पर विपरीत असर डालने की सोच भी कैसी जा सकती है।

साथ ही नारप्लांट-आर को लगाने के लिए औरतों के शरीर की पूरी

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जांच करना आवश्यक है क्योंकि ऐसे बहुत सारे रोग व हालात हैं जिनके रहते नारप्लांट-आर का इस्तेमाल एक बड़ा खतरा बन सकता है। नारप्लांट लगाने व हटाने के लिए आपरेशन करना पड़ता है - साथ ही नारप्लांट लगे रहने के दौरान औरत को रक्तचाप, हृदयरोग, लकवा, अंडेयानी में पौड़ा इत्यादि की शिकार हो सकती है। यह सब देखते हुए जरूरी है कि नारप्लांट लगाने के पहले हमारे देश में उपलब्ध स्वास्थ्य सेवाओं की और एक सरकारी निगाह डाली जाय। यह स्पष्ट हो जाएगा कि ~~के~~ <sup>की</sup> सेवाएँ नैपेदिक व मलेरिया की जांच तक नहीं कर पातीं उनके जरिए नारप्लांट-आर का प्रचलन एक नई महामारी फैलाने के बराबर है। जैसे अभी परीक्षण पूरे न होने के कारण हमें नारप्लांट के पूरे दुष्परिणामों का अंदाजा भी नहीं है - सरकारी संस्था इंडियन ~~का~~ <sup>काउंसिल ऑफ</sup> मेडिकल रिसर्च का स्वयं यह कहना है कि शेषण किए जाने वाले दूसरे गर्भनिरोधकों के साथ उसके अनुभव से उसका यह मत है कि फिलहाल नारप्लांट-आर से निपटने लायक आवश्यक सुविधाएँ सिर्फ मेडिकल कॉलेजों से लगे अस्पतालों में ही मौजूद हैं।

हमारी सरकार अपने विशयज्ञों की बात को भी पूरी तरह से नजरअंदाज करने पर तुली हुई है और नारप्लांट-आर का प्रचलन स्वैच्छिक संस्थाओं द्वारा करवाना चाह रही है - या तो ऐसा स्वैच्छिक संस्थाओं को बंदनाम करने के लिए किया जा रहा है अथवा अब तक प्राथमिक स्वास्थ्य व पैरा मेडिकल काम करती आई संस्थाओं को मेडिकल कॉलेजों के स्तर तक उठाए जाने के लिए किया जा रहा है - भले ही इससे नारप्लांट-आर संबंधित काम हो जाए ऐसा कदम देश के बकि निवासियों की सरासर अवहेलना का होगा। नारप्लांट-आर को स्वास्थ्य सेवाओं का आधार बना देना भी उतना ही गैर जिम्मेदार कदम है जितना बगैर स्वास्थ्य सेवा उपलब्ध कराए औरतों को नारप्लांट के दुष्परिणामों का भोगी बना देना।

जैसे एक इंडियन ~~का~~ <sup>काउंसिल ऑफ</sup> मेडिकल रिसर्च की समझ से भी सहमत नहीं है। क्योंकि उनके ही एक आरोपित होने वाले गर्भ-निरोधक नारप्लांट - 2 के परीक्षण में उनके मेडिकल कॉलेज

12 प्रतिशत औरतों से सम्पर्क रखा है - अर्थात् करीब 300 औरतों

के शरीर में अब भी ऐसे गर्भ निरोधक मौजूद हैं जिनकी असरकारिता खत्म हो चुकी है। इसका एक भयंकर परिणाम हो सकता है - दूध औरतों का गर्भ अब गर्भशय की अपेक्षा अंडों को प्रवाहित करने वाली नली में ठहर सकता है जिससे उनकी जान भी जा सकती है।

नारप्लॉट-डार उन लम्बे समय तक असर रखने वाले गर्भ निरोधकों में से है जिसपर इस्तेमाल करने वालों का कोई नियंत्रण नहीं रहता। सरकारी परिवार नियोजन कार्यक्रम में इस प्रकार के गर्भ निरोधकों का प्रचलन का एक ही अर्थ है - जबरन औरतों की प्रजनन शक्ति पर रोक लगाना। इस बात से कोई भी अनभिज्ञ नहीं है कि आज भी जकरतमंद औरतों को अस्पताल के स्वास्थ्य कर्मी गर्भ निरोधक लगवाने को मजबूर करते हैं। औरतों को गर्भ निरोधकों की जरूरत अवश्य है पर ऐसे अपरिष्कृत व हानिकारक गर्भ निरोधकों की नहीं जिनपर उनका कोई नियंत्रण ही नहीं रहा। यहाँ यह बात कान्ही जरूरी है कि आने वाले समय में में एक नई गर्भ निरोधक सूई नेट-एन देवेंगं जिसकी निरापदता विवादास्पद है पर जिसे सुप्रीम कोर्ट में केस के बावजूद सरकार ने परिवार नियोजन कार्यक्रम में शामिल कर लिया है। इसी प्रकार एक टीके पर आजकल परीक्षण हो रहा है जिसे काली खांसी के टीके के माध्यम से औरतों को लगा दिया जाएगा।

यह बात याद रखनी होगी कि गर्भ निरोधकों की निरापदता साबित करना अत्यंत ही आवश्यक है क्योंकि इन्हे मरीजों की संख्या में स्वस्थ औरतों जालों तक लगातार इस्तेमाल करती हैं और इसलिए इन्हें दूसरे क्वार्डों के विपरीत असर के भापेंद से नहीं लौटा जा सकता। पर अब हमारी शोध संस्थाओं अब निरापदता के बारे में सोच ही नहीं रही है - बल्कि इंडियन काउंसिल ऑफ मेडिकल रिसर्च ने नारप्लॉट-डार पर वह शोध ही नहीं की है जिससे उसमें निहित खतरों का पता चल सके। साथ ही नारप्लॉट-डार को बच्चों के बीच अंतराल बढ़ाने वाले तरीके के रूप में प्रचलित किया जा रहा है। ऐसे गर्भ निरोधक में यह गुण होना आवश्यक है कि उसका प्रभाव अस्थायी हो - साथ ही वह धात्री माताओं के जटिल बच्चों के अविभक्त शरीर पर विपरीत प्रभाव नहीं डाले।

नारप्लांट-आर के साथ इस विषय में कोई शोध नहीं की गई है।

बात यहीं खत्म नहीं हो जाती क्योंकि सरकार ने स्पष्ट रूप से कहा है कि वह गर्भ निरोधकों की सामाजिक बिक्री (सोशल मार्केटिंग) करेगी। आए दिन इस पर आने वाले "भाला" के विज्ञापन इस बात की पुष्टि करते हैं कि बात निरर्थक अथवा अन्य व्यापकात्मक गर्भ निरोधकों की हो रही है नहीं बल्कि गोलियों पान व किराने की दुकानों से बेची जाने की हो रही है। सोशल मार्केटिंग का गर्भ निरोधकों के संदर्भ में अर्थ ही यह है कि किसी प्रकार गर्भ निरोधकों से उस दूर-दराज की जगहों तक पहुँचा जा जाय जहाँ पर स्वास्थ्य सेवाओं की पूर्ति नहीं हो। नारप्लांट-आर की तरह गोलियाँ भी हार्मोनों से बनी हुई हैं और इन्हें देने के पहले नारप्लांट के प्रकार ही औरत की सम्पूर्ण जाँच होनी आवश्यक साथ ही इसके विपरीत असर व इस्तेमाल के दौरान गर्भ ठहर जाने इत्यादि सिद्ध स्वास्थ्य सेवाओं के बगैर नहीं हो सकता साथ ही अन्य बीसरी दुनिया के देशों की गई सोशल मार्केटिंग के कारण जन्मदर घटने के बजाय बढ़ गई है।

आखिर जनमत से चुनी हमारी सरकार ऐसे प्रयत्न कर मदद उठाने क्यों आया है? किस की बात पर यह काम हो रहा है। जवाब बहुत आसान पहले-पहल तो नारप्लांट-आर के पुनर्जन के लिए आर्थिक सहायता देने की संस्था अमेरिकी है सरकार की संस्था है। आठ सौ करोड़ की राशि उसने अठारह सालों के लिए के लिए उत्तर प्रदेश मात्र के लिए दी है। नारप्लांट-आर का अविष्कार भी अमेरिका की पाप्यूलेशन काउंसिल ने ही किया है - यही नहीं उसका परीक्षण भी पाप्यूलेशन काउंसिल के माध्यम से ही होता आ रहा है। वहीं अमेरिकी सरकार जो प्रत्यक्ष व अप्रत्यक्ष रूप से हमारे साथ व्यापक संबंधों के लिए एकतरफा बदलाव लाने के लिए कोई भी हथकंडा अपनाते हैं वे बाज नहीं आती भला आज क्यों इतनी उदारता से जनसंख्या

नियंत्रण के लिए पैसा जुटा रही है। जवाब दें पेंसियन के मागजात में मिलता है जो तीसरी दुनिया की बढ़ती जनसंख्या को अमेरिकी सुरक्षा के लिए सबसे बड़े खर्चों के रूप में देखते हैं। जाहिर है उन्हें हमारी जान की कोई परवाह नहीं है - मामला तो युद्ध का है।

प्रिंतिप ग्रुप .

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Draft Press Statement

Trials with Norplant- 6 : A cruel joke on unsuspecting women

In an unprecedented move the Indian Government has decided to throw the laws of the land to the wind and has announced that a new and as yet incompletely tested contraceptive, Norplant-6, will be introduced into the Family Planning Programme, first in the urban areas and then throughout the country.

India is one of the few third world countries which has had a history of taking an independent stand on the introduction of new contraceptives. Our laws make it mandatory to conduct in the country atleast phase III and phase IV trials , if not phase I and phase II as well, in humans, before a new contraceptive is introduced into the market. For the introduction of new contraceptives, which are distributed through the Family Planning Programme, the Indian Council of Medical Research plays a Pivotal role. It is the ICMR which is supposed to conduct the necessary trials and recommend the contraceptives in question to the Drug Controller. The trials are supposed to look into the question of efficacy as well as safety of the contraceptive. Also after the three phases are over a phase IV trial is conducted to determine the logistical problems which even a safe and efficacious contraceptive may pose when introduced in the Governmental Health System, this is also known as the pre Programme Introduction Study. As such until the four phases of trials are not completed a new contraceptive cannot be introduced, except in total violation of the laws of the land.

However, with Norplant-6 , only phase II trials have been conducted in India so far. Instead of going through the usual procedure of conducting phase III and then phase IV trials, what is being envisaged is the recruitment of 20000 women this year in whom Norplant-6 will be inserted as an approved and tested method of contraception. Technically, this exercise is a phase III trial but the ICMR and the Drugs Controller are trying to circumvent even the already lax regulations governing clinical trials by calling this a controlled Programme Introduction study.

We are opposed to the introduction of Norplant-6 on many counts. First of all, Norplant-6 is a long acting invasive contraceptive proposed to be used as a spacing method. It is a sub dermal implant which requires a minor surgery for being put in position and a relatively complicated surgery for removal after it loses its contraceptive action at the end of five years. Its active ingredient is a Hormone which is artificially produced and has similarity to naturally occurring Progesterone in woman's body. The drug present in Norplant-6 does not only affect the reproductive system but also the higher brain centres in a woman's body. The effects of such continuous administration of hormones and the way in which this disrupts the entire endocrinological and metabolic processes in the body is not well understood. What is clearly understood is that such disruption does take place as more than 60% women using this contraceptive experience a disruption of their menstrual cycle. Continuous administration of hormones has also been associated with disturbances in the clotting mechanism (of blood ) leading to the possibility of

thromboembolism and heart disease. The effect of such hormones on the reproductive system is known to cause ovarian cysts and endometrial atrophy. We fail to understand why the entire body of women has to be interfered with for small gains in contraceptive effect.

Because the removal of Norplant-6 is done by specially trained Doctors, women have to be at the mercy of these Doctors who are the main stay of an extremely coercive and callous Family Planning Programme. In doing so, a contraceptive like Norplant-6 takes control away from women. Norplant-6 is not alone in this but is only a representative of a series of new contraceptives which do not rely on user motivation. Infact, to day trials are going on for a number of methods such as anti-fertility vaccines, nasal sprays etc. where the user does not even have to be aware that he /she is using a contraceptive. We are opposed to this entire trend in contraceptive research which assumes that men and women are irresponsible and produces contraceptives which have a great potential for misuse in a Family Planning Programme like the one being run in our country.

Norplant-6 is being promoted as a spacing method. Spacing implies that the contraceptive under consideration should be useable by women post partum and their reproductive health should be fully restored once they stop using the contraceptive, making return of fertility a vital attribute.

No study has been carried out in India to show that women are able to concieve bear and produce healthy children after using Norplant-6. Further Norplant-6 is contraindicated for use in lactating women, atleast for the first six months of breastfeeding. Norplant-6 once inserted has contraceptive efficacy of five years, and due to its high cost (approximately US\$ 34 per device) health providers are very reluctant to remove it from women before this period is over. Even if one takes the word of researchers that return of fertility is prompt after discontinuation, it still means that a woman would have a birth interval of some where in the order of seven years between two children assuming that she will be able to concieve within six months to a year after discontinuing use. Is such a large gap between two children in the interest of women when all along the medical community has advocated a gap of 2-3 years?

There is yet another area of concern. In phase III trials with a similar implant carried out by ICMR, with the best of medical services at its command, it was unable to follow up all the women recruited for the trial even for a period of three years which was the duration of the contraceptive effect. Infact in the study it conducted in Medical Colleges more than 12% women were lost to follow up and remain untraceable. Use of Norplant-6 requires that an extremely efficient medical system be available to deal with complications resulting from Norplant-6 use and to monitor the health status of these women to prevent medical emergencies. A system which fails to keep track of 12% women in three years is totally incapable of replicating even this level of followup when women are reduced to the staus of regular contraceptive users and stop

contraceptive users and stop being a part of experiments where their condition is of greater concern to the establishment. One can only imagine the fate of women when they will be recruited in large numbers as users of a contraceptive which is effective for five years. We need to mention here that just one result of not keeping track of these women would be that their devices are not removed at the end of five years. In other words then the women will face the possibility of conceiving with the ineffective implant still in the body - a situation which can lead to an ectopic pregnancy (when the embryo implants in the fallopian tubes). Ectopic pregnancy can give rise to a life threatening situation, which can cause infertility if not death.

Research on human beings must be carried out with their full informed consent. We maintain that this is not done as is amply clear from the films you have just viewed. Illiteracy or poverty does not render people foolish or for that matter irrational. At least they deserve to know that they are a party to experimentation. In the proposed study ICMR not only has no intention of getting an informed consent but is deliberately attempting to mislead women in to believing that Norplant-6 is a safe and appropriate method of spacing and that there are no long term risks associated with its use. This is unethical and is in contravention of national and international norms.

Further by being part of research women do risk their life and health. We must not forget that contraceptive research is done, by design, on women who are young healthy and fertile. In highlighting this risk we are not saying anything new. In the west the liability insurance that is required to cover any possible litigation arising out of such research is with such a high premium that multinational drug companies have stopped being involved with contraceptive research (the risk is real and hazards from new contraceptives can be life threatening). Now contraceptive research is being largely carried out by non profit organizations which are not so prone to liability suits. Instead of making women of the first world the subjects of these experiments, the venue has also shifted to the third world where women are unlikely to get involved in litigation. By simply refusing to follow up women ICMR the Drug Controller and the Ministry of Health and Family Welfare preclude the possibility of being sued for damages.

We believe that any scientifically designed study on contraception has to have a long term followup built into it. In most instances of disasters with hormonal drugs it is not only women but the entire future generation is at stake. Why are we ready to sacrifice the future of our country? Whose interests are we serving? Why do we need ever new methods of contraception whose only advantage lies in ease of service delivery? Strangely we can not find an answer to this in our own country. Instead some top security documents of US Government provide us with a clue. These documents unequivocally view the population of the third world as a security threat to the developed world. The same US Government which at present is busy twisting our arm over matters related to trade is the biggest funder of contraceptive research as well as programmes. It funds the Human Reproduction Programme of WHO, the UNFPA <sup>as well as</sup> the Population Council which has developed Norplant-6. It must be remembered that the concern of all these agencies is not the health of the Third World women but to somehow contain the population of the third world. Research is carried out with the primary objective of finding newer contraceptives which require little effort in service delivery & motivating users but not at the cost of their contraceptive effect - cost in terms of the health of the users is totally immaterial. Whatever research is done in respect of safety is primarily for first world.

While under the diktat of the IMF and the world bank our government is cutting down expenditure on health services, it is even more shocking that it is ready to swallow first world adventurism by subjecting millions of Indian women to life threatening hazards from contraceptives developed without an iota of concern for women's health.

We call upon all to save our women from the dangers of indiscriminate testing.

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Dear friend

Sahali

I was told about your organization by Dr. Mira

Shiva and Manisha, while

I was in Pune for a program.

I was in hurry so I could not meet you. But I am

sending you a small

report of my experience

of Norplant. I was told by

my friends to do that.

Hope see you in Delhi

when I be there.

Reply soon  
Aruna Uprey

0.0

### Nor plant

A long article on Family planning method was published in one of the leading family digest with circulation of 30,000 name as 'Sadana' in January 92. In this article, I tried to show the need of family planning in our country and the sametime about the knowledge and sideeffects of those contraceptives. Most of the time in our country the people in government try to impose different contraceptive and most of the time knowledge about sideeffects are not given to women. This article was written purely on my personal experience. But I tried to ~~show~~ the side effects in women and 381 cases only 27 did not complain at all. Many of them requested to remove the Nor plant. Reason on removing is given below.

*Time of insert 1989 - May to 1991 June*

No.	Came to visit	Result
22	did not appear at all in 2 years period	a. They went to other clinic b. They did not had any problems
21	chest pain off and on	in 13 patients this effect went away after some time 8 patients had persistent chest pain
50	heavy vaginal bleeding	37 were cased after given hormone in 13 women it had to removed because of resistant bleeding
32	Nausea, Headache, No menstruation	Little beat relief after some time but nausea persistent
55	irregular bleeding	persistent
40	Backache, No menstruation	persistent
67	Heavy Bleeding and Vertigo	persistent
37	Tingling sensation on hand and foot	persistent
27	No complain	

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No.	Side Effect and cause of removed (40 cases were removed)
2	joint pain and muscle pain
2	severe Backache
1	Bleeding for a long time and lower pain abdomen
1	After 2 weeks of inserting she developed mass on the Breast
2	During insertion they suffered from Tuberculosis
5	wanted to have baby
1	Sense of pain on in place of insertion

In 2 years 40 women Nor plant was removed in the various reasons

No Reason

14 heavy bleeding and vertigo and not stopped after medicine

1 High blood pressure (she had normal B.P. during insert)

3 in 4-6 their weight decrease by 10 kilos and Backache

2 heavy weight gain

2 Vertigo + tingling sensation

2 All the time vertigo

3 with different complains - like headache, weight loss, bleeding.

According to this data it clearly shows that many women had side effects. But it needs more experiments to clearly identify.

My experience showed that women with low nutrition and g habits has more tendency to have side effects. The most common side effect was irregularities in periods. Either heavy bleeding or stoppages of bleeding. Backache was another problem.

After the publication of this article

I removed of 40 more women

with those same side effects - like

heavy bleeding, nausea, severe backache etc

It showed need to have more

Scientific research.

DR. Aurna Upret  
Kathmandu  
Nepal