"Vaccination" Against Pregnancy

The Politics of Contraceptive Research

by

Judith Richter

For the past 25 years, scientists have been developing a new class of birth control methods — immuno-contraceptives, also known as an anti-fertility "vaccines" — which aim to turn the body's immune system against reproductive components. Immuno-contraceptives are already being heralded as a breakthrough in contraceptive research, although it is debatable whether they will ever be sufficiently effective as a contraceptive. From what is known about immune responses in general, however, immuno-contraceptives are likely to be unreliable as far as an individual is concerned and to entail an unprecedented potential for abuse; severe health risks cannot be discounted. Anti-fertility "vaccines" are thus a clear example of the impact "population control" has had on contraceptive research.

"The research conducted during the past two decades has brought us to the threshold of making available a new method for more effectively meeting the challenge of ever-increasing population expansion."

Vernon Stevens
originator of WHO's anti-fertility "vaccine"

"[The development of immuno-contraceptives is] asking unnecessarily for trouble . . . Whatever risks there are can hardly be predicted in any test. But what we know of physiology suggests that they could be very serious."

Graham N. Dukes, Editor
International Journal of Risk and Safety in Medicine

Since the 1970s, several medical research institutions have been developing a totally new class of birth control methods — immuno-contraceptives, also known as anti-fertility "vaccines".[1] They aim to induce the body's immune system to act against reproductive components so as to prevent pregnancy. The idea dates from the turn of the century: experiments conducted independently by three leading immunologists, Austrian Karl Landsteiner and Russians Elie Metchnikoff and Sergei Metalnikoff, indicated that injection of sperm or testes' extracts into animals could cause the generation of anti-bodies against sperm.[2] Some scientists went on to investigate possible immunological causes of existing infertility while others, in "a wave of Malthusian fervour", began to develop ways of actually inducing it.[3]

At least 12 studies into immuno-contraception were carried out in women in the 1920s and 1930s, but a discouraging evaluation report concerning the method's effectiveness in 1939 and unspecified "ethical restrictions" brought research to a halt.[4]

Three decades later, new immunological techniques and a favourable funding climate enabled the interrupted endeavour to be resumed. Today, the bulk of research into various immuno-contraceptives is being coordinated by five major institutions around the world — the National Institute of Immunology in India; the World Health Organization in Switzerland; and the Population Council, the Contraceptive Research and Development Program, and the National Institute for Child Health and Development in the United States.[5] In theory, immuno-contraceptives could act in men and women, but so far most research has been directed towards versions which act in women.

None of the current prototypes has gone beyond the second of three trial stages in humans while some research is still at the laboratory stage. Yet anti-fertility "vaccines" are already being portrayed as a breakthrough in contraceptive research. According to the World Health Organization's research coordinator, David Griffin, "the vaccine may prove as important a development in birth control as the contraceptive pill",[6] while immunologist N. Avrion Mitchison maintains that "it is now generally accepted that vaccines will come to be used for the control of fertility".[7]

The Immune System

Most descriptions of the body's immune system — a complex collection of interacting cells, molecules and tissues — focus on how it acts to ward off illness and disease. Its success in doing so depends primarily on two features: its ability to generate anti-bodies specific to each type of micro-organism — viruses, bacteria and fungi, for instance — and its "memory".[8] Once the immune system has encountered a micro-organism, it "remembers" it and generates a faster and stronger immune response every time it subsequently encounters it.

Few people realise, however, that besides "foreign" micro-organisms, the immune system also "recognizes" cells and molecules of our bodies themselves; it can differentiate between these "self" antigens (an antigen is any material which the immune system recognizes) and "non-self" ones. It "learns" to eliminate or neutralize the foreign ones with anti-bodies, but not to react against healthy self antigens. This protection of a

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person's own body constituents against immune reactions is called self-tolerance. If self-tolerance fails, immune reactions against specific body components may cause auto-immune diseases. Juvenile diabetes, for instance, is thought to be caused by immune reactions against the insulin-secreting cells of the pancreas.[7]

Our immune system also tolerates the many components essential for reproduction. A woman's immune system does not usually consider a man's sperm, for example, as foreign nor a fertilized egg or fetus as "half-foreign", even though half its genetic material comes from the man.[8] If it did, the human species would no doubt have become extinct long ago. Some immunologists therefore classify sperm, embryos and fetuses as "self-like" to indicate that they habitually enjoy immune self-tolerance.

Immunological Birth Control

An immuno-contraceptive aims to trick the immune system into generating a temporary immune reaction against those cells or molecules essential to reproduction — namely, the hormones that trigger the monthly ripening and release of egg cells in women or the continuous production of sperm in men; the egg or sperm cells themselves; or pregnancy-related hormones.

To make the chosen reproductive constituent — the target antigen — appear "foreign" to the immune system, researchers have linked it to a foreign carrier such as the diphtheria or tetanus toxoid used in vaccinations against these diseases.[9] The principle is to administer the combination of reproductive antigen and carrier so that a person's immune system learns to react against the naturally-occurring reproductive component as if it were a micro-organism to be eliminated.

The most advanced immuno-contraceptive research has been carried out by the World Health Organization, the National Institute of Immunology in India and the New York-based Population Council into inducing the immune system to act against the hormone hCG (human chorionic gonadotropin). hCG is secreted by the early embryo shortly after an ovum has been fertilized. Its effect is to keep a woman's ovaries producing another hormone, progesterone, which causes the lining of the uterus to stay in its thickened state so that the embryo can implant itself. If hCG were to be intercepted by anti-bodies, progesterone levels would drop — as usually happens if the egg is not fertilized — and the lining of the uterus would shed; the embryo would not be able to implant and the woman would have a menstrual-like period.

Can It Be Done?

This all sounds simple, but designing an immuno-contraceptive has proved to be not quite so easy. Indeed, immuno-contraceptives are a totally new class of contraceptive "and a complete novelty in terms of vaccine technology.

One of the few similarities between immuno-contraceptives and anti-disease vaccines is that the action of both is mediated by the immune system. But whereas anti-disease vaccines aim at long-term (preferably lifelong) immunization against foreign micro-organisms, immuno-contraceptives aim for a highly-effective immunization against human cells or molecules which should be reversible after a predictable length of time.

A first difficulty has been to immunize against a reproductive component so that a sufficiently high contraceptive effect is achieved. USAID official Jeff Spieler has cautioned that "a fertility regulating vaccine . . . would have to produce and sustain effective immunity in at least 95 per cent of the vaccinated population, a level of protection rarely achieved even with the most successful viral and bacterial vaccines"[5] because of genetic differences between people.

According to WHO researchers David Griffin and Warren Jones, "the annual pregnancy rate associated with the use of the vaccine should not exceed two per cent, similar to the most effective methods already in use".[6]

But raising the immune response against a reproductive component so that it prevents pregnancy effectively runs the risk of inducing unintended immune-mediated reactions elsewhere in the body.

As far as the immune system is concerned, if the target antigen is similar to other cells or hormones in the body, the immune response will be induced not only against the reproductive component but also against these other body components. For example, the pregnancy hormone, hCG, is immunologically similar to a range of hormones produced by the pituitary gland at the base of the brain, a fact that was known when research into anti-hCG contraceptives began. If the whole hCG molecule was used as the target antigen, immune reactions would also be induced against two reproductive hormones, FSH (follicle stimulating hormone) and LH (luteinizing hormone) and against TSH (thyroid stimulating hormone). Cross-reactions against these hormones could interfere with the functioning of the thyroid and potentially cause long-term damage to the pituitary and thyroid glands.

To avoid these cross-reactions, the research teams have taken just a small part of the hCG molecule as the target antigen, but have then found that contraceptive effectiveness dropped.[7] The anti-hCG prototype developed by the Indian National Institute of Immunology, the only immuno-contraceptive to date which has been tested in fertile women for its effectiveness, induced an anti-hCG reaction in 80 per cent of the women in the trial for an average of three months.[5]

A major tension in immuno-contraceptive research has therefore been to find a target antigen such that the immune system does not generate immune cross-reactions yet still generates sufficient anti-bodies to prevent pregnancy. The smaller the inducing antigen is, the less likely such cross-reactions may be — but also the less likely that immune responses will prevent pregnancy.

Another potential problem relates to the target antigen's other functions in the body (besides its reproductive function) which could also be disrupted by induced immune responses. The National Institute of Immunology and the Population Council have tested a product which targets GnRH (gonadotropin releasing hormone) "a hormone which regulates the production of oestrogen and progesterone in women and testosterone in men. Its neutralization could cause men to lose their low voices and body hair and to become impotent, a "side effect" which researchers propose to counter by administering synthetic testosterone derivatives.[8]

Meanwhile, in trying to develop an immuno-contraceptive to act against a mature egg cell, researchers have found it difficult to identify a cell structure on the surface of the mature egg which is not also present on immature eggs within the ovaries. Any immune response against a structure present in both could affect all the egg cells, making a woman permanently infertile. Immune reactions against sperm in the testes could cause chronic inflammation of the testes which ultimately leads to infertility.

Opinions are thus divided among the research community as to whether immuno-contraception is actually feasible. Some maintain that it is still too early to conclude that it is not; they claim that new vaccine technology, such as more specific target antigens, could solve most problems and that the final products are likely to differ substantially from the prototypes now being tested in animals and humans.[21] Others, however, are more doubtful. As David Hamilton, a researcher in male contraception at the University of Minnesota, says:

> "Doesn't the inherent problem remain — that we are immunizing against body constituents and that this may cause auto-immunity? . . . I am very sceptical that immunization against body constituents would ever work without side-effects."[22]

Ron Gilling/Panos Pictures

Patients at a clinic in western Zambia. Widespread promotion of injectable immuno-contraceptives could increase the spread of HIV via unsterile needles and the undermining of public health campaigns to encourage condom use. They could also, however, deter people from using healthcare services. Rumours about "abortifacient vaccines" have already led people to refuse tetanus immunizations in India, the Philippines, Tanzania, Mexico, Peru and Bolivia.

A User-Centred Perspective

Although still under development, the characteristics of an immuno-contraceptive can be extrapolated from what is known about the immune system in general and body responses to anti-disease vaccination, and from information gathered from animal and human trials to date. These characteristics indicate that, even if the "perfect" target antigen could be isolated, immuno-contraception would still pose several problems for an individual user because "the immune system does not operate in isolation. This is one of its cardinal features".[23] Its complex, interconnected functioning depends on a plethora of factors both internal and external to the body.

As far as an individual user is concerned, a contraceptive should reliably prevent pregnancy; the health of any baby born after contraceptive use should not be affected, nor that of any baby born if the method fails; the contraceptive effect should be reversible; and the method should pose no short- or long-term risks to the user's health or well-being.[24]

• Reliability

In theory, after a "model" immuno-contraceptive had been administered, the body should build up its immune response to the target antigen until it had generated enough anti-bodies to prevent pregnancy — the "anti-fertility threshold". Until that time, another highly-reliable and effective contraceptive which did not interact with the action of the immuno-contraceptive would have to be used to prevent pregnancy.

Once the anti-fertility threshold had been reached, the level of anti-bodies should be sufficient to prevent pregnancy for a predictable amount of time, after which it should decrease and drop below the threshold unless a booster injection is given.

However, immune responses vary considerably between individuals, depending on their genetic make-up, nutrition and health. It will be difficult to predict the duration of the lag and contraceptive phases for any one individual. In some people, the anti-body level might not reach the anti-fertility threshold at all, while in others, it might reach it for only a short time before it started to drop. The immune response of those with a predisposition to allergic or auto-immune diseases may never go into the waning phase, making them indefinitely infertile.

Any disturbance of the immune system — for instance, as a result of malnutrition, stress, or diseases which suppress the immune system such as malaria, tuberculosis or HIV — could cause the anti-body level to drop unexpectedly below the anti-fertility threshold. In practice, a woman would not know whether the anti-bodies were sufficient to prevent pregnancy unless she had a blood test.

The initial lag period,[25] the variability and lack of predictability of immune responses are not technical flaws which can be ironed out simply by adjusting the formula or finding the "perfect" target antigen. They are basic characteristics of the immune system which mean that immuno-contraceptives would probably be highly unreliable in preventing pregnancy as far as an individual was concerned.

• Effects on a Baby

Because the action of an immuno-contraceptive would be unreliable and unpredictable, some women who received an immuno-contraceptive would be highly likely to become pregnant, and there would be a high risk of fetal exposure to ongoing immune reactions. The consequences of such exposure are as yet unknown and would depend on the reproductive component targeted by an immuno-contraceptive: damage could include various visible malformations and less apparent hormonal abnormalities (some of which might manifest themselves only at puberty).[26]

It is also unknown whether anti-bodies produced from immuno-contraceptives pass into breast milk and, if so, what effects they might have on a baby. Yet WHO's consultant Warren Jones believes that immuno-contraceptives would be "ideal" for breastfeeding women in Third World villages.[27]

• Reversibility

With a vaccine against a disease, the duration of the induced immune response does not need to be exact; the longer the immunological memory, the better. The disease-preventing effect is prolonged not only when immunized persons receive a

"booster" injection of the vaccine but also when they come into contact with the disease-causing micro-organism itself.

To act as a contraceptive rather than a sterilizant, however, the immune response generated by an immuno-contraceptive should *not* be boosted when the immune system encounters the naturally-occurring reproductive component. If it is, the person may become permanently infertile.

"As long as immuno-contraceptives are percieved as 'vaccines' against pregnancy epidemics, or as 'weapons' in the family planning 'armamentarium', the well-being of individuals using them is likely to remain a lesser priority."

This risk depends partially on the target antigen. Anti-hCG immuno-contraceptives have been reported in trials to be reversible, while in the case of immunization in women against sperm, some scientists are concerned that frequent exposure to sperm during sexual intercourse could prolong the effects of the anti-sperm immunization indefinitely.[28]

For the research community, however, reversibility does not seem to be a critical characteristic of an immuno-contraceptive. WHO's consultant Warren Jones stated in 1982 that "the capability of reversal is an attractive but not essential facet of any contraceptive method" while the Population Council maintains that "irreversibility . . . is not always an adverse effect; some vaccines may be designed to be used as non-surgical means of sterilization."[29]

- **Health Risks**

Apart from potential auto-immune diseases induced by cross-reactions, an immuno-contraceptive might also cause allergies or immune-complex diseases and might interfere with or exacerbate existing diseases and immune-disturbances, a risk of any vaccination. Immuno-contraceptives may, for instance, increase the risk for people infected with hepatitis B of developing chronic liver disease. This includes those who do not show any symptoms of the disease, an estimated 5-10 per cent of the population in many African and Asian countries.[30]

It would be too impractical and expensive for most healthcare systems, particularly those being dismantled as a result of structural adjustment programmes, to test people for diseases such as HIV and hepatitis B or to define and identify persons genetically predisposed to auto-immune diseases to ensure that they did not receive an immuno-contraceptive.

Potential health risks for woman and fetus are compounded by the fact that immune reactions cannot just be "switched off". In the case of severe adverse effects, drugs might have to be given to suppress the immune system, curtailing healthy as well as adverse immune reactions.

A Population Framework

Given immuno-contraceptives' predictable unreliability and probable low method effectiveness,[31] the relatively high risk of fetal exposure to ongoing immune responses and the difficulty of discontinuing immune responses at will, the potential risks involved in interfering with the immune system seem hard to justify, particularly since other contraceptive methods are available.

Researchers have not, in fact, focused on the reliability of immuno-contraceptives as far as an individual is concerned; they cite instead the advantages of long-action, low risk of "user failure", ease of administration, low cost and widespread appeal because of the general popularity of vaccination[32] — characteristics which, from the perspective of an individual user, are of doubtful value, if not a liability, but which, from the perspective of "population control", may well appear as advantages. As Australian immunologist A. Basten said in 1988 after the first clinical trial in humans of WHO's product:

> "Fertility-regulating vaccines offer the most practical way of controlling the birth rate, particularly in developing countries."[33]

A conceptual framework underscored by a preoccupation with "overpopulation" does not mean that those engaged in contraceptive research and family planning *intend* to disregard people's health and well-being. Many and closely-spaced pregnancies can certainly be detrimental to women, and mainstream family planning organizations include people who regard contraceptives as a means of decreasing maternal mortality and those whose major focus is women's self-determination.

But they also include many who see methods of birth control primarily as tools of population control, in particular, of the population growth rates of certain groups of people — poorer people, non-whites and those from Third World countries. Within this conceptual framework, birth control is regarded as a weapon of war against the "teeming multitudes", a war in which people are treated as mere numbers or statistics to be controlled, manipulated, reduced and dispensed with.[34]

When Pran Talwar, the leading immuno-contraceptive researcher at the Indian National Institute of Immunology was interviewed about his motivation and zeal during human trials of one of his formulations, his explanation was simple:

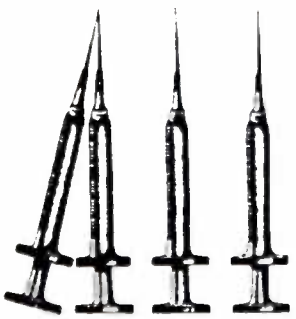
> "Well, you just have to go, for example, to Bombay, or to any other metropolis for that reason; at the time that the offices close; see this sea of humanity that flows; trains are overloaded, buses are overloaded, everything is overloaded. The population stress is expressing itself in many walks of life. I would even say that several of our political problems — the uneasiness of the youth, the uncertainties of getting jobs . . . — are all caused by this problem of too large numbers looking for too few places. I would even say that the terrorist problem is related in a way to the population problem and the social strain that it is causing — the inability of the structure to cope with the numbers."[35]

Similarly, Executive Health Officer Kathuria of India's Bombay-based Population Project 5 is clear as to who the targets of birth control methods should be:

> "this class of people — especially in the slums — who have four and five children . . . They are spoiling the demographic pattern of Bombay and India."[36]

As long as immuno-contraceptives are perceived as "vaccines" against pregnancy epidemics or as "antigenic weapons"[37] in the "family planning armamentarium",[38] the well-being of individuals using the contraceptive is likely to remain a lesser priority.

Contraceptive Abuse



Modern reliable contraceptives have certainly made it easier for women (and men) not to have children for a while but still to have sexual intercourse. Many of them, however, have also made it easier for powerful social actors to attempt to control certain women's fertility so that they do not have "too many" children, irrespective of their wishes.

Argentinian women's health advocate Mabel Bianco considers abuse of birth control methods to be:

> "any instance in which a method is imposed upon a person or in which a person in induced to use a particular method in a way that the decision is not the result of free and informed choice".

Thus besides administering a contraceptive against someone's will or without their knowledge, abuse can also take more subtle forms:

- providing financial incentives to encourage "preference" for a particular method;
- giving biased information about a method, such as emphasizing its effectiveness while playing down or not mentioning its adverse effects;
- implementing sanctions against non-users;
- refusing to remove a contraceptive when the user requests.

Much of the biomedical and family planning literature attributes such abuse (when it is acknowledged) to "over-zealous" providers (without considering why they are "overzealous"), portraying the contraceptives themselves as neutral. But as social scientist Judy Wajcman points out, social forces determine what contraceptives technologies are available (or not available) — and available birth control methods in turn shape our life "choices" in both technical and social terms.

The actual abuse of a particular contraceptive thus depends on the specific socio-political and cultural context in which it is introduced *and* on its technology-inherent features. A contraceptive's potential for abuse can be assessed by aggregating the duration of the anti-fertility effect; the possibility for users to stop this effect when they wish; and whether it is a barrier device, pill, injection, implant or intrauterine device (IUD).

The longer the action of a method, the more easily it 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. It is difficult, for instance, to imagine abuse of barrier methods. As Maggie Helwig of the Coalition for East Timor said in concluding her description of soldiers rounding up women from East Timorese villages so that the implant, Norplant®, could be inserted: "You can't force a guy to use a condom at gunpoint".

Of the various hormonal contraceptive methods, the Pill has little potential for abuse because the action of a single tablet lasts for one day only and a woman can stop taking it at any time. The effects of injectable hormonal contraceptives, however, last for one to three months and cannot be reversed during this time; injectables therefore have a higher abuse potential.

Hormone-releasing vaginal rings, currently under development, will be effective for three or six months, but a woman can remove them by herself any time she wants. So although injectables and vaginal rings have a comparable duration of action, they have a profoundly different abuse potential because of a different degree of user control.

The implant, Norplant®, acts for five years and is regarded by its developer, the Population Council, as being a means of temporary sterilization. When it was introduced, women were told that its effects could be stopped whenever they wished. In theory, this is true; in practice, Norplant® needs the cooperation of a health-care provider to remove it surgically. Women have often had difficulties in getting the implant removed before the end of its five-year contraceptive duration, not only in countries with "demographically-driven" population programmes but also in countries such as Britain and the United States.

Beyond Control

Contraceptive methods developed in a "population" framework also tend to lend themselves to abuse. The longer the action of a method, the more difficult it is for someone to discontinue this action and the more easily a method can be promoted and administered on a mass scale without people's knowledge or informed consent, the higher the risk that it will be abused.

If a contraceptive's potential for abuse is defined as technology-inherent features which increase the likelihood of uninformed, disinformed and coercive administration of a birth control method, the abuse potential of anti-fertility "vaccines" puts them way beyond any social means of preventing or containing such abuse.

The aim of immuno-contraceptive research is to develop a relatively long-acting method; the anti-hCG versions, for instance, are designed to act for one to two years, while anti-sperm immunization in women might act for life.

Immuno-contraceptives could easily be administered on a mass scale with or without a person's knowledge or consent because their delivery system will be an injection, pill or drinking liquid. Even relatively complicated procedures such as IUD insertion and sterilization have been carried out without women's knowledge, for example, immediately after a woman has given birth or under general anaesthesia when she may not be fully aware of what is happening around her, or during a routine gynaecological check-up. With immuno-contraceptives, there would be no need to wait for such occasions; they could be given whenever someone requested or agreed to an injection or pill for the treatment or prevention of a disease.

The research community has emphasized the acceptability and popularity of vaccines in general as a significant factor in facilitating the introduction of immuno-contraceptives — it is also a factor in exacerbating the method's abuse potential. The use of the vaccine metaphor obscures profound differences between the two technologies: vaccines stimulate normal im-

Choice? What Choice? Whose Choice?

Several individuals and groups, in particular those concerned with women's health and rights, have been apprehensive for some time now about the development of immuno-contraceptives. In 1987, women's groups in Brazil initiated the collection of 10,000 signatures, including 300 scientists, opposing the Population Council's proposed testing of its anti-hCG "vaccine" in the country — the trial was subsequently abandoned.

Concern has now developed into concerted international action. In 1993, a wide-ranging group of women's and health activists drafted a petition calling for an immediate stop to all research on immunological contraceptives and a radical reorientation of contraceptive research.

The petition — a Call for a Stop of Research on Anti-fertility "Vaccines" (Immunological Contraceptives) — expresses concern about the method's abuse potential, questions the legitimacy of manipulating the immune system for contraceptive purposes given the distinct lack of advantages but significant potential risks of the method, and draws attention to specific problems in the clinical trials that have taken place so far. It criticizes the shaping of contraceptive research by population ideology and a narrow scientific framework.

By June 1995, over 430 groups and organizations from 39 countries had signed the petition, ranging from a multitude of women's organizations and health groups to human rights and consumer action groups, from alternative development policy groups to aid agencies, from student associations to workers' unions.

Most of the research institutions and a few funders of immuno-contraceptive research have responded to the petition. One of the most pervasive characteristics of their responses is the assurance that they are fervent supporters of "free and informed choice" for women in the matter of reproduction. The president of the Population Council, Margaret Catley-Carson, asserted that:

> "The Population Council is dedicated to advancing the reproductive health of women . . . We develop contraceptives to enable women and men to regulate their own fertility in accordance with their own goals."

The Director of WHO's Human Reproduction Programme, Giuseppe Banagiano, wrote:

> "I agree completely with . . . the 'right of women to decide whether, when and how to have children'. It is, however, my contention that this . . . also includes the right of women to choose what method of family planning to use, including, if they wish, an antifertility vaccine."

It would be easy to conclude from these statements that anyone concerned about the contraceptive "vaccine" is against women's choice. Yet women's health advocates have repeatedly emphasized that increasing the number of methods available does not automatically lead to expanded choice. Choices are shaped by what is available and the power to choose. As community health researchers Rani and Abjay Bang report from India:

> "In reality, the choice of contraceptive methods is not made by women. The decision is actually often made by the government health programme officials and workers."

Increasing reproductive "choice" cannot be understood as the right of research institutions to develop whatever they consider to be attractive and feasible, nor should it be seen as a "choice" between immuno-contraceptives of different durations while a prior issue is excluded: should certain technologies be developed at all? Annette Will of the German group, BUKO Pharma-Kampagne, points out that:

> "The introduction of one more family planning method does not give people more or less freedom to choose but more or less things to choose from. Nobody deprives women of the freedom to choose when one objects to one or more (bad) contraceptives to choose from. Furthermore, more choice has no meaning in itself, what is important is the question: more choice of what? . . . Reproductive self-determination . . . is not a question of developing another control device, but it is a complex social and political issue that affects men and women differently."

Many critics of immuno-contraceptives feel that this debate is of critical importance. The Call for a Stop maintains that the aim of contraceptive development should not be population control but:

> "to enable people — particularly women — to exert greater control over their fertility without sacrificing their integrity, health and well-being. Contraceptive development must be oriented at the realities of women's lives. Above all it must consider local health care conditions and the position of women in society."

The "vaccines" are still some years away from being approved by drug regulatory authorities. Annette Will says that:

> "We must not postpone reflecting and evaluating a new technology in all its potential consequences to a later point of time. History teaches us that there is no such thing as a neutral technology or a neutral science. Scientific research is always carried out within a social, political, religious, cultural and economic framework . . . The leading questions are: Why are immunological contraceptives being developed? For whom are they meant? By whom are they researched? Who has which interest in the development of immunological contraceptives? What will they do to women and men? How are they going to influence people's health, dignity and integrity?"

In 1995, the coordinator of WHO's research on immuno-contraceptives, David Griffin, stated that he would stop the research if potential users said they did not want immuno-contraceptives. Campaigners are therefore urging anyone concerned about the method to register their disquiet with WHO on a postcard. As the Forum for Women's Health in Bombay, a group which has grown out of campaigns against prenatal sex-determination, stresses:

> "The campaign against antifertility vaccines is . . . not merely a women's issue as issues of contraceptives have so far been seen . . . It is an issue of human relations, of the whole understanding of what is development and the meaning of progress in science and technology."

For a copy of the petition, pre-printed postcards and more information on the Stop Anti-Fertility "Vaccines" campaign, contact the office of the international campaign coordinator: Women's Global Network for Reproductive Rights (WGNRR), NZ Voorburgwal 32, 1012 RZ Amsterdam, THE NETHERLANDS. Fax: +31 (20) 622 2450. Write to (please copy to WGNRR): David Griffin, Task Force on Vaccines for Fertility Regulation, Human Reproduction Programme, World Health Organization, 1211 Geneva 27, SWITZERLAND.

mune responses to ward off diseases, whereas immuno-contraceptives induce a particular immune disorder, namely (immunological) infertility. Pregnancy is a natural and healthy process, not a disease and even less an epidemic, while the fetus is not a harmful germ invading the body. Ironically, the widespread introduction of immuno-contraceptives may cause people to lose any trust they have not only in family planning services but also in healthcare systems: they could no longer be sure what an injection or pill was actually for, but would no doubt be aware that the effects of immunizations cannot just be switched off.

Li Sanli

At the May 1994 World Health Assembly, the annual meeting of the World Health Organization in Geneva, women's groups performed street theatre depicting the realities of contraception for many women worldwide. Large banners called on the WHO to stop research into anti-fertility "vaccines".

Stop Research

Some contraceptive researchers may not see a conflict of interest between developing contraceptives to limit population growth and to meet women's needs or enhance people's reproductive rights.[40]

But as this analysis of immuno-contraceptives has shown, a contraceptive assessment centred on reducing birth rates is very different from assessments concerned with the integrity, dignity and well-being of individual users. It is questionable whether birth control methods can be designed and provided in such a way so as to meet the goals of both simultaneously. Without addressing the impact of a population framework on the contraceptives which have been developed and made available, meeting women's needs so as to meet (even unspoken and unspecified) demographic targets is, at most, a shift from "hard" to "soft" population control.[41]

Some contraceptive developers see anti-fertility "vaccines" as "an unprecedented effective instrument for demographic control".[42] Because of their technology-inherent features and given the history of population control, I see them as contraceptives with an unprecedented potential for abuse. Such potential is reason enough to call for an immediate stop to this line of research.

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1. Stevens, V.C., "Current status of antifertility vaccines using gonadotropin immunogens", *Immunology Today*, Vol. 7, No. 12, 1986, p.374.
2. Dukes, G.N., letter to the author, 24 January 1995.
3. I refer to these birth control methods under development as "immuno-contraceptives" rather than "vaccines", as the research community calls them, because they differ in significant ways from vaccines against diseases. However, Indian women's rights activists Swatija Paranjape and Chayanika Shah have said that they would "continue to call it the 'anti-fertility vaccine' ... We feel that the basic assumption behind the development of this contraceptive is an understanding of fertility as a disease — a communicable one at that! It is considered to be an epidemic in the context of the poor marginalized women all over the world. The name that [the researchers] have given highlights their mentality in producing it."
4. See Katsh, S., "Immunology, fertility and infertility: A historical survey", *American Journal of Obstetrics and Gynecology*, Vol. 77, No.5, 1959, p.947.
5. Jones, W.R., *Immunological Fertility Regulation*, Blackwell Scientific Publications, Oxford, 1982, p.9.
6. See ibid and Clarke, A., *Disciplining Reproduction: Modernity, American Life Sciences and the Problem of Sex*, University of California (forthcoming).
7. The research at WHO is coordinated by the Special Programme of Research, Development and Research Training in Human Reproduction (HRP). Funders include the World Bank, the United Nations Fund for Population Activities (UNFPA), the United Nations Development Programme (UNDP), the Rockefeller Foundation, the US Agency for International Development (USAID), the International Development and Research Center (IDRC, Canada) and the governments of Germany, Britain, India, Norway, Sweden and the US. Immuno-contraceptives are also being researched by several smaller research teams at the Indian Institute for Science in Bangalore; the Reproductive Biology Unit at the University of Edinburgh, Scotland; and Institut Gustave Roussy, France.
8. World Health Organization, "First human trial of birth control vaccine begins in Australia", WHO press release, Geneva, 17 February 1986.
9. Mitchison, N.A., "Lessons learned and future needs", in Alexander, N.J. et al., *Gamete Interaction: Prospects for Immuno-Contraception*, Wiley-Liss, New York, 1990, p.607.
10. In fact, the immune system's functioning and interactions with other body systems are not fully understood. I use a simplified, mechanistic model of the immune system to describe how immuno-contraceptives are designed to work. The mechanistic, molecular model is, however, just one way of describing the immune system. For critiques of this model, see Haraway, D.J., "The biopolitics of postmodern bodies: constitutions of self in immune system discourse" in Haraway, D.J., *Simians, Cyborgs and Women: The Reinvention of Nature*, Free Association Books, London, 1991 and Martin, E., *Flexible Bodies: Tracking Immunity in American Culture — From the Days of Polio to the Age of AIDS*, Beacon Press, Boston, 1994.
11. Auto-immune diseases tend to be more frequent and more severe in women than in men. See Playfair, J.H.L., *Immunology at a Glance*, Blackwell Scientific Publications, Oxford, 1989 (4th edition), p.33.
12. In some people, however, the immune system does react against hormones, cells or other body secretions indispensable for human reproduction. Immune factors are thought to play a role in many early miscarriages. Some women and men also generate spontaneous antibodies to sperm.
13. A toxoid is a version of a disease-causing toxin which has been altered so that when a person is vaccinated with it, the toxoid stimulates the immune

response against the toxin but does not cause the disease. If a person subsequently encounters the disease-causing toxin, the primed immune system reacts quickly and vigorously to it.

14. Existing reversible methods of birth control fall into three main classes: barrier methods (male and female condoms, diaphragms); intra-uterine devices (IUDs); and hormonal contraceptives (Pill, injectables, implants). In contrast to hormonal contraceptives, the active principle of immuno-contraceptives is not what is injected into the body but what is produced by the body in response to the administered substance.

15. Spieler, J., "Development of immunological methods for fertility regulation", *Bulletin of the World Health Organization*, Vol. 65, 1987, p.779. The effectiveness of anti-disease vaccines depends not only on the vaccine's action in an individual but also on the proportion of people in a given population who are immunized. If a vaccine induces an immune response in the majority of people, those who have not been vaccinated or who have weaker immune responses are still protected because it is harder for the disease to gain a foothold in the population and thus such people are less likely to be exposed to the disease. Thus it has never been necessary to develop anti-disease vaccines which are 100 per cent effective (or nearly so) in an individual.

16. Griffin, P.D. & Jones, W.R., "The preliminary clinical evaluation of the safety and efficacy of a fertility regulating vaccine", *Statistics in Medicine*, Vol. 10, 1991, p.188.

17. The hormone hCG and the related FSH, LH and TSH hormones are composed of two sub-units: a short alpha unit and a longer beta unit. The alpha sub-unit is virtually identical in all four hormones, but hCG's beta sub-unit is similar only to the beta sub-unit of LH. In addition, the hCG beta sub-unit has a small end section of 37 amino acids — a carboxyterminal peptide (CTP) — which is not found on the other hormones. WHO's anti-hCG immuno-contraceptive research has been directed at this small end peptide, the most unique and distinct part of the hormone molecule, to avoid the risk of potential cross reactions with other hormones.

    The Population Council and the National Institute of Immunology, however, opted for the whole hCG beta sub-unit because they considered the peptide too small a target antigen for the immuno-contraceptive to be effective as a contraceptive. They hoped that any immune reactions generated against LH with its similar beta sub-unit would not be unduly problematic; however, some of these, such as damage to the ovaries or pituitary gland, may only manifest themselves after years of repeated immunization. Despite the larger target antigen, the prototypes of both the Population Council and the NII still fall far short of inducing an immune reaction of one to two years in the majority of women immunized.

    Meanwhile, because of the anticipated low immune reactions to the peptide, the WHO research programme added a strong adjuvant (a substance which stimulates the immune reaction to the antigen with which it is mixed). The adjuvant, muramyl dipeptide (which has not been approved for use in anti-disease vaccines) seems to have been the cause of muscle and joint pain and fever in several participants in the product's safety trials which took place in Australia and its efficacy trials which took place in Sweden. In June 1994, the Swedish trials were suspended after most of the seven participants developed one or more of these symptoms.

18. Talwar, G.P. et al., "A vaccine that prevents pregnancy in women", Proc Natl. Acad. Sci, Vol. 91, August 1994, pp.8535-8539.

19. It has, as yet, been tested only as a product against prostate cancer. But depending on trial results, there are plans to test it as a male contraceptive.

20. At the outset of research in the 1970s, researchers agreed not to target any substance whose neutralization could interfere with other functions besides reproduction. Although hCG is considered by many researchers to be the most "promising" antigen because it is produced only by the early embryo and would need to be neutralized once a month at most, research has now established that the pituitary gland and certain types of lung cancer may also secrete hCG. As the WHO research team states, "It is not known whether there are other elements in the body which also secrete hCG." See HRP, "Fertility regulating vaccines: report of a meeting between women's health advocates and scientists to review the current status of the development of fertility regulating vaccines", World Health Organization, Geneva, (Doc. WHO/HRP/WHO/93.1)(1993), p.17.

21. See Griffin, P.D., Jones, W. and Stevens, V., "Antifertility vaccines: current status and implications for family planning programmes", *Reproductive Health Matters*, No. 3, 1994, pp.108-13.

22. Cited in Alexander, N.J. et al., op. cit. 9, p.615.

23. Staines, N., Brostoff, J. and James, K., *Introducing Immunology*, Mosby, St Louis and London, 1993, (2nd edn) p.5.

24. There should be no difference between what is often termed a "user perspective" of a contraceptive and a "researcher's perspective". The research community and women's health or consumers' advocates should try to put themselves in the position of all anticipated users and assess the technology from their various perspectives with their differing views and in their differing contexts.

    Even though two immuno-contraceptives are being designed for use in men, most of my assessment centres on prospective women users for three reasons. Most research has been carried out into ones which act in women's bodies. Theoretical and practical criteria by which to assess a contraceptive from the perspective of a man are lacking, partly because the condom is still the only reversible means of contraception for men but also because of power differences in most societies between women and men. It has been and still is harder for women to prevent outside control over their bodies.

25. The duration of the initial lag phase will depend on the type of contraceptive and on the woman's immune system. The current formula of the Human Reproduction Programme of the World Health Organization acting against hCG takes around five to six weeks to build up to this level while that of the NII in India takes about three to four months. The shortest possible duration is unlikely to be less than two to three weeks. For WHO, see Jones, W.R. et al., "Phase I clinical trial of a World Health Organization birth control vaccine", *The Lancet*, 11 June 1988, pp.1,295-8; for NII, see Talwar, G.P. et al., "Vaccines for control of fertility", paper presented at the HRP meeting between women's health advocates and scientists to review the current status of the development of fertility regulating vaccines, Geneva, 17-18 August 1992 and the 8th International Congress in Immunology, Budapest, 23-26 August 1992, p.5; for shortest duration, see Stevens, V.C., "Future perspectives in vaccine development", *Scandinavian Journal of Immunology*, No. 36, Supplement 11, 1992, p.139.

26. Report of the Symposium, "Points to consider in the assessment of the safety and efficacy of vaccines to regulate fertility", in Ada, G.L. and Griffin, P.D., (eds.) *Vaccines for Fertility Regulation: The Assessment of Their Safety and Efficacy*, World Health Organization, Cambridge University Press, Cambridge, 1991, p.289. Some commentators maintain that if a woman becomes pregnant, she can simply have an abortion because presumably she was taking the contraceptive because she did not want to have a child. Such a comment does not consider whether a woman has access to safe, legal abortion, nor does it recognize that the wish not to have a child when one is not pregnant does not automatically translate into a wish not to have a child when one is pregnant. I am in favour of abortion as a woman's right, but oppose it as a duty.

27. Quoted in Guymer, L., "Anti-hCG vaccine: Contraception for women or a tool for population control?" (mss), Deakin University, Geelong, p.33.

28. Anderson, D.J. and Alexander, N.J., "A new look at antifertility vaccines", Fertility and Sterility, Vol. 40, No.5, 1983, p.567; Schrater, F.A., "Immunization to regulate fertility: biological and cultural frameworks", *Social Science and Medicine*, Vol. 41, No. 5, p.661.

29. Jones, W.R., op. cit. 5, p.16; Thau, R. et al., "Advances in the development of antifertility vaccines" in Mettler, L. and Billington, W.D. (eds.) *Reproductive Immunology*, Elsevier, Amsterdam, 1990, pp.237-44.

30. Report, op. cit. 26, pp.289-290; Nossal, G.J.V., "Life, death and the immune system", *Scientific American*, Vol. XX special issue, September 1993, p.30.

31. An effectiveness rate of 95 per cent is no higher than that recorded for contraceptives often considered by family planners to be relatively ineffective — condoms, diaphragms and some "natural" methods such as ovulation monitoring and breastfeeding on demand.

32. Ada, G.L. and Griffin, P.D., "The process of reproduction in humans: antigens for vaccine development", in Ada, G.L. and Griffin, P.D. op. cit. 26, p.18.

33. Basten, A., "Birth control vaccines", *Ballière's Clinical Immunology and Allergy*, Vol. 2, No. 3, 1988, p.771.

34. See Duden, B., "Population" in Sachs, W., (ed.) *The Development Dictionary*, Zed Books, London, 1992, pp.146-157.

35. Filmed in "Antibodies Against Pregnancy: The Dream of the Perfect Birth From the Laboratory" (a film by C. Schaz with E. Schneider), 1991.

36. Ibid.

37. Shearman, R.P., foreword to Jones, W.R., op. cit. 5, p.vii.

38. Griffin, P.D., "A birth control vaccine", *World Health*, November 1987, p.25.

39. Mauck, C.P. and Thau, R.B., "Safety of antifertility vaccines", *Current Opinion in Immunology*, No. 2, 1990, p.731. Early on in immuno-contraceptive development, researchers stressed that "immunization as a prophylactic measure is now so widely accepted that ... one method of fertility control which would have wide appeal as well as a great ease of service delivery would be an anti-fertility vaccine." See HRP Task Force on Immunological Methods for Fertility Regulation, "Evaluating the safety and efficacy of placental antigen vaccines for fertility regulation", *Clinical and Experimental Immunology*, Vol. 33, 1978, p.360.

40. For instance, the Rockefeller Foundation's senior adviser for biomedical health research, Mahmoud Fatallah, maintains that "respecting women and responding to their needs is one of the best strategies for saving the planet. The demographic impact will not be diminished but enhanced." See Fatallah, M., "Fertility control technology: a women-centred approach to research" in Sen, G., et al., *Population Policies Reconsidered: Health, Empowerment and Rights*, Harvard University Press, Boston, 1994, p.229. WHO's David Griffin, meanwhile, acknowledges that the anti-fertility "vaccine" was originally developed in a "demographic-driven, science-led" framework, but thinks public debate should now focus on whether it could enhance women's choices (Personal communication, June 1993).

41. Hartmann, B., *Reproductive Rights and Wrongs: The Global Politics of Population Control*, South End Press, Boston, 1995, p.154.

42. Avrion Mitchison summarizing the opinion of a number of participants at a WHO seminar on immuno-contraceptives. See Mitchison, N.A., "Chairman's summary: present status and future prospects of antifertility vaccines" in Ada, G.L. and Griffin, P.D. (eds.) op. cit. 26, p.249.