

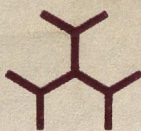
Berne Declaration
HAI Switzerland
P.O. Box 177
CH - 8031 Zürich
Switzerland

End of December 1991

Information Sheet

"WHO-anti-pregnancy-vaccine, phase II clinical trials, 1992"

1. According to a confidential source, the trials of phase II will take place in **Sweden** "sometime in 1992".
2. The trials still have to pass the Swedish **Ethic Commission**. At the time there are negotiations going on between the WHO/HRP (Human Reproductive Program) and the 4 to 5 companies involved in the production of the vaccination concerning **liability questions**. There seem to be some problems. Which the involved companies are, is unknown to us at the moment.
3. The **General Assembly of the WHO** will take place in May '92 in Geneva. The main topic will be 'Promotion of Medicaments', and there will be nothing about women's health or contraception, as far as we know. The next **Task Force Meeting on the Vaccine** (small, mostly researchers) will take place in August '92 in Geneva.
4. This Information Sheet is being sent to:
 - . FINRRAGE Sweden
 - . HAI Sweden
 - . HAI Finland
 - . FINRRAGE International Coordination, Hamburg
 - . FINRRAGE Switzerland
 - . FINRRAGE Australia (where phase I took place)
 - . some individual FINRRAGE-members



राष्ट्रीय प्रतिरक्षाविज्ञान संस्थान

NATIONAL INSTITUTE OF IMMUNOLOGY

आचार्य जी. पी. तलवार
G.P. TALWAR
Professor of Eminence

No.P.20.1/ 263

5496

October 12, 1993

Ms. Lakshmi Murthy
"SAHELI"
Women's Resource Centre
Unit About Shops 105 to 108
Shopping Centre, Defence Colony Bridge
NEW DELHI - 110 024

Dear Ms. Lakshmi Murthy,

Your letter dated 18th September, 1993 to the Director, NII has reached my desk on 8th October. I hasten to reply.

We have dedicated many years of our research life towards development of a Product which may be more physiological for women and which may not interfere with her normal pituitary ovarian functions. As you are aware, oral pills and other steroid contraceptives act by blocking the pituitary ovarian axis. The woman does not ovulate nor does she make her sex hormones. These are substituted by the synthetic steroids.

One of our basic aims in developing the anti-hCG vaccine was to have a method which does not interfere in the pituitary function nor in the normal ovarian function. The method should not disturb ovulation nor the normal ability of the woman to make her own sex hormones. This is exactly what has been achieved in the vaccine that we have developed. The vaccine, being the first of its type has gone through extensive safety and toxicology studies not only in India but also in other countries. Realizing the importance of the approach, The Population Council laboratories in New York also conducted independent life long toxicology studies in monkeys. The results of all these investigations are published or available to you and to others who would like to get acquainted with the progress in the field.

Another important feature of the vaccine is that it does not disturb the menstrual regularity nor causes changes in the number of days or amount of bleeding. You would realize, this is again an issue which is bothersome to women and several of the present day contraceptives, such as IUDs, the steroidal injectibles, cause disturbances in the bleeding pattern and the blood loss. You and your representatives will be welcome to see the complete record of menstrual diaries of women who were immunized with our hCG vaccine.

2.../-



NATIONAL INSTITUTE OF IMMUNOLOGY

-2-

It is true that 20% of the women during Phase II trials did not make antibodies above the threshold fixed for testing, namely 50 ng/ml. What is positive is that all women did make antibodies against hCG and that 80% were above the threshold. This is an important observation and shows for the first time anywhere in the world that a birth control vaccine can prevent pregnancy. Although researches are going on everywhere in the world on such vaccines, it is a matter of satisfaction and pride that the Indian Science has leadership on this account.

We are in agreement with you that we have to further improve the vaccine. What we have achieved are the basic premises, namely of safety of the vaccine, of its complete reversibility and of its efficacy. Optimization has still to be done to make the vaccine workable in a larger percentage of acceptors. Moreover, there has to be a self doable test to tell a woman if she has or not enough antibodies. This test is under development.

We appreciate your concern and your interest in development of more convenient, safe and acceptable methods for enabling women to have the option to choose from. I am personally involved alongwith my colleagues in developing at least 3 new methods. I would suggest that you and your colleagues may visit us on a day and time mutually convenient, where we can put at your disposal all the information and data that has accumulated over the years to satisfy your querries.

Yours sincerely,

(G.P. TALWAR)

Saheli

Women's Resource Centre

4.10.93

Date.....

Dear Friends,

As you may be aware, women's groups in Delhi have been meeting regularly to plan a sustained campaign against hazardous, long-acting contraceptives, and population control policies pursued in India and abroad. At an international meeting held in Germany in June this year, many women's groups working on this issue, decided to organise world-wide protest actions on November 11th 1993, calling for a halt to research on antifertility vaccines. We have enclosed the statement prepared there and are collecting signatures from various places. We are organising a protest demonstration in Delhi on NOVEMBER 4th 1993. The signatures collected will also be sent to Women's Global Network for Reproductive Rights before the 4th of Nov. 1993.

Please respond to this with urgency, in support of our efforts. Send as many signatures as you can collect, AS SOON AS POSSIBLE.

Do keep in touch with us on this issue.

In solidarity,

Ranjana Padhi Elizabeth (for Saheli)

18-9-93

To,
The Director,
National Institute of Immunology
JNU Complex, Shaheed Jeet Singh Marg,
N.Delhi - 67.

Sir,
We are a women's organization working actively on issues relating to women's health. We are particularly interested in new contraceptive technologies and their impact on women's health.

We are writing to you to seek information on the anti-HCG vaccine and other vaccines developed by your Institute, and the trials underway or planned in this regard.

We are given to believe that in Phase II trials of the anti-HCG vaccine, in 20% of the instances, the antibody concentration did not reach the levels required for contraception. We would like to know whether this formulation is being rejected on account of this high failure rate.

We are also given to understand that the vaccine developed by the NII utilizes the entire B subunit of the HCG molecule and hence has potential for cross-reaction with LH. We would like to know what studies have been carried out in this regard.

Have any studies been done to evaluate the impact of the vaccine in the context of the fact that small levels of circulating HCG have been detected in non-pregnant women ?

We are given to understand that monetary compensation was offered to women undergoing vaccine trials. Could you detail the rationale and amount for the same .

We would be grateful if you could provide us with published reports on all research done so far.

Sincerely,

Lakshmi Narayan
(For Saheli)

Saheli

Women's Resource Centre

1-9-93

Dear friends,

- (1) You must be aware of the International Conference on Population and Development scheduled to take place in Cairo in June 1994. Parallel NGO conference will be taking place at the same venue, simultaneously. However, in the NGO's conference, representatives of the Population Council, USA, (of NORPLANT fame) and the Safe Motherhood Initiative of the World Bank have taken it upon themselves to represent the NGO voice.

Women throughout the world have suffered at the hands of these very agencies, and hence it is likely that confrontation rather than co-operation will set the tone of the NGO forum, where women's organizations will also be present.

In view of this various planning initiatives are underway throughout the world. So far we have received three statements in this regard, and Saheli has endorsed one of them. We need to discuss these positions and see whether we can choose/modify one of them and lobby to have it adopted. This exercise will be helpful for us to understand our own alliance and also recognise differences.

- (2) In June '93 Saheli had participated in a conference on Anti-Fertility vaccines, attended by women from all over the world. It was decided that we should make a joint effort at stopping vaccine trials throughout the world.

As many of you may know, the Indian vaccine is the most advanced. While those present at the conference were united in their stand against the vaccine, it was felt that the campaign ought to be more broad-based and allow for a more inclusive approach.

In view of this a statement was drafted and is being circulated to women's groups all over the world to initiate a campaign in November 1993. If this campaign is launched worldwide, it will be the first opportunity for women to take initiative before the product is in the market. In other cases we have only reacted to abuse.

We would like to discuss these issues in the NEXT MEETING ON SEPTEMBER 10 th 1993 at 2.00 pm at our office.

Please bring address lists for UP and Bihar so that NORPLANT material can be mailed to other organizations. (ref: reports that Norplant insertions are taking place on a large scale in these States).

In Solidarity

Udharma / Lakshmi
(for Saheli)

Attached : Three statements on Population and Development
Statement on Anti- Fertility vaccines

Kalpana Mehta and Nalini Bhanot
SAHELI Women's Resource Centre
Above shop #105
Defence Colony
New Delhi 110 024



**WOMEN'S GLOBAL
NETWORK FOR
REPRODUCTIVE
RIGHTS**

NZ VOORBURGWAL 32
1012 RZ AMSTERDAM
THE NETHERLANDS
TEL (31-20) 620 96 72
FAX (31-20) 622 24 50

August 25, 1993

Dear Kalpana and Nalini,

I am herewith sending you the **Call for a Halt to Research on Antifertility 'Vaccines'** and the corresponding cover letter, directed to all participants in the International Action Workshop in Bielefeld, Germany.

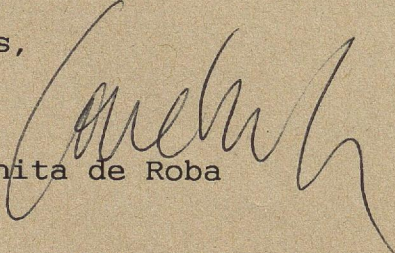
Because of the urgency of this action, I have also faxed you these both documents today, to the following fax #: +91 11 375 5275. I understand from your letter dated August 6 that we should send faxes directed to you to a Kawaljit Singh. You do not however mention the corresponding number, and we don't have it on our list.

I am also including background information on the diaphragm and the cervical cap. Our documentation centre is not up to date, however. For current information I would like to refer you to the Boston Women's Health Book Collective, PO Box 192, West Somerville MA 02144, USA. Newsletter 42 has an article dedicated to the female condom on pages 18 and 19.

I am very sorry to hear you feel upset with us for not including SAHELI on the subscribers' list of Antigena's critical appraisal to the Women's Voices Declaration. I must admit that you are quite right. I do want you to understand that this has nothing to do with 'reluctance' or 'resistance' from our part. I should have considered all these things you say (timing, costs) and just include you at least in the Spanish and French version. I feel very bad about this, and hope it will not repeat itself.

We have been having some troubles contacting you in general. Working from the list that was distributed and checked by all participants in the Workshop in Bielefeld, it seems that neither your phone nor your fax numbers are correct. Now, we have no other means than the mail and this fax number you don't want to use. **Could you please let us know how we can contact you in the future?**

Yours,


Conchita de Roba

Date
3.11.94.

Dear friends at Saheli,

~~the~~ Some of us met and discussed the forthcoming AFV meet. (International).

Here are some suggestions

- 1. This meeting could be held in Delhi around March / April 95.

Delhi being more appropriate and strategic place, it would be better to have the meet at Delhi

- 2. It is necessary to involve ~~the~~ other groups/ individuals at national level, ~~etc~~

There could be a national level meet coinciding with ICAFV. We should interact with groups of scientists, to find out their position on AFV. Other groups are:

AP network, Varaja's group, MFC women and health cell, Amita's group from Cal., Vimochana (one should explore) Daisy from T.N; Malini, Revu, Nimita, Padmini Swaminathan & other people from Delhi & Veena Sharmma & Indira Jena.

- 3. The suggested planning.
 - 1. National level meet - (AFV, Norp. Depo. 1 day)
 - 2. National level Ancil E.V. meet. (legating, PP.)
 - 3. Public Meet ^{1 day} - 1. Dialogue with scientists
2. Press conference
3. Demo. at funding agencies office

4. ICAFV (2 days)

FFWH can take responsibility of National level Co-ordination for the national level meet.

Suggestion - we could offer hospitaling for national level groups. (one can find from WGNRR if possible to give hospitaling for about 50 people for 3 days).

The ICAFV should be away from Delhi (preferably Suggest place Sainik Farm etc.

Two team heads working on male fertility vaccine ① Dr. Mudgal B'lore ② Dr. A.R. Sheth B'lore they could be called for the public meet. we could write to B'lore groups to follow it up.

Saheli could take responsibility for international ~~was~~ international meet.

These are suggestions & we are expecting response from you, with lots of Swatiya, Sabala, Kranti, Chayanika Swadhyay.

17.4.95

Dear Kalpana, Ranjana, Laxmi, Vani, Chitra, Brinda and other Sahelis,

We had a conversation with Kalpana and this is a follow up to that talk. Actually when we spoke we had not read the fax that WGNRR had sent on the 6th so we could not understand the reason why Saheli had asked for postponement of the meeting.

Well after we got the fax and saw the public event that was being planned we were quite upset and had sent a fax to which we got an immediate reply. We send both of these to you. We wish you people had also contacted us at least some time before sending in your answer. Anyway now as it stands we feel that it is important that we make it a point to attend. Chayanika has agreed to go from the Forum and hopes that at least one of the Sahelis would give the benefit of her company, enthusiasm and energy.

As a preparation before going we feel that we need to get at least some information on the research status on the various vaccines. It looks like a number of them are being developed although very few have reached to the stage of human trials. We have written to Deepa, Ammu and Vanaja in Bangalore and asked them to get the following information from the IISc, if they can.

1. What are the various vaccines that are being developed?
 2. What stages of development are they in?
 3. Who is funding the research?
 4. In case there are clinical trials initiated, what is the status of the trial? Is it possible to meet the subjects of the trial and find out how actually the trial was conducted?
 5. How do the researchers respond to the points raised by the campaign against the AFV?
 6. What are the other contraceptive methods for which these teams are conducting trials?
- Would it be possible for you to obtain this information?

We are trying to do a similar exercise in the Institute for Research in Reproduction, Bombay and probably Saheli and Jagori could try to do the same in the National Institute of Immunology, Delhi. Even if we are not able to get anything out of the research teams we feel that also would help as part of the campaign.

One of the ideas that we had which we shared with Kalpana is that we could ask Lynette Dumble to go and get information for us in case we fail. We are planning to take appointments for her here in the IRR and the KEM. Another thing we were wondering is whether it would be possible for Saheli to organise some kind of press and other publicity after the meeting in any case.

How is the Norplant survey coming along? What are you planning in the eight day long workshop with Lynette? We do not know who would be able to attend from Bombay.

Waiting to hear from you and favourably.

Chayale for

Forum for Women's Health
95/2 Bhau Daji Road; Matunga; Bombay 400 019.

Dear friends,

In November 1993, all of us have signed a call letter asking for a halt to research in anti-fertility vaccines. November 8th 1993 was the day chosen by the international campaign group against these vaccines as the day of launching the campaign. The call letter that you had signed is being circulated even now and more and more groups are joining the campaign. As of Nov. 1994 when a reminder was sent to all the researchers and funding agencies, almost five hundred organisations and individuals from all over the world had signed the call letter.

To the call letter, from the researchers and funders there have been very few responses up till now. These include the research team of the WHO-HRP, the funding agencies ODA, U.K. and CONRAD, Canada and the pharmaceutical Organon. All the responses have been very wishy washy, not able to answer most of the questions raised in the call letter.

The research has been going on. There has, however, been a new development with the vaccine research undertaken by the WHO-HRP. **Due to the adverse reactions seen in the animals on whom the testing was done, the further clinical trials of this vaccine to be carried out in Sweden have been suspended.** In India third phase trials of the anti-hCG vaccine have either just begun or are about to begin, There is no clear information that we have.

We are even now in the initial part of the campaign when the stress has been to acquaint as many people as possible with information about the AFV. Efforts have been made to talk about these issues and about the campaign at every possible national and international forum. There have been a few public actions also, a major one being outside the annual World Health Assembly of the WHO at Geneva in May 1994.

In India the issue was discussed at the North India regional conference at Kanpur and a resolution passed. The same was done at the fifth National Conference of the Women's Movements at Tirupati in January 1994 and the annual MFC, Women and Health Cell meet at Wardha in January 1995. There was a demonstration in Delhi organised by a number of groups together in November 1993 outside the WHO headquarters. Prof. Talwar of the National Institute of Immunology, 'pioneers' in AFV research invited groups for a dialogue but as expected hardly could answer any of the queries.

In India the stress has been on raising the demand for halt to research on the AFV in the context of an emerging campaign against all long-acting, provider controlled contraceptive methods that produce systemic changes in the body. With injectables like Depo Provera and Net-en in the Indian market now for almost a year and Norplant being tested in thirty centres all over the country, the campaign has to be broadbased.

It would be helpful for the campaign if you could let us know information from your region about the use of contraceptive methods. Especially if you could get details about which of the new methods are available or being tested and also experiences of women who have used any of these methods. So please do let us know any information you can collect.

There has been a lot of material produced on each of these contraceptive methods. We at the Forum have some of this material available in English, Hindi and Marathi languages. On the vaccine in particular we have a short write up in all three languages which gives the technical aspects in greater detail. The international campaign group has printed the poster that we are enclosing with this letter. Please do write to us if you want any information and do let us know how you as an organisation can contribute to the campaign. Those of you who are in Bombay can contact us on Monday evenings between 7 p.m. and 9 p.m. at 2, Vishwadeeep; 95, Bhau Daji Road; Matunga; Bombay 19, telephone no. 4010482.

The campaign against the AFV is right now being co-ordinated by the Women's Global Network for Reproductive Rights, Amsterdam and they are basically acting as the clearinghouse for information. In India so far Saheli, Delhi and the Forum in Bombay have been in touch with them and trying to co-ordinate nationally. A next meeting of the international campaign group is being planned in Canada in June 1995. Please do write back if you have any suggestions and ideas regarding the campaign.

Waiting to hear from you.

Veena, Swatija, Sandhya, Sabala, Kranti, Kamaxi, Jaya, Gopi and Chayanika from the FFWH.

The booklets available with us:

- 1) Booklet on Norplant experiences (Re. 1/-)
Available in all three languages.
- 2) A leaflet on injectable contraceptives (Re. 1/-)
- 3) Media packet on the AFV (Rs. 5/- for photocopying)
- 4) Call letter demanding halt to research on AFV
Available in English and Marathi.
- 5) 'Prajanan' by Chayanika, Swatija and Kamaxi - a book in Hindi dealing with technical and social aspects of technological interventions in fertility control. (Rs.15/-)
- 6) - a book in English and Hindi by Saheli giving short descriptions of all contraceptive methods. (English Rs.30/- and Hindi Rs. 15/-)

Action India
New Delhi

12.4.95

Dear Beatrijs,

We received your fax dated 6th April '95 only today. We are very upset by IDRC's suggestion of getting the Indian researchers to the panel discussion and your acceptance of this suggestion.

According to us IDRC is ~~not~~ accountable as a funder. Calling Indian researchers to Canada, and making a scapegoat of them while not taking any responsibility as a funding organisation funding research on AFV for last 15 years is a racist act on their part. They are also diverting attention from AFVs as a concept to the trials. Our objections as a campaign are to all AFVs and IDRC is responsible to take a public stand against this opinion.

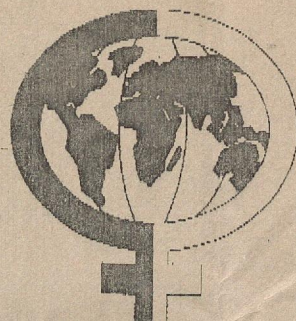
We wish to emphasise that we will surely not participate in any public event with Indian or other third world researchers in Canada, that too on the behest of the first world funding agency.

Swatiya, Sandhya and Chayanika for FFWH.

P.S.: Please respond soon as it determines our participation in the meeting.

Forum for Women's Health
Bombay, India
Fax 91 22 401 8782

April 13 1995



**WOMEN'S GLOBAL
NETWORK FOR
REPRODUCTIVE
RIGHTS**

NZ VOORBURG WAL 32
1012 RZ AMSTERDAM
THE NETHERLANDS
TEL (31-20) 620 96 72
FAX (31-20) 622 24 50

Dear women,

Thank you for your fax of yesterday. I had assumed that you had received my fax of April 6 earlier and had already been surprised that you did not respond to the idea. My reaction is that this plan should not be pursued if you are so strongly against it. I sent a fax to the Canadian organisers and informed them about your opinion and said that any plan regarding IDRC should be kept on hold until we have sorted out a proposal which is acceptable for you and for others as well. I am not sure if you had actually understood my idea. I find it totally unacceptable that someone of the Indian Research team would be invited for the panel instead of IDRC. In my opinion IDRC and the Indian Research team (and both Governments) are both responsible for the kind of research they are developing and for the way the trials are conducted. My approach is that it is incredible that IDRC just babbles away about all their ethical committees, guidelines and what have you, ignoring what happens in reality. And what happens in reality is obviously not in the first place to blame on the Indian researchers. IDRC should know and does know that all their beautiful ethical guidelines are an illusion in the political and practical context of India. They just put their heads in the sand.

However, after reading your fax I agree with you that it could turn out to be the scapegoat scenario that you describe and that should of course be avoided by any means.

Please think about and write about your idea for a public event and the role that IDRC should or should not have in that and what kind of role that should be.

I can imagine that we would mainly question them about funding this kind of research and not focus on the trials. I talked to Annette Will this morning and we thought that (if we would have a panel and a public event) we could maybe also invite the Population Council, as to widen it to North American funding and not only on Canada. Annette would also discuss it with Ulrike and come up with some ideas.

Let's put all our the ideas together and circulate them to get comments and try to take a decision as soon as possible (within two weeks I would think) as it will be too late to invite anyone otherwise.

I hope this settles in a positive way your participation to the meeting, because it can take place. We got money from another German Fund and altogether we have now sufficient funding for around 30 participants (including travel and accomodation costs for most of them, including for 3 Indian women). Next week I will send you the list with all the women who have confirmed their participation. This means that we are

WGNRR is a worldwide autonomous network of groups and individuals who are working for and support reproductive rights for women: the right of women to decide whether, when and how to have children.

working with an absolute minimum budget which for example does not allow for a report (and translation of that report) afterwards. Therefore it would still be important that you approach the Commonwealth Foundation for your travel and accomodation costs. I will fax them the Background information and mention that they can expect a letter from you. I am not sure what you mean by the head reader for the Budget but after all I think it would be best to take off the WGNRR letter head and put the name of your group since it is you and not WGNRR that requests for the money. I had not thought about that. I will send an invitation to Yorini from ACASH and ask her to send a letter to the Commonwealth as well. I will write to Saheli and ask them to take a decision on their participation and let me know by next week Monday or Tuesday. I hope they react positively.

Next week I will send you a formal invitation (I will give it a bit more neutral title) which you may need for your application for a visa. I don't know if that is necessary for residents of Commonwealth countries. Please check that.

I thought I sent you Talwar's research report of August 94? And his Guest Editorial in "Current Biology" 1994 ? That is the most recent information I have. If I did not send it, please let me know and I will do it right away.

Best wishes and hope to hear from you soon. Did you try our E mail? And it did not work? Please tell us because we are still having some problems.

Best wishes to all of you,

Beatrijs
Beatrijs Stemerding

Oct. 30, 1993

Conchita de Roba
WGNRR,
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

Dear Conchita,

Preperations for the propest action against the Anti fertility vaccine are in full swing. Our correspondence with Dr. Talwar has finally paid off and he has invited us over to see the research himself. Contrary to the information from the workshop, no trials are in i progress for the vaccine at present. We have staked out the major centres in Delhi atleast.

Since the National Institute of Immunology is situated in theback waters of Delhi we will be protesting at the main street corner near the WHO headquarters.

The response is quite enthusiastic despite the forthcoming elections in Delhi.

Please send us the signatures you collect on fax no.0091-11-6810121 c/o Mr. Kawaljit Singh.

Saheli's Telephone no. has changed and now you have to add a 4 before the old number. So the number is 4616485. My residential number is 2221159.

We are waiting to know more about the meeting in January 94 in Brazil being organized by the IWHC Beatrice had said that she had included our name for the same. We should start preparing if we have to travel. Nalini is not very active in Saheli these days and so for this meeting along with me Lakshmi Murthy will be participating.

I hope that you will be able to find sponsors for our travel. Lots has been happening here. We have been sending decoys for the NORPLANT trials and are getting shocking information from them. Our government has also set up a committee to formulate the Population Policy for India. Last Saturday we barged into their meeting and made a presentation on contraceptives, incentives and dis incentives. The members were suitably impressed.

Nafis Sadiq was here to attend the Population Summit of the World

7!

Oct. 30, 1993

Conchita de Roba
WGNRR,
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

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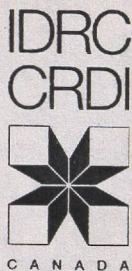
Academies of Sciences. But she was also going to meet the Indian govt. regarding the extension of NORPLANT centres even though the trials have yet to start full swing. We met her and asked her to not support this move of the government.

Please do respond to all our points. We are trying to initiate our own study on the use of barrier methods for women. Please let us know if you can help in this regard.

One little piece of gossip - Talwar made a presentation before the scientists and was told that what he was doing was neither ethical nor scientific. Anna Runborg of SIDA told us that the Population Council was doing some nice piece of research on some female method which would be under the control of women and will also take care of HIV & STD. Do you know more about this.

In Solidarity

(KALPANA MEHTA)



RECEIVED MAY 31 1995

22

International Development Research Centre
Centre de recherches pour le développement international

President
Président

May 26, 1995

Ms. Karen Seabrooke
INTER PARES
85 Arthur Street
Ottawa, Ontario
K1R 7B9

Dear Ms. Seabrooke:

Thank you for your letter of May 5 in which you described the International Action Meeting you are planning on June 5 at which you will be sharing information about the types of contraceptive research underway around the world. I am pleased to see that your panel includes women from the Third World as well as women from Canada. We at IDRC feel that it is important that information on contraceptive research is shared as broadly as possible, particularly with women from the Third World where pregnancy involves risks far greater than those faced by women in the industrialized world, and where 99% of maternal deaths occur.

Dr. Don de Savigny and Janet Hatcher-Roberts from IDRC's Health Sciences Division have informed me that they had a very constructive meeting with you and your colleagues Dr. Shree Mulay and Dr. Carla Marcelis on May 18, 1995. During that meeting, Don brought you up-to-date on the current status of IDRC funding to the Fertility Regulating Vaccine which has completed Phase II trials. IDRC has not received a request for further funding since 1989. Regarding the question of Phase III trials, we have received written confirmation that **Phase III trials are neither underway nor planned.**

IDRC remains committed to research in this vital field and in women's health issues in general. While issues of population are not the driving force of our research, we are of course very aware of population issues and the need for alternatives in reproductive choice. We have taken considerable steps to ensure that ethical and moral considerations are taken into account during research. A representative of a women's non governmental organization now participates in the project steering committee of India's National Institute of Immunology, under whose auspices the research on the vaccine is taking place.

.../2

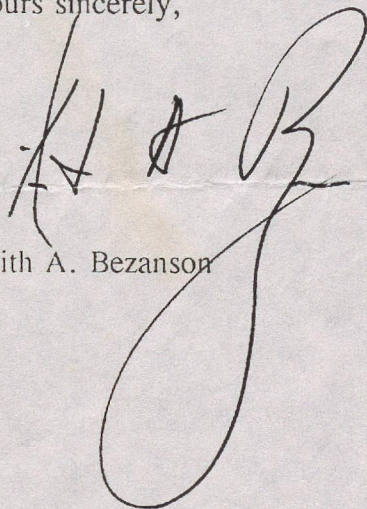


The project was also reviewed and approved by the Ethics Committee of the Indian Council of Medical Research and the Ethics Review Committee of the IDRC, and underwent an external ethics review by people recommended by Canada's National Council on Bioethics in Human Research.

I am looking forward to meeting with you and other members of the Women's Global Network for Reproductive Rights on June 5 at 9:30 a.m. as you requested, to discuss this contraceptive research program further. A few IDRC program staff will also be in attendance.

We will be pleased to meet you on June 5 from 9:30 to 11:30 at IDRC, 250 Albert Street. There will be someone in the lobby of IDRC to greet you and show you to the meeting room.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'K. A. Bezanson'. The signature is stylized with a large, looping flourish at the end.

Keith A. Bezanson



27 JAN. 1994

22

Téléphone Central/Exchange: 791.21.11
Direct: 791 3309

In reply please refer to: H9/445/15
Prière de rappeler la référence:

Ms Beatrijs Stemerding
Women's Global Network for
Reproductive Rights
NZ Voorburgwal 32
1012 RZ Amsterdam
Pays-Bas

21 January 1994

Dear Ms Stemerding,

I should like to acknowledge receipt of your letter of 8 November 1993 together with the accompanying document entitled "Call for a Stop of Research on Antifertility Vaccines".

I am sure you would agree that the currently available methods of family planning are limited in number and choice and that they do not meet the individual and changing needs of men and women throughout their reproductive lives and in the widely differing cultural, religious and service settings that exist around the world. Part of the mandate of the WHO Special Programme of Research, Development and Research Training in Human Reproduction, therefore, is to provide a wider choice to users by developing new and improved methods of fertility regulation that are safe, effective and acceptable.

The anti-hCG vaccine being developed with support from the WHO Task Force on Vaccines for Fertility Regulation is being designed to offer protection against an unplanned pregnancy for a period of up to 12 or 18 months as a result of taking a single dose of the vaccine. In the preclinical animal toxicology and efficacy studies and Phase I clinical trial carried out with the Task Force's prototype anti-hCG vaccine, a high level of efficacy was obtained, no menstrual cycle disturbances or other adverse side effects were observed, and the vaccine was well accepted by the clinical trial volunteers. We feel that a fully developed and tested family planning method with these properties will be an attractive option for those women who wish to postpone their first pregnancy, to space births at an interval that has positive health benefits for the mother and her children, and who wish to use a long-acting but not permanent method on attainment of their desired family size.

/continued

... ENCL: as indicated

You may be aware that the WHO Special Programme of Research, Development and Research Training in Human Reproduction convened a meeting in August 1992 to enable women's health advocates and scientists to review the current status of research on this novel approach to fertility regulation. I am enclosing a draft copy of the report of this meeting from which you will see that agreement was reached during the meeting on a number of important points although major differences of opinion remained on other issues, largely as a consequence of the widely differing backgrounds, philosophies, interests and objectives of the participants. The meeting provided a valuable forum for the exchange of information and views and has established an important dialogue between the method developers, providers and women's health advocates.

We feel the development of any new family planning method should be accompanied by honest and objective debate among all interested parties. It is a pity, therefore, that the authors of the document entitled "Call for a Stop of Research on Antifertility Vaccines" which accompanied your letter, have used what is, in our opinion, alarmist speculation, technical and scientific inaccuracies, and distortions of the facts to support their opposition to the development of this new technology.

The research on antifertility vaccines underway today deals with a number of approaches, many of which are intended to be used by men. In addition, some of the information gathered from these studies will greatly benefit the treatment of some types of male infertility. To stop all of this research cannot be justified. Having said this, I want to add that I am personally committed to seeing that all questions concerning the safety of the methods presently being developed with the scientific and financial support of the Special Programme continue to be properly assessed in a scientifically valid way.

Let me finish by stating that I agree with your statement 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". I also agree completely with the aim of WGNRR stated in the footer of your letter, namely, "the right of women to decide whether, when and how to have children". It is, however, my contention that this aim also includes the right of women to choose what method of family planning to use, including, if they so wish, an antifertility vaccine. I understand the concerns that have been expressed, that this method could be abused; however the same concern applies to almost anything else in medicine. Although we must stand firm to eliminate abuse, we cannot, at the same time, deprive people of the freedom to choose a safe and effective method of family planning that they may want to use.

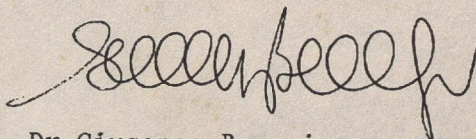
/continued

Ms B. Stemerding, Amsterdam
H9/445/15

Page 3
21 January 1994

We have accepted an invitation from the editorial advisory board of Reproductive Health Matters to submit a paper addressing the concerns expressed in the document from the biomedical and reproductive health perspectives. The paper is in preparation and should be submitted to the journal during the first half of 1994. We feel that this will be an appropriate and, hopefully, beneficial contribution to the current debate.

Yours sincerely,



Dr Giuseppe Benagiano
Director
Special Programme of Research,
Development and Research Training
in Human Reproduction

Fax 91 11 334 8589

Kalpana Mehta
Saheli
Delhi, India

November 30 1994



22

**WOMEN'S GLOBAL
NETWORK FOR
REPRODUCTIVE
RIGHTS**

NZ VOORBURGWAL 32
1012 RZ AMSTERDAM
THE NETHERLANDS
TEL (31-20) 620 96 72
FAX (31-20) 622 24 50

Dear Kalpana,
I hope my fax of last week arrived. Yesterday I spoke again to Karen Seabrooke. She told me that everyone had reacted enthusiastically at their meeting last Thursday about organising the International Action Workshop on the "vaccines". However, they would like not to do the organisation by themselves (it is a small group) but with the support of the National Action Committee on the status of women. Shree Mulay (of that committee) who is much involved in the "vaccines" campaign will return today from a trip to Toronto, so hopefully by the end of this week I will have a definite answer. I hope you all will not be too disappointed if the meeting would not take place in Delhi in the end.

Other point that I like to inform you about is that on November 8 1994 I sent again the Call for a Stop -including the most recent signatures list- to those organisations that did not respond after November 8 1993. Among the non-responders are also the National Commission for Women and the National Institute for Immunology in India. By regular mail I will send you copies of the letters. First of all for your information but maybe you could follow it up by sending a letter on behalf of Saheli as well. I sent copies to the Bombay Forum as well.

I hope that you received the letter of November 15 that we sent to all the signatories of the Call of which we had the addresses (enclosed a Call for a Stop, recent signatures list and a Campaign flyer). From the Indian signatories we had 28 addresses.

Please let me know if you could use more flyers.

You will soon hear from me again, best wishes,

Beatrijs
Beatrijs Stemerding

22

Nias Str.14
1095 VA Amsterdam
The Netherlands

10-5-94

Dear *Kalpana & other at Saheli*

Perhaps you have heard from the WGNRR about the recent developments in the campaign group here (of which I am part). I thought it would be useful to inform you'll about what happened at the WHA that took place in Geneva on the 2nd. May.

As part of the campaign work against the Anti-fertility vaccine a protest was organised by the Zurich group, Antigena and FINRAGE, on the 2nd. of May outside the building where the World Health Assembly was held. A group of about 30 women dressed in red, black and white performed a *tabla* (since no voices could be heard on the busy street anyway) showing some pregnant women being given an injection containing the vaccine and the women later breaking the syringe. There were also boards calling for a stop to the vaccine research. It was very impressive we are told - I missed seeing it since Rina and I were inside meeting the press. I was invited by the Zurich and Geneva groups and FINRAGE to speak at a press conference and if possible to talk to the international press within the WHA.

This was difficult since we had no formal invitation to attend the sessions nor were we likely to get one. So Rina Nissen used a strategy she found out from other activists to smuggle our way into the WHA! And it worked! I was very excited at having got 'legalised' once we got in. We (Rina and I) managed to approach some of the press who gave us about 45 min. of their time. So it was an unexpected success. What for us was also exciting was that the person who was interested in the Indian developments was the journalist Chitra Subramanian! She was impressed by the protest on the street and came in looking for more material. I gave her all I had on the Indian vaccine that Judith had given me and told her of the protests in India. She took everything I gave with great interest. I hope she does a good story and manages to nail Talwar. As you can imagine I was nervous. I was the only Indian and was solely responsible for doing my best to present our case as effectively as possible as quickly as possible. I hope the story meets with your approval when published!

The Geneva group had also organised a press conference for the local (Swiss) press, which went well since we were all together and others filled in the details that I missed out. It appeared that the press was sympathetic but we never know what shape their story will eventually take. The London paper, the Guardian and some international press agencies also came for the press meeting we held inside the WHA (this we did on the advice of Chitra who was very helpful).

So we all went home feeling very happy with the way things went. The tablaue of the women was being discussed by several participants within the WHA - we overheard some of their conversations. This was good to hear. I hope it gives the WHO_HRP some nightmares and causes infighting on policy!

That is all for now. The Zurich women have promised to send me copies of the photographs they have taken of their tablaue and I will send you'll some copies when we get them. As you can imagine holding together the kind of coalition we have now formed against the vaccine in Amsterdam is not very easy! Some women in the group, for instance, are very convinced that "sicence" and "objectivity" have to be respected if we are to make any gains. While several others of us find it a self defeating position to take since this so-called obejectivity works against women anyway. We are to have our next meeting on the 27th. of May and we hope to make plans to draft out a leaflet for wider public circulation. In case you have any concrete ideas on how to make an eye-catching one please don't hesitate to write to me/us.

Looking forward to hearing from you'll.
Warm regards and in solidarity,

Aurrati

Copy Judith



CONRAD PROGRAM

A Program For Contraceptive Research and Development

1611 North Kent Street • Suite 806 • Arlington, Virginia 22209 U.S.A.
(703) 524-4744 • Telefax (703) 524-4770

3 MAR 1994

22

2 March 1994

Ms. Beatrijs Stemerding
Women's Global Network for
Reproductive Rights
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

Dear Ms. Stemerding:

In response to your letter transmitting the petition calling for the halt of research on contraceptive vaccines, I would like to put forward briefly the position of the CONRAD Program. We are committed to expanding the free and informed choice of women and men to regulate their fertility as safely and in as user-friendly fashion as possible. In that context, we have been sponsoring research in many areas ranging from vaginal barrier methods, including spermicides and virucides, to systemic male steroidal methods. In our research portfolio, we have included a sizable effort in immunocontraception as we believe that, at least in the long-term, it offers the possibility of safe, reversible and effective new methods for family planning. The CONRAD Program clearly accepts the responsibility of ensuring that any new method is safe as well as effective and that all studies receive proper ethical review at both the local level and by our ethical review board in the United States as well as the usual safety review by the U.S. Food and Drug Administration.

With respect to the distribution of effort in our research portfolio, our Technical Advisory Committee, which has a representative of a women's health advocacy group as well as feminist scientists and physicians, reviews our research projects in the context of suitability and acceptability to the ultimate user. We have major efforts in female-controlled barrier methods and did the research that led to the approval in the U.S. of the female condom. On the other hand, we believe that there are advantages *for the user* in long-acting reversible methods of fertility regulation. Therefore, we will not abandon research on immunocontraception unless scientific evidence demonstrates that the methods are not safe and effective or if it becomes apparent that there are no advantages over existing long-acting technology, e.g., prevention of disruption of bleeding, normal hormonal patterns, etc.

I would like to respond to one other specific point of the petition, namely, the potential for abuse. It strikes me that the assumption of ill intent inherent in this fear is inappropriate and largely unjustified. It is true that potential for abuse exists in many areas; however, by assuming the worst about people's behavior and designing our lives so that protection from



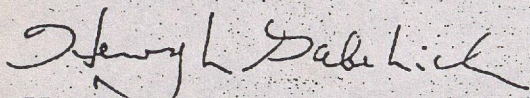
STERN VIRGINIA
MEDICAL SCHOOL
ESTABLISHED 1973
Department of Obstetrics
and Gynecology

Send article
+ ill intent!

Ms. B. Stemerding
Page 2

the ill-intent of others is the paramount guiding principle, we establish a fortress mentality and a paranoid society. I hope that we can go beyond that and build some trust so that women and men are in a position to choose what is best for themselves with respect to their methods of family planning and overall health care.

Sincerely yours,



Henry L. Gabelnick, Ph.D.
Director

→

27 DEC. 1994



U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

December 2, 1994

22

Ms. Beatrijs Stemerding
Women's Global Network for Reproductive Rights
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

Dear Ms. Stemerding:

Thank you for your letter of November 8, 1994, regarding the anti-fertility vaccines. Concern is expressed in your letter that you did not receive a response directly from my office. At the time we chose not to respond directly because we thought it more appropriate for you to receive responses from the Cooperating Agencies (CA) that the US Agency for International Development (USAID) supports. USAID, as you may know, does not itself conduct biomedical research on contraceptive development, but contributes to those CAs that have an established reputation in the contraceptive development field. In the case of vaccines, these include the Population Council and the Contraceptive Research and Development (CONRAD) Program, which were mentioned in your petition.

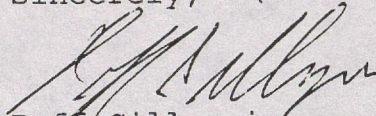
USAID has had a longstanding commitment to expanding contraceptive choice through the provision of a broad range of options to meet diverse user needs. Our research portfolio supports the development of user-controlled technologies with potential for preventing STD/HIV transmission, in addition to those methods that require specially trained clinic personnel. We firmly believe that improving the quality of available services and broadening access to services is key to allowing users to make the best choices for themselves and their families.

With regard to the development of new drugs and devices, USAID follows the regulations of the US Food and Drug Administration, perhaps the highest drug regulatory standard in the world. With regard to the programmatic implications of new technologies, our strategy for contraceptive introduction encourages appropriate assessment of the service setting and method mix prior to adding new methods. We have also devoted considerable attention in the past decade to understanding, and pilot-testing interventions to improve the service environment through operations research.

- 2 -

We appreciate the concerns expressed in your petition, and thank you for raising them with us.

Sincerely,



Duff Gillespie
Deputy Assistant Administrator
Center for Population, Health
& Nutrition

- 5 DEC. 1994

The World Bank
INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT
INTERNATIONAL DEVELOPMENT ASSOCIATION

1818 H Street, N.W.
Washington, D.C. 20433
U.S.A.

(202) 458-2381
Cable Address: INTBAFRAD
FAX: (202) 522-3235

November 29, 1994

222

Ms. Beatrijs Stemerding
Women's Global Network for Reproductive Rights
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

Dear Ms. Stemerding:

Mr. Preston has asked me to reply to your letter of November 8, 1994 calling for a stop of all research on anti-fertility vaccines. You correctly note that the World Bank supports the World Health Organization's Special Program of Research, Development, and Research Training in Human Reproduction (HRP), and that research on vaccines is funded by HRP.

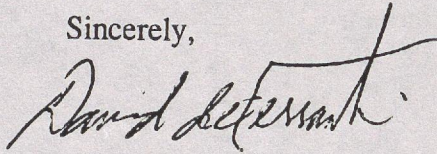
Concerns about HRP research on vaccines were raised several years ago. In response, HRP's sponsors requested that the Programme enter into a dialogue with women's health advocates who raised those concerns. As you are aware, a meeting was held in August 1992, leading to a report entitled "Fertility Regulating Vaccines" issued last year.

We recognize that there are continuing concerns about vaccines and their appropriate use. The Bank recognizes the possibility of abuses in the provision of all fertility regulation methods. Increased efforts are being mounted to address the reproductive health rights and needs of users of services that are supported under Bank loans. However, we concur with the conclusions of the HRP report that these concerns must be balanced against the potential benefits for women's and men's reproductive health (recognizing that, in fact, one of the most promising leads in this area of research is a male vaccine) from continued efforts to develop new methods, including vaccines.

It is our view that scientific issues relating to the their safety and efficacy should be addressed by HRP's Scientific and Technical Advisory Group. It is also our view that ethical concerns regarding methods should be addressed by HRP's newly established Scientific and Ethical Review Group, which has been mandated to prepare ethical guidelines both for clinical trials and for the introduction and service provision of fertility regulating methods, including the potential for abuse.

In reference to the point in your letter about the Bank's failure to respond to a letter of November 8, 1993 to Mr. Preston, we have checked the log of incoming correspondence for that period and could find no record of such a letter. All incoming correspondence to the President's office is logged.

Sincerely,

A handwritten signature in cursive script, appearing to read "David de Ferranti".

David de Ferranti
Director

Population, Health and Nutrition Department,
Human Resources Development and Operations Policy



**WOMEN'S GLOBAL
NETWORK FOR
REPRODUCTIVE
RIGHTS**

To Saheli, Delhi and the Forum
for Women's Health in Bombay

December 29 1994

NZ VOORBURGVAL 32
1012 RZ AMSTERDAM
THE NETHERLANDS
TEL (31-20) 620 96 72
FAX (31-20) 622 24 50

Dear Kalpana, Swatija, Chaynika, Sabala and all others,

Thank you so much for your letter from Bombay of December 12.
Soon you will receive a packet with Campaign flyers.

Annet sent you by regular mail a copy of the HRP magazine
"Progress" (no 30, 1994) in which suspension of the HRP trials
(already in June!!!) in Sweden has been reported: "following
the occurrence of unexpected but transient side effects in the
majority of the first seven women volunteers admitted to the
trial" "It is thought the side effects might be due to an
excessive local reaction to the vaccine".
They went back to animal trials. As soon as we have more info
we will let you know of course.

I received a positive answer from Canada that Women's Health
Interaction and the Committee on New Reproductive Technologies
of the National Action Committee on the Status of Women will
both be co-organizers of the meeting. It was very difficult to
settle the dates but finally it came out on June 2,3,4 and 5.
The meeting will take place in or very near to Ottawa.

I know that Kalpana wrote a letter to Ulrike in which she
expressed frustration about the decision making process. I
understood that Ulrike already tried to explain that it was
certainly not a decision which was "easily" taken from our
side. Nevertheless I understand very well that Saheli felt
that they waisted time and energy in discussing the
possibility of having the meeting in Delhi, when later the
decision changed from our side. I want to apologise for this
procedure and hope that it will not hamper our relations.

My idea is to send a first invitation letter to groups in the
beginning of February. I intend to include a first rough idea
for the agenda (as in the funding proposal that I sent you)
and want to ask all the participants to give their ideas for
the agenda. Besides that, I would like to form a small
international consultation group that in some cases I can ask
for advice on the proceedings for the meeting, since it will
be difficult to communicate quickly with all the participants.
Since Bielefeld there have been a few consultation meetings in
Amsterdam with mostly Bielefeld participants (Sumati Nair,
Nicolien Wieringa from WHAF, Ulrike Schaz, Annette Will,
Barbara Mintzes from HAI and Judith Richter) but we thought
that it would be good to have an internationally composed
group as well.

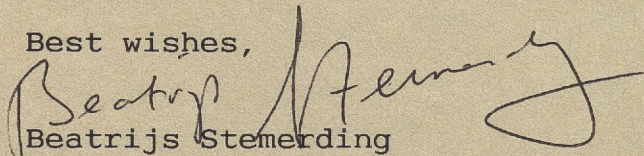
I already asked SOS Corpo (Maria Betania Avila) from Brazil to

be in this group (and she agreed), the Canadian co-organisers will of course participate in it and I would like the Forum and Saheli to take part. It means that we will mostly have to communicate by fax and the costs for that can be paid for by WGNRR. Please let me know if you are able and willing to be in the consultation group? I would like to have one or two more women in it, certainly from Africa.

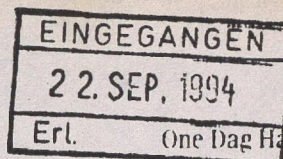
As you know from the proposal that I sent you, we are thinking about thirty to thirty five participants and hope that we will get the funding for that. Would it be possible for the Bombay Forum and Saheli to be represented by two or three women altogether? Please let me know if that would be all right and if yes who would come. Maybe we could have four or five Indian participants, it also much depends on the funding. Which other groups or organisations would you consider? In general I think it would be important to have representatives from groups who would be able and willing to really develop activities after the meeting.

I think this is all for the moment. I hope you received NL 47 and the third Campaign Report. I wish you all a very good 1995 both in your personal lives as well as in your work.

Best wishes,


Beatrijs Stemerding

The Population Council



19 JUL 1994

copy Anette
will

28 June 1994
Beatrijs Stemerding
Women's Global Network for
Reproductive Rights
NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands

(22)

Dear Ms. Stemerding:

The Women's Global Network for Reproductive Rights has called for an end to research and development of antifertility or contraceptive vaccines. My letter to you reflects the seriousness with which we in the Population Council have considered your communication and its perspective on women's reproductive health. In many discussions within the Council, we have examined the assertions, viewed our work, and assessed our rationale and future intentions. We hope you will disseminate this letter and the attached scientific assessment as widely as you have distributed your petition, so that all of the organizations and individuals who have signed it will be aware of our intentions and perspectives.

The Population Council is dedicated to advancing the reproductive health of women. We work with governments and family planning programs to improve the quality of services; we are committed to preventing unsafe abortions and to making motherhood safe; we seek to prevent the spread of HIV and other sexually transmitted diseases.

The mandate of the Population Council's contraceptive research and development program is to increase the number of safe and effective contraceptives available. We develop contraceptives to enable women and men to regulate their own fertility in accordance with their own goals. All volunteers in clinical trials must give their informed consent.

We strongly believe that no woman -- or man -- should be coerced into using, or not using, a particular contraceptive. We also believe that provider-dependent contraceptives should be provided by trained health workers and that a critical element of quality service is choice. Our rationale for undertaking the complex goal of developing vaccines is that we believe they have the potential to significantly expand contraceptive choice.

Most existing contraceptive methods, and most methods under development or already completed by Council biomedical scientists, are for use by women. The Council also has a strong program of basic research in the area of male reproductive physiology, and several male methods are being developed.

A vaccine for men would be a valuable addition to the limited choices they now have -- condom, vasectomy, withdrawal, or periodic abstinence. Availability of antifertility vaccines for men would provide a long-acting, yet reversible, new option, would not be coitus-related, and would not interfere with normal sex drives.

A vaccine for women, as well as preventing unwanted pregnancy, offers new advantages not available in their entirety in any existing contraceptive. Vaccines would be private and not coitus-related, and could be used without the partner's or family member's knowledge, for those women for whom this is a necessity. Vaccines will not interrupt normal menstrual cycles as many long-acting contraceptives do. There would be no need for storage of a supply of the contraceptive in the home, as is the case for barrier methods. In addition, a contraceptive vaccine for women would be reversible, long-acting, easy to use, and should be possible to offer at low cost. Unlike IUDs or implants, vaccines do not require a return visit to health care providers in order to discontinue use. For all these reasons we believe that for many women a vaccine would have decided advantages over implants, IUDs, and injectables.

The most advanced immunologic method we have studied for women is the hCG (human chorionic gonadotropin) vaccine. Phase 1 clinical trials with the hCG vaccine to test safety and the correct dose for optimal immune response were carried out in 1990 with favorable results. 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 2 clinical trials.

The LHRH (Luteinizing Hormone Releasing Hormone) vaccine for men is now at the stage of Phase 1 trials. It involves three injections of LHRH coupled to tetanus toxoid, and it acts to suppress two hormones necessary for sperm and testosterone production. It is expected to last for one year, and will be administered together with a one-year implant delivering a synthetic androgen (MENT) to enhance the antifertility effect and maintain normal sexual behavior. Only seven men have been immunized to date. One or more decades remain before this proposed male method passes our rigorous standards and is developed sufficiently to test in large scale, Phase 3 clinical trials.

From the data we have been able to gather so far, both the hCG vaccine for women and the LHRH vaccine for men are fully reversible methods of contraception. Normal fertility returns when the antibody titers decline, i.e., when the effect wears off. No return visit to the clinic is necessary. All vaccines tested to date have been reversible and no serious side effects have been observed.

The above are the reasons why the vaccine work has been undertaken. We subject this and all work to continuing scrutiny on a variety of safety criteria, some of which correspond to points raised in your letter. The early stage of this work means that some of the answers to some of

the questions you have posed regarding potential safety issues to users and offspring are as yet unavailable. These questions must be answered as trial work continues; the lack of answers today should not be taken as proof that the vaccines are dangerous or will be used unethically.

We share many of your concerns about how these vaccines may be provided, and their potential for abuse. There is a chance that a vaccine may be used inappropriately, confused with other injections or immunization programs, or provided with unclean needles. Some of these concerns apply to existing contraceptives as well.

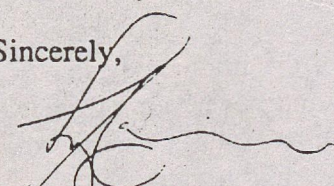
We have participated with women's health advocates in several fora, sponsored by the World Health Organization, the Population Council, and others to reach mutual understanding of how each group perceives and approaches contraceptive development and introduction. We believe we have found common ground on many issues. There already have been some constructive exchanges between women's health advocates and scientists about contraceptive vaccines, and we hope there will be additional discussions that focus on the science and service delivery aspects.

The Population Council believes its work to expand contraceptive options is a component of its efforts to improve access to and quality of family planning programs. We believe family planning should be a strictly voluntary service, free of demographic and provider targets, to assist individuals in reaching personal fertility goals healthfully. Enclosed is a new pamphlet from the Population Council, *Population Growth and Our Caring Capacity*, which I hope you will read. It provides a fuller explanation of our institution's approach to population and related issues.

Annex,
not
copied

On the following pages, under the heading "Development of Contraceptive Vaccines" are point-by-point comments relating to your petition.

Sincerely,



Margaret Catley-Carlson
President

cc: Rosemarie Thau, Ph.D.
C. Wayne Bardin, M.D.
George Brown, M.D.

Development of Contraceptive Vaccines

The "Call for a Halt to Research on Antifertility Vaccines," issued by the Women's Global Network For Reproductive Rights and related groups and organizations, is based on the premise that the expected female and male contraceptive vaccines may be harmful and do not offer any advantage over existing contraceptives; their development, therefore, the petition maintains, should not be the subject of scientific inquiry and all funding should be halted. The group's statement contains three major reasons for opposing continued research on all antifertility vaccines, and a fourth argument regarding contraceptive research in general. Although the Council is currently conducting research only on a male vaccine, we will respond to each point in the following scientific discussion:

1. Abuse potential

Opponents of antifertility vaccines fear potential abuse by mass administration of immunological contraceptives without people's knowledge or informed consent. We also oppose such abusive use. Any provider-dependent contraceptive method could potentially be used in an abusive fashion by an unscrupulous family planning or health program. Such potential could be publicly debated and safeguards taken in any country where any new contraceptive technology is introduced. Furthermore, the use of any new technology should be carefully monitored over time in order to ensure that systems of informed consent are in place and are functioning effectively. Since the vaccines that are currently being tested have a duration of effectiveness of less than one year, they are less likely to be open to abuse than sterilization or other longer-acting contraceptives. The system of informed consent used worldwide for sterilization is a good model to follow if and when any vaccines reach the introduction stage.

2. Manipulation of the immune system for contraceptive purposes

a. Function of the immune system

There are fears of unexpected problems due to the complexity of the immune system. In fact, vaccines have been used for years to combat infectious diseases and have been of great benefit to humanity. The immune system is no more or less complex than any other system of the body. The mechanism of action of vaccines is based on the fact that our immune system has the capacity to synthesize specific reaction substances, or antibodies, in response to a huge variety of response provoking substances, or antigens. The human and animal body is exposed to scores of antigens from birth onward. Our immune system responds uniquely and specifically to each of these.

It is a normal body function of the immune system to remove foreign antigens as well as antigens that are normal components of human cells. In fact, about half of the antibodies produced naturally by humans are against such cell components.

Antifertility vaccines take advantage of this highly specific response system for their mechanism of action. The antigens that compose the vaccines are highly purified peptides and proteins that are modified to elicit a very specific immunological response leading to an antifertility effect.

In order for either hCG or LHRH to act as immunogens, they must be attached to a foreign protein such as tetanus toxoid to enhance their ability to provoke a response. With this modification, these substances will then provoke the production of antibodies which then neutralize the usual biological action of specific target compounds that are involved in the reproductive process. This causes the antifertility effect.

b. How vaccine safety is assessed.

Early in the development of any therapy, a variety of plausible safety concerns are raised. These concerns have to be taken into account and tested one-by-one in animal systems. If no adverse effects are seen in animals, then -- and only then -- can studies in humans proceed.

The objective of preclinical and clinical trials is indeed to determine any major safety risks. All vaccines and drugs have side effects that will be defined by clinical studies. If a vaccine is approved for general use, potential adverse effects will be included in the labeling, as is the case with all pharmaceutical products. Some individuals unfamiliar with this process feel that the fact that additional rare side effects occur indicates inadequate testing. The occurrence of very rare side effects -- which occur in a few people per million -- will not be detected during clinical trials. These will be found once the product is approved and is used widely. This is why continuing surveillance is necessary for all pharmaceutical products, even after approval for distribution.

c. How the hCG vaccine (female) has been tested to date.

The Population Council's human trials on hCG vaccines were approved by regulatory agencies after the vaccines were shown to be safe in extensive preclinical animal studies. Long-term toxicology tests of the hCG vaccine included studies in monkeys and baboons. Based on animal toxicity data and results from earlier clinical trials as well as on an understanding of the science of immunology and immunopathology, scientists and physicians have found no evidence to lead them to expect long-term serious adverse effects induced by the hCG vaccine or any other vaccine under development. The United States Food and Drug Administration (FDA) concurred with this assessment by granting an IND (Investigational New Drug Permit) in 1985 to conduct clinical trials of the hCG vaccine in the United States. A Phase 1 trial was conducted in Chile, the Dominican Republic, and in Finland in a total of 24 sterilized volunteers; as was noted earlier, this work is suspended.

d. How the LHRH vaccine (male) has been tested to date.

The clinical trials of the LHRH vaccine for men are being conducted as a potential therapeutic treatment in prostate cancer patients because, when used in the absence of the androgen implant, it could have a benefit for this disease. This vaccine has undergone extensive animal experiments. The animal studies indicate that active immunization against LHRH is a safe, effective and reversible method of fertility controls. After more than five years of preclinical animal testing, the aggregated data were submitted to the FDA for review. An IND was approved in 1990 and Phase 1 clinical studies are in progress in the United States. To date, no adverse effects have been observed in any of the immunized volunteers.

e. Safety concerns for the fetus.

A serious concern related to all drugs is the risk and consequences of fetal exposure. For this reason, all pharmaceuticals, certainly including all contraceptives that come to market, have had to be tested in pregnant animals to see if there is an effect on the fetus.

To date, no data are available on the effects of human children whose mothers or fathers were using a contraceptive vaccine. No pregnancies have occurred with the two vaccines (hCG and LHRH) tested in the Population Council's Phase 1 clinical trials. However, studies on Rhesus monkeys conducted over a seven-year period showed that long-term immunization against CG and significant cross-reaction of the antibodies with LH had no adverse effects on offspring in these primates. Nearly thirty male and female infant monkeys were examined and found to be normal at birth. Three of the females were followed through puberty. At that time, the monkeys began to experience normal menstrual cycles and their pituitary and ovarian functions were normal.

f. Vaccine safety in AIDS victims.

An additional area of concern is the possibility that immunological contraceptives may directly or indirectly increase the risks of HIV infection or hasten the onset of full-blown AIDS. The present state of knowledge does not allow any predictions as to how any drug or vaccine affects the transmission of HIV. It should be recalled, however, that each human comes into contact with antigens every day that stimulate antibody production by the immune system. The contraceptive vaccine would be only one of many antigens to which users will be exposed.

g. Need for improvement of currently available vaccine preparations.

Our present studies suggest that vaccines tested to date fail in approximately 20% of women, about the same failure rate as seen with some barrier methods. Contraceptive vaccine developers agree, however, that this failure rate is unacceptable and would not recommend a vaccine with a 20% failure rate for distribution to the public.

The principal concern that has emerged from testing to date is the relatively high variability in immune responses among individuals. Sustained release technology, the use of multiple antigens, or the use of adjuvants that raise the response of all users above the effective threshold could be used to decrease this variability.

At present it cannot be precisely predicted as to what degree of immune response or antibody titer is needed to have an antifertility effect for a particular vaccine. For example, a male contraceptive may completely abolish sperm production in only 70% of men. However, the remaining men may exhibit such low sperm counts that they may also be infertile. To obtain more specific data, clinical studies would have to be expanded. Research is in progress to improve the vaccines by the use of novel adjuvants or by incorporating the antigen into a delivery system that will increase immunogenicity and lead to a more consistent immune response in the subjects.

3. Ethical aspects of vaccine trials

Some critics say that the clinical trials conducted to date may be unethical. They based their claim on the view that vaccines are not known to offer advantages over other contraceptives with regard to efficacy, reversibility, safety, etc. We do not accept this view.

Population Council Scientists share the concerns of the Women's Global Network for Reproductive Rights and other responsible organizations that clinical trials on all new pharmaceutical products, including vaccines and contraceptives, be carried out according to the highest ethical standards. To ensure this, scientists must conduct clinical trials according to accepted codes of ethics that are safeguarded by strict monitoring procedures. This requires that the products to be tested be approved by a drug regulatory authority in the country where they are manufactured or administered. In addition, volunteers who participate in such trials must give informed consent. The process of obtaining informed consent is monitored by local regulatory authorities in the countries where the trials are conducted, as well as by the agency sponsoring the trials.

The Population Council's Human Investigation Committee, which is composed of physicians, lawyers, and ethicists, reviews all studies on an annual basis. The trials are monitored on a regular basis through several visits each year by our clinical monitors to all study sites. Obtaining written informed consent from all volunteers is a prerequisite for all trials. The Population Council's informed consent procedures are reviewed on a regular basis to determine whether additional safeguards are needed to protect volunteers and to ensure ethical conduct. These measures go beyond what is required to conduct studies in the United States under FDA regulations.

Concerns about the immune system responding to an immunogen (i.e. the vaccine) and the possible harmful effects that could result are justified, and vaccines must be studied to show that they are safe. However, we should bear in mind that the immune system responds safely to many foreign and self immunogens. Thus the immune system is a surveillance system and is not a self-destructive system.

In the case of the two vaccines studied by the Council, we decided it was appropriate to start clinical trials with humans only after extensive preclinical studies had indicated that the hCG vaccine for women and the LHRH vaccine for men were safe in animals.

Speaking for the Population Council, we can state that we are fully satisfied with the scientific standards and ethical conduct of the vaccine trials that are being carried out and monitored by the Population Council.

4. Framework of contraceptive research

The Population Council believes there still is a need for additional contraceptive methods for currently underserved populations -- breastfeeding mothers, adolescents, older women, unmarried women, women at risk for HIV and other sexually transmitted diseases, and men.

Women need additional choices: There is no one method suitable for all women; there is no one method everyone will like; women must be able to switch methods several times during their reproductive years to suit their marital or economic status, health, or fertility goals. Until now, most contraceptives have been developed for women, a situation we are attempting to remedy. The Council is one of the leading research centers into male reproductive physiology, and development of male contraceptive methods has been a high priority for many years.

As the Council undertakes development of a female-controlled microbicide to protect against HIV and other sexually transmitted diseases, we are consulting with women's health advocates to design and implement a process through which they can advise and work with scientists on the research, formulation, and ultimate distribution of this method.

The Council agrees with women's health advocates that many government population policies have been driven by demographic concerns. As stated in our new pamphlet, *Population Growth and Our Caring Capacity*, "Population policies designed to accelerate voluntary fertility decline have increasingly been equated in the public mind and in the budgets of policymakers as fertility reduction implemented through family planning programs. This approach is inadequate and, in some cases, counterproductive. Some family planning programs have been misshapen by implicit or explicit demographic imperatives while the vast potential of progressive social, economic, and health measures to affect population growth have been underplayed." Family planning services should be voluntary, provide a range of contraceptive choices, and inform women and men of available methods, their side effects, risks, and benefits.

June 1994

1. BACKGROUND INFORMATION: from concern to action

1a. Development of anti fertility 'vaccines' (immunological contraceptives)

In the early 1970's, contraceptive researchers set out on a quest for a totally new type of contraceptive. The aim was to develop a long-acting, highly effective and easy to administer contraceptive method using the immune system: in short an anti fertility 'vaccine' or immunological contraceptive. The decision to develop such a method was made with population control objectives in mind "a method for more effectively meeting the challenge of ever-increasing population expansion" according to Stevens, a prominent researcher of one of the major coordinating research institutes.

It is tried to cause immunological reactions whereby - instead of helping the body to build up natural resistance as is the case with anti disease vaccines- fertility is being influenced on several levels:

- * on the level of the production of fertility hormones, whereby the production of sperm and egg-cells is slowed down;
- * on the level of the production of the pregnancy-related hormone hCG (human Chorionic Gonadotrophin), whereby pregnancy is terminated in a very early stage.
- * by bringing about immunological reactions against the very sperm and egg-cells.

Five main research teams from Europe, USA and India are working on the development of immunological contraceptives. Trials have been carried out in Australia, Brazil, Chile, Dominican Republic, Finland and India.

The most advanced research is on methods which attack the hormone hCG. Phase two trials on this method took place in India in 1993 by the National Institute of Immunology and are presently carried out in Sweden under the auspices of the Human Reproduction Programme of WHO. Phase 3 trials are being planned in the near future in India.

1b. International Campaign

In June 1993 an International action workshop to discuss concerns about the development of contraceptive "vaccines", took place in Bielefeld, Germany. The workshop was jointly organised by BUKO Pharma Kampagne, the Women's Health Action Foundation and WGNRR.

There were nineteen participants in the workshop, mainly from women's health and reproductive rights groups from the following countries: Argentina, Chile, Dominican Republic, Egypt, Finland, Germany, India, the Netherlands, South Africa, Switzerland, Zambia and Zimbabwe. Women from Brazil and Peru who had been invited could not attend.

From : Sumati Nair
Date : 1 November 1994
To : Forum for Women's Health, Bombay, India
Fax #: (91.22) 937 1397

Dear Swatiya, Chayanika and others,

This is a short follow-up to the telephonic conversation I had with Swatiya while I was in Bombay in September. As you may have realised from the fax from Ulrike we had a meeting here at the office of the WGNRR on the 21st October to discuss among other things, the next international meeting of the vaccine campaign.

I don't know how far the discussions have proceeded at your end. Have you'll had the possibility to discuss it with the Delhi groups? Who would be involved? Would you be the co-organiser together with WGNRR for the meeting? Since Beatrijs will have to fund raise as early as possible she will need to know some details of this kind.

At our meeting the choice seemed to be between Sweden, Canada and India. Sweden got eliminated due to the lack of a strong local group working on the issue, and then although we did not go into great detail about the Canada idea, we all were most happy to agree that India would be a good place to hold it. All this happened on the 21st. Beatrice called a few minutes ago this afternoon (28th) asking me to let you know that if any of you feel that at this point you cannot organise it or that it would be otherwise problematic, please let her know and we could get the Canadian groups to find out if they are willing to hold the meeting. (We realised that we had not given you'll the option not to hold the meeting in India!)

I hope you'll got the material I had sent with Indira (Rose) and that you'll find it useful. Thanks for sending me a copy of Beyond Illness - I've just looked through it and it seems interesting. Once I read it properly I will send you a more detailed reply. You people really do get a lot of work done!

Warm regards to all of you,

Sumati



WOMEN'S GLOBAL
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REPRODUCTIVE
RIGHTS

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FAX MESSAGE

FOR *Forum for Women's Health Bombay*
Swatiya, Chayniha & others
Telefax number *91 22 437 13 97*
From *Beatrij Steurding*
Date *November 1 9*
Number of pages (including this one) *7*
In case of poor receipt, please call us.

Special remarks

Dear women,
Letter from Swati (one page). Draft
funding proposal (5 pages.)
How are you doing? Herewith I am sending
you a draft funding proposal that I
made on the basis of our discussions here
on October 21.
If you would agree to co-organise the
meeting, I would like to get your comments
on the proposal as soon as possible. We
can reimburse fax or phone costs to you.
I look forward to your response.
Warm greetings,
Beatrij

Many serious concerns about the development of this completely new class of contraceptives were discussed in the workshop and it ended with the conclusion that the research on contraceptive "vaccines" should be stopped. To this aim the workshop participants wrote an Open Letter: "Call for a Stop of Research on Anti Fertility 'Vaccines'" (see appendix 1) directed to the main Research Institutes and Funding Bodies involved in the research on these methods (see appendix 2 for a list of these organisations).

In the four months following the workshop the Call was disseminated and discussed by many groups and organisations, including during workshops at the International Women and Health Meeting (IWHM) in Uganda in September '93 and at the Latin American Feminist Encuentro in October '93 in Nicaragua. At the IWHM the publication "Vaccination against pregnancy: miracle or menace?"¹ was launched and this publication served as important background information for the workshops.

On November 8 1993 the Call-including the signatures of 232 groups and organisations from eighteen countries collected by then- was mailed to the research institutes and funding bodies. This remarkable result was largely due to the very active involvement of the participants of the Bielefeld workshop who also organised all kind of activities around and on November 8, the date of the mailing of the Call.

The mailing of the Call was the first step in a growing International Campaign on the anti fertility 'vaccines'. Among others this is shown by the increasing support for the Call. By November 1994 the Call has been signed by 401 groups and organisations from 40 countries. Please see the enclosed Campaign Report number 2 for more information on the development of the Campaign.

¹ "Vaccination against pregnancy: miracle or menace?" by Judith Richter. Published by BUKO Pharma Kampagne and Health Action International-Europe, 1993.

2. INTERNATIONAL ACTION MEETING ON ANTI FERTILITY 'VACCINES'

2a. Aim and content of the meeting

Aim : to map out strategies to further develop the Campaign:
a. to stop the research on anti fertility 'vaccines'
b. to redirect contraceptive research

The development of strategies and activities to stop the research will be directed towards the major coordinating research institutes, the institutes that conduct the trials and the organisations/institutions that fund the research. Consequently the strategies and activities will differ per country.

Content

The program of the meeting will mainly consist of:

- * exchange of information on major developments regarding research, trials, funding and campaigning activities in each country; (Participants will be requested to put this information on paper beforehand)
- * workshops to develop strategies towards funding organisations and major research institutes -including cooperating institutes that conduct(ed) trials - with the aim to stop the research;
- * workshops to develop ideas on the redirection of contraceptive research, based on a critical analysis of the population control framework and the basic underlying scientific conceptions of current contraceptive research;
- * skill sharing workshops on various campaigning methods (for example how to approach the media), applicable in this Campaign;
- * discussion and agreement on Campaign Strategies;
- * public event (not worked out in detail yet)
- * press conference

2b. Initiative and organisation

The ideas to organise this meeting stem from the International Action Workshop on anti fertility 'vaccines' in Bielefeld Germany, June 1993 (see background information). The initiative for the planned International Meeting has been taken by the organisers and some of the participants of the Bielefeld workshop.

All participants of the International Meeting will be consulted on the proposed program.

The meeting will be co-organised by WGNRR and the Forum for Women's Health in Bombay (?) in collaboration with BUKO Pharma Kampagne Germany and the Women's Health Action Foundation (WHAF) in the Netherlands.

The WGNRR Coordination office (contactperson Beatrijs Stemerding) will be responsible for the financial administration and the financial account of the meeting.

2c. Participants

Participants will mainly come from countries where the major coordinating research institutes or funding organisations (including Governments) are based, or where trials took place, are currently being held or planned. This includes participants from Latin America, Asia, Africa, Europe, USA and Canada.

The participants are from women's health and (reproductive) rights groups and organisations which are actively involved in the Campaign or which decided to become involved.

The organisers aim for approximately thirty participants to keep the meeting workable and affordable.

2d. Time and Venue

The meeting is scheduled in April 1995 and should last four days. Half a day is planned for the public event and press conference.

- ? The meeting place and accomodation is located in Bombay, India. India has been chosen as meeting place because one of the major Coordinating Research Centres is based in India (New Delhi) and phase 1 as well as phase 2 trials were held in New Delhi and Bombay. Phase 3 trials are scheduled to start in the near future. Besides many Indian (women's) groups and organisations are actively involved in the Campaign and many others are supporting it. The Bombay Forum for Women's Health (?) offered to be the co-organiser of the meeting.

2e. Results

A tangible result of the meeting will be a concise report of the meeting, mainly consisting of the planned strategies and activities for the Campaign at international and at national level. The report is first of all meant as a reference-document for the participants in the development of their campaign activities. The report will be sent on request to groups and organisations that decide to become involved in the Campaign.

To enable participants to make optimal use of this report in their own groups and networks, it will be published in English, Spanish and French.

Most importantly the meeting aims at resulting in a broader and firmer developed Campaign at national and international level.

Organisations that funded the meeting will receive from WGNRR a financial account and a brief description of proceedings and results of the meeting.

WGNFR Coordination Office, November 1994
Contactperson: Beatrijs Stemering

CALL FOR A STOP OF RESEARCH ON ANTIFERTILITY 'VACCINES' (immunological contraceptives)

We, the undersigned, call for an immediate halt to the development of immunological contraceptives because of concerns about health risks, potential for abuse, unethical research, and the assumptions underlying this direction of contraceptive research.

Groups of contraceptive researchers worldwide have been developing a completely new class of contraceptives for the past two decades. Immunological contraceptives, also known as antifertility 'vaccines', are being developed primarily for women in LACAAP* countries.

Five major institutions are currently carrying out the research:

- * The National Institute of Immunology, New Delhi, India;
- * The World Health Organisation, Geneva, Switzerland;
- * The Population Council, New York, USA;
- * The Contraceptive Research and Development Programme (CONRAD), Norfolk, USA; and
- * The National Institute for Child Health and Development (NICHD), Bethesda, USA.

A variety of organizations are funding this research. They include the World Bank, the United Nations Population Fund (UNFPA), the United Nations Development Programme (UNDP), the Rockefeller Foundation, the US Agency for International Development (USAID), the International Research and Development Center (IDRC, Canada), and the governments of India, Norway, Sweden, United Kingdom and Germany.

The stated aim of those developing antifertility 'vaccines' is to induce temporary infertility by turning the immune system against body components which are essential for human reproduction. A variety of immunological contraceptives - mainly for women but also for men - are now being tested in clinical trials. The 'vaccine' which is most far advanced aims to neutralize the human pregnancy hormone hCG (human chorionic gonadotrophin), a hormone produced in a woman's body by a fertilized egg shortly after conception. This hormone is altered, then coupled to a bacterial or viral carrier (for example, a diphtheria or tetanus toxoid) so that the immune system mistakes the natural pregnancy hormone for an infectious germ and reacts against it. The body thus does not get a signal to prepare for pregnancy and the fertilized egg is expelled. Other immunological contraceptives are developed to interfere with the production of sperm, the maturation of egg cells, the fertilization process, or the implantation and development of the early embryo.

We oppose the development of immunological contraceptives. Our main reasons are:

1. ABUSE POTENTIAL

Immunological contraceptives will not give women greater control over their fertility, but rather less. Immunological contraceptives have a higher abuse potential than any existing method. They will be long-acting (depending on the type they may last from one year to life-long). They cannot be 'switched off', and they are easy to administer on a mass scale because they will be injectables or a single pill. Researchers claim that the popularity and wide-spread acceptance of anti-disease vaccines could facilitate the introduction of antifertility 'vaccines', especially in LACAAP countries. This compounds our concern about mass administration of immunological contraceptives without people's knowledge or informed consent.

2. MANIPULATION OF THE IMMUNE SYSTEM FOR CONTRACEPTIVE PURPOSES

Immunological contraceptives present no advantage for women over existing contraceptives. Because they use the immune system, they are inherently unreliable. Individuals can react completely differently to the same kind of immunological contraceptive. For example, the Indian anti-hCG formula, the most advanced method, did not work for 20% of the women; while its effect lasted from less than three months to over two years in other women. In addition, stress, malnutrition and disease will cause unpredictable failures of the contraceptive. In women and men with a predisposition to allergies and autoimmune diseases, on the other hand, the 'vaccine' may cause life-long sterility. People will have no outward sign to know whether and when an immunological contraceptive is working.

Immunological contraceptives are unlikely to ever be harmless. They interfere with delicate and complex immunological and reproductive processes. There are many potential risks: induction of autoimmune diseases and allergies, exacerbation of infectious diseases and immune disturbances, a high risk of fetal exposure to ongoing immune reactions. As research on antifertility 'vaccines' began 20 years ago, little or no thought has been given on how immunological contraceptives may directly or indirectly increase risks of HIV infection, or hasten the onset of full-blown AIDS.

Interference with the immune system for contraceptive purposes is indefensible at a time when primary health care systems in many countries are being dismantled, when the incidence of many infectious diseases are increasing, and when we have become acutely aware of the preciousness and complexity of our immune defense.

* LACAAP = Latin American, Carriibbean, Asian, African and Pacific

3. UNETHICAL CLINICAL TRIALS

Clinical trials have taken place in India, Brazil, Sweden, Finland, Dominican Republic, Chile, Australia. Trials are currently taking place in Sweden (perhaps also in the United States) and further trials are planned in India.

International standards of ethics in clinical trials state that human experimentation should only take place if the product being developed offers advantages over existing options. Immunological contraceptives offer no advantage in terms of efficacy, reversibility, safety, protection against sexually transmitted diseases or control by the user. The risks to women and men cannot be justified.

In addition, these trials are of concern because:

- * There has been insufficient testing of the anti-hCG contraceptive on animals before testing in humans; the animals used do not give enough indication of adverse effects for women and their children;
- * The enrolment of women was not based on informed consent. The efficacy and safety of the immunological contraceptive has been overstated. Consent forms have compared immunological contraceptives to anti-disease vaccines. This analogy obscures the differences in principle of action and purpose between the manipulation of the immune system for contraception and the induction of immune defense against harmful micro-organisms;
- * There has been insufficient data collection about adverse effects to women and to children born to women during trials.

4. FRAMEWORK OF CONTRACEPTIVE RESEARCH

The interplay between population control institutions, Northern and Southern countries, religious institutions, the medical establishment, as well as the community, the society and male partners profoundly influences the type of contraceptives available and the way they are being provided - or not provided. As many researchers readily admit, the concept of antifertility 'vaccines' was conceived in a 'demographic driven, science led' framework. The major funders of contra-

ceptive research want to increase the effectiveness of population control programmes. Most of the scientists involved in the research have been taught to see the body as a machine. The major trend in contraceptive development has been to create technologies which are long acting, have a low user failure rate, which lend themselves for mass fertility control - and which interfere with delicate and complex processes in the human body. Research on intrauterine devices, long-acting hormonal injectables and implants (Norplant) has been given precedence over user controlled low-tech methods such as diaphragms and condoms, or over existing local practices of fertility control. Women are seen as better contraceptive acceptors than men. Most contraceptive research is still directed at methods for women.

Antifertility 'vaccines' are a logical culmination of this framework.

WHAT DO WE WANT?

We call for a radical reorientation of contraceptive research. Population control ideology should not guide the development of contraceptives. Approximately 10% of public funding for new contraceptive research worldwide is currently being spent on antifertility 'vaccines'. We would like to see this funding redirected. The aim must be 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.

We call on all research institutions involved, in particular the National Institute of Immunology, The Population Council and the World Health Organization to immediately stop all research on immunological contraceptives.

We call on all funders to stop financing this type of contraceptive.

Name and Signature	Organisation	o	i	Address

* o = on behalf of, i = for individuals who cannot sign on behalf of organisations. Please tick.

Please return this form to Women's Global Network for Reproductive Rights, NZ Voorburgwal 32, 1012 RZ Amsterdam, the Netherlands.

WOMEN'S GLOBAL
NETWORK FOR
REPRODUCTIVE RIGHTS

RED MUNDIAL DE
MUJERES POR LOS
DERECHOS REPRODUCTIVOS

RÉSEAU MONDIAL DES FEMMES
POUR LES DROITS
SUR LA REPRODUCTION



To the participants of the Ottawa meeting
19 October 1998

NZ Voorburgwal 32
1012 RZ Amsterdam
The Netherlands
Tel. (31-20) 620 96 72
Fax (31-20) 622 24 50
E-Mail office@wgnrr.nl

Dear women,

On July 24, 1998, a meeting between Canadian activists and the new leadership of IDRC took place following-up the negotiations regarding their former involvement in anti-fertility 'vaccines' research. Karen Seabrooke and Rita Parikh from InterPares and Shree Mulay attended this meeting. France Tardif of Federation du Quebec pour le Planning des Naissances unfortunately could not attend. The women met with Maureen O'Neil, President, Dr. Enis Baris, Chief Scientist, and Robert Robertson, Corporate Council and Chairman of Ethics Review Committee. As you may be aware, none of the IDRC people that we met three years ago in Ottawa are with the organisation anymore.

This meeting came about in response to our protesting IDRC's intention to "close the files" on the anti-fertility 'vaccines' matter. Beatrijs Stemerding of the WGNRR gave you more information on this in her letter of 10 June 1998.

The three women from Canada prepared a detailed and informative set of papers reporting on the July 24 meeting which I enclose for your information. I also enclose their follow-up letter after the meeting. It appears that since IDRC decided not to fund research on anti-fertility vaccines anymore, they feel that they have no leverage left with the National Institute of Immunology (NII) in New Delhi to demand long-term follow-up of women subjected to trials and an independent review of informed consent procedure with those women. Negotiations with IDRC seem to be at a dead-end now and the question arises whether this particular line of Campaign activity should be stopped. Karen Seabrooke feels that there is not much left that can be achieved. She and her colleagues will of course follow-up some responses still to be expected, but future energy and time should probably be invested in different things. InterPares wants in any case to have another meeting with IDRC to discuss their perspective on population policy which seems to be a good idea, and I am looking forward to hearing about the outcome.

As you all know there will be a meeting of the international consultation group in December (see below). At this meeting, the issue of whether to pursue negotiations with IDRC will also be raised. I would be very happy if you can give me some feedback on what you think about this. I will pass on your comments to the Canadian women and also report to the international consultation meeting. If you have further questions relating to the discussions with IDRC, please contact Karen Seabrooke.

International Consultation Group Meeting

The international consultation group was set up during our action workshop in Ottawa, 1995. For the first time all members will come together. The role and the function of the group had not been clearly defined in Ottawa, so this will be one issue to raise during the meeting.

The meeting will take place 2-6, 1998 in the vicinity of Geneva. The following women confirmed their participation: Maria Betania Avila (SOS Corpo, Brazil), Rajani Bathia (Committee on Women, Population and Environment, US), Jean Kamau (FIDA, Kenya), Renate Klein (FINRRAGE,

WGNRR is a worldwide autonomous network of groups and individuals who are working for and support reproductive rights for women:
the right of women to decide whether, when and how to have children.

We welcome gifts to our work: Postbank N.V., # 2791755, Arnhem, The Netherlands

Addresses

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Australia), Jaya Velankar (Forum for Women's Health, India), Ulrike Schaz (FINRRAGE, European Campaign Group, Germany) and Annette Will (international co-ordinator, WGNRR, Netherlands). In this meeting we will discuss how the Campaign evolved so far, which regional activities have taken place, what kind of strategies we want to adopt for the near future and what activities can be stimulated region-wise.

During this meeting there will be an action by the European Campaign Group to meet Dr. Gro Harlem Brundtland, new Director-General of WHO, and hand over to her a petition which asks for a reconsideration of population control policies and a stop to anti-fertility 'vaccines' research within WHO. I will keep you informed and pass on the petition which is at this moment in the final stages of drafting.

I am interested in receiving your comments or suggestions regarding the evaluation of five years campaigning and future strategies. Please feel welcome to contact me or your regional representative to the international consultation group and share your opinion and experiences and also your ideas regarding activities in your own country or region.

Research in South Africa in the Past

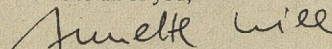
We learned that in the 80s there had been clandestine work on an anti-fertility 'vaccine' under a biological warfare programme in South Africa (see *WGNRR Newsletter* 63). I enclose two pieces of news about this for your information. We were quite shocked by this information and wonder whether there has been clandestine work going on elsewhere. We also wonder whether the other researchers knew about this. Unfortunately, as of to date we do not have more information than the one included. The Human Rights Project in Cape Town is working on the issue.

5 years celebration of Campaign

As of now there are only four responses to the mailing from Beatrijs which was sent out in August regarding the 5th celebration of the Campaign. Please consider again if you wish to respond to it.

So much for the time being. I will keep you updated.

My best wishes to all of you,


Annette Will

CC: to Antigena