

An illustration of three syringes with green barrels and grey plunger heads, arranged diagonally. A black banner with white text is superimposed across the middle of the syringes.

TARGET PRACTICE

**ANTI-FERTILITY VACCINE RESEARCH
AND WOMEN'S HEALTH**

A *Saheli* REPORT

OCTOBER 1998

TARGET PRACTICE

Anti-Fertility Vaccine Research & Women's Health

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BACKGROUND

The world-wide obsession with 'over population', relentlessly propagated by the population control establishment has resulted in making women the target of coercive policies, and subjected them to the trials and use of many invasive contraceptives. In the name of 'increasing women's choices', long-acting, hazardous contraceptives are dumped on women. Implants and injectables such as Norplant, Net-En and Depo Provera have been tested and used on countless women, especially in the Third World.

Scientific research to control women's fertility by causing immune reactions has been continuing for almost three decades now. This desperate search for 'suitable targets within the body' that has dominated the work of several scientific institutions and reproductive immunologists all over the world, has been extremely controversial. National and international action by women's groups and health activists has opposed the development of the 'vaccine-approach' to contraception that treats pregnancy as a disease. It has highlighted the unethical and unsound scientific basis of this research, the health hazards it poses for women and the social implications of its use.

On one hand, this debate has forced the scientific establishment to become more accountable to health activists. But on the other hand, concerted attempts have been made to obscure the issues at hand. Changes in the nomenclature of Anti-Fertility Vaccines, from Birth Control Vaccines to Fertility Regulatory Vaccines and now, to Immunological Contraceptives reflect no real shift in the perspective of the developers of such a technology. Research and funding institutions claiming to be pro-women repeatedly reassure women's groups that the development of Anti-Fertility Vaccines for men is also under way. Yet, serious concerns about the health risks of these vaccines on men persist. Moreover, the fact is that most of the vaccines being developed are designed to be used on women.

This report attempts to trace a history of the development of various Anti-Fertility Vaccines all over the world; elucidate the problems inherent in the immunological approach to contraception; discuss the hazards it poses for women's health; deliberate its immense potential for abuse, and expose the population control agenda of scientific and research institutions. The women's movement has for long questioned the proclaimed 'neutrality' of science and exposed its patriarchal and class bias. We have placed the Anti-Fertility Vaccine debate in the context of its use in society where women are neither in a position of equality nor have equal access to resources. This problem is further compounded by the misplaced emphasis on 'population control' over women's health needs. In terms of the social implications of the use of these vaccines, we have located our arguments within the Indian context. Finally, we have stressed upon the urgency to redefine priorities for women's health.

We hope this report will be useful to those engaged in the struggle against coercive population policies, hazardous contraceptives and unethical research; and to those striving to build a safer and healthier future for women, men and children. This report is also a reminder to the scientific community that what they are dealing with is not mere 'statistics', but real human beings.

THE IMMUNE SYSTEM : THE BODY DEFENDS ITSELF

Anti-Fertility Vaccines, or immunological contraceptives, aim to prevent conception by inducing an immune response in the body. In order to understand the basic premise of these vaccines, the way in which they are meant to work and the potential health risks they pose, we need to begin by taking a brief look at the function and key characteristics of the immune system.

The immune system is an integrated system of vessels, organs, cells, and molecules that helps protect an individual from infectious diseases. This sophisticated body system is designed to recognise micro-organisms such as viruses, parasites and bacteria as being 'foreign'. The body then generates specific protective responses - in the form of antibodies - to combat them. Typically, the first immune response against specific micro-organisms is slow and not very effective. Over a period of time, after the primary exposure to micro-organisms, the body develops a specific immune response as a consequence of exposure to these foreign components (called 'antigens'). In cases of severe infection with extremely toxic organisms, death can occur before immunity is effective.

The three main features of an immune response are: self/non-self discrimination, specificity and memory.

Self/Non-self discrimination: The efficiency of the immune system is dependent upon its ability to distinguish between foreign micro-organisms and body components. This protection of a person's own body components against attack by the immune system is known as 'self-tolerance'. In fact, cells capable of reacting to the 'self' are either continuously deleted during one's lifetime or are functionally suppressed by immuno-regulatory cells. Without this self-tolerance, auto-immune disease can ensue, resulting in the destruction of one's own cells and molecules by the immune system. Occasionally, however, self-tolerance does break down, e.g. diabetes, multiple sclerosis, arthritis and some forms of anaemia are considered to be auto-immune in nature. Genetic factors also play a role in break down of self-tolerance. As a group, auto-immune diseases affect 5-7% of the population, often resulting in severe disabilities.

How the body learns to distinguish between 'self' and 'non-self' is still unclear. Although it is known that the learning process starts in the foetal stage itself, the body's ability for self-tolerance is further challenged at the time of puberty when many new cellular components make their appearance in the body for the first time. A clear vision of the process must await a better understanding of the basic mechanisms by which self-tolerance to a wide variety of self-components is established and maintained. At the same time, events leading to the breaking down of normal mechanisms of self-tolerance also need further research. Immunological self-tolerance to body components can be intentionally bypassed by presenting 'self' antigens (molecules) physically linked to 'non-self' antigens. In such a situation, the immune system is known to act upon the entire unit as if it were 'non-self'.

Specificity: Antibodies are a certain class of proteins found in the blood. T cells, one of the components of white blood cells, are one of the major components which endow 'specificity' of recognition to the immune response. Antigens as parts derived from various foreign components are recognised by antibodies and/or by T cells. If one antibody or a T cell recognises more than one antigen, the phenomenon is described as cross-reactivity.

Memory: Once a person has developed an immune response to a specific micro-organism, be it a virus, bacterium, parasite or fungus, the immune system remembers the micro-organism by means of its antigens and helps to combat a repeat infection more efficiently. When the individual re-encounters the original antigen (or a cross-reactive one) the immune system responds with more speed and vigour than it could upon initial exposure. Because of memory, immunity is seldom completely reversible, though it may wane to low activity.

These fundamental characteristics not only provide a basis for understanding the immune system, they also govern the safety and efficacy evaluation of any vaccine. Moreover, it is also essential to ascertain that any vaccine does not disturb the delicate balance of the immune system and impact its overall functioning. This is particularly true in the development of Anti-Fertility Vaccines that aim to intervene in the immune system to disrupt the human reproductive process.

IMMUNOLOGICAL CONTRACEPTION: TREATING PREGNANCY AS A DISEASE

The vaccine paradigm was established more than two centuries ago, when, in 1796, Edward Jenner inoculated an 8-year old boy with cowpox and effectively prevented smallpox. Since then, many vaccines have been developed, their purpose being to provide protection against debilitating or life-threatening diseases. Today, most existing vaccines are meant for the prevention or control of acute bacterial or viral infections.

Almost 100 years ago, antibodies toxic to sperm were identified by Landsteiner and Metchnikoff in 1899. But it was in the 1960s that researchers realised that some cases of infertility in women and men were due to an immune response to sperm, either preventing the development of sperm in men or destroying the sperm as they entered a woman's body. Scientists then sought to use this 'accident of nature' to develop vaccines to induce infertility by immunological means. Today, research on the immunology of reproduction is working towards both, the design of therapeutic strategies to overcome infertility due to immunological causes, as well as the development of methods for the deliberate control of fertility.

At this point it is worth noting that **the process of reproduction** involves the following stages:

1. Production of sperm in the male and production of eggs in the female.
2. Ovulation (release of the egg) and its transport down the fallopian tube.
3. Coitus.
4. Transport of the sperm into the uterus and fallopian tube.
5. Fertilisation i.e. union of the egg and sperm.
6. Transport of the blastocyst (fertilised developing egg) from the fallopian tube.
7. Implantation i.e. attachment of the fertilised egg to the uterus.

These processes are governed by a delicate hormonal balance. Two hormones produced in the pituitary gland in the brain, i.e. follicle stimulating hormone (FSH) and human luteinising hormone (LH) control development of eggs in women; FSH also controls sperm development in men. Secretion of both these hormones is regulated by gonadotropin-releasing hormone (GnRH) which is synthesised in the hypothalamus in the brain. Another hormone called human chorionic gonadotropin (hCG), produced in the woman's body subsequent to fertilisation of the egg is essential for its implantation and continuation of pregnancy.

At the same time, immunological processes are of major importance in the normal process of reproduction. Immunologically, sperm are 'foreign' even to the male, because the development of several proteins unique to the sperm takes place at puberty and the sperm are protected from blood circulation by a tight barrier within the testicle. Any interference with this blood-testis barrier could cause an auto-immune response against the sperm and result in infertility.

Although the sperm are 'foreign' to the woman's immune system, they are not normally immunologically destroyed, inspite of repeated exposure. Further, the mother's body does not reject the embryo even though it carries paternal genes 'foreign' to her.

Anti-Fertility Vaccines can theoretically intervene at most stages of reproduction. For instance, an anti-FSH vaccine, an anti-LH vaccine, or even an anti-GnRH vaccine can disrupt the development of eggs and sperm. Since all these three hormones travel via the bloodstream they are open to interception by antibody molecules. Anti-sperm and anti-egg vaccines can also disrupt the production, movement and transport of sperm and eggs. An anti-zona pellucida vaccine (which acts on the zona-pellucida - the jelly-like covering of the egg) can prevent or disrupt the union of the egg and sperm (fertilisation). An anti-hCG vaccine can disrupt development and/or the implantation of the fertilised egg.

But the fact is that any vaccine that aims to trigger an auto-immune response in the body, must interfere with its self-tolerance. In the case of Anti-Fertility Vaccines, researchers have not only to choose a target antigen that plays a critical role in reproduction, they also have to make the body component appear foreign to induce the immune system to attack it. Towards this end, they typically combine the reproductive substance to a carrier like Tetanus Toxoid (TT) or Diphtheria Toxoid (DT). The combined molecule then provokes an immune response, not only against TT or DT, but also against its natural body component.

As one of the later approaches, instead of using the whole hCG or only its beta-chain as an antigen for vaccination, a new target was introduced. This involved using beta-hCG along with an alpha-chain of LH derived from sheep (ovine LH or oLH). Such a vaccine is called a heterospecies dimer (HSD), which consists of alpha-oLH + beta-hCG. This, it was believed, can potentially increase the immunogenicity of the vaccine preparation while decreasing the 'selfness' of the vaccine.

Although Anti-Fertility Vaccines work by evoking immune responses, they differ in fundamental ways from vaccines for control of infectious diseases.

Anti Fertility Vaccines As Opposed To Traditional Vaccines

The difference between vaccines for infectious disease control and Anti-Fertility Vaccines can be discussed within several frameworks. e.g. biological bases, immunological targets, recipient population etc. Other grounds include differing perspectives of developers, providers and users and the right of the state to impose programmes of control.

Almost all of these differences are grounded in the social, economic and gendered aspects of societies. Traditional vaccines aim to provide protection against debilitating or life-threatening diseases, while Anti-Fertility Vaccines aim to prevent conception, which is a normal physiological process, and not a disease. Hence, traditional vaccines are generally administered to susceptible individuals, whether men, women or children, while Anti-Fertility Vaccines are meant for use on healthy persons of reproductive ages. Moreover, while Anti-Fertility Vaccines can theoretically be given to both men and women, most of them are designed to be administered to women.

The action of traditional vaccines is directed against foreign or 'non-self' antigens present in the body, while Anti-Fertility Vaccines direct their action against 'self' antigens. Consequently, they also carry the potential for inducing an auto-immune disease rather than preventing development of a disease (Schrater 1992).

Furthermore, traditional vaccines, usually aided by a booster, aim to confer long-term/lifelong protective immunity. The specific 'memory' of the immune system continues to protect the body against re-infection. On the other hand, Anti-Fertility Vaccines are ideally meant to act only for a short, well-defined time period, and to be reversible in their effect.

Additionally, in the case of disease control, traditional vaccines may often be the only means of prevention available. However, while understanding and evaluating the risks and benefits of Anti-Fertility Vaccines, it is important to remember that numerous safe and effective alternate methods of contraception are already available to women all over the world.

Researchers and developers of Anti-Fertility Vaccines have been exploring countless possibilities of 'appropriate target' molecules which will render contraceptive results. Their search is technically meant to be governed by the following scientific criteria:

Relevance of the target antigen in the process of reproduction. *Specificity* of selected molecules that should be secreted only in the target tissue, and not be present in other body tissues. The *existence of a homologous* (an identical or closely related) *animal model* in which safety, efficacy and immunogenicity studies can be carried out. The ability to achieve *magnitude* - sufficient antibody response, that is induced in the right place and at the right time to achieve contraceptive efficacy, while at the same time avoiding complications such as immune complex diseases. And *transience*, the selection of reproductive antigens that are only present in the body transiently (temporarily) so that the immune response will be called into effect only when the antigen is present.

The **standard procedure for the trials** of Anti-Fertility Vaccines, is that prior to any human trials, adequate trials on two animal species, including one primate animal model (e.g. chimpanzee, baboons, etc.) must be completed to test for immuno-genicity, safety and efficacy. It is only then that **Phase I Clinical Trials** on human beings - to test for safety and dosage (not contraceptive effect) - can begin on a small sample of sterilised subjects. If these trials do not reveal any toxic effects, further trials on suitable primate animal models can be conducted to look at issues of safety. At this stage, effects on reproduction, risks of birth defects, genetic mutation (changes) and cancer are meant to be looked into. Then only can **Phase II Clinical Trials** on human beings proceed - to test for effectiveness and safety - on a few hundred fertile subjects. Successful completion of these trials can lead to **Phase III Clinical Trials** on human beings - to test for effectiveness and safety on a large sample, of usually over a thousand people. Lastly, there can be **Phase IV Clinical Trials** on human beings - an acceptability study to look into the use of the method with family planning programmes, how users respond to it, how many continue/discontinue usage, and for what reasons.

However, as we will see in the chapters that follow, in the three decades of research into Anti-Fertility Vaccines all over the world, many of these scientific criteria have been compromised along the way. Demographic concerns about 'over-population' have played a significant role in determining the direction of research, priorities of researchers and adherence to ethical norms.

CURRENT STATUS OF ANTI-FERTILITY VACCINES : **MANY TARGETS, SAME AIM**

Over the past three decades, scientists in institutions all over the world have been pursuing the hunt for different types of Anti-Fertility Vaccines. The five major institutions involved in this process are : The World Health Organisation (Switzerland); The National Institute of Immunology, (New Delhi); the Contraceptive Research and Development Programme (CONRAD) of the USAID (USA); the Population Council (USA); the National Institute for Child Health and Development (USA). Among other smaller agencies involved in the development of various Anti-Fertility Vaccines, are The Centre for Reproductive Biology and Molecular Endocrinology at the Indian Institute of Science, (Bangalore); the International Centre for Genetic Engineering and Biotechnology (New Delhi); and the University of Strathclyde (Britain). Currently, research is being conducted on more than 27 vaccines, including anti-hCG vaccines, anti-FSH vaccines, anti-GnRH vaccines, anti-sperm vaccines and anti-egg vaccines.

While most of the other Anti-Fertility Vaccines are still at the animal testing or Phase I trial stage, the anti-hCG vaccine has entered Phase II human trials.

Anti-hCG (human Chorionic Gonadotropin) Vaccines

The hCG hormone is first produced by the blastocyst (the fertilised developing egg) before it gets implanted in the uterus. As mentioned before, hCG is produced in the woman's body only after fertilisation has occurred. Hence, the rationale behind the hCG vaccine is to produce antibodies with the ability to inactivate hCG as soon as this hormone is produced in the body. hCG helps in sustaining the levels of the hormone progesterone in the blood circulation. Progesterone in turn helps in thickening the endometrium (lining of the uterus), which offers support to the developing embryo for implantation. If the hCG signal to the ovaries is blocked, the progesterone levels fall and menstruation-like bleeding will occur. The exact molecular events taking place which prevent implantation of the fertilised developing egg in the absence of hCG are not known. But the result is that the anti-hCG vaccine brings about very early abortion after fertilisation.

hCG consists of two sub-units, the alpha and the beta, of which only the beta is unique to hCG. Since it was possible to procure hCG from the urine of pregnant women, work began in the late 1960's on a contraceptive vaccine based on hCG. G.P.Talwar in India was one of the main proponents of this approach. However, the beta sub-unit of hCG is also similar to the beta unit of the lutenising hormone (LH), thus opening the possibility of cross-reaction. A cross-reaction with LH can interfere with ovulation and cause menstrual disturbances. But subsequently, it was found that a portion of the beta-hCG was completely unique: a 43-amino acid carboxy-terminal peptide (CTP). This approach, with the synthetic CTP-beta-hCG vaccine has been pursued by Vernon Stevens and his team at the Ohio University, USA, with support from the World Health Organisation.

Talwar's Vaccine, The Indian Trials

G.P.Talwar is one of the scientists who has been involved with research on the anti-hCG vaccine since the early 1970's. Until the early 1980s, he carried out his research through the Department of Biochemistry at the All India Institute of Medical Sciences, New Delhi. In 1982-83, he was instrumental in setting up the National Institute of Immunology, New Delhi, from where he continued this research.

Talwar was the first to put the anti-hCG vaccine into human trials in 1974. Six fertile women were vaccinated with hCG coupled to tetanus toxoid (hCG-TT) vaccine in 1976 when its efficacy was still in doubt. Two of the women became pregnant. However, this gave rise to a controversy that he had prematurely gone into clinical trials with humans without completing the requisite animal studies. WHO withdrew support and questions of ethics raised by the Indian scientific community forced Talwar to go back to the laboratory and animal trials (Jayaraman KS, 1986). But Talwar, to prove the safety of his vaccines, stressed that the babies born to the two immunised women in the 1974 trial were 'perfectly normal'.

In 1976-78, Talwar's vaccine then went into clinical trials on 63 women in India, Finland, Sweden, Chile and Brazil under a programme supported by the Population Council. Further trials were abandoned because of wide variations in the amount of antibodies produced and low response in 25% of the trials subjects.

In the mid-1980's, **Phase I clinical trials** on a modified vaccine preparation (supposedly more 'effective') were conducted under the supervision of the Indian Council of Medical Research (ICMR) on 116 sterilised women recruited at 5 centres in Delhi, Bombay and Chandigarh. According to the report of the trial, out of 88 women immunised, 25 (28%) had complaints such as redness and pain at site of injection, fever, edema, generalised rash, transient joint-pain, nausea, muscle pain and giddiness. 15 women reportedly dropped out of the trial for reasons such as pain at the site of injection and reactions such as dizziness, palpitation, fever, edema, redness, itching, rash etc.

At this point of time, anti-hCG antibody levels of 20 ng/ml was assumed to be the level above which hCG could be neutralised and pregnancy prevented. All women in the study produced these levels, but

there was great unpredictability in the duration of reversibility of the method. Talwar claimed that immunisation with these vaccine formulations did not 'significantly alter' menstrual regularity, though they did have antibodies partially cross-reactive with LH, they continued to ovulate normally. In fact, Talwar further claimed that cross-reaction with LH is 'beneficial' and that it would in fact, enhance the effectiveness.

Unrelenting Attempts to Improve Efficacy for Mass Use. Even as Phase II clinical trials were under way, Talwar and his team realised that "the vaccine at present is not ready for adoption in family planning programmes." (G.P.Talwar, Om Singh et al, 1992). Several short-comings persisted:

i) *Primary immunisation demanded three injections:* In order to make the anti-hCG vaccine 'suitable' for use in a mass family planning programme, the need was felt to deliver at one visit, the dose required to ensure efficacy for a defined period, say 6 months, 1 year or 2 years. Another attempt in this direction was the development of the possibility of a slow-release, long-acting mechanism in the form of capsules of polymer microspheres.

ii) *Since it took about 3-4 months to build up antibody levels above the protective threshold, this period was vulnerable to pregnancy.* In order to cover this 'lag period', Talwar had been developing 'Praneem VILCI' (Vaccine Inducing Local Cell-mediated Immunity), an intra-uterine contraceptive based on a purified extract of seeds Neem (Azadirachta Indica) since it was 'observed to activate locally the cell mediated immune reaction' (G.P.Talwar, Om Singh et al, 1992). Calling Praneem a companion vaccine, it was claimed, 'Administration of a small amount of Praneem in the uterus blocks fertility for several months in rodents. (Upadhyay et al. 1990) On the basis of this claim, researchers working on Praneem have gone so far as to declare it 'An alternative to intra-uterine contraceptive devices(IUDs)' (Garg S et al, 1998) . However, several problematic issues persist starting with the very categorisation

CONTROVERSIAL ANIMAL STUDIES

Because of the species-specificity of human CG (hCG), no animal, even the higher ape, provides a completely satisfactory model in which to determine the efficacy and safety of a hCG vaccine. The primate species closest to the human are the gorilla and the chimpanzee. It is obviously not feasible, because of their status as protected species, to conduct a detailed and extensive safety evaluation of an hCG vaccine in either of these species and therefore the baboon has been selected as the most suitable model. Unfortunately, in the case of many of the tests carried out in this safety evaluation, there is no baseline data available relating to the baboon.

Although the baboon is the best available animal model for the evaluation of the safety and efficacy of an anti-hCG vaccine, great caution needs to be exercised in relating the events observed in this heterologous situation to those to be expected in the eventual homologous clinical situation. Due to species difference, antibodies raised in baboons to the heterologous (foreign) beta-hCG-CTP vaccine cross-react with endogenous baboon CG (bCG) by approximately 5% compared to hCG. Whilst this comparatively low level of cross-reaction is sufficient to produce an anti-fertility effect in the immunised baboons, it may not be sufficient to stimulate all of the acute or chronic side-effects that might occur when the homologous (self) beta-hCG-CTP vaccine preparation is used in women. The WHO Task Force set itself the task of developing a homologous animal system, which could provide a direct correlate of the eventual clinical situation. According to the Task Force, this will be important not only in determining the threshold antibody level needed to maintain anti-fertility efficacy but will also be important for gaining some insight into the possible long-term immuno-pathological risks associated with hCG vaccine administration. However, by 1992, WHO had abandoned the development of an 'appropriate animal model'.

Talwar has faced criticism for using beta hCG (human CG) in baboons. Since it is not a self-antigen for baboons, these animal studies are not adequate or conclusive to predict its effect on humans. Unless baboons are immunised using baboon CG, the situation will not be analogous to using a self-hormone in humans to induce a vaccine response. This question remains unresolved till date.

of Praneem as a 'vaccine'. Praneem does not contain a defined antigen against which an immune response should and can be evaluated. It is an agent which produces non-specific enhancement in the ability of the local immune system to destroy sperm as well as other infectious micro-organisms. Moreover, Praneem, like all other contraceptive methods, would need to undergo all the mandatory clinical trials before claims can be made about its safety and effectiveness.

iii) Commercial viability was another criterion: The search intensified for cheaper vaccines amenable to large scale production for mass use. Talwar's team cloned the beta-hCG gene in the vaccinia virus, resulting in the expression of hCG in a bio-active and immuno-reactive form. It is claimed that high and sustained antibody responses were obtained in monkeys following a single immunisation with the recombinant virus with a conventional booster. However, this approach is even more dangerous than the previous one. Immunisation with recombinant vaccinia virus by scarring of the skin could potentially result in the unintentional spread of this virus from person to person by superficial skin contact. Thus, this approach might produce an immune response to hCG in unsuspecting men and women.

By the time **Phase II Clinical Trials** started, 50 ng/ml was now assumed to be the level above which hCG could be neutralised and pregnancy prevented. These trials were carried out with an 'improved' formulation of the hCG vaccine on a total of 162 women in Delhi and Chandigarh. While all women reportedly made antibodies to hCG, only 80% generated titres above 50 ng/ml. 28 pregnancies occurred among participants who had titres <50 ng/ml.

Cross-reactivity of the anti-bodies to LH was also high, going up to 75%. Talwar, however, continued to maintain, "Cross-reactivity with LH does not impair ovulation or cause luteal insufficiency, therefore menstrual regularity is maintained." He claimed that 85% of the cycles were within the normal range (22-35 days). These statistics however do not reflect the details of alteration in the menstrual cycles of individual women.

The trials also revealed that the immune response depends on genetic and nutritional factors, and admitted that further optimisation may be required to enhance immune response, such as use of a better adjuvant - a substance which helps to elicit a better immune response against the protein it is mixed with.

On the matter of **follow-up of children** born to women who participated in the Phase II trials, the researchers claimed that the pregnancies encountered 'usual obstetric problems' but the children developed 'normally'. (Singh M, Das SK, Talwar GP et al., 1998). However, it is important to note that the children were followed up only for 3.5 years, instead of 10 years as agreed upon with their funders, the International Development and Research Centre (IDRC) and the WHO recommendation to follow up progeny until puberty.

Following pressure from the International Campaign to Stop Research on Anti-Fertility Vaccines, the funding from IDRC, Canada, for further trials on the anti-hCG vaccine stopped after these Phase II trials. After 1996, Talwar has been working at the International Centre for Genetic Engineering and Biotechnology, New Delhi, mostly with funding from the Department of Biotechnology (DBT). In March 1997, funding for research on anti-hCG vaccines was slashed by the DBT and it has been downgraded from a 'high-priority mission' to a regular 'research mode'.

At the Presidential address of the VII International Congress of Reproductive Immunology on 27 October, 1998, Talwar admitted that, "active immunization for fertility control has some inherent problems, those of uncertainty of adequate immune response by every recipient, and the need for monitoring of the titres every month to take timely boosters." He declared that an assured way out of this problem is to "resort to passive immunisation" and that a major application of such a vaccine would be for 'emergency contraception' in cases of rape or incest." In any case, such a vaccine is unlikely to be effective as a repeat emergency measure. Since these new approaches are still in the stage of animal studies, it would seem that human trials are not on the anvil in the near future.

NOTHING INFORMED ABOUT CONSENT

The research of Anti-Fertility Vaccines has been marked by an indecent rush towards human trials even before animal trials had been satisfactorily completed. In the absence of adequate and conclusive data from laboratory and animal tests to rule out possible short and long-term side-effects, it is unethical for researchers to make claims of safety and reversibility of the method under trial. Such misrepresentation of available data should not form the basis on which women make an 'informed choice' of whether or not they wish to be part of the trial. It is incumbent on researchers to be honest about the limitations of their knowledge. In practice, such an information lacunae makes the entire procedure of procuring 'consent' from participants nothing more than a farce.

Every code of ethics in the world stresses upon 'informed consent' as the foremost criteria for human trials. The Policy Statement on Ethical Considerations involved in Research on Human Subjects by the Indian Council of Medical Research, 1980, states, "The patient for a new clinical trial should be informed briefly of the potential possible benefits of the new treatment as against the existing and the possible side-effects or hazards of the new treatment when compared to the existing treatment". The Statement goes on to state, "Although the procedure of obtaining the signatures of the person giving his/her consent cannot be dispensed with, at the same time, it must be emphasised that in the context of the conditions prevailing in the country, mere signatures would not ensure the requirements of informed consent."

The ICMR guidelines were already in effect when Phase II trials of the Anti-hCG Vaccine took place in India. Yet, the procedure for informed consent was inadequate and unethical from start to finish. In the first place, the 'Information Brochure' downplayed side-effects as 'potential discomforts'. Further, the Informed Consent form stated, "Side-effects like some temporary soreness/discomfort at the injection site may be encountered. No other adverse effects are expected due to immunisation." (italics added). Such sweeping statements prior to the completion of trials are both, misleading and deceptive. At the commencement of Phase II trials, it is impossible, unscientific and irresponsible to make such a claim. It is incumbent on researchers to be honest about the limitations of their knowledge. It is only when trial participants are fully aware of the possible risks and areas where full knowledge of hazards is not yet known (e.g. effect on offspring), that their participation can be called genuinely 'informed'.

In a country like India, obtaining 'informed consent' from trial subjects, especially women, has always been a problematic issue. Low literacy rates, women's unequal status in society and decision making are further compounded by the fact that most trials (including those of the Anti-hCG Vaccine) are carried out in Family Planning Centres of public hospitals where women (especially the poor) go to seek contraceptive options. It is extremely unethical for medical practitioners to capitalise on women's need for contraceptive choices by offering untested methods under trial as a contraceptive 'choice' on par with other approved methods. In such a situation, the presence of doctors also helps to give untested methods the legitimacy they have not earned. It is easy to understand how women arriving at such Family Planning Centres expecting a service, suddenly find themselves duped into becoming 'trial subjects'.

The Population Council Trials with the anti-hCG Vaccine

In 1976-78, Talwar's vaccine then went into clinical trials in Finland, Sweden, Chile and Brazil under a programme supported by the Population Council. Further trials were abandoned because of wide variations in the amount of antibodies produced and low response in 25% of the trials subjects.

A Phase I clinical trial was then initiated in 1986 using the anti-hCG vaccine developed by Talwar, following USFDA (United States Food and Drug Administration) approval of an investigational drug exemption. The objectives of this study were to study the safety and efficacy of the vaccine. These clinical trials were conducted in 3 centres in Finland, Chile and the Dominican Republic on a total of 24 women who were already sterilised. All women developed antibodies following immunisation, but great variability in response and duration was noted. Some women reported soreness and slight

redness after injections. The study cautioned that repeated immunisation with the same carrier protein (TT or DT) may induce immuno-suppression and hypersensitivity.

Significantly, cross-reactivity with LH was about 22.4%, and the researchers noted that the possibility exists of greater cross-reactivity with LH if higher antibody titres were obtained with improved vaccines. These researchers asserted that the cross-reaction with LH is beneficial since would cause an additional anti-fertility effect by impairment of luteal function.

Although the Population Council claimed that the Phase I trials yielded 'favourable results', they admit that, "We have not proceeded further and have no current plans to continue this work. The work is suspended and would be renewed only if we were satisfied that the method would be safe and promises advantages not available with other contraceptives, and that concerns about delivery systems were being addressed. We would also have to be able to raise the substantial funding required for Phase II clinical trials." (Catley-Carlson M, President, Population Council, 1994). The withdrawal of funding from the anti-hCG vaccine is possibly because of the pressure from the pro-life lobby in the US. Rosemary Thau, former research co-ordinator at the Population Council said in a 1995 interview, "I was unable to get government funds for the human trial because the (anti-hCG) vaccine stopped pregnancy after fertilisation occurred." (Down to Earth 1995:16). Given the strong anti-abortion stance in the US, funding priorities at the Population Council seem to have shifted to anti-FSH and anti-GnRH vaccines.

The WHO Anti-hCG Vaccine

The WHO Special Programme of Research, Development and Research Training in Human Reproduction (HRP) was set up in 1972 with a view to co-ordinate, promote, conduct and evaluate research in human reproduction. The WHO Task Force on Vaccines for Fertility Regulation was established in 1973 to 'investigate the feasibility of inhibiting reproduction by immunological means'. "Because of the large number of questions that require to be resolved, this development effort may be considered high risk and fairly long-term (10-15 years). However, the impact of a vaccine, to be used either by men or women, especially in developing countries, would be so great as to warrant this involvement." (WHO Annual Report 1974). Demographic and programmatic concerns were obviously among the foremost for the WHO, since the cited 'advantages' are all from the policy maker's perspective: "The potential advantages of an immunological approach to fertility regulation are that active immunisation with an Anti-Fertility Vaccine could provide long-acting fertility control, the vaccines could be administered by paramedical personnel and large-scale manufacture of vaccines at relatively low cost may be possible." (WHO Annual Report 1976)

Vernon C Stevens and his team at the Ohio University, USA, designed the synthetic hCG peptide to achieve specificity and to avoid the possibility of cross-reactive auto-immunity involving the beta sub-unit of LH. This reduces the risk of autoimmune-induced hormonal imbalance and menstrual cycle disturbance that is possible with the whole beta sub-unit vaccine (WHO/HRP, Annual Technical Report, 1995). Talwar, however, questioned the efficacy of the synthetic beta-hCG-CTP vaccine, and maintained that it was not viable for use on a large scale.

At the same time, despite these stated 'safety considerations', the WHO was supporting work on the whole beta-sub-unit being carried out under G.P. Talwar at the All India Institute of Medical Sciences, New Delhi, which was one of its five Collaborating Centres for Research and Training in Human Reproduction (RTC). Following allegations of unethical and premature human trials in the mid-1970s, WHO withdrew support to Talwar, though the reason was never officially stated.

However, it is clear that the WHO was not unaware of the research being conducted in AIIMS. According to David Griffin, Manager, Task Force, "We (WHO) were funding the basic research on animals. Around 1974-75 there was a request from Talwar for material for laboratory tests. The beta-hCG was sent with strict instructions that it was to be used only in animals. Six months later he sent information

regarding clinical trials on four women who showed antibody response. That was a difficult period. We felt that human trials could not be done till a group of WHO consultants were sent to see if all the basic research was done and it was OK. We felt that the full range of animal tests may not have been done. But Talwar said he had all the necessary tests and published the results in the 1978 issue of Contraception. By this time he was beginning to get support from other places such as the Population Council. We offered to support the animal studies and helped set up a primate colony. After that, we ceased to be involved." (Interview with Vishwanath and Kirbat, 1996). Despite knowledge about human trials being conducted by Talwar, the WHO continued to fund research till the late '70's on the anti-hCG vaccine being carried out at AIIMS, though there is an insistence that it was for animal studies alone.

The 'WHO' vaccine was approved for use in **Phase I clinical trials** by the Australian Department of Health and the USFDA. Thirty women between 26 and 43 years of age, who had been surgically sterilised participated in the trial. The vaccine was tested in five dosages.

There was reportedly no evidence of cross-reactivity with FSH or LH. While none of the women were reported to have experienced serious side-effects, several had mild and transient muscle pain, two reported itching and redness at the injection site. Significantly, the study reveals that in view of the conversion of one subject to DT skin test positive after her first injection, it would be necessary to screen all individuals with this simple test before repeat vaccinations - a precaution which has logistic implications for family Planning Programmes.

According to WHO documents, it was originally intended that the Task Force's prototype anti-hCG vaccine would not be used beyond the Phase I clinical trial stage, but that an improved and eventually, optimised vaccine formulation would be developed for large-scale clinical testing and product development. However, despite criticism from certain quarters, especially Talwar, regarding the efficacy of the hCG-CTP vaccine, the results of the Phase I trial were considered sufficiently encouraging for the Task Force to propose carrying out a Phase II trial with the prototype formulation with the objective of testing effectiveness.

In 1993, a **Phase II clinical trial** was conducted in two centres in Sweden to assess its effectiveness in fertile women. All the first 7 trial participants experienced side-effects which included pain, slight fever and, in two cases, sterile abscesses following injections. No obvious cause(s) of these side-effects could be found, despite extensive analyses of the individual components of the vaccine. This Phase II trial was interrupted in June 1995. Work continued on a different formulation of the advanced prototype anti-hCG product that would not cause reactions at the injection site. In January 1997, David Griffin, in a meeting of the Gender Advisory Panel of the Special Programme stated, "No further research in women can be undertaken until this problem is solved."

Since 1994, there have been various studies to identify the vaccine component responsible for the adverse effects that lead to the suspension of Phase II trials. By 1998, it was clear, that HRP could not go ahead with the formulation that was used in these trials. According to Griffin, Phase I/II human trials will be resumed earliest in mid-1999 – depending on the currently ongoing "preliminary animal studies" and further formal toxicology studies (Griffin 1998 in interview with Judith Richter).

The Anti- GnRH (Gonadotropin Releasing Hormone) Vaccine

Gonadotropin releasing hormone (GnRH) is essential in regulating the synthesis of gonadotropins in both males and females. These in turn regulate gonadal function, i.e. the maturation of the egg and the production of the sperm. Interception of GnRH can cut-off the entire chain of events leading to sperm and egg production in both males and females.

The **Population Council** conducted Phase I trials of GnRH auto-immunisation for treatment of prostate cancer in 1990 in the US (Catley-Carson 1994), as did G.P.Talwar in the early 1990s.

The Population Council has also been involved in developing a two-component **contraceptive for men**. Funding support was also extended by the National Institute of Child Health and Human Development and the USAID. One component is a vaccine which stimulates the immune system to create antibodies to GnRH, which results in the suppression of testosterone, the male hormone essential for sperm production. The other component is MENT, an under-arm implant which supplies synthetic testosterone to maintain libido (sexual desire). Since MENT implants can provide hormone replacement therapy for men deficient in testosterone (which results in low sex-drive, depression and low energy), several pharmaceutical companies have expressed interest in forming commercial partnerships with the Population Council to develop MENT in various delivery forms and for various uses (Kumar N, Janne Suvisaari et al., 1997).

In women, it was proposed to use the **Anti-GnRH Vaccine** be used in the period immediately after childbirth to prolong lactational amenorrhoea (period when breast-feeding provides some contraceptive effect). Despite a published article (Talwar GP et al., 1992) reporting a Phase I clinical trial with this vaccine in two centres in India on 20 postpartum women, on 27th October 1998, in his Presidential Address at the VIIIth International Congress on Reproductive Immunology, New Delhi, GP Talwar blatantly denied having gone into human trials with the anti-GnRH vaccine. Thus, the critical question of studying the effect of such a vaccine on breast-feeding infants is hardly likely to be resolved if the main researcher denies having done the trial at all!

Anti- FSH (Follicle Stimulating Hormone) Contraceptives for Men

This research, co-ordinated by NR Moudgal, is currently being carried out at the Centre for Reproductive Biology and Molecular Endocrinology, Indian Institute of Science, Bangalore. Phase I trial was conducted on 6 men (Moudgal and Suresh, 1995).

The researchers concluded that "the oFSH vaccine does not result in any overt toxicity and is apparently safe." There has been some apprehension that gonadotropin vaccines might lead to problems in recognition of self-antigen, leading to autoimmune diseases, etc. Following immunopathology and clinical toxicology studies with oFSH vaccine, Moudgal claimed that 'this fear is largely unfounded'.

Although the efficacy and safety of the anti-FSH vaccine was nowhere near being established, Moudgal was thinking a few steps ahead to mass manufacture of the vaccine. "Active participation of and collaboration between pharmaceutical industries and the basic research scientists, being initiated or already in progress at many institutions/research centres, may hasten the entire process", he said (Moudgal NR 1995). To increase the speed with which their products would reach the market, Moudgal and some colleagues from the IISc set up the Reproductive Biotechnologies Private Limited (RPBL), a company to manufacture and distribute contraceptive methods [Jayaraman 1994, quoted in Richter J, 1998]. In 1994, RPBL entered a collaboration with the US Company Zonagen. Zonagen would provide funding for pre-clinical and primate studies and receive product manufacturing and marketing rights in the US. The agreement covers Anti-Fertility Vaccines against egg-cells and male Anti-Fertility Vaccines.

Interestingly, in a recent turnabout from his original convictions, Moudgal states that the role of FSH in regulating testicular function of the adult male continues to be debated. "The evidence currently available in favour of the concept is still circumstantial and more work needs to be done to establish the hypothesis beyond any doubt." (Moudgal NR and MR Sairam, 1998).

Research on an anti-FSH vaccine is also being carried out in the University of Strathclyde, Scotland under John Aitken. Since 1991, the Dutch company Organon Pharmaceuticals co-funds this research.

Anti-Sperm Vaccines

The immunology of infertility has, ironically, provided many openings for the deliberate control of fertility. Sperm antigens are also potential vaccine candidates because spermatozoa can

accidentally induce antibody responses in both men and women. The process of fertilisation is said to occur when the sperm fuses with the egg. This process is a complicated one which can be intercepted at several sub-stages. Several sperm antigens have been identified, and the process to isolate one unique to sperm is currently ongoing at the Center for Recombinant Gamete Contraceptive Vaccinogens, University of Virginia, USA and the Medical Research Council's Reproductive Biology Unit in Edinburgh.

The presumed efficacy of sperm vaccines is still a matter of debate. In one study, both men and women, fertile or infertile, had similar frequencies of anti-sperm antibodies, thus raising the question of whether the antibodies were clinically significant. In theory, sperm vaccines could be given to both men and women. However, the high probability of inducing autoimmune orchitis (inflammation and cellular invasion of the testes) with attendant testicular damage makes it unlikely that these vaccines can be used as male contraceptives. As for women, while they would not develop auto-immunity, some might develop permanent immunity from antigen 'boosting' as a consequence of sexual intercourse. Relevant to this concern are reports that some women undergoing intra-peritoneal insemination as therapy for infertility developed anti-sperm antibodies.

News reports about Johnson and Johnson, the New Jersey-based pharmaceuticals group, declaring that it was seeking to develop a new contraceptive vaccine for women that would stimulate antibodies to sperm, reveal the close nexus between scientific research and commercial viability. The company reportedly entered a licensing agreement with the University of Virginia's Center for Innovative Technology, which was working on the vaccine. J&J, already an important manufacturer of birth control pills, will finance the Virginia centre's testing of the vaccine on baboons (Friedman A, 1992).

Significantly, the development of anti-sperm vaccines was one of the research lines followed by the WHO Task Force since its formation in 1973. This research line was interrupted between 1982 and 1985 because of the diminishing financial resources available to the Programme and the prioritising of the Task Force's budget to the development of anti-hCG vaccines. Activities in this area were restarted in 1986, with WHO essentially taking on a co-ordinating role.

Anti-Egg (Zona Pellucida) Vaccines

The zona pellucida (ZP), the jelly-like outer coating of the mature ovum (egg produced by the female) is another target for an Anti-Fertility Vaccine. When tested in a laboratory, anti-zona pellucida antibodies inhibit sperm attachment to the zona pellucida.

The development of ZP vaccines was one of the research lines followed by the WHO Task Force from its formation in 1973. This work was terminated in 1981 because of 'lack of funds'.

Animal studies on Anti-Zona Pellucida Vaccines are currently being carried out at the National Institute of Immunology (New Delhi) under SK Gupta. The future of ZP vaccines remains uncertain. No one agrees on the significance or incidence of anti-zona antibodies in women who are infertile. Indeed, some infertile women who tested positive for anti-zona antibodies became pregnant after being treated for other fertility problems such as endometriosis. A major potential health hazard of zona pellucida vaccines lies in the potential for eradicating all of a woman's eggs, since the 'target protein' is also present in immature eggs in the ovary. It is as yet too early to predict whether, or how soon it will be possible to test these vaccines on humans.

While research on several Anti-Fertility Vaccines is placed at a 'high priority' by governments, research and funding institutions, serious questions about possible health hazards and high potential for abuse remain, especially in the context of a state-controlled population control programme.

INHERENT RISKS : HEALTH HAZARDS AND HIGH POTENTIAL FOR ABUSE

The development and clinical trials of Anti-Fertility Vaccines has come under scrutiny from various quarters. Scientists and medical personnel have raised issues relating to several scientific and technological aspects of this method. The women's movement, in addition to the technical issues, has raised several questions relating to the applicability and use of Anti-Fertility Vaccines, specially in the context of countries like India where health and 'family welfare' programmes are driven by demographic imperatives. Thus, while some issues are inherent in the technology itself, others stem from the social context of their use. But, it is apparent that both interact and have an impact on the other.

The immune system is a delicately balanced complex. Any intervention in this system has several known and unknown effects. Since the immunological approach to controlling fertility is a new one, several issues of concern emerge, which need to be tackled at each step of research before going to the next. Since contraceptives are for use on healthy populations, mostly women. Therefore, judging their risk-and-benefit trade-offs has to be done along different parameters as compared to traditional vaccines which are designed to prevent pathological processes, namely infectious diseases. Pregnancy is a normal function of the human body, and any intervention to prevent it should not disrupt the rest of the body functions.

1. Safety Not Established

There are two aspects of safety in connection with the use of immunological contraceptives : One is the need to ensure that the components of the vaccine, either singly or in combination, do not present a risk to the user in terms of toxic effects. The other is to ensure that the immune response elicited by the vaccine does not cause any unacceptable, adverse or potentially hazardous endocrine, metabolic or immunological disturbances. One of the most probable risks is that of **cross-reactivity**.

There is a risk of producing unexpected cross-reactions with body-components other than the intended target. The antibodies so generated 'also react with substances other than the intended targets because of similarity in the structure of the target molecule and some other substances in the body. These substances may have an essential function in the body, and therefore their removal may have unexpected side-effects.' (Bal V, 1994). For example, the hCG molecule contains a part (the beta-subunit) that is structurally similar to the beta-subunit of another hormone, the luteinising hormone (LH). Laboratory tests have shown that beta-hCG vaccines could induce the production of antibodies that cross-react with LH. In this way, the production or functioning of LH may get disrupted. The hormone LH is essential for maintaining the normal menstrual cycle and ovulation in women. Thus, such disruption of LH may cause disruption in ovulation or disruption in the menstrual cycle.

In clinical trials on women, the extent of disruption caused by cross-reaction with LH has not been adequately studied. For instance, in the Phase II clinical trial of the beta-hCG vaccine by the National Institute of Immunology, cross-reactivity of the anti-bodies to LH was high, ranging from 10% to 75%. Talwar claimed that 85% of the cycles were within the normal range (22-35 days). But, a woman with a 22 day cycle could end up with a 35 day cycle after immunisation, and these statistics will not show that. Such disruption of the menstrual cycle would count as a significant side-effect if it were not obscured by manipulated data.

Cross-reactivity could also result in **auto-immune disease**. The fundamental principle of an immunological contraceptive is to induce an immune response against a body substance which is usually protected by mechanisms of self-tolerance. When self-tolerance breaks down, auto-immune diseases could result. Auto-immune diseases tend to be more frequent and more severe in women than men.

It was also feared that the continuing presence of antibodies cross-reacting with LH might induce long-term problems caused by autoimmunity in the pituitary gland, the organ in which LH is produced. While Talwar maintained the claim that 'cross-reaction with LH is beneficial and not harmful', according to the WHO, "Nevertheless, there is a possibility that the cross-reactivity with LH that is elicited by the beta-hCG vaccines might have long-term effects as yet undetected in the animal studies and clinical trials carried out so far. Furthermore, cross-reactivity with other unidentified substances in the body could not be ruled out and might go unrecognised" (WHO/HRP 1993).

Similarly, research has established that the pituitary gland and a number of tumours make hCG. These include not only the trophoblastic tumours (choriocarcinomas, hydatiform moles), but also tumours of ovarian and testicular origin. It is not known if there are other elements in the body which also secrete hCG. The effect of the immune response produced by anti-hCG vaccines on such hCG producing tissues is as yet unknown. Thus, the requirement of specificity of the target antigen comes into question.

According to some researchers, it is doubtful whether it will be possible to induce a satisfactory anti-fertility effect without inducing unacceptable adverse effects. David Hamilton from the University of Minnesota, in a CONRAD Symposium in 1989 stated, "I am very sceptical that immunisation against body constituents would ever work without side-effects". According to David Griffin, scientist at the WHO, "Although recent evidence suggests that many healthy people have varying amounts and types of auto-immune antibodies in their circulation, it is still not known whether these antibodies are always harmless or whether they may sometimes denote the presence of an underlying auto-immune disease that may become apparent clinically after many years." (WHO/HRP, 1993). While other researchers involved in the development of Anti-Fertility Vaccines are not in agreement that the probability of auto-immune diseases increases with the use of Anti-Fertility Vaccines, the fact is that there is no conclusive evidence to back their assurances of safety.

A further possible risk of immunological contraceptives are **allergies**. Allergies are exaggerated or inappropriate immune responses. Such reactions could manifest themselves as redness, soreness at the site of injections, or a generalised rash. Allergies can be caused by the antigen or the carrier at each subsequent exposure to an agent which stimulates the immune system. In fact, following the Phase I trials of the WHO vaccine, researchers concluded, "In view of the conversion of one subject to diphtheria-toxoid skin-test positive after her first injection, it will be necessary to screen all individuals before repeat vaccinations." Needless to say, the adherence to such guidelines in a field situation is bound to be near impossible. Allergic reactions were also encountered in Phase I and Phase II trials of the anti-hCG vaccine in India, as well as the suspended WHO Phase II trials.

Moreover, the history of drug and vaccine development suggests that the incidence of side effects, such as **hypersensitivity** reactions to the DT carrier, will increase and might even reach unacceptably high levels as more and more people are immunised. (Annual Technical Report 1991,WHO).

2. Doubtful effectiveness

Effectiveness of a contraceptive method is measured in theoretical effectiveness rates, based on controlled clinical trials and actual-use effectiveness rates, based on conditions of normal use. In immunological methods, theoretical effectiveness rates are based on the levels (titres) of antibodies present in the blood. Once the level is above a certain limit, pregnancy is theoretically not possible. Like with other vaccines, the immune response induced by Anti-Fertility Vaccines will vary from one individual to another and will depend on the general body constitution, genetic, nutritional and health status of the person. Thus, to maintain effective levels of immunity in a general population, some individuals would need to be given a higher dose of vaccine than they actually need to achieve and maintain contraceptive protection. There are as yet no conclusive studies regarding the impact of such an approach.

So far, Talwar's beta-hCG vaccine has shown itself to be the most effective. However, even this effectiveness, after 25 years of research, is as low as 80%. A contraceptive with a failure rate of 20% in the well-controlled conditions of a trial is an unviable proposition. Further, actual-use effectiveness rate of an anti-fertility vaccine would be much lower, given the fact that women may not get the booster shot in time, or alternate contraception during the lag period may not be available, or may not be effective.

Pregnancy is also possible during the lag period (usually of about eight weeks), during which the antibodies are building up before the period of effectiveness is reached. The duration of effective immunity is as yet unclear, and could vary from user to user. The waning (declining) phase that follows, during which the vaccine may not be effective, is another period when pregnancy could occur. Clinical trials have shown that there is a great variability of response. There is variability in duration and magnitude of the 'effective' period, since different individuals have differing lag periods, plateau phases and waning phases.

For pregnancy to be successfully prevented, an additional contraceptive will have to be used during the lag period. In an actual-use situation, this is a crucial issue, where the user would have to understand the implications of the lag period, and also have access to an alternate contraceptive during this period. The proposal to promote intra-uterine 'Praneem-VILCI' as a 'companion' contraceptive is yet to be scientifically proven as viable. From a women's perspective, however, the use of Praneem-VILCI makes little sense. If indeed this contraceptive is safe and effective for three-six months as is claimed, why would a woman want to use an Anti-Fertility Vaccine which also supposedly provides contraceptive cover for three-six months?

During the waning phase, when the contraceptive effect is wearing off, booster shots are also needed to maintain the effect of the vaccine. However, because of the variability of the immune response, it becomes necessary to give standardised booster injections whether or not the individual needs it. Alternatively, scientists propose to develop 'self-test' kits for home use to monitor the level of immunity. Such a proposal seems hardly practical in the Indian setting where basic health services are inaccessible to a large majority.

3. Reversibility Not Assured

An important concern for a temporary/spacing method is reversibility, or return of fertility. Especially in a country like India where the infant mortality rate is as high as 72 per 1,000, it is mandatory that a spacing method should have proven reversibility. Since the immune response is not predictable, some people may experience "an excessive response resulting in irreversible infertility" (Basten et al., 1991:78, quoted in Richter 1993). If anything, the immune system is typically empowered with a 'memory feature'. This is the ability of the body to protect itself against re-infection, when the response of the immune system is usually more speedy and effective upon subsequent exposure to the target antigen. This characteristic of the immune system raises crucial concerns about the claimed reversibility of Anti-Fertility Vaccines.

An additional concern is the difficulty, if not impossibility of 'switching off' the action of such immunological contraceptives once they are introduced into the body. So, it may not be possible to ensure 'reversal-on-request'. In the context of a state-controlled population control, these aspects of the technology are open to abuse by providers of health services. The decision of the woman to stop using the contraceptive may not be in her own hands.

4. Future of progeny (children) uncertain

During the clinical trials conducted in various parts of the world, pregnancies occurred in the presence of sub-effective levels of immunity, either during the rising or falling phases of the immune

response or if the level of immunity reached by the individual was not adequate. In addition, some women also expressed a desire to have children, and opted out of the study. In all of these cases, the effect of the Anti-Fertility Vaccines on the children born has not been adequately studied. Adverse teratological effects, i.e. adverse effects on the foetus have not been ruled out conclusively. Follow-up studies of children born to women who participated in the Phase II (NII) trial show claimed that the pregnancies encountered 'usual obstetric problems' and the children developed 'normally'. On the basis of this, it is concluded that 'low titres of antibodies below the protective threshold have no *apparent* side-effects on the progression of pregnancy and the early development of the progeny.' (italics added). However, the children were followed up only for 3.5 years. This is in contravention of the 10 year follow-up agreed upon with the funding institution, IDRC, and WHO recommendations which suggest follow up progeny until puberty.

In the light of prior experiences like the diethyl-stilbestrol (DES) tragedy, it seems safer to err on the side of caution. In the DES case, drugs were given to pregnant women with a history of premature births, etc. There was a higher incidence of vaginal and uterine abnormalities, higher risk of vaginal cancer and higher incidence of infertility in 'DES daughters' and higher incidence of testicular abnormalities, low sperm count and lowered fertility in 'DES sons'. It is important to note that some adverse effects became apparent only after these children attained puberty, and many effects became apparent only when they reached the age of reproduction. It is more than 20 years since the first human trials on the anti-hCG vaccine were carried out. However, the offspring born to women who became pregnant during the trials either accidentally or intentionally, have not been systematically followed up. Data does not exist to rule out the possibility of adverse effects on the fetus even in these few cases.

5. Concerns About Anti-Fertility Vaccines and HIV Infection

Whilst there is no evidence that Anti-Fertility Vaccines accelerate or impair the development of HIV-related illness or AIDS, this issue does not appear to have been investigated in a systematic and controlled manner. In what seems to be an answer to criticisms raised by women's organisations in the petition 'Call for a Halt...', the WHO Task Force states, "To consider the separate needs for contraception and prevention of infection as being inextricably part of the same problem and not capable of independent solution is likely to be inefficient, cost-ineffective and not in the best interests of the user population to be served." (Griffin, PD, Warren Jones and Vernon Stevens, 1994).

Such a fragmented view of the health needs of people, especially women, is also not 'in the best interests' of people. In the context of the AIDS pandemic, an effective method of birth control that would not additionally offer protection against HIV/AIDS would obviously, from the perspective of a user, not be a preferred method. A barrier method would be far more preferable, being safe, effective, and also offering protection from STDs and HIV infections. Since HIV can lead to immuno-deficiency, great care is required when administering vaccines or other foreign antigens, particularly on a repeated basis as is proposed with Anti-Fertility Vaccines. With these concerns in mind, the WHO has made the following recommendations:

- a) That evidence of HIV infection be an exclusion criterion for Phase I, II and III clinical trials of Anti-Fertility Vaccines.
- b) That research be carried out, as a matter of priority, on possible interactions between HIV infection and Anti-Fertility Vaccines to identify any potential effects of the vaccines in the course of HIV infection and any potential effects of HIV infection on the efficacy and safety of the vaccines.
- c) That Anti-Fertility Vaccines should not be considered among the preferred options for birth control in populations with a high prevalence of HIV infection, until concerns about the safety and efficacy of these vaccines in immuno-compromised individuals have been resolved (Ada and Griffin 1991).

By the turn of the century, India is expected to have the highest incidence of HIV/AIDS in the world. Figures are projected to be around 5-8 million cases of HIV/AIDS by 2000 AD. The National AIDS Control Organisation (NACO), reports a sero-positivity rate as high 18.6 per 1000 (1997). While research continues to make Anti-Fertility Vaccines suitable for mass use, there is no conclusive scientific evidence so far to assess the impact Anti-Fertility Vaccines on risk of HIV infection. A holistic view has to be taken of the health and social situation of the vast majority, before skewed priorities of research are set.

6. Potential for Abuse

Due to their very nature, Anti-Fertility Vaccines carry an inherent potential for abuse. Experiences of women all over the world has highlighted the situations in which long-acting, invasive, provider-controlled contraceptives are abused. Whether it is women in prisons or mental asylums, immigrants into the USA and UK, or women of colour in white-dominated countries, their powerlessness is the same. A recent news report from Johannesburg (Munnion 1998) contained revelations by the former head of a secret plan to test the Anti-Fertility Vaccine on chimpanzees, which had the ultimate aim of reducing the birth rate of blacks in Soweto. Further, coercion and violation of rights is possible in several ways through state-run Family Planning Programmes. When demographic imperatives are foremost, the rights of people, especially women, take a backseat.

Several aspects of a contraceptive technology determine the degree to which a contraceptive can be abused:

If the duration of the anti-fertility effect is for a longer period, there is more potential for abuse. For instance, a permanent method is more open to abuse than a temporary one. Providers of contraceptives prefer longer acting contraceptives from a logistics point of view. In demographically driven population programmes, efficacy and high continuation rates are priorities. Thus, it is more 'convenient' for health professionals to insert/inject a woman with a contraceptive and not have to repeatedly 'motivate' her to use a method. Provider-controlled contraceptives such as Anti-Fertility Vaccines are designed to take away control from a woman. She is not left with the option of rejecting the contraceptive entirely or discontinuing it when she wishes to.

From a woman's point of view, however, the possibility or impossibility of stopping the effect of the contraceptive when she wishes, is an important factor (**degree of user control**). A woman may want to stop using a contraceptive for many reasons. She may experience severe side-effects, due to which she may want to stop its use. Or she may want to have another child. Another situation, which is common in a country like India with its high mortality rate of children under five years old (100.5 per 1000), is that a child may die, and a woman may want to have another baby. With provider controlled contraceptives, women's experience has been that they have hardly any say in the matter. In Indonesia and Bangladesh, women activists found that it is difficult for women to get the Norplant removed before its duration of 5 years. In fact, studies have shown that women were not even aware that the device could be removed before 5 years.

The abuse potential is also dependent on the **type of contraceptive** in question. Three dimensions are important:

- the ease with which a method can be distributed on a mass scale;
- the intrinsic ability with which it can be administered without people's knowledge;
- the ease with which people can be persuaded of its advantages'

The more easily a method can be administered on a mass scale and given without people's knowledge, and the more easily its 'acceptability' can be engineered to increase its use, the higher the risk that it will be abused.

"If some excesses appear, don't blame me... You must consider it something like a war. There could be a certain amount of misfiring out of enthusiasm. There has been pressure to show results. Whether you like it or not, there will be a few dead people." Dr DN Pai, Director of Family Planning in Bombay (quoted in Hartmann, 1995:243-4).

This sentiment sums up the attitude of the population control establishment, in the shape of scientists, doctors and policy makers. Developing invasive and hazardous technologies, and then applying them on a mass scale in Family Planning programmes are all influenced by this mind set. India has a history of forced sterilisations, and forcing women to 'accept' intra-uterine devices or sterilisation after an abortion or childbirth. Instance of abuse with newer long-acting hormonal methods like Norplant and injectables abound.

The abuse of contraceptives is defined from the point of view of the user. Since users of most contraceptives are women, it would mean viewing the problem from the point of view of women. The social and economic situation of women – their secondary status, is a determinant of many aspects of abuse. Fully informed consent in writing is a crucial requirement for genuinely free choice. Yet, written informed consent is not the only requirement, since genuine consent and choice depends on many variables. Consent can be violated or manipulated in various ways. It could mean that a woman does not know she is being administered a contraceptive – for instance, she may not know that she is being sterilised after a Caesarean section delivery. Or she may not know that the injection she is receiving is a contraceptive.

Secondly, she may not know exactly what contraceptive she is being given. For instance, the intra-uterine device (IUD) – a spacing method, inserted may actually be quinacrine sterilisation- a permanent method. A woman may not be told all the risks/potential hazards of the method she is persuaded to use and a biased picture of its supposed 'benefits' may be presented. The practice of 'recruiting' trial participants from functioning Family Planning Clinics at public hospitals, whether for Norplant, Net En or Anti-Fertility Vaccine trials, is one that is fraught with the potential for abuse. Women go to hospitals for services, least expecting to be part of a trial. Contraceptive 'choices' are presented to them without revealing that one of them is as yet untested and potentially hazardous. Experience has shown that in these situations, women's lack of information has been exploited by the research-medical-state establishment in the interests of population control.

Women's position in the family and their status in society makes them vulnerable to abuse. In general, women have little control over their bodies, sexuality and fertility. They have little decision making power about whether, when and how many children to have. The unequal power relations between men and women ensure that women have hardly any determining role within the family. Since women have to bear the brunt of repeated childbirth, miscarriage and abortions, they are very keen to use contraceptives. In situations where their partners or other family members do not want them to use contraceptives, a 'secret' contraceptive is a seemingly attractive option. An injection or implant which is not connected to coitus, and is not directly related to the reproductive organs seems specially designed for these situations. However, this sort of 'solution' is one which deliberately accepts the status quo, without any attempt to address the basic inequalities between men and women.

Seen from this point of view, Anti-Fertility Vaccines carry a high potential for abuse. The experience of supposedly controlled, well-monitored clinical trials on Anti-Fertility Vaccines has shown how easy it is to violate the requirement of genuine informed consent. In an actual situation, it is difficult to believe that the requirements will be met even up to a minimum extent.

8. Issues Related to Health Delivery

Anti-Fertility Vaccines, in common with other long-acting contraceptives, are fully dependent on providers. Several problematic issues emerge. Potential users need extensive screening to identify

women who should not be given Anti-Fertility Vaccines, for instance, those with allergies, those with auto-immune diseases etc. Tests need to be conducted to rule out **contraindications**. For instance, it is very important to ensure that the woman is not pregnant before giving her an anti-fertility vaccine.

Further, following an immunisation, a woman will have to be **followed up** to monitor side-effects. She has to know what warning signals to watch out for, and the health personnel should be fully cognisant of the possible **adverse reactions**. The user also has to be explained and cautioned that the contraceptive effect does not take effect immediately. She has to be supplied with an **additional contraceptive** to cover the lag period when antibodies are building up. As important, she has to be fully aware of the waning period when antibodies are declining, and there is a possibility of her becoming pregnant. The health personnel have to carry out a test to discover when the contraceptive effect is wearing off, and when exactly the woman needs a **booster injection** to maintain contraceptive effect. The wide variability in immune response implies that detailed and accurate individual records will have to be maintained by health personnel in order to follow-up the woman when needed.

The health delivery system also has to be capable of responding to any **emergency** that may crop up as a result of the contraceptive. A strategy of dealing with unintended pregnancies has to be worked out. Given the abysmal state of health services in the country, especially in rural areas, it is impossible that the above minimum requirements for the use of Anti-Fertility Vaccines will ever be met. In fact, the state of the public health system is getting worse, as budgetary allocations for primary health care are plummeting, and health care is being increasingly privatised. Rather than a basic right that the government should provide, primary health is being viewed as a consumer item which is dependent on the amount of purchasing power.

In a social situation fraught with inequalities, claiming that Anti-Fertility Vaccines, with high potential for abuse can be administered in accordance with global ethical standards is a blatant attempt to ignore ground realities.

RESISTANCE TO ANTI-FERTILITY VACCINES: VOICES OF PROTEST

In June 1993, women's health activists from all over the world met in Germany for a meeting, "Vaccination against Pregnancy: Researcher's Dream, Women's Nightmare?" Highlighting the unethical research, inherent health risks, and potential for abuse, a resolution was passed declaring that "research on Anti-Fertility Vaccines should not be pursued." Following this meeting, an open letter, the "Call for a halt to Research on Anti-Fertility Vaccines" was written, directed at the main research institutes and funding agencies involved in this research.

The "Call for a halt" petition was endorsed by a wide spectrum of groups and individuals all over India. On November 8th, 1993, about sixty women and health activists leafleted in public and demonstrated at the office of the WIIO in New Delhi focussing attention on the inherent risks of the Anti-Fertility Vaccines. Following this, NII was forced to meet with women and health activists, who questioned the scientists about the unethical research. Since then, the "Call for a Halt" petition has been signed by almost 500 organisations in 39 countries the world over.

Following a Campaign Meeting in Canada in 1995, representatives of women's organisations met with IDRC, the funders of the trials of the anti-hCG vaccine and raised issues of concern. Sustained pressure from the Campaign compelled the IDRC to stop funding this research. At the Canada meeting, the Campaign was broadened to a wider opposition to all hazardous contraceptives and population policies. A worldwide postcard campaign to pressurise WHO to withdraw its trials was taken further in India by Saheli. Opposing research on Anti-Fertility Vaccines, demanding accountability from the scientific establishment, highlighting violations of basic rights and putting forth alternatives of safe, effective, user-controlled contraceptives has been a major focus of the Campaign. With population policies overshadowing the lives of a majority of people in India, it is crucial to step up the resistance at all levels.

ETHICAL CONCERNS : A HISTORY OF VIOLATION

At the end of World War II, the Nuremberg Trials held a number of German doctors and scientists guilty of appalling and inhuman experiments carried out on inmates in the Nazi concentration camps. Subsequently, in June 1964, the first international set of guidelines on the ethics of medical research, the "Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects" was adopted by the 18th World Medical Assembly, Helsinki, Finland. The 'Declaration of Helsinki' was later amended in 1975, 1983 and 1989. It has also served as the basis for ethical guidelines formulated all over the world, including the guidelines laid down by the premier research institute of India, the Indian Council of Medical Research (ICMR). In addition, the other guidelines that set international norms for biomedical research includes that of the Council for International Organisations of Medical Sciences (CIOMS, 1993), prepared in collaboration with the WHO. In 1978, WHO had also laid down specific safety guidelines for the research of Anti-Fertility Vaccines.

Yet, it is apparent that the trials of Anti-Fertility Vaccines all over the world have consistently flouted numerous norms and guidelines. The ethical standards adhered to in Anti-Fertility Vaccine research in India also stand exposed. While this is not a comprehensive account of the ethical violations committed all over the world, it is sufficient indication of the unethical nature of trials of Anti-Fertility Vaccines.

1. **a) Guideline on scientific basis for human trial:** *Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and a thorough knowledge of the scientific literature.* [Helsinki Declaration: Basic Principles - para 1].

b) Guideline on predictability of hazards: *Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable.* [Helsinki Declaration: Basic Principles - para 7].

Violation: As we have seen, Anti-Fertility Vaccines function by inducing immune reactions to cause contraception. Yet, much remains to be learnt about the immune system itself. In the context of Anti-Fertility Vaccines, this has many implications. One of the most important concerns is the effect of cross-reactions. Published reports carry ample evidence of the incidence of such cross-reactions. As long as the controversy of whether these are 'beneficial' or problematic, it is clearly insufficient information on which to base human trials. Additionally, other potential hazards include hypersensitivities, auto-immune diseases and permanent infertility. Until there is conclusive evidence to rule out these possibilities, or predict accurately, the risks they pose for subjects of the trials, it is clearly unethical to proceed with human trials of Anti-Fertility Vaccines.

In a blatant violation of all ethical norms of research, in 1974, Anti-hCG Vaccine trials in India were conducted on six women prior to completion of animal studies. It goes without saying that such 'scientific' practice is absolutely unethical and unacceptable.

2. **Guideline on Risk-Benefit Assessment preceding human trials:** *Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison to foreseeable benefits to the subjects or to others. Concern for the interests of the subject must always prevail over the interests of science and society.* [Helsinki Declaration: Basic Principles - para 5].

Violation: Almost three decades after the research of Anti-Fertility Vaccines began, the failure rates of the method are still unacceptably high, immunological safety has not been established, long term toxicity and teratological effects not ruled out and the effect on pregnant women not conclusive.

Other concerns include the hazards of repeated immunisation and the unpredictability of immune response among trial subjects. While several researchers and scientists engaged in the development of Anti-Fertility Vaccines use this as a justification to further this line of research, such an argument is totally inadmissible from an ethical standpoint. Contrary to the letter and spirit of accepted ethical codes, such scientific pursuit clearly places the so-called interests of science and society above those of the individual.

3. **a) Guideline on Informed Consent:** *In order to give informed consent to participate in a clinical trial of an Anti-Fertility vaccine, subjects must understand ...theoretical risks including adverse reactions not seen in previous studies, irreversibility of Anti-Fertility effect and failure of Anti-Fertility effect resulting in unplanned pregnancy (in Phase II and III trials). [Proceedings of a Symposium on Assessing the Safety and Efficacy of Vaccines to Regulate Fertility, convened by the WHO/HRP, Geneva, June 1989 quoted from Viswanath and Kirbat].*

b) Obtaining Informed Consent: *Although the procedure of obtaining the signatures of the person giving his/her consent cannot be dispensed with, at the same time, it must be emphasized that in the context of the conditions prevailing in the country, mere signatures would not ensure the requirements of informed consent ... the proposed participants in a clinical research programme should be made aware, by a person not in a position to influence the patient such as a treating physician but for example, by a social worker, of the fact that a new drug or procedure is being evaluated. [ICMR Guidelines].*

Violations: In the absence of adequate and conclusive data from laboratory and animal tests to rule out possible short and long-term side-effects, it is unethical for researchers to make claims of safety and reversibility of the method under trial. Such misrepresentation of available data should not form the basis on which women make an 'informed choice' of whether or not they wish to be part of the trial. It is incumbent on researchers to be honest about the limitations of their knowledge. In practice, such an information lacunae makes the entire procedure of procuring 'consent' from participants nothing more than a farce.

As we have seen before, in the Anti-hCG Vaccine trials in India, the procedure for informed consent, starting with the 'Information Brochure' was unethical all the way. Downplaying side-effects. Prematurely declaring safety of the method and conducting trials from Family Planning Centres in government hospitals, are all measures adopted to capitalise on women's ignorance and vulnerability. Such a procedure and any 'consent' that is obtained in this manner cannot be regarded as a genuine effort towards informed consent.

4. **Guideline on use of lactating women as research subjects:** *As a rule, pregnant or nursing women should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects. [CIOMS, Guideline 11].*

Violation: In yet another instance of blatant violation of ethics, Talwar conducted Phase I clinical trials of the Anti-GnRH Vaccine in at least 20 postpartum women through two Indian centres. These trials cannot be justified on any grounds. Contrary to the guideline, these trials were neither designed to protect nor advance the health of the nursing women or their infants. Instead, they exposed both, the mothers and their infants to unknown health risks.

5. **Right to Compensation:** *Research subjects who suffer physical injury as a result of participation are entitled to such financial or other assistance as would compensate them equitably for*

any temporary or permanent impairment or disability... The right to compensation may not be waived. [CIOMS: Guideline 13: Right of subjects to compensation].

Violation: It is clear that Anti-Fertility Vaccines pose potential health risks to women and men who have been part of its trials. Yet, besides a WHO-HRP trial where the Swedish government covered any potential damages from clinical trials approved by the Swedish Medical Products Agency, few instances of any kind of compensation/health insurance cover for trial subjects have come to light. In India, women and men participating in Anti-Fertility Vaccine trials have had no such cover or assurance of treatment/medical attention in case of ill-effects. Of course, the issue of compensation is a complicated one. Caution must be exercised to ensure that it does not get misused as incentives to induce people to be part of a trial. In this context, a health insurance cover is probably the best way to insure the health and well-being of trial subjects.

In more ways than one, scientists and researchers involved in the development of Anti-Fertility Vaccines, have fallen far short of the ethical standards they claim to adhere to. In addition, **several other ethical issues remain untouched by established guidelines for biomedical research.** While these critical areas of concern are *not* covered by either, national or international conventions, they have grave implications for the health and well-being of women, men and children involved in clinical trials.

The first among these concerns *Follow-up of women involved in the trials.* In contraceptive trials, especially with methods like Anti-Fertility Vaccines that impact both, the immune system and the reproductive processes in the body, it is essential that women be followed up for the length of time necessary to assess any side-effects or problems that could become apparent only in the long term. It is shocking that none of the established guidelines for biomedical research, including the Draft Consultative Document on Ethical Guidelines on Biomedical Research involving Human Subjects, ICMR 1997, have thought it an important enough issue worth laying down some norms for. Not surprisingly, both research and funding institutions, relieved of the 'burden' of having to conduct long term follow up, are content to make unsubstantiated claims.

According to published reports of Talwar's Anti-hCG Vaccine trial, only 94 out of 162 women interviewed 'volunteered' for long term follow-up. Clearly revealing that follow-up was not built into the study design in the first place. Enquiries with the NII on long term effects of Anti-hCG Vaccines, merely elicited this response: "Data available till date on subjects who have completed four to ten years post-immunization is not indicative of any residual ill effects." (Letter to Saheli dated February 27, 1998). Even the WHO, which is believed to set the standard for ethical research, conducted long term follow-up of the subjects of its Anti-hCG Vaccine trials in Australia, only when urged to do so by its Gender Advisory Panel at a meeting in February 1996. About a decade after it conducted its trials, it comes as no surprise that out of 45 subjects, only one could be traced. Such an indifferent and hypocritical attitude from the very scientists and institutions who claim to be working for the welfare of the people, is extremely worrisome.

Unfortunately, the same apathy is also carried forward in the matter of *Follow-up of children* born during or after the trials. As has been discussed before, after the experience with DES and other such harmful contraceptives, it is essential that children born due to method failure, or even subsequent to termination of trials must be monitored at least until their childbearing years. Unfortunately, even the WHO has so far, only made a 'recommendation' that suggests follow up progeny until puberty. Such lack of concern about the long-term impact of trials cannot continue.

The scientific community must act responsibly and look at the long term effects of trials. Moreover, it has to be accountable towards the people on whom it conducts clinical trials. It cannot leave them to suffer the consequences of their 'scientific pursuits'.

POPULATION CONTROL : THE PRIORITY OF CONTRACEPTIVE RESEARCH

"International family planning also serves important U.S. foreign policy interests : elevating the status of women, reducing the flow of refugees, protecting the global environment, and promoting sustainable development which lead to greater economic growth and trade opportunities for our businesses."

- Secretary of State, Madeleine Albright (USIS, September 1998)

Population growth has been held responsible for poverty, hunger and the degradation of the environment. This distorted focus on the symptoms of poverty obscures the real roots of poverty – i.e. inequitable economic and social relations. The 'burgeoning numbers' in the Third World are viewed as rapacious consumers of limited global resources. The resource-heavy lifestyles and unsustainable development of industrial nations are seldom held responsible for depletion of natural resources. For instance, the US, with 1/3 of the population of India consumes nearly 3 times as much iron ore as India; 4.6 times as much steel and 12 times as much petroleum. The per capita energy consumption in the US is an astounding 7,819 as compared to 248 in India. International agencies promoting population control have a clear agenda. Elites in the country are also responsible for a disproportionately high consumption of the country's resources. Consumption by the highest income-group (1.44 percent of the population) of electricity, petroleum products and machine-based household appliances - products that have global environmental impact - is about 75% of the total consumption of these commodities in India.

Population Control in the Indian Context

In 1951, the Government of India launched, with much fanfare, 'the world's first official Family Planning Programme' with the objective of 'reducing the birth rate to the extent necessary to stabilise the population at a level consistent with the requirement of national economy'. Since then, a systematic population control programme has been put into operation, garbed in euphemisms - from Family Planning to Family Welfare, and now Reproductive Health. Whatever the nomenclature, whatever the means, the objective has been to reduce numbers. The perspective of population control is one that views human beings as a burden on the economy, as responsible for the destruction of the environment. This perspective echoes the dire predictions made by Malthus in 1798 - that man's (sic) propensity to beget would soon outstrip earth's capacity to produce food. However, 200 years later, Malthus has been proved wrong - the earth is producing more than enough food to feed all its inhabitants. In reality, widespread hunger and malnutrition exists due to lack of purchasing power and unequal distribution of resources. However, in its special sitting for the 50th anniversary of Indian independence, the Parliament resolved that, "a vigorous national campaign be launched ... to combat economically unsustainable growth of population, recognising that such growth lies at the root of most of our human, social and economic problems." (MOHFW 1998).

The Population 'Explosion' : Curtailing Numbers at all Costs

The reasons for population growth are varied. It is well known that the plunge in mortality rates is also responsible for population growth. Further, for many decades, demographers have shown how birth rates are affected by the means of production i.e. whether it is a subsistence economy or an industrialised society; standard of living, women's status and education, infant mortality rate, family structures; women's entry into the labour force, etc. Contraception is only one of the variables which determines the birth rate. Rather than look at a holistic picture, however, planners have consistently chosen to focus on the provision of more and more effective contraceptives. Such a technological fix

ignores the social, economic and cultural causes behind high population growth rate. For governments, population control is a more attractive development option than genuine challenges to the status quo such as land reform, expansion of social services or more equal distribution of resources.

While refusing to acknowledge the impact of these skewed consumption patterns, the poor and marginalised, especially women, are seen as mindless breeders. The focus has been to 'motivate' people to become 'acceptors' of various contraceptives, from condoms and intra-uterine devices to injectables and implants in 'cafeteria' approach. Planners have consistently chosen to ignore statistics that clearly show that 95% women in India have contraceptive access/knowledge (UNFPA, 1998). When the government propaganda of 'information, education and communication' failed to yield results, incentives and disincentives were marshalled to do the trick. And when this too failed to have any perceptible impact on growth rates, health functionaries, especially at lower levels, were coerced to recruit 'acceptors' by any means possible in order to fulfil targets.

With intensified efforts to bring down the birth rate came a shift towards long-acting, hormonal contraceptives with higher effectiveness rates, like implants (Norplant) and injectables (Net En and Depo Provera). However, these methods were also more invasive, with serious hazards for the women using them as well as for children conceived accidentally. A more concerning fact was that these methods carried with them a high potential for abuse. The development of Anti-Fertility Vaccines raises the same issues of concern. Not surprisingly, G.P. Talwar, the 'pioneer' of these vaccines has said, "If great epidemics can be controlled through vaccines, why not the population was my query." (1997)

Since policy makers had concluded that leaving the decision to the woman was not 'successful', they (the providers) would have to take control into their own hands. Active intervention of women's groups compelled the government to pay heed to the objections against hazardous contraceptives. However, their response was merely to present old wine in new bottles.

Reproductive Health Policy : Has the Paradigm Shifted ?

In some measure, pressure on the government did ensure some degree of accountability, but changes were more cosmetic than real. The early 1990's saw a shift in the language of the population control policy, if not its substantive aspects. The United Nations International Conference on Population and Development (ICPD) held in Cairo in September 1994 has come to represent a watershed of sorts for health planners and women's health advocates alike. A much touted 'paradigm shift' was said to have been set in motion by the Government of India, which reflected a departure from its 'population control' policy to one of 'holistic reproductive health'.

The Government of India from 1992 had begun to recognise that the top-down target approach to family planning should change. "Targets based on micro-level planning suiting the local specific needs be fixed for monitoring the program." Going further, a Child Survival and Safe Motherhood Program (CSSM) was also launched in 1992.

In the years preceding the Cairo Conference, women's groups were networking to reshape population agendas, especially in Third World countries. Development issues were sought to be placed at priority. Governments were pressurised to depart from the 'demographic imperative language' and accommodate women's perspectives on sexual and reproductive health; link population and consumption patterns and address the issue of male responsibility in reproduction and contraception.

The Programme of Action of the ICPD 1994, endorsed by the Government of India proclaims, "States should take all appropriate measures to ensure, on a basis of equality of men and women, universal access to health care services, including those related to reproductive health care, which includes family planning and sexual health... and provide the widest range of reproductive health-care services without any form of coercion. All couples and individuals have the basic right to decide freely

and responsibly the number and spacing of their children and to have the information, education and means to do so." At various international forums, the Government of India is constrained to demonstrate its commitment to women's rights. The Beijing Declaration state that governments were "Determined to advance the goals of equality, development and peace for all women everywhere in the interest of all humanity." Such rhetoric came to assume a permanent place in government policies henceforth.

By March 1996, a 'Target Free Approach' (TFA) had been launched, to be followed by the 'Community Needs Assessment Approach' (CNAA). An official commitment was made towards a reorientation to the client-centred approach with an emphasis on 'quality of care'. However, these seem to be mere exercises in semantics, rather than a change in the real situation. The abysmal condition of primary health services inspires little hope that things will change. With basic equipment like instruments to measure blood-pressure and supplies of iron and folic acid tablets being unavailable and routine ante-natal care not made possible, 'Safe Motherhood' is a far cry. The government is increasingly shrugging off its responsibility for health. With liberalisation of the economy following Structural Adjustment in the early '90's, health services are becoming increasingly privatised. The cutbacks in the social sector are apparent in the budget allocation for health which has been steadily shrinking, while that for 'Family Welfare' continues to grow. For instance, in 1997, the budget for 'Family Welfare' is almost double to that of health.

National Population Policy and Women's Organisations' Response

In 1993, the Ministry of Health and Family Welfare set up an Expert Group under the chairmanship of MS Swaminathan to prepare a draft National Population Policy (NPP). Women's organisations in Delhi played a critical role in publicising the proposals of the Expert Group, and initiating a public debate on the whole issue of population control. Despite mouthing a commitment to women's rights and appearing pro-people, the Policy, when finally submitted in 1994, contained several objectionable items. The same draft is still pending for debate in the Parliament. The Policy states that, "the unsustainable lifestyle of the wealthy nations and persons in our country are responsible for using far more than a fair share of natural resources and causing grave threats to the environment." However, the Expert Group, reverting to Malthusian thinking, puts the blame for environmental degradation on "population and poverty" and states that access to food, education, health and work for all will "remain illusory" without limiting population growth. ~~Its recommendations do not contain any measure to curtail the numbers of the poor.~~

The perspective of the NPP is clearly revealed in its position on 'Contraceptive Methods', "India has an efficient scientific set-up for testing for safety, efficacy, reliability and acceptability of contraceptive methods before introducing them into the Family Welfare Programme." The scientific bodies mentioned, however, have not been following strictly scientific guidelines with regard to long-acting hormonal contraception. It was only pressure from vigilant women's groups that ensured that ICMR completes Phase IV clinical trials on Norplant instead of introducing it straightaway into the FP Programme. Although the NPP admits that "controversies are raised from time to time", it does not see it fit to resolve these controversies before proceeding with development and introduction of these methods.

Further, by upholding the undemocratic and unconstitutional proposal to enact the 79th Amendment to the Constitution, to disqualify those with more than two children from contesting elections, the Expert Group once more displays its faith in disincentives. In fact, the MOHFW states, "This (the proposed Bill) seeks to incorporate promotion of population control and small family norm within the framework of Article 47 dealing with the Directive Principles of State Policy and including in the list of Fundamental Duties (Article 51-A), a clause enjoining the citizens of India to promote and adopt the small family norm." (MOHFW Annual Report 1996-97). Thus, being subjected to coercive population control is equated to a national duty!

It is clear that mere lip service is being paid to the 'Target Free Approach'. It is well accepted by now that pressure to fulfil targets contributes to imposing coercive measures on people. However, the NPP continues to adhere to the goal of achieving a national average of Total Fertility Rate (TFR) of 2.1 by the year 2010. With a present TFR of 3.07, the achievement of such an unrealistic target of 2.1 can only be achieved by coercive measures. At every step, the true objective of the NPP is plainly visible: "The emergence of grassroot level democratic structures provides opportunities for correcting the prevailing gender imbalance in the acceptance of contraception."

Despite proposing such anti-people measures to deny the basic rights of people, the NPP mouths its supposed concern for 'empowerment of women'. Yet, it even views education for girls in terms of its impact on adoption of contraception and the 'small family norm'.

RESEARCH AND FUNDING INSTITUTIONS : **ACQUIRING A GARB OF 'GENDER SENSITIVITY'**

The development of Anti-Fertility Vaccines the world over has been carried out by five major institutions : The World Health Organisation (Switzerland); The National Institute of Immunology, (New Delhi); the Contraceptive Research and Development Programme of the United States Agency for International Development, USAID; International Committee for Contraception Research of the Population Council (ICCR) (USA), the National Institute for Child Health and Development (USA). Other agencies involved in the development of various Anti -Fertility Vaccines are :The Centre for Reproductive Biology and Molecular Endocrinology at the Indian Institute of Science, (Bangalore); the International Centre for Genetic Engineering and Biotechnology (New Delhi), and the University of Strathclyde (Britain).

While demographic concerns have clearly propelled these institutions to fund and/or carry out research on Anti-Fertility Vaccines, there has been a growing attempt to don a garb of "gender sensitivity". After the launching of the International Campaign to Call a Halt to Research in 1993, a correspondence was initiated with the funders and of the research on Anti-Fertility Vaccines, raising concerns about the health hazards, potential for abuse and unethical trials of these vaccines. Not surprisingly, many of the funding institutions like Population Council, USAID, WHO and World Bank (one of the co-sponsors of the WHO/HRP) responded 'positively'. In fact, they all agreed that the aim of contraceptive research "must be to enable people – particularly women to exert greater control over their fertility without sacrificing their integrity, health and well being". Yet, they justify the funding and research on hazardous, provider-controlled Anti-Fertility Vaccines because they do not want to "deprive people of the freedom to choose a safe and effective method of family planning"! A closer look at some of the key players who fund and carry out research on Anti-Fertility Vaccines will enable an understanding of the double standards and biases underlying the development of this method.

Since its inception in 1948, the World Health Organisation (WHO), a specialised agency of the United Nations has taken upon itself 'primary responsibility for international health matters and public health'. Over the years, the organisation has defined the international standard for guidelines for medical research that has provided the foundation for the ethical norms in many countries all over the world. Yet, it has itself initiated and/or supported numerous research projects that require closer scrutiny.

The Special Programme of Research, Development and Research Training in Human Reproduction (HRP) was established by the WHO in 1972 with a view to co-ordinate, promote, conduct and evaluate research in human reproduction. It is co-sponsored by the United Nations Development

Programme (UNDP), United Nations Fund for Population Activities (UNFPA) and the World Bank.

In the context of development of Anti-Fertility Vaccines, the concern for safety evaluation is first expressed in the WHO/HRP Annual Report of 1977. "In the case of a fertility regulating vaccine which represents a totally new approach to therapeutics, a thorough safety evaluation is of major importance since the vaccine will be administered to healthy individuals."

The WHO stressed that its focus on the development of the anti-hCG vaccine was due to its relative safety (since it was present in the body only if pregnancy occurred). Intervention in sperm and egg production, on the other hand (a constant process), could have more impact on the body, and thus safety might be compromised. The choice of the synthetic beta-hCG CTP vaccine, which uses only a part of the beta-subunit, was further justified on grounds of safety over effectiveness. Despite these declarations, WHO was at the same time supporting work in India under Talwar on the whole beta-subunit, a formulation which has more potential for cross-reactivity. Moreover, successive Annual Technical Reports of the WHO state that work on sperm and egg vaccines is held up only due to lack of funds.

The gradual but perceptible shift away from the WHO emphasis on "safety first" was seen in the mid-to late-1980's. The summing-up speech of the Chairman of a WHO Symposium in 1989 revealed the underlying reasons for the shift in emphasis from safety to efficacy, "Foremost in my mind during these discussions was our difficulty in assessing the urgency of the demographic crisis. To the extent that the impact of the crisis increases, the need for more effective family planning methods must increase. At the very least, failure to develop something that might provide a more effective technology would be a grave and unnecessary risk". Significantly, following this Symposium, one of the unequivocal Principles for the Development, WHO/HRP in 1977, i.e. "To minimise the risk of immune-complex disease, the target antigen should not be present continuously in the in the vaccine recipient, but only intermittently and/or in low concentrations" was changed to "Preferably, the molecules should be present transiently and in relatively low amounts so as not to overwhelm the predicted immune response" and reclassified as 'efficacy criteria' (quoted in Richter J, 1992).

The push for efficacy and mass applicability of the vaccine continued. By 1995, an anti-hCG vaccine was also being developed, offering higher effectiveness and the possibility of 12-18 months of contraceptive effect after a single injection. This, the Task Force claimed (Annual Technical Report 1995) will have major efficacy, service and cost advantages for both users and providers in developing countries. The 'advantages' claimed are, as is obvious, benefits from a Family Planning Programme point of view rather than from the perspective of a user. Research on the development of an oral vaccine, in order to 'ease' vaccine delivery was also set in motion. However, the potential for abuse in an oral vaccine is even greater.

The WHO, in a December 1995 meeting, reaffirmed in November 1997 the six/twelve monthly hCG vaccine as a 'high priority' lead. Despite all the problems associated with the anti-hCG Anti-Fertility Vaccine mentioned by WHO itself, a 1997 statement claims, "If it (Anti-Fertility Vaccine) lives up to its promise, there would be few, if any, medical contraindications for its use. Thus, most women would be able to use it. It would be easy to make the method widely available through reproductive health services since it would be delivered in much the same way as other injectables are provided..." (Progress, 1997). Such a position completely ignores the realities of most developing countries. It is clear, that despite its stated commitment to women's health, demographic imperatives are the underlying driving force of the activities of the HRP.

'Women's Rights' becomes the catch-word. Since the 1980's, there has been a pressure on governments, funding agencies, research and implementing agencies, from different streams of the women's movement. Activists, lobbyists and 'women's health advocates' have been articulating different positions on women's rights. This has had a perceptible impact on various institutions. Although this has not resulted in a substantive shift in their priorities, it has certainly forced international research

CONTRACEPTIVE RESEARCH : WHO FOOTS THE BILL?

International financial institutions also view rapid population growth as a threat to world security and economic stability. A document articulating US international population policy says, "Slowing world population growth also benefits our country as part of a long-term strategy that promotes economic development abroad, thereby improving trade opportunities for Americans, and mitigates future global crises." (USIS 1998). Thus, funding contraceptive research makes good business sense. Adjustment programmes and lending has always been linked to population control conditionalities. As far back as 1974, the International Federation of Family Health, which is linked with the Republican far right, were instrumental in getting a study commissioned on "Implications of World Population Growth for US Security and Overseas Interests". The document targets 13 countries, including India, Pakistan, Brazil and Egypt, and supports population control to stem radical dissent and protect US access to strategic minerals. It advocates using food aid as leverage and recommends 'mandatory programmes' and coercion as possible tactics. 'Gender sensitivity', reproductive rights and sexual health have since become buzz words, and international aid agencies are among the first to adopt such terminology to present a progressive face. However, despite a transformation in rhetoric, population continues to be viewed as a major threat, and attempts to control numbers continue to be on the agenda of funding agencies.

The World Health Organisation through its Special Programme in Research (WHO-HRP) has been one of the most consistent funders of Anti-Fertility Vaccines, the anti-hCG vaccine in particular. The total expenditure by the WHO on the development of anti-hCG vaccines for the period 1973-1990 amounts to US\$ 7,852,000. The WHO in turn received raw material for some of the trials from the Center for Population Research of the National Institute of Child Health and Human Development of the National Institutes of Health (USA). Indirect contributions for anti-hCG vaccine research has also come from the Swedish government i.e. HRP was not responsible to pay liability because the Swedish government covers any potential damages from clinical trials approved by the Swedish Medical Products Agency (MPA).

WHO has also funded animal studies on the anti-hCG vaccine in India. Other funders of Indian trials were Department of Biotechnology (Science and Technology Mission) through a project that is co-funded by Contraceptive Research and Development Programme (CONRAD) of the United States Agency for International Development (USAID), and the International Development and Research Centre (Canada).

Other significant funders of worldwide research into Anti-Fertility Vaccines include: the Population Council, the Medical Research Council (MRC) in the UK, and the National Institute of Health (NIH). Several private trusts in the US such as George J Hecht Fund, the Andrew W Mellon Foundation, the Rockefeller Foundation, the Dodge Foundation and the Ford Foundation have also played a role in funding research on Anti-Fertility vaccines.

Pharmaceutical Companies are entering tie-ups with research institutes while the research is ongoing, in order to secure patent rights. For instance, Johnson & Johnson, New Jersey, USA-based pharmaceutical company has entered a licensing agreement with the University of Virginia's Center for Innovative Technology, which has been working on the vaccine. J & J, already an important manufacturer of birth control pills, will finance the Virginia centre's testing of the vaccine on baboons. It is hoped that human trial will begin within 2 years.

Additionally, Sandoz provided financial assistance (Update) to WHO on the Anti-hCG trials. Then in 1986, HRP planned to give Sandoz the right to market its product in private sector. Other companies investing in research of Anti-Fertility Vaccines are Organon Pharmaceuticals, Ortho Pharma, Zonagen Inc., and Reproductive Biotechnologies Ltd.

institutions and funding agencies to change their language.

In 1990, the WHO/HRP initiated a 'dialogue' with representatives of the women's health advocates in order to 'foster greater understanding of women's reproductive health needs'. A meeting in February 1991 co-sponsored by the HRP and the International Women's Health Coalition (IWHC) resulted in the establishment of mechanisms to articulate women's perspectives. Accordingly, a meeting to discuss the development of fertility regulating vaccines in August 1992, was attended by 'women's health advocates' from Africa, North and South America, Asia and Europe.

Following the International Conference on Population and Development (ICPD, Cairo, September 1994), there was increased pressure to take into account the views and experiences of users of contraceptive technologies, most of whom are women. The Special Programme in order to ensure the participation of representatives of women's health groups on its scientific and policy-making committees, established a Gender Advisory Panel which had its first meeting in February 1996 in Geneva. In the second meeting of the Gender Advisory Panel in January 1997, it was clear that most of its recommendations had not been acted upon. Follow-up studies of trial participants had not been carried out, and no new studies to gauge user-perspectives about Anti-Fertility Vaccines had been planned by the Task Force. Only a cosmetic change of changing the nomenclature of the 'Anti-Fertility Vaccines' to 'immuno-contraceptives' had been carried out. In our opinion, individual efforts to bring 'change-from-within' is a gross underestimation of the power of these institutions and ignoring the nexus within the population control establishment.

To what extent the presence of women's groups and consumer representatives in such joint forums makes any difference, and how much pressure it is possible to exert to effect any real changes in the agenda of institutions like the WHO, is questionable. It is also worthwhile to consider how much the presence of these 'people's representatives' legitimises a process which may not be in the best interests of the people. Judith Richter, a strong critic of the Anti-Fertility Vaccine, gives a personal account of the WHO Symposium in 1989 on Anti-Fertility Vaccines. Her critique of the manner in which the symposium developed and the way points of view were presented offer insights into the process of advocacy and the need for caution. The WHO/HRP Newsletter, Progress (No. 7, 1989), proclaimed in bold headlines, "WHO Symposium recommends high priority for research into Anti-Fertility Vaccines". Richter, who participated in the Symposium points out that the recommendation was merely to "re-endorse" the development of Anti-Fertility Vaccines on 'medical and scientific grounds' - a recommendation that the WHO/HRP newsletter later translated to mean "high priority" - once again, clearly demonstrating their pre-occupation with demographic concerns.

Great caution needs to be exercised when interacting with agencies such as the WHO, since the credibility of women's organisations and consumer groups is used to justify activities which may have come in for severe criticism were it not for the presence of "people's representatives".

The National Institute of Immunology (NII), New Delhi has been carrying out research on Anti-Fertility Vaccines ever since its inception in 1982-3. Ethical concerns about clinical trials on women before completing the requisite animal trials, as well as violations of the requirement of informed consent were discussed in scientific forums as well as in the mass media.

Saheli, along with other women's groups has been campaigning against hazardous contraception and coercive population policies, demanding accountability and adherence to ethical norms. The interaction between the NII and Saheli is another example of the concerted attempt of the scientific and research establishment to co-opt the feminist agenda while in real terms having little concern for women's health. Except for biased reports in the press about the 'breakthrough' in scientific research' etc, there has been no information forthcoming from NII regarding vaccine research, despite repeated requests. However, following the launching of the 'International Campaign to Call a Halt to Research on Anti-Fertility Vaccines' on 20th November 1993, the NII was pressurised to hold a meeting

with signatories to the campaign. During this meeting, G.P.Talwar (then Professor Emeritus at the NII) the Director of NII, Sandeep Basu, researchers from PGI, Chandigarh and a battery of 'experts' were present. Women's groups and health activists raised several points of concern in the meeting.

Not so surprisingly, G.P.Talwar and his team went out of the way to reassure us that they were only concerned about 'increasing the choices for women'. They were keen to enhance women's reproductive rights, they claimed. G.P.Talwar patronisingly warned the activists against trying to limit women's right to choose a contraceptive method that was 'safe and effective' – this even when Phase II trials had not yet been completed, and there was no scientific evidence to support such a claim. In a further encroachment on to the jargon of 'women's rights', G.P.Talwar stated that long-acting contraceptives were not in the best interests of women, and that he was therefore focussing his attention on developing shorter acting vaccines (2-3 months duration). In fact, he claimed, 'control over their own bodies will now lie entirely with women, since they can decide the period they want immunity from pregnancy, and decide not to go in for the next booster shot.' Manipulating the concerns of the women's movement, the scientists claimed that they could not give us the addresses of women who had participated in the trials because it would be a breach of confidentiality. No matter that one hour of the meeting had been spent in projecting full-length transparencies of trial participants, in an effort to prove that they were 'middle-class', educated women, and not 'poor, illiterate' women who had been tricked into participating in tests.

The Protocol for Informed Consent of the Phase II trials is a classic example of misinformation, and the practice of recruiting women from Family Planning clinics is fraught with problems. Yet, researchers refused to accept that there was anything problematic in the research process, nor that their direction of research was harmful to the interests of women. The backing and legitimacy offered by funding agencies supporting unethical research is a matter of serious concern.

The Canada-based **International Development and Research Centre** has been supporting the Phase II trials of the hCG vaccine in India. Since the inception of the Campaign to Call a Halt to Research on Anti Fertility Vaccines in 1993, sustained lobbying with the IDRC continued, raising the concerns about safety of the vaccine, unethical trials and the abuse potential of the vaccines. A meeting of thirty women's health activists with the IDRC in 1995, and continued pressure for more than two years, was instrumental in the discontinuing of funding of the next Phase of trials. However, despite their professed commitment to women's rights, the IDRC, in a shocking move, announced their intention to 'close their files' on the matter of monitoring of the women who had participated in the Phase II trial, and long-term follow up of their progeny. The IDRC claimed that since they were no longer funding NII, they had no way of pressurising the NII to ensure adequate follow-up. This shrugging off of responsibility was justified by hollow assurances that IDRC had 'fulfilled its obligations' to the women who participated in the trial.

In a meeting with representatives of the International Campaign on 24 July 1998, Dr Enis Baris, Chief Scientist at IDRC revealed the casual manner in which medical research on women in the Third World is carried out, "The relationship between IDRC and Southern institutions depends on trust – trust that the Southern partner will follow ethical conduct in carrying out its work. The project was reviewed by the internal ethics committee, who had no problems with it, but perhaps should have – they could have asked for more opinions on how informed consent is done." He further revealed that NII was not necessarily 'obliged' to follow up, but did so out of its goodwill!

Despite an espousal of the 'women's cause', the double standards of institutions like the IDRC, the WHO and the NII regarding research on women in countries considered as 'over' populated is clear when the demographic centred perspective is unmasked.

REDEFINING PRIORITIES FOR WOMEN'S HEALTH :

A FEMINIST PERSPECTIVE

"What can be a more fitting justification for research on an Anti-Fertility Vaccine? Since the inauguration of this Congress, 2054 people have been added to the Indian population."

- G.P. Talwar, Presidential Address,

VII International Congress on Reproductive Immunology, 27th October 1998.

All over the world, a relentless search continues for 'appropriate sites' within a woman's (or a man's) body that can be targeted by Anti-Fertility Vaccines for contraceptive effect. In India, as in several other countries, countless animal and human trials have resulted in a method that is scientifically unsound and inherently unsafe.

In medical terms, the potential risks that all subjects of human trials have been exposed to range from allergies and hypersensitivities to auto-immune diseases and permanent infertility. Almost three decades after the research on Anti-Fertility Vaccines began, the method still has an efficacy rate that at best is an unacceptable 80%, its safety is not yet conclusively established; long term toxicity and teratological effects not ruled out and the effect on pregnant women or children born during or after the trial not conclusive. While scientists and institutions engaged in the pursuit of Anti-Fertility Vaccines cite lack of data as the very reason for continuing this line of research, women and health groups have consistently contested this argument on several grounds.

Opposition has been raised against the very principle of 'treating pregnancy as a disease' and causing an immune response against it. Other characteristics of Anti-Fertility Vaccines like the long duration of effect, and the fact that they can be distributed on a mass scale, and administered to people without their knowledge, open up another critical area of concern: their inherent potential for abuse. Experiences of women all over the world have highlighted the numerous situations in which such long-acting, invasive and provider-controlled methods of contraception are abused. This is of particular significance in a country like India where the 'population control' agenda of the state, has already cost countless women their health and well-being.

The unethical research so far carried out has further substantiated these apprehensions. Human trials have been initiated without adequate or conclusive animal studies, internationally accepted requirements for 'informed consent' have been flouted and long term follow-up remains, till date, completely unsatisfactory. Contrary to all ethical norms of 'scientific practice', the interests of science and society have taken precedence over the interests or well-being of trial subjects.

While the development of Anti-Fertility Vaccines has broadly followed the pattern of other invasive, provider-controlled contraceptives, certain new elements have characterised it. The media has been consistently used to garner support against, mounting protests from the women's health movement. Many of the criticisms of the women's movement about long-acting, provider controlled contraceptives are also sought to be turned on their heads. Researchers claim that Anti-Fertility Vaccines do not cause hormonal disturbances and disruption of the menstrual cycle like other long-acting hormonal methods. Such a claim masks the fact that these vaccines do interfere with the hormonal balance, and in addition have serious potential health risks. Researchers claim that they are in agreement that long-acting duration are not in women's interests, and that these vaccines are not 'provider controlled' because a woman can 'choose' whether or not to get a booster shot and continue with the vaccine. And so, while these hazardous Anti-Fertility Vaccines work to control

women's fertility by any means, we are told that women's choices are being widened by the development of these vaccines.

The co-option by the population control establishment of the language and concerns of the women's movement masks the extreme dichotomy between the needs of women and the priorities of providers. Carrying on a 'dialogue' in the terms of reference set by providers of contraceptives is fraught with contradictions. Getting caught up in 'preferring' one hazardous contraceptive over the other; improving the health services infrastructure to provide 'better' follow up of contraceptives; or formulating 'feminist' population policies does not strike at the root of the problem.

We need to question why there is a need for a population policy at all, and change the terms of the debate. Land reforms, provision of basic needs, ensuring equitable access to food, housing, health, education and other necessities will contribute to moving towards a more humane society. Top-down, resource-intensive research and planning can only serve the interests of the dominant in any society. A radical reorientation of contraceptive research will of necessity have to encompass women's need for safe and effective barrier methods which are within the control of women. Scientific research must take into account the real needs of people, and patriarchal and class biases have to be challenged. Tackling the real inequalities between men and women and addressing women's needs would contribute to overall change.

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