Conceiving contraceptives: the involvement of users in anti-fertility vaccines development
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Chapter 3

Involvement of the women’s health movement

1. Introduction

In chapter 2 I concluded that the emergence of the user-script of anti-fertility vaccine development was shaped by specific material, institutional, and political opportunities. There was nevertheless some room for manoeuvre for reproductive researchers, and the technology might have developed otherwise. In this light, the importance of studying the political aspects of representing users becomes apparent. In the examples of Akrich (1992, 1995), the politics of cognitive representations of users and the politics of their alignment becomes especially clear in the encounter between the designers’ projected users and the real users, once the technology is introduced. Might it not be possible to study the politics in the script set out by the contraceptive developers before it is acted out? Could one not try to influence the inscription of user representations at earlier stages of technology development? And who might want to do this?

In the case of anti-fertility vaccines, members of women’s health groups have tried to influence the development of anti-fertility vaccines. Worldwide, the developmental stage of anti-fertility vaccines is varied, but as of today no final product yet exists. This creates a possibility for members of the women’s health movement to attempt to influence the technological designs and the ways in which the research and development has been carried out. In this chapter, I will therefore extend my analysis of the involvement of users in contraceptive development to include the representations of users envisioned by this social movement. Women’s health advocates provided a set of representations of the users of contraception that differed from that of the designers. By comparing the representations of users advanced by the women’s health groups with those of the contraceptive developers, the politics of various cognitive representations of users can be made explicit.

Whereas Akrich (1992, 1995) has contrasted the projected users with the “real users” once the artefact was introduced, I have compared the foreseen users and the proposed script of anti-fertility vaccines in the texts and discussions between two groups of actors. This is not to say that the generation of images
of future users, or the inscription of the envisioned users into technological development, are entirely discursive processes, although some discourses definitely enable certain practices. Again, representations of users are but one element in the mediation processes between users and technologies, embedded in material and institutional factors, research traditions, political and ethical considerations, and personal commitments, and indeed the work of social movements, such as the women's health movement. In fact, neither the dominant representation of the women's health advocates nor the preferred portrayal of the reproductive scientists could actually be realized in the evolving script of anti-fertility vaccines. However, this way of analyzing corresponds well to my purpose of making explicit the politics involved in specific representations of users and in the proposed script of anti-fertility vaccines, before the new methods are introduced into family-planning practices.

To include women's health advocates in this analysis of technological development entails two new problems. First, there is the problem of whether and how women's health advocates can be considered as spokespersons for the future end-users of anti-fertility vaccines. The women's health groups are not necessarily well-equipped to speak for the practical needs and interests of contraceptive users worldwide. They are organized on the basis of the political-strategic goal of empowering women to control their own fertility and sexuality with maximum choice and minimum health problems. The issue of representing the enormous diversity of contraceptive users is politically complex. I will not try to address the normative question of who should be allowed to speak on behalf of users. Instead, I will analyze how this question has been handled by the actors involved. In particular, how did women's health advocates become identified as the political representatives of users? Who else could claim to speak on behalf of users? And in what other ways could women's health advocates obtain a voice in contraceptive development?

The second problem is whether and how the perspectives voiced by women's health groups could be taken into account in the technological design of the new method. The strategies employed by political representatives of end-users of a medical technology to achieve participation in the making of scientific knowledge have been analyzed by Steven Epstein (1995). Epstein has shown how AIDS activists gained acknowledgement as political representatives of patients and were able to influence the course of research by acquiring credibility in the eyes of scientists. At the same time, these "activists succeed in changing the rules of the game, transforming the very definition of what counts as credibility in scientific research (...)" (Epstein 1995, 409). Women's health advocates, especially in the U.S., have also successfully influenced regulatory criteria for the admission of new contraceptives (Gelijns 1991, 160-183). The social world of women's health
advocates can be compared in many respects to the world of AIDS activists described by Steven Epstein. Like the AIDS movement, the women’s health movement is broad and diverse. Women’s health advocates and groups differ in their assessment of medical and scientific claims-making, and in their strategies to empower women. Also comparable to the AIDS movement is the presence of many advocates who are themselves social scientists, medical doctors, or scientists. An additional characteristic of the women’s health groups is that they mostly rely on voluntary work and often face difficulties of inadequate funding, especially in developing countries. This is important, since it might influence their access to information and other resources in building up credibility and the right to participate (interview with Preeti Kirbat 24 May 1998). Epstein (1995) has distinguished four tactics that AIDS activists have employed in trying to influence the research and development of AIDS drugs. Epstein says that the most crucial tactic employed by AIDS activists to acquire credibility was to learn the language and culture of medicine and to get a foot in the door of the institutions of biomedicine. Women’s health advocates hold a great potential to develop this tactic. And while some women’s health advocates have indeed used this tactic of acquiring cultural competence on immunocontraceptives, they have also chosen to criticize the language and culture of biomedicine.

The women’s health movement also differs from the AIDS movement and has different historical roots. Importantly, according to Epstein (1995), AIDS activists derived part of their power from being potential participants in clinical trials to test new drugs against AIDS. AIDS researchers depended on patients, and vice versa. Participation in a clinical trial might mean immediate access to potentially life-saving drugs for a person with HIV/AIDS. Women’s health groups in the area of contraception in general do not have such a symbiotic relationship with reproductive scientists. Scientists can invite all women who meet certain age and health criteria to participate in clinical trials for new contraceptive methods, and a number of more or less satisfying contraceptive methods already exist for many women. Therefore, the risk-benefit ratio of participating in a clinical trial for an individual woman differs greatly from that of a person with HIV/AIDS. Thus, women’s health advocates and the researchers involved in contraceptive development do not depend upon each others’ collaboration in the way that AIDS researchers and patients do. Because of this difference, women’s health advocates are not able to employ Epstein’s second tactic of gaining credibility by establishing themselves as representatives of future users. Epstein writes: “once activists monopolized the capacity to say ‘what patients wanted’, researchers could be forced to deal with them in order to ensure adequate enrollment in their trials. On the basis of their credibility, activists thus constructed themselves as an ‘obligatory passage point’, standing between the researchers and the trials
they sought to conduct" (Epstein 1995, 420). The AIDS activists described by Epstein seem to share a number of practical interests, while women’s health advocates mostly share a political analysis. The third way in which AIDS activists achieved credibility in the eyes of scientists, according to Epstein, was to combine moral and methodological arguments in trying to influence the way in which the research was carried out. For example, AIDS activists insisted that participants in clinical trials to test new drugs should be more fully representative of the variety of social groups affected by HIV/AIDS. They reasoned that this would be important both to ensure fair access to experimental drugs and to produce more generalizable data. Such a mixture of normative and methodological rationales for involving women’s health advocates and potential users also happened in the field of contraceptive development, as I will describe in this chapter. Not only women’s health advocates, but also scientists and policy-makers are engaged in this reasoning. The last tactic that Epstein discusses is the taking of sides in pre-existing debates between researchers. For example, in deciding which patients might be eligible to participate in a clinical trial, different criteria were used by the researchers. On this basis, the AIDS activists were able to enroll allies from the scientific community, and in this manner they succeeded in effectuating modifications of the designs of clinical trials. Also in the case of anti-fertility vaccine research and development, there exist different views among researchers about a number of issues on which the women’s health groups might want to express their own view. But, as Epstein’s analysis suggests, this tactic might carry the risk of reproducing the different viewpoints of the scientific community within the social movement. As I will point out later, the same considerations apply to the international women’s health movement.

In this chapter I will describe how women’s health advocates came to be recognized as spokespersons for the users’ perspectives. "Integration of users’ perspectives" was the Trojan horse by which women’s health advocates gained access to reproductive and social scientists at the WHO. The representations that women’s health advocates advanced seriously challenged the scientific authority of the reproductive scientists. In this chapter I will therefore also analyze what happened in the encounters between scientists’ the representations of users and those of women’s health advocates. One strategy that scientists have traditionally used to pursue and maintain their scientific authority is to construct boundaries between science and various forms of non-science. From a constructivist perspective, what counts as science and what does not in a certain situation is a matter of construction, and it is therefore not surprising that work has to be done to construct and maintain such boundaries (Gieryn 1983, Jasanoff 1987). In the words of Gieryn (1995): "Boundary work occurs as people contend for, legitimate, or challenge the cognitive authority of science - and the credibility, prestige,
power, and material resources that attend such a privileged position" (Gieryn 1995, 405). I will show that the boundary work of the reproductive scientists had far-reaching consequences in determining which aspects of the development of anti-fertility vaccines would be open to what came to be known as the integration of users' perspectives and which would not.

The structure of this chapter is as follows. In order to understand women's health groups' interaction with the development of anti-fertility vaccines, it is necessary to take a broader view of their engagement in contraceptive development. I will therefore first discuss the context in which the women's health movement developed an infrastructure for lobbying and advocating. Next I will trace the meanings of "integrating the users' perspectives". What are the different actors talking about when they speak of integrating the users' perspectives? Subsequently, I will analyze the extent to which alternative users' perspectives were indeed taken into account in anti-fertility vaccine development. How did the scientists and the women's health advocates try to achieve alignment between their respective representations of users and the developing technology?

2. The emergence of the discourse on users' perspectives

In the late 1980s, a number of women's health groups from all over the world became actively involved in anti-fertility vaccine development. The late 1980s were a favorable period for getting users on the agenda of international organizations in the field of contraceptive technology development. This was due to two related factors: the strong position that the international women's health movement had built up over the years, and major conceptual changes in international policies concerning the relation between family planning and development. I will discuss these factors briefly.

2.1 Women's health advocates gain ground

The development of modern contraceptive methods for women started to flourish after World War II and almost immediately became highly politicized (Clarke 1998). Reproductive technologies profoundly affect women's lives, and it is therefore not surprising that the women's health movement is concerned about them. Most modern contraceptives have been developed within a framework of population control. Within this framework, the premises were that there is a problem of overpopulation, that contraceptives are a relevant technology to curtail population growth, and that especially the growth of poor populations in Third World countries should come to a stop. In the 1980s, women's health groups documented recurrent instances of
the coercive and not fully informed administration of contraceptive methods which occurred in the context of population control programmes, especially in Third World countries. These practices, and the appraisal of women’s health advocates, have been comprehensively reported and analyzed by Hartmann (1987) in *Reproductive rights and wrongs: The global politics of population control and contraceptive choice*. The other major critique of the women’s health movement has been the neglect of women’s health, and the biomedical standards for assessing the safety of methods such as the early Pill, Depo Provera® and Norplant®. The women’s health movement has used strategies such as watch-dogging, drawing in the press and lobbying, and setting up alternative services. For example, the potential side-effects of the early Pill, especially the risk of cancer, has received substantial attention in the medical and lay press since the late 1960s. During the 1970s this led to a decrease in the use of oral contraceptives. This decrease was especially marked in the United States, where a U.S. Senate Select Committee on Small Business considered whether users were adequately informed about side-effects. Women’s health advocates argued that there was insufficient concern for the health of women. There was extensive and dissenting press coverage of this event, which rendered the sociocultural environment more critical of contraceptive development. As a consequence, the United States regulatory Food and Drugs Administration became more cautious in granting approval (Gelijns 1991, Djerassi 1979). The women’s health advocates were increasingly vocal and influential. Regulatory decisions on Depo Provera®, a three- to six-monthly hormonal injectable, were adjusted due to the efforts of the women’s health movement. On the basis of testing in beagle dogs, Depo Provera® was suspected of causing breast cancer. Following congressional pressure by American women’s health groups, the U.S. FDA decided to postpone its approval in 1974, and again to withhold it in 1978 (Gelijns 1991, 160-183). Approval by the FDA for use of Depo Provera® as a contraceptive in the U.S. was granted only in 1992 (Cottingham and Benangiano 1997). The introduction of Norplant® in the early 1980s had an important galvanizing effect upon the women’s health movement. Brazilian women’s health advocates denounced the testing of Norplant® in women without their full knowledge and acceptance, and they were successful in convincing the Ministry of Health to cancel the authorization for the tests in 1986 (Pitanguy 1994, Garcia and Dacach 1991). International women’s health advocates profoundly disagreed with contraceptive developers about the relevance of the common side-effects of Norplant®, especially menstrual disturbances and headaches. In addition, instances of abuse were signaled again, for example the refusal of health care workers in Indonesia and Bangladesh to remove the implant when women experienced side-effects that were unacceptable to them (Hardon 1992, Hanhart 1993, Fraser *et al.* 1998). In response to the above-
mentioned problems, the women’s health movement has successfully developed an infrastructure for lobbying and advocating. In 1984, the Women’s Global Network for Reproductive Rights was founded, with a coordination office in Amsterdam. It became the most extensive international network in the field of reproductive rights. The Network currently has about 1500 members in 113 countries in every continent. Their affiliations include major U.S. groups, such as the International Women’s Health Coalition and the Boston Women’s Health Book Collective.

Barbara Mintzes and Catherine Hodgkin (1996, 83) have signaled that the consumer groups involved in drugs campaigns have increasingly developed a broader perspective. These groups no longer address only a specific drug problem, but also the policies that allowed the problem to develop. The same is true for the women’s health groups contesting specific contraceptive methods. They increasingly advocate the development of policies that take more account of the situations and views of users, also in the development of new methods for fertility regulation.

2.2 From population control to reproductive health

In the late 1980s and early 1990s, the dominant conceptual framework of international organizations in the field of contraceptive development began to change. At the United Nations International Conference on Population and Development held in Cairo in 1994 (ICPD 1994), this shift was articulated clearly for the first time. The rationale behind family-planning programmes had been to reduce birth rates, especially in developing countries, by making contraceptive methods available. Women’s health groups had argued that this policy focus should be broadened towards reproductive health. Rather than focusing on demographic targets, the Program of Action adopted at the 1994 Conference in Cairo placed reproductive health at the center of plans to address population growth. This change can largely be attributed to the work of women’s health advocates who raised these issues during the three-year preparatory phase (Hardon and Hayes 1997). One of the consequences of the greater concern for reproductive health was that the users of family planning methods became highlighted.

Illustrative of the shift from population policy towards reproductive health is the way in which anti-fertility vaccines are portrayed in the subsequent annual reports of the WHO/HRP. The WHO/HRP Biennial Report 1986-1987 still clearly reflects the framework of eliminating the explosive growth of population. Anti-fertility vaccines, it says,

(...) would be an attractive addition to the present armamentarium of fertility regulation methods and would be likely to have a significant impact on family planning programmes (WHO/HRP 1988).
In the 1990-1991 Biennial Report, concern for the users of contraceptives and for reproductive health had started to prevail, without abandoning the importance of "continuous use" to safeguard the concomitant demographic aims:

Birth Control Vaccines: Many of the currently available methods of fertility regulation are associated with a number of logistical problems and minor side effects which can influence their acceptability and continuous use (...) It has been proposed, therefore, that one method of fertility regulation that would be attractive to both users and providers of family planning services [are birth control vaccines, jvk] (WHO/HRP 1992).

In 1992, the way of presenting anti-fertility vaccines in the Annual Technical Report had become entirely geared towards users and their perceived needs: If such vaccines could be developed they are expected to become attractive and acceptable additions to the options available to the users of family planning services. (...) The Task Force is aiming at the development of a vaccine which will be effective for a period of up to 18 months since this is perceived to be a useful interval for users at all stages in their reproductive lives (WHO/HRP/ATR 1993).

In comparison with the WHO, the Population Council was rather more traditional. This organization remained explicitly directed towards curtailing the growth of population until well into the 1990s. Attending to reproductive health and users' needs was seen as instrumental to the overall mission of "applying science and technology to the solution of population problems in developing countries" (Population Council 1990). For example, in their 1990 Annual Report they stated that

While such [family-planning, jvk] programs are widely promoted for health reasons, it is clear that demographic objectives are a primary rationale for their existence (Population Council 1990, 32).

But after the United Nations International Conference on Population and Development in Cairo in 1994, the Population Council slightly changed the emphasis in their mission. In the President's Message of the 1995 Annual Report:

Two bedrock themes in the [Cairo, jvk] document also are positions long advocated by the Population Council. The first is that family planning programs should be designed to meet individual needs and function as part of a broader approach to reproductive health care. The second is that those of us who are concerned about rapid population growth should promote a just and effective population policy (Population Council 1995).
Note that the discourse on reproductive health and taking users into account could be assimilated in such a way as not to contradict the demographic perspective of the need to slow down population growth.

In spite of the major changes in the discourse and the international policy on family planning and contraception, situations of abuse persisted. The contemporary sterilization of thousands of women in India, Vietnam, and Indonesia with Quinacrine, a method that has not been approved by any drug-regulating agency in the world, bears testimony to this problem. Despite the request of the WHO to researchers to go back to the first stage of laboratory tests, trials on women continue (Dasgupta 1997). Coercive use, such as the lack of fully informed consent at the clinical trial stage of research, and neglect for women's health therefore have remained key issues to women's health advocates. This setting has played an important role in their analysis of subsequent technological developments.4

Against the historical and current background that I have outlined here, the women's health movement watched Argus-eyed the development of immunological contraceptives in the late 1980s. The women's health groups were very worried about the development of anti-fertility vaccines. Women's health advocate Judith Richter wrote a report on anti-fertility vaccines development, *Vaccination against pregnancy: miracle or menace*, the purpose of which was to make scientific information on anti-fertility vaccines more accessible and to foster a public discussion on the issue (Richter 1996, 111). At an international conference held in Bielefeld in June 1993 to launch this report, some hundred participants supported a resolution to mobilize broad support calling for a stop to research on anti-fertility vaccines. Subsequently, a group of 19 women's health advocates from 12 countries met to plan an international campaign against the development of anti-fertility vaccines. They drew up a petition in which they outlined their concerns: the Call for a Stop to the Research on Anti-Fertility "Vaccines".5 They also called for the redirection of contraceptive research towards the development of methods that would enable people to exert greater control over their fertility without affecting their health. It was agreed that the Women's Global Network for Reproductive Rights would coordinate the Campaign. The petition was circulated at the International Women's Health Meeting in September 1993 in Kampala, Uganda, and at the Latin American Feminist Meeting in November 1993 in San Salvador, El Salvador. It was also sent to the members of the Women's Global Network for Reproductive Rights. The Call was an important instrument in the Campaign. By November 8, the date chosen to launch the Campaign, the petition had been signed by 232 groups and organizations from eighteen countries. On that day, the Call - including the list of endorsers - was mailed to the main research institutes and funders, as well as to the ethics committees of hospitals where clinical trials were being carried out.
and to the international press. In various countries women held press conferences, and the Call for a Stop received media coverage in national newspapers and magazines. By 1996, over 430 groups and organizations from more than 39 countries had signed the Call for a Stop (Richter 1996). The Call for a Stop was rather broadly based within the women’s health movement.

3. Different meanings of users’ perspectives

As a consequence of the strong position of the women’s health movement, and on the eve of the International Conference on Population and Development in Cairo, international agencies such as the WHO/HRP and the Population Council were increasingly attentive to the importance of taking users into account, and the relevance of dialogue with members of the women’s health movement for this purpose. Notably, some women’s health advocates had worked to acquire policy positions in organizations involved in contraceptive development and funding agencies. In 1987, Judith Bruce, working at the Programs Division of the Population Council, published a study with the title *Users’ perspectives on Contraceptive Technology and Delivery Systems: highlighting some feminist issues* (Bruce 1987). In this seminal article the author concluded:

> Decisions taken in designing products - determining essential features as well as assuring their safety - should constantly refer back to the aspirations of the prospective user. Who is this woman? What is her world? What are her beliefs? What are her possibilities as well as her hopes? (Bruce 1987, 380).

At the WHO/HRP and the Population Council, it was stressed that especially at the introduction of a new method, the users should be more actively involved. Norplant® was the first new method for fertility regulation to be introduced into family planning programmes by the Population Council together with a systematic plan to assess its acceptability by providers and users (Zimmerman et al. 1990). The WHO/HRP followed a similar approach in its introduction of the monthly injectable Cyclofen® (Hall and d’Arcangues 1988, 147; WHO/HRP 1992). These experiences would also inform the development of a specific strategic approach to the introduction of contraceptive methods at the WHO/HRP, in which research into users’ needs and preferences was an important element (WHO/HRP/ATR 1990, 182; Simmons et al. 1997). The WHO/HRP Task Force on the Introduction and Transfer of Technology, established in 1990, developed a methodology for running a series of post-marketing clinical trials to assess whether the introduction of a
new method, the once-a-month injectable Cyclofem®, actually led to the broadening of contraceptive choice for users (WHO/HRP/ATR 1991, 140). Subsequently a more encompassing approach was developed, in which the (re)introduction of additional contraceptive methods would be preceded by an assessment of the service delivery system and users’ needs. (Progress 1996 (38), Simmons et al. 1997).

The WHO/HRP also developed a number of initiatives to take into account the users’ perspectives in earlier stages of contraceptive development. In June 1989, two representatives of what was called ‘consumers’ were invited by the Programme for the first time to participate in a symposium specifically to assess the safety and efficacy of anti-fertility vaccines. This experience was followed up by an External Impact Evaluation team that in 1990 recommended that the Programme should give "(...) special attention to the impact of reproductive health on women’s well being" and "(...) that women and women’s groups be kept informed of, and involved in the development and introduction of methods of fertility regulation." (HRP/EVAL/1990, cited in WHO/HRP/ATR 1990, 16 and WHO/HRP/ATR 1991, 146). These recommendations were followed up by Joanne Spice-handler and her colleagues at the Task Force on the Introduction and Transfer of Technology. This Task Force chose to consult with women’s health advocates as one of its strategies. In the 1990 Annual Technical Report account of their ongoing and planned work, this Task Force allotted a paragraph to "Women’s Health Networks", saying:

(...) The demographic perspective of unmet contraceptive need can never be influenced significantly unless the user perspective is addressed in a positive and sensitive manner (...) It is, therefore, critical to establish what women in developing countries really want with regard to contraception and how this relates to their reproductive health and their rights in society (...) As part of its goal to ascertain user’s needs, the Task Force is coordinating a meeting on "Women’s Perspectives in the Introduction of Fertility Regulation Technologies" in February 1991 (WHO/HRP/ATR 1990, 186).

This Task Force thus explicitly related the idea of integrating users’ perspectives to the reproductive health needs and rights of women in developing countries, and they proposed to consult women’s health advocates as a way to become acquainted with these needs.

Also in 1990, the then director of the WHO/HRP, Mahmoud Fathalla, had invited one major women’s health advocacy group, the International Women’s Health Coalition in New York, to assess whether the activities of the WHO/HRP were women-oriented. The International Women’s Health Coalition in turn had proposed co-organizing a meeting between scientists
working in the Programme and women’s health groups from different parts of the world to discuss specific aspects of the Programme’s work (interview with Cottingham 1:6). The resulting meeting, organized in February 1991, was called the ‘Creating Common Ground’ meeting. It marked the beginning of a dialogue in which the social world of the women’s health advocates and that of the scientists were brought together. The explicit aim was "to create understanding and strategies that will enhance scientific exploration, improve the quality of technology, and encourage advocacy on behalf of women’s health and women’s well-being" (WHO/HRP/ITT 1991, 5). The meeting was considered a landmark by the participants.

The views of users/consumers and the concerns of women’s health advocates about women’s health and rights were bracketed together at this Creating Common Ground meeting. The Introduction to the report summarizes the concerns of women’s health advocates and concludes:

Recognizing the importance of these concerns and of consumers’ views, researchers, policy-makers and service providers have recently begun to seek dialogue and collaboration with women’s health advocates (WHO/HRP/ITT 1991, 6).

Major policy documents from the early 1990s also mention both users and women’s health advocates, reflecting a common denominator for all actors involved. The Program of Action of the United Nations International Conference on Population and Development in Cairo in 1994 reiterated that:

This [contraceptive, jvk] research needs to be guided at all stages by gender perspectives, particularly women’s, and the needs of users (...).

And:

Users’, in particular women’s, perspectives and women’s organizations should be incorporated into all stages of the research and development process (ICPD 1994).

The need to mention both "users" and "women’s health advocates" in these documents indicates that, according to most of the actors involved, users’ needs do not necessarily coincide with the perspectives of women’s health advocates. The political position of the women’s health movement was strong enough to assure the advocates a place in the process of research on contraceptives. But it was not taken for granted that members of the women’s health movement would represent users. While there was increasing international consensus about the normative point that users ought to be taken into account in contraceptive development, it was uncertain what this would mean in practice. At the same time, a number of practices "to integrate the users’ perspectives" had begun to develop and provided a starting-point. The
questions that arose were: Who is entitled to voice users' perspectives? Perspectives on what exactly? And into what should these be integrated?

3.1 Women's health advocates as spokespersons for users?

The way in which women's health advocates related to users of fertility-regulating methods was among the central themes debated at the first Creating Common Ground meeting in February 1991. According to the report:

While there was consensus about the need to bring women's perspectives and experiences to bear on the development, selection, and introduction of fertility regulation technologies, the participants debated the question of who can legitimately and effectively articulate those perspectives. A number of scientists questioned whether, for instance, women's health advocates, such as those at the meeting, represent the views of poor and rural women (WHO/HRP/ITT 1991, 13).

Specifically in the area of immunological contraceptives, the representativity of concerned women's health advocates and the extent to which they could speak on behalf of users was questioned. As the principal investigator of the WHO Task Force on Immunological Fertility Regulation, Vernon Stevens, commented in an article:

The number of women who have expressed these objections to anti-fertility vaccines is very small and there are no data available to suggest that these views represent those of a significant proportion of women from any country or region in the world (Stevens 1996, 149).\(^{11}\)

And the head of the Indian research team at the National Institute of Immunology in New Delhi, Pran Talwar, said in a guest editorial to a medical journal:

Very recently, some feminist organizations have protested against the introduction of injectable contraceptives (e.g. Norplant and Depo Provera) and against research on anti-fertility vaccines. (...) They are not justified, however, in denying the benefits and options of the new contraceptives to women in the Third World (Talwar 1994a, 701).

Did women's health advocates indeed claim to speak in the name of users? Beatriz Stemerding, staffmember of the international coordination office of the Women's Global Network for Reproductive Rights, who coordinated the Campaign to Call for a Stop to the Research on Anti-Fertility "Vaccines", said:
We never said that the Campaign represents the users. Such claims have never been made. (...) It often struck me that scientists mostly raise this question of representativity about the people in the Campaign and not about the researchers. I wonder if the scientists question their own legitimacy for doing this research (interview with Beatrijs Stermerding 1;66/73).

When questioned about the issue of representativity, some women’s health advocates would turn the question around strategically. For example, at a Conference on Anti-Fertility "Vaccines" convened by women’s health advocates in Bielefeld in 1993, Task Force Manager David Griffin posed the question of how representative the opinion of the conference participants was of women in general. Women’s health advocate Judith Richter reports that one of the participants

(…) advised him to go back to his Geneva office, look into the faces of his colleagues and ask them ‘Let’s be honest friends, how representative are we to take decisions for the world’s female population?’ (Richter 1993, 122).

In this way, the women’s health advocates made it clear that the issue of representativity, and especially of politically representing a diffuse group such as potential contraceptive users, cannot easily be resolved.

But if they did not represent the users, on what basis should contraceptive researchers and policy-makers take their voices into account? The women’s health groups considered that their perspectives were relevant to contraceptive development. As the Technical Officer at the Women’s Desk of the WHO/HRP, Jane Cottingham, said:

Women who are working in women’s health groups and women’s health projects have an understanding of women’s situation and perhaps an analysis of the situation that has not necessarily been taken account of and that should be represented. And I think that is valid.(…) You cannot have someone from, say Bangladesh, representing ‘women in Bangladesh’. We are never going to get to that situation, so let’s just forget it. But she represents a particular kind of experience focused on women’s health and women’s rights, where there has been a lot of reflection and action. That is why her experience and viewpoint are valuable (interview with Cottingham 1;12).

In addition, the contribution of women’s health groups was seen as potentially beneficial to the Programmes’ work. This in turn contributed to their legitimacy and to the basis on which they were taken into account by the
Programme. The Task Force Manager on Immunological Methods for Fertility Regulation, David Griffin, said:

This democratization of the research process is not only a welcome addition in its own right, but is likely to lead to greater success of the research effort by ensuring that the methods developed meet the expressed needs and preferences of individuals and couples (Griffin 1996, 144).

In other words, neither the women’s health advocates nor the scientists involved assumed that women’s health advocates would be representative spokespersons for users. Instead, it was proposed that members of women’s health groups could represent perspectives that were different from those of the scientists. As with Epstein’s AIDS activists (1995), a mixture of political and instrumental arguments was mobilized to account for the legitimacy of taking into account these different perspectives. Yet the way in which women’s health advocates became dialogue partners of the scientists differed from the situation of the AIDS activists examined by Epstein. The women’s health advocates could not constitute themselves as an obligatory passage point, nor did they aspire to do so. The women’s health advocates came to be considered as political representatives of users, on the basis of their experience in working on women’s health and rights issues. Their differing perspective on contraceptive users was regarded as a worthwhile addition to the process of technology development. They were therefore said to speak in the name of users’ perspectives, to emphasize that what they were supposed to contribute was their differing experience and analysis of users’ situations, and not necessarily the practical needs and interests of contraceptive users worldwide. The perspectives of the women’s health advocates were diverse, though distinguishable from those of the scientists involved in contraceptive development.

Crucially, for members of the women’s health movement this meant that they could relate to contraceptive technologies in capacities other than that of potential future users. They were not restricted to voicing the supposed needs and preferences of people wanting to plan their families. Instead, they could relate to contraception in other ways, as researchers or as advocates. Room was created for women’s health advocates to introduce different frames of meaning, such as the kind of relations that one or another technology might constitute. In other words, there were distinctive strategic advantages for women’s health advocates to be gained by speaking in the name of users’ perspectives rather than engaging in the essentially impossible task of voicing the needs and preferences of the users of the world.
Eventually, the situatedness of both the scientists and the women’s health advocates was specified. In the report of the meeting Creating Common Ground, the consensus was reached that:

Both scientists and women’s health advocates emphasized that there is neither one monolithic "scientists’ perspective" nor one "women’s perspective", but rather a broad spectrum of opinion within each community (WHO/HRP/ITT 1991, 10).

However, the consensus reached at this meeting could not prevent questions on the legitimacy of different voices from being raised periodically.

3.2 Various meanings of "users' perspectives"

The policy agreements had not been explicit about exactly what aspects of users would be relevant for integration into contraceptive research and development. Would "integrating users’ perspectives" mean learning more about users’ contraceptive needs, or would it stand for taking into account women’s reproductive health and their rights? This was the other issue that needed to be elaborated in practice.

Following the first Creating Common Ground meeting, Jane Cottingham was appointed as a special Technical Officer at the WHO/HRP to put into effect the recommendations for action that had been formulated. Cottingham had been working in women’s health advocacy for years, and holds a Master’s degree from the prestigious Harvard School of Public Health. She was appointed firstly to the Task Force on the Introduction and Transfer of Technology, and since 1992 to a special Women’s Desk that was created to advise the whole Programme. Her task is "to help integrate women’s perspectives into the activities of the HRP" (WHO/HRP/ATR 1995). As she says:

Immediately when I came here, I came up against the problem of what is meant by ‘women’s perspectives’. And I think some women’s health advocates tacitly understood that ‘women’s perspectives’ meant ‘feminist perspectives’. But it was easier to talk about ‘women’s perspectives’ (interview with Cottingham 1:2).

A feminist women’s perspective would mean taking into account women’s reproductive health and rights, and not to restrict the understanding of users’ perspectives to their expressed needs for products with certain attributes. But different ideas of the meaning of women’s perspectives prevailed amongst the other actors concerned with integrating the users’ perspectives into contraceptive development.

To refer to the envisioned contraceptive needs of users was a widely practiced convention for reproductive researchers and policy-makers to
articulate the necessity to develop new methods. "Integrating the users' perspective", or "the women's perspectives" therefore did not appear to be a drastic new issue for them; they had understood it simply to mean taking into account women's needs and gathering information on what kind of attributes of contraceptive methods were appreciated. As I mentioned in chapter 1, for this purpose the WHO/HRP had already established special Task Forces on Psychosocial Research in Family Planning as well as on Services at its creation in 1972 (Kessler 1991, 48). Social scientists had been appointed by the Programme to present the needs of users to the reproductive scientists. Since the 1970s, numerous studies on mainly women's/users' needs, preferences, opinions, experiences, and understandings of contraceptives were carried out by social scientists. Part of this research had been directed explicitly towards providing contraceptive developers with more clues as to what kind of products users would prefer. However, before then these representations of users' needs had not played a major role in contraceptive development. Hardon (1994) reviewed 20 articles published in scientific journals such as Contraception and Fertility and Sterility within the past decade which present results of clinical studies on anti-fertility vaccines. She reports that "While making explicit what they aim to develop, the researchers do not explain where these requirements originate. Nowhere do they refer to empirical research on the perceived needs of users and providers who actually live in the diverse sociocultural settings in which the new contraceptive technology is eventually to be used."

After the Program of Action had been ratified, in 1995, the WHO/HRP organized a conference, the Meeting on Women's and Men's Perspectives on Fertility Regulation Methods and Services, "to review what knowledge exists on users' perspectives, what methodologies have been employed to collect the available information and what gaps exist in our knowledge" (WHO/HRP 1996a). The social scientist Igbal Shah, from what now was called the Social Science Task Force of the WHO/HRP, prepared an extensive overview of the social scientific literature on contraceptive usage. Shah reviewed and summarized a selection of 150 studies published since 1984 about the views of women and also about the views of men in developing countries on contraceptives, in addition to data from Demographic Health Surveys and information from key persons (Shah 1995). Shah explicitly positioned the social scientific data that had been generated by his Task Force as work on users' perspectives:

The understanding of the perspectives of people toward methods of fertility regulation has been an integral part of the activities undertaken by the Programme since its inception in 1972. The bulk of this work has been carried out by the Social Science component of the Special Programme. More recently, the Task Force on Research on the Intro-
duction and Transfer of Technology for Fertility Regulation, Women’s Issues Desk and the Unit of Resources for Research have also considered the perspectives of users (Shah 1995, 2).

By labeling this body of social scientific literature as studies on users’ perspectives, the social scientists of the Programme could claim that their work would suffice to meet the recommendations of the Cairo Program of Action that contraceptive development should be guided by women’s/users’ needs. This would make any further involvement of women’s health advocates superfluous. The women’s health advocates agreed that social scientific research could indeed be important to gain insight into the situation of users. But the women’s health advocates amongst the social scientists found the representations of users provided by mainstream social scientists too limited. These social scientists had studied and configured users mainly in terms of having unmet needs and preferences for certain attributes of products. The recurrent finding of these studies was that users would prefer a method that was very reliable, safe, and free from side-effects. Further, users’ needs were found to vary widely, and to change throughout the life cycle (Shah 1995, Report of a meeting 1995, Cottingham 1997). But what if the contexts in which people plan their families were taken into account? What if such an ideally safe and reliable method was not available, or not accessible? Therefore, instead, the women’s health advocates recommended a different type of social scientific research that was needed for what they meant by the integration of users’ perspectives. As WHO/HRP Technical Officer Jane Cottingham said:

Well, they may be women, they may be men, they are all in a particular context and they may be aware of their rights or not. And so the problem is that we can’t necessarily get a clear picture of users’ perspectives or arrive at a conclusion that, for instance, 10,000 women all say: yes we like X (interview with Cottingham 1;14).

From a feminist perspective on social scientific research, it was important to broaden the scope of what was studied to include the users’ reproductive health and rights. Medical anthropologist and women’s health advocate Anita Hardon presented a paper at the meeting on Women’s and Men’s Perspectives on Fertility Regulation Methods and Services in which she asserted:

The bulk of the reviewed studies have in common that (...) they do not contextualize the technologies in women’s lives, and relate the technologies to gender-issues. (...) To gain understanding of users’ perspectives of fertility regulation we should look at fertility regulation in a dynamic way. (Hardon 1995).
And the American women’s health advocate Lori Heise wrote in a paper presented at this same meeting:

Future research must place more emphasis on the context of women’s choices and on the interrelationship between methods attributes and other factors in women’s lives, such as the quality and power dynamics of their current relationship(s), the present stage of their reproductive lives, and the interface between them and the service system (Heise 1997, 6).14

These feminist social scientists proposed to place the user in the middle of a contextual and relational analysis. In their view, the integration of users’ perspectives would also mean a more active role for users as subjects in social scientific research.15 Instead of studies that seek to predict the future uptake and use of contraceptive methods, they proposed to solicit practical feedback on existing or developing products and to explore how women choose from among available methods. In relation to the reorientation of the scope of users’ perspectives studies, these scholars suggested that a wider variety of methodologies should be used. They asked for more qualitative studies, focus group discussions, in-depth interviews and contraceptive life-histories (Hardon 1997, Heise 1997). Following the feminist tradition in social scientific research, they were more explicit than other social scientists about the politics in the techniques by which they proposed to represent the users. As Lori Heise said:

Gaining a better understanding of how women make choices and negotiate trade-offs among methods will undoubtedly yield insights that are useful to policy-makers and programme managers, as well as to women themselves (Heise 1997, 6).

At the Meeting on Women’s and Men’s Perspectives on Fertility Regulation Methods and Services, the possibility of involving groups of users in the design and interpretation of social scientific studies into users’ perspectives was also discussed. In addition, it was suggested that clinical trials in which newly developed methods are tested would offer an opportunity to examine participants’ experiences, views on side effects, and perceptions of safety (Cottingham 1997).

In the terms of Akrich (1995), these members of women’s health groups proposed to widen the diversity of techniques for constructing representations of users. In addition to market surveys, they proposed to gather more information by the technique of feedback on experience. The proposal to locate social scientific research in a clinical trial setting to gain insight into the experiences and views of the participants resembles the technique of consumer testing. But for these feminist social scientists, the aim of using a
wider variety of techniques to generate representations of users was not merely to provide the contraceptive developers with more information or better specifications about the types of methods that users prefer. In addition, they wanted to change the focus on how to develop better contraceptive technologies towards how to improve users’ reproductive health, and make them participants in the process. This highlights the importance of focusing on the techniques by which representations are generated in order to understand how users are involved in technological development. The particular facets of the users that are considered relevant, and the specific techniques considered appropriate, influence the definition of the problem to be solved.

3.3 Integration of users’ perspectives into what?

The policy-makers and reproductive scientists at the WHO/HRP looked upon women’s health advocates in the same way as the social scientists had been regarded, as a source of information on users’ needs for contraceptives. They hoped that members of the women’s health movement would act as spokespersons and advise them on the needs of users for certain contraceptive products. After the first Creating Common Ground meeting, in February 1991, Faye Schrater was asked to assist the Steering Committee of the Task Force for Immunological Contraceptives. As an immunologist with feminist sensibilities, she was identified by the Task Force Manager as the person who could bridge the gap between scientists and women’s health advocates. As Faye Schrater said:

I went to the Steering Committee meeting and we were talking about something, and all of a sudden one of the scientists would turn to me and say: "Well, Faye, what are the women going to say about this?" Good grief, how many women in the world are there?! I can’t answer. I can’t answer the question in the way they want it answered (interview with Schrater 1:16).

Also at the Meeting on Women’s and Men’s Perspectives on Fertility Regulation Methods and Services the contraceptive developers had hoped that the women’s health advocates would present a survey of users’ needs and preferences. The question of how these research findings could be integrated into technological development was not addressed at this meeting.16 Anita Hardon, who had participated in the meeting, commented:

At the Meeting on Women’s and Men’s Perspectives on Fertility Regulation Methods and Services they wanted to hear what users want. The only thing that came out of it is that you can’t tell (interview with Hardon 1:17).
The women’s health advocates did not conform to the role of providing policy-makers and reproductive scientists with information on users’ needs, but proposed a more interactive approach. Women’s health advocates had not claimed to be able to speak in the name of users. Accordingly, they rejected being addressed as representative spokespersons for users. They also refused to limit their role to that of market advisors. Instead, they aimed at a more interactive approach and yet another shift in the name of integrating users’ perspectives. Women’s health groups sought access to scientific committees and policy-making boards. In their view, the integration of users’ perspectives into contraceptive research and development required engaging in dialogue with scientists and policy-makers. More than providing contraceptive developers with alternative representations of users, they aspired to become participants in the practices of technology development.

There were a number of locations at which members of the women’s health movement could engage in dialogue with the contraceptive developers. The recommendations of the first Creating Common Ground meeting included a statement about the incorporation of women’s health advocates into the policy and research work of the Programme. This issue was energetically taken up by the Women’s Desk. The appointment of Faye Schrater to the Steering Committee of the Task Force of Immunological Methods for Fertility Regulation followed from this, which was important, because the Steering Committee was in charge of generating and appraising research proposals, reviewing the scientific work, and deciding on future research needs. In 1996, the name of the Women’s Desk was changed into Gender Issues and Women’s Perspectives Unit. This change reflected and at the same time reinforced the more central position of this Unit within the Programme.

The Unit would aim to bring a gender analysis to bear across the Programme (GAP 1997). This aim was more encompassing than the earlier objective of helping to integrate women’s perspectives into the activities of the Programme. The use of the term "gender issues" pointed to a level of analysis that went beyond women’s expressed needs and preferences. In addition, a Gender Advisory Panel was formed in 1996. The Panel would meet once a year and report to the Director of the Programme and the Policy and Coordination Committee. The Gender Advisory Panel consisted of twelve experts on gender and reproductive health issues, eight of them women. (Benangiano 1995, ToR GAP). The terms of reference had been drawn up by the Gender Issues and Women’s Perspectives Unit. The objectives of this Panel were to ensure that gender considerations were brought into all of the Programme’s work, and to provide guidance in the ongoing project of integrating women’s perspectives and experiences into all its activities (ToR GAP). The Gender Advisory Panel was thus devised as a mechanism by which the Programme could take into account users’ perspectives in the way that women’s health
groupss had envisioned. Largely due to the existence of the Campaign, the work of the Programme on immunocontraceptives was reviewed at the first meeting of the GAP, in February 1996. In correspondence with its broader mandate, the Panel recommended that representatives of women’s health groups should be included in an advisory capacity in the design, monitoring, and evaluation of clinical trials with anti-fertility vaccines (GAP 1996). This was an important recommendation for the women’s health advocates, since it created conditions under which their alternative perspectives on users could actually be taken into account in the research and technology development process.

In sum, the discourse on "integration of users’ perspectives" that evolved in the area of contraceptive development did not initially alarm reproductive scientists and policy-makers. On the contrary, they hoped that "the integration of users’ perspectives" would enable them to get advice on users’ preferences and to develop suitable contraceptive methods. But backed by the favorable international climate, women’s health advocates introduced a different understanding of integration of users’ perspectives. This understanding of the integration of users’ perspectives went beyond the question of what kinds of contraceptive products users want. It meant taking into account the users in their contexts, including women’s health and their rights, and recognizing the perspectives of women’s health groups as valid in contraceptive development. It remained to be seen whether and how these perspectives could indeed be taken into account in technological development, and what the role of women’s health advocates would be in this process.

4. The integration of users’ perspectives into technological development

The integration of users’ perspectives into technological development in the way that the women’s health advocates had proposed was a whole new experience for all the actors involved. As Faye Schrater commented:

It is complicated, I mean how do we get users’ perspectives into this when we don’t even have a product yet? We have a potential product. How are we going to get users’ perspectives into that? And which users’ perspectives are you going to take? (...) I think that that is one of the things that makes the scientists crazy, women’s health advocates coming to these meetings saying: "you don’t have users’ perspectives, you got to take into account users’ perspectives." Give me a users’ perspective (interview with Schrater 1;26).

How did the reproductive scientists involved in the development of anti-fertility vaccines react to the changing meaning of integrating the users’
perspectives? The reproductive scientists made various attempts to align the developing product with the user-in-her-context. At the same time, they wanted to maintain their scientific autonomy and to continue their research. Policy-makers at the WHO/HRP had to preserve good relationships not only with the women’s health movement but also with member states, donors, the pharmaceutical industry, and all kinds of scientists. The agenda of the women’s health groups at some points went beyond taking into account distinct perspectives in contraceptive development to include other feminist goals, such as the empowerment of women. First I will discuss the opposition of women’s health advocates to anti-fertility vaccines. Then I will analyze which issues the actors involved agreed to discuss, and how certain issues came to fall outside the area in which alternative perspectives could be taken into account.

4.1 Women’s health advocates’ critique of anti-fertility vaccines

The perspectives of women’s health groups led to a specific critique of anti-fertility vaccines. Their central concern was to assess anti-fertility vaccines in their context of use. But there were divergent opinions about what would be an adequate strategy to influence contraceptive development, and this also affected the content of the critique. Although the Call for a Stop aimed to address all forms of immunological contraceptives, the women’s health advocates decided to concentrate first on the most advanced types, the anti-hCG vaccines. This meant primarily that the research at the National Institute of Immunology in New Delhi, by Pran Talwar and his team, and the research under the auspices of the WHO/HRP at Ohio State University, Columbus, lead by Vernon Stevens, were being challenged. As I explained in the first chapter, there were differences between these two lines of research, both in their prevailing representations of users and in the technical objects that were being developed. These differences between the two groups of researchers would have created an opportunity to employ the fourth tactic described by Epstein, of trying to influence scientific development by enrolling allies from one of the research groups. The women’s health advocates who launched the Campaign opted not to try to establish such alliances, because of the danger that Epstein (1995, 1997) signaled, of reproducing within the women’s health movement the split that existed between the research groups. This point was discussed at the workshop in Bielefeld in 1993 (Report Bielefeld workshop).

The strategic decision not to distinguish among various lines of research on anti-fertility vaccines also affected the content of the critique of these women’s health advocates. The Campaign did address technical features and the safety and efficacy of the vaccines, but the primary emphasis in the
Campaign was geared towards the broader issue: opposition to the population-control framework in which anti-fertility "vaccines" had been conceived. As Beatrijs Stemerding, who coordinated the Campaign, said:

I think that one should recognize that there are differences between the research by HRP and the Indian research (...) But that does not change the more fundamental critique upon this whole direction of contraceptive research (interview with Stemerding 1;81).

And also in the Call for a Stop:

As researchers readily admit, the concept of anti-fertility "vaccines" was conceived in a "demographically driven, science-led" framework. (...) We call for a radical reorientation of contraceptive research. Population control ideology should not guide the development of contraceptives (Call for a Stop 1993, 4).

Another important strategic decision by the women's health advocates who launched the Campaign was to call for an immediate and complete stop to research on anti-fertility "vaccines". According to Beatrijs Stemerding, there were two reasons for this:

An important point was that clinical trials were actually going on in India and women were being exposed to the method. That prompted a kind of urgency, to prevent women from being further exposed to the risks of anti-fertility "vaccines". And also one important argument was to give a very clear signal that this direction of research, of developing contraceptive methods in a population control framework, should come to a stop (interview with Stemerding 1;45).

The campaigners chose to take a clear and recognizable position: they demanded a complete stop to all lines of research in anti-fertility vaccines. Ironically, these strategic decisions could not prevent disagreements from occurring within the women's health movement. Some women's health advocates did not agree with the Call for a Stop. They considered that carrying on the research on anti-fertility vaccines was worthwhile, since it could eventually lead to a new, safer, and higher quality contraceptive method (Schrater 1992, Berer and Ravindran, 1994). Other women's health advocates thought that the campaign strategy could block other possible venues for influencing contraceptive development, such as engaging in dialogue and establishing alliances with some of the researchers and policymakers (Hardon 1997). In other words, these women's health advocates wondered how their credibility in the eyes of scientists would be affected by the position taken by the Campaign.
In spite of these differences, there was also considerable agreement about what was problematic in anti-fertility vaccine development. For example, it was broadly emphasized that the research should be conducted in an ethical manner (Call for a Stop 1993, Schrater 1992, Berer and Ravindran 1994, Hardon 1997). This was also a major issue in the Campaign. The Call for a Stop stressed that unethical clinical trials should cease immediately. Doubts were expressed that sufficient animal testing had been done before researchers had proceeded to do clinical trials. Secondly, the campaigners found that the enrollment of women was not always based on informed consent. And thirdly, they considered the data collection on adverse effects to women and to children born to women during trials insufficient (Call for a Stop 1993, 3). There was also agreement among members of the women’s health movement about the need to contextualize contraceptive users. This concept was also reflected in the Call for a Stop. By envisaging the future users of anti-fertility vaccines in their specific contexts, the campaigners found that the method would prove unreliable in relation to both efficacy and safety. They considered the method to be inappropriate for the contexts in which it was meant to be used. According to the Call:

Because they use the immune system, they are inherently unreliable. Individuals can react completely differently to the same kind of immunological contraceptive. (...) In addition, stress, malnutrition and disease will cause unpredictable failures of the contraceptive. (...) Immunological contraceptives are unlikely to be ever harmless (...) 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 is increasing, and when we have become acutely aware of the preciousness and complexity of our immune system (Call for a Stop 1993, 2-3).

According to these women’s health advocates, the assessment of safety and efficacy should reckon with the context in which the contraceptive might be used, including diseases, malnutrition, stress and deficient health care systems. Another point that was emphasized in the Campaign was the potential for abuse of anti-fertility "vaccines". The women’s health groups emphasized that abuse could occur especially in developing countries (Call for a Stop 1993, 2). They thought that the technical features of the proposed method contributed to its potential for abuse. On this basis they criticized certain technical features of the proposed technology. In the Call:

Immunological contraceptives have a higher abuse potential than any existing method. They will be long-acting (...). They cannot be
"switched off", and they are easy to administer on a mass scale because they will be injectables or a single pill (Call for a Stop 1993, 2).

In sum, the assessment of anti-fertility vaccines from a women's health perspective led to specific concerns about the proposed features of anti-fertility vaccines and about the way in which the research was carried out. Women's health advocates emphasized the embeddedness of phenomena such as safety and efficacy. Their contextualized assessment of other technical features, such as the duration and the mode of administration, prompted concern about potential abuse. Their perspective differed from that of the scientific community. To the scientists, safety and efficacy were clear-cut concepts. They could study the safety and efficacy of contraceptives abstracted from specific surroundings. What happened in the encounter of these two social worlds?

4.2 Demarcating the boundaries of science

The scientists and policy-makers at the WHO/HRP took the critique of the women's health movement seriously enough to react to it. In August 1992, the WHO/HRP organized a special Meeting between Women's Health Advocates and Scientists to Review the Current Status of the Development of Fertility Regulating Vaccines. And after the Campaign started, in November 1993, paragraphs with titles like "women's movement" and "the acceptability of anti-fertility vaccines" began to appear in the publications of the involved scientists (Griffin, Jones and Stevens 1994, Talwar 1994a, Stevens 1996). Jane Cottingham, from the Gender Issues and Women's Perspectives Unit, and the new Director of the HRP, Giuseppe Benangiano, co-authored an article entitled "Contraceptive Methods: Potential for Abuse" published in the International Journal of Obstetrics and Gynecology. In this article, the Campaign's argument about the high abuse potential of anti-fertility "vaccines" was taken as an occasion to examine more closely what abuse and abuse potential might mean (Cottingham and Benangiano 1996, 41). Other institutions that were directly or indirectly involved in conducting or funding anti-fertility vaccine development, such as the Population Council, USAID, CONRAD, IDRC and the World Bank, sent responses to the letter that they received from the Campaign. The women's health advocates were clearly effective in putting their concerns on the agenda of the contraceptive developers. The issues they raised were debated at meetings and in the scientific literature.

The responses of the reproductive scientists to the concerns of the women's health groups were mostly centered on protecting the area of what they considered the science of vaccine from interference from other as-
sessments. As Vernon Stevens from the WHO/HRP Task Force on Immunological Methods for Fertility Regulation said:

I think that safety and efficacy are pretty clear-cut. I mean there are hard, dry scientific facts. Acceptability is somewhat more subjective (interview with Stevens 1;21).

But as I will show, one of the effects of the boundary work was that a whole set of problems in the emerging technology had been labeled as ‘application problems’, and therefore declared not of central concern to the scientists. And remarkably, the attempts of these researchers to adapt the emerging technology to the user-in-her-context produced the same effect.

Pran Talwar, from the National Institute for Immunology in New Delhi, proposed that the women’s health movement could confidently leave the issues of safety and efficacy to the scientists. In an interview with two journalists he asserted:

More safety studies have been done for this vaccine than for any other birth control method. (...) Ours is the only vaccine in the world to go through such stringent safety and efficacy trials.

The world’s most reputed institutions and its most eminent scientists have been involved. (Shah and Sunny 1994, 21).

The argument that issues relating to safety and efficacy should be addressed by the experts was also stressed in the letters of the organizations that responded to the Call for a Stop. And as WHO/HRP Task Force Manager David Griffin wrote in a response to Beatrijs Stemerdink of the Women’s Global Network on Reproductive Rights:

It has always been our intention to thoroughly evaluate the fertility regulating vaccines we develop in order to address safety and efficacy issues such as those raised by Ms. Richter and others, and this will form an essential part of the ongoing and future research effort. In the same context, if we encounter any adverse event which cannot be eliminated or reduced to a clinically acceptable level, no further development of that particular version of the vaccine will be carried out (Letter by Griffin 13 May 1994).

At the WHO/HRP Meeting to Review the Current Status of the Development of Fertility Regulating Vaccines in August 1992 it was reiterated that the assessment of the safety and efficacy of the vaccines, and the decision to stop or continue the research, was a matter of scientific competence. As the report of the Meeting concluded:

(...) it was recognized that many of the concerns expressed by the women’s health advocates are also of concern to scientists, had
influence their work over the past 20 years, and continue to be subject of ongoing research. It was recognized also that the fertility-regulating vaccines under development and in clinical trials were still at an early stage of development and that many of the concerns raised were applicable to these prototype vaccines which are unlikely to be the ones to proceed to final product development (WHO/HRP 1993, 31).

Thus, the contraceptive developers at this meeting responded to the concerns of women’s health advocates by two means: first, by claiming that the issues of safety and efficacy were their own scientific concern, and that the voice of women’s health advocates was therefore superfluous; and second, by bringing to the fore the prototype status of what had been talked about.

This labeling of the developing vaccine as a prototype had far-reaching consequences for the kind of critique that was considered relevant. At least some of the women’s health advocates had argued that safety and efficacy were not as clear-cut as the scientists had suggested. The women’s health advocates regarded the context in which the method was used relevant to the assessment of safety and efficacy (Ravindran and Berer 1994, Schrater 1995). For example, in the case of Norplant®, they had explicitly shown that the scientific understanding of safety could conflict with the experiences of users (Hardon 1992, Mintzes 1991). This type of critique could not be applied to a prototype. By implication a prototype is not meant to be appropriate for use, and it therefore cannot sensibly be assessed in its context of use. The prototype was therefore not amenable to the kind of critique voiced by the women’s health groups. Another effect of emphasizing the prototype status of the technology was that notions of safety and efficacy other than those of the scientists were considered not applicable. In this way, safety and efficacy began to fall outside the scope of issues that could be discussed from different perspectives.

It is interesting to note that prototype vaccines had a complex status in connection with the way in which reproductive scientists presented their research. While the provisionality of the developing product was emphasized in encounters with the women’s health advocates, in other contexts the prototype was deemed a sufficient basis for assessing the safety and efficacy of anti-fertility vaccines. For example, the Indian research team would refer to safety found in research on a prototype vaccine in order to lay the basis for their own further research:

This prototype vaccine was effective in inducing in women the formation of antibodies against hCG (...). The antibody response was reversible and phase I studies conducted in six centers located in five
countries showed the safety and lack of side effects of immunization with this vaccine (Om Singh et al. 1989, 739).

And the team at the Population Council, after clinically testing a prototype version of their anti-hCG vaccine, wrote:

Our study further confirms the safety of this vaccine (...) The promise of the development of an anti-fertility vaccine, which emerged almost 20 years ago, still holds true. The process has been slow and we may still be far from the final product (Brache et al. 1992, 10-11).

Similarly, Stevens referred to evidence obtained with a prototype to account for the efficacy of anti-fertility vaccines. Referring to the phase II clinical trial by Talwar’s team, in which the efficacy of an anti-hCG vaccine was claimed for the first time, he wrote:

This vaccine, while not representing a product acceptable for general use, did suffice to demonstrate that immunization against hCG can be effective in preventing pregnancy. This milestone was very important for justifying further research and development of hCG anti-fertility vaccines (Stevens 1996, 149).

As I will elaborate in the next chapter, Talwar and Stevens considered their vaccines to be very different in nearly all other aspects. Yet Stevens could borrow the decontextualized efficacy results from Talwar’s prototype vaccine to justify further research.

Although considered not amenable to critique, prototypes played a central role in safeguarding the progress of the research. They were repeatedly mobilized to underline the scientific feasibility of imunocontraception and thereby legitimize the continuation of the research. For example, as the British researcher and member of the Steering Committee of the WHO/HRP Task Force on Immunological Methods for Fertility Regulation from 1985 to 1990, Avril Mitchison, stated:

(...) finding funding is competitive, and the earlier we have something to show for our efforts, the more likely we are to secure further support. In this sense a prototype vaccine is needed, even though we know that it may not be the optimal choice and may never enter into widespread use (Mitchison 1990a, 612).

The researchers labeled products under development as prototypes very selectively. This boundary work of the reproductive scientists proved very effective in maintaining their scientific autonomy in matters of safety and efficacy. They considered prototypes a pertinent basis on which to appraise the safety and efficacy of the vaccine themselves, but not sufficient to
warrant questions on safety and efficacy raised by non-scientists. Women’s health advocates were unable to counter this strategy, since they themselves had called attention to the importance of assessing contraceptives in the contexts in which they were to be used.

4.3 Distinguishing between the vaccine and its application

Boundary work also resulted from the way in which ‘the vaccine itself’ was distinguished from ‘the application of the vaccine’. This can be illustrated by the discussions and events surrounding three phenomena: first, the occurrence of a time lag before the antibody response to the vaccine reaches a protective level; second, the difficulty of predicting the duration of effective immune response; and third, the impossibility to switch off an immune response once it has been set in motion. These three issues were related to the immunological nature of the new method. According to women’s health groups, these problems were intrinsic to the vaccine itself. Moreover, they saw these issues as intimately related to their concerns about the safety and efficacy of the vaccine. Reproductive scientists had already identified these phenomena before members of the women’s health movement appeared on the scene; but the scientists were convinced that these were not problems of the vaccine itself but only of the applications of the vaccine in practice. Most scientific articles on the development of immunological contraception did not mention these issues. When the reproductive scientists faced these problems, their way of addressing them followed a similar pattern. First of all, they recognized the existence of the phenomena and categorized them as problems of application. Then they reasoned that to address these problems would require further biomedical research. At the same time, they worked on the development of additional measures to deal with these problems in practice. These measures consisted of finding different ways to reconcile future users with the emerging immunological contraceptive. I will now illustrate this by describing the ways in which the reproductive scientists dealt with these issues.

One of the issues was the occurrence of a time lag: primary immunization inevitably entailed a period of three to six weeks before the requisite immune response was achieved. Women’s health advocates rated the occurrence of a lag period as an inherent characteristic of immunoecontraception, and related this feature to the safety of the product. For example:

Should pregnancy occur during the lag period or occur later due to fluctuations in immune response, the fetus will be exposed to ongoing immune reactions as the contraceptive cannot be switched off. Because of unknown risks for the fetus, this situation is unacceptable for any
pharmaceutical product, but in particular for a contraceptive with a lag period inherent in its design (Wieringa 1994, 4).

Stevens considered the occurrence of a lag period as a problem that was only relevant in the application stage and not as a problem of the vaccine itself. For example, in an article on the development of anti-hCG vaccines published in the *American Journal of Reproductive Immunology* in 1996, Stevens first described the "Current vaccines", i.e. the prototype vaccines. Next he discussed the "Development needed to prepare useful vaccines". He devoted the last paragraph to "Applications problems to be solved" where he addressed the problem of the lag period as follows:

> Once a safe, effective and acceptable hCG-vaccine has been formulated (...), still other problems must be overcome before practical application to family planning is feasible. First, administration of the vaccine will not provide ‘instant’ protection against pregnancy (Stevens 1996, 154).

Subsequently, Stevens pointed to the possibility of dual application with a currently available method to bridge the lag period. Talwar applied the same compartmentalization of the research process. The occurrence of a lag period is not discussed as part of the vaccine, but under headings such as "Conversion of a potential vaccine to utilisable product" (Talwar *et al.* 1993, 210) and "Special problems raised" (Talwar 1994a). For example, in a 1994 guest editorial for the journal *Current Opinion in Immunology*, he wrote:

> During the ‘lag’ period, unless they either abstain from sex or use an alternate contraceptive with strict discipline, they will be vulnerable to pregnancy. It is, therefore, necessary to develop ‘companion’ methods for assuring protection during the initial period (Talwar 1994a, 701).

The second example of what the reproductive scientists considered an application problem, while women’s health advocates saw it as a problem inherent in the immunological method, was the variability in duration of effective response following injection. Women’s health advocates considered this variability in the duration of an effective immune response among individual users to be in the nature of immunological responses, and therefore a problematic feature of the safety and efficacy of the evolving technology (Call for a Stop 1993, Wieringa 1994). For example, the Forum for Women’s Health, a major women’s health group in Bombay, referred to these problems and stressed:

> We wish to once again emphasize that these are not problems of the kind that would get ‘solved’ with (...) more research. (...) These are aspects that cannot be delinked from the vaccine. They are the ‘risks’
that are bound to accompany such methods (Forum for Women’s Health 1995, 4).

And as Faye Schrater also wrote:

Some basic biological concerns are related to the nature of the immune response. (...) Because the degree and duration of immunological responses vary among individuals, it will be difficult to predict the time span of protective immunity for each person. And because immunity is cryptic, the body gives no immunological signal that the response has fallen to non-protective levels. (Schrater 1995, 665)

Women’s health advocates assumed that individual users would need to know the time span of protection. This problem, although recognized, was also rated as external to the vaccine by the contraceptive developers. In the 1990 Annual Report of the WHO/HRP Task Force on Immunological Methods for Fertility Regulation it was defined as a problem in implementing the vaccine in large-scale clinical trials:

The magnitude and duration of the immunity elicited by vaccines vary from one individual to another largely as a consequence of the genetic diversity of the recipients. (...) [this variation] will remain an important factor in managing clinical trials of anti-hCG and other anti-fertility vaccines from the Phase III stage onwards (WHO/HRP/ATR 1990, 103).

For Stevens, the unpredictable time span of protective immune response was not a problem of the vaccine itself, but it entailed the need to combine the vaccine with other means of birth control. He wrote:

While not technically a part of new vaccine design, the probable use of anti-fertility vaccines in combination with other means of birth control will surely be a reality and is worthy of mention in regard to new vaccine development. (...) At the point in time when immunological birth control methods are ready to enter family planning programmes, this issue will need to be seriously addressed (Stevens 1992, 139).27

The third issue to illustrate the different ratings of problems by the women’s health groups and by the reproductive scientists was that the effect of the vaccine cannot easily be stopped. Stevens also considered this an application problem (Stevens 1996). Again, the women’s health advocates viewed this impossibility to switch off an immune response as a safety problem related to the immunological nature of the method. For example, as Hardon wrote:
(...) the method stops working when antibodies to hCG are secreted from the women's body. If side-effects occur within that period, the drug cannot be "switched off" (Hardon 1990, 23).

And Richter also wondered:

The desire to have a child is not the only reason a woman may wish to stop using a contraceptive. If a woman experiences severe side effects shortly after an injection, (...) will it be possible to switch off the immune response? (Richter 1993, 36).28

Whether application problems or intrinsic problems of immunological contraceptives, these issues needed to be addressed. The research teams of the WHO/HRP and of the NII dealt with these issues in two ways: by proposing further biomedical research and by delegating the problem to an additional technology. They did take into account the concerns of the women's health movement, but in such a way that the distinction between the vaccine itself and the application of the vaccine could remain intact.

The Indian team devoted part of their research to the development of a companion method to overcome the lag period (Upadhyay, Kaushic and Talwar 1990; Talwar et al. 1993, 210). In the terms of Akrich (1995), delegating the problem of the lag period to this additional technology can be viewed as an attempt by these researchers to reach alignment between the envisioned anti-fertility vaccines and the eventual users. Another proposal for alignment was provided by Griffin, who suggested the possibility of synchronizing vaccine administration with the infertile days of a woman's menstrual cycle, but then the length of the lag period would need to be reduced (Letter by Griffin 13 May 1994). And a researcher at the Population Council, Kalyan Sundaram, who worked on an anti-fertility vaccine for men, suggested that the vaccine could be administered to a man while his wife was in the anovulatory period after giving birth (interview with Sundaram 18 October 1996), i.e. to delegate the alignment of the vaccine and the user to the couple. Note that the image of a monogamous couple is implicit in this proposal. But the women's health advocates did not consider an additional method an appropriate answer. At the August 1992 Meeting to Review the Current Status of the Development of Fertility Regulating Vaccines, the need for an additional method to bridge the lag period was discussed. According to the report:

The women's health advocates were particularly concerned about this aspect of the vaccine, because little is known about the interaction between the vaccine and some of the additional methods that would need to be used during the lag period or about the duration and variability of the lag period. Furthermore, the need to use an additional
method during this lag period was seen to be a disadvantage (WHO/HRP 1993, 20).

The scientists maintained that the problem of the lag period could be resolved within their scientific domain, by doing more research. The report continued:

The scientists indicated that information relevant to the question of possible method interactions would be obtained from animal studies, and information on the length of the lag period would be obtained in ongoing and planned clinical trials (WHO/HRP 1993, 20).²⁹

The same reference to the need for more biomedical research was cited in confronting the problem of the vaccines' unpredictable duration of effective response. Talwar and his team found this result in their phase I clinical trial (Talwar et al. 1990) and indicated that they considered this to be one of the main drawbacks in the development of immunological contraceptives (Talwar and Raghupathy 1989, 99; Om Singh et al. 1989, 739). In response to this problem, the Indian team made various modifications to the design of the vaccine to make the preparation more immunogenic for a protracted period of time (Talwar et al. 1992, 948; Talwar et al. 1994, 8532).³⁰ But the problem of individual variation in the immune responses had not disappeared in the phase II clinical trial by the Indian scientists (Talwar et al. 1994). For the same purpose of reducing individual variation in immune responses, Stevens developed an injectable biodegradable microsphere system from which the antigen would be released gradually (Stevens 1992, 140). Further, Stevens asserted that more research would settle the problem:

However, in the absence of antibody titre information, an individual subject will not know exactly when he or she has returned to a fertile state and method failure and/or anxiety could comprise method acceptability. Following the extensive clinical testing of a particular vaccine, the definition of a 'safe period' for most subjects might be apparent (Stevens 1992, 142).³¹

As an additional means to address the issue of the unpredictable duration of effective response, the Task Force initiated investigations in 1990 to develop a test kit to monitor the level of immunity on an individual basis in a fingerprick blood sample, for home or clinical use (Gupta et al. 1991). The Indian team also planned to address this issue by continuous monitoring. In his paragraph on "Special problems raised", Talwar said:

(Antibodies) must be present at titers above a threshold if the vaccine is to be efficacious. Titers must, therefore, be monitored on a continual basis each month. Easy to perform 'user friendly' colour tests are needed and are currently being developed. The availability of these
tests is a prerequisite for the introduction of contraceptive vaccines for family planning (Talwar 1994a, 702).

The test kit was also an attempt by the contraceptive developers to align the emerging technology with the future users. As with their solution to bridge the lag period, the problem was delegated, this time to an additional technology. But from their way of viewing the user-in-her-context, solutions such as a test kit to monitor the antibody level appeared problematic to women's health advocates. As the feminist immunologist Schrater noted about the test kit:

But without adequate distribution, rural and poor women may need to return to the clinics for blood tests. If so, how will they get to the clinics? How long must they wait for the results? Who will pay for the tests? (Schrater 1992, 45).

And the Bombay's Forum for Women's Health suggested:

From the point of view of women and demands of women's groups (...) would it not be safer and better to evolve simple user friendly kits for detection of occurrence of ovulation? (Forum for Women's Health 1995, 4).

In other words, these women's health advocates suggested that the users of anti-fertility vaccines, and the contexts of use, had already been defined by other characteristics of the artefact. Anti-fertility vaccines were meant to be long-acting, low-cost, and easy to administer. These characteristics, and the involvement of the WHO/HRP, pointed towards users in developing countries. They wondered if the alignment of these users with the users implicated in the test-kits was indeed feasible. The issue was discussed at the Meeting to Review the Current Status of the Development of Fertility Regulating Vaccines in August 1992. According to the report:

(Women's health advocates) felt that use of a home based test kit was impractical, particularly in many developing countries, not only because of the difficulty of such a test kit being made regularly available, but also because of the potential hazards of taking finger-prick blood sample in unhygienic conditions (WHO/HRP 1993, 21).

The scientists involved in the development of immunological contraception answered:
The possibility of using a skin patch or saliva based test (both of which would be non-invasive) to monitor the level of antibodies is also being considered, and this area is already the focus of intensive research efforts for other applications (WHO/HRP 1993, 21).
These scientists thus responded to one part of the concerns raised by the women’s health advocates: that part which they thought could be addressed within the technological artefact, and therefore within their domain. They did not respond to the other concerns that were related to the contextual embedding of the technology. These were considered logistical problems, and logistical problems fell within the domain of application. The scientists thus maintained their compartmentalization of the research process.

The third issue, the impossibility to switch off an immune response, displayed the same pattern. Again, the point of women’s health advocates that this might matter to users was taken seriously. In response, additional technologies were suggested that would hold out the prospect of reversal on demand. As Stevens wrote in his paragraph about "Application Problems to be Solved":

Finally, efforts must be made to devise means to neutralize vaccine effects on demand to allow a vaccine recipient to chance her mind about having a baby after she has received an hCG-vaccine. (...) Other than general immune suppression, experimental procedures have demonstrated that hCG antibodies can be purged from the circulation for a sufficient period to allow conception to occur and pregnancy to be established. Whether any of these methods can safely be applied to vaccine reversal can only be determined by further studies of their efficacy and safety in experimental animals, and eventually in clinical trials (Stevens 1996, 154).

The scientists involved in the development of the hCG vaccine did not consider reversal on demand instantly feasible (Stevens 1992, 142; Griffin 1994, 93). Schrater wrote about possible procedures for reversing on demand an immune response to an anti-hCG vaccine:

Although scientists say the immune response to beta hCG can be thwarted by injecting large doses of progesterone or the hCG hormone itself, the method would be prohibitively expensive and would probably require hospitalization to monitor for and treat any untoward effects of ‘the cure’. (...) The fact that reversal is possible by no means insures that such reversal would be available to all women (Schrater 1995, 666).

Therefore, a second way to reconcile the anti-fertility vaccines with the users was envisaged. The contraceptive developers proposed that the service providers should take charge. As I outlined in the Introduction, to delegate the alignment of a technology and the users to intermediaries was another strategy that Akrich (1995) analyzed. Immunological contraceptives were discussed in the Newsletter of the WHO/HRP, Progress:
One aspect of this method will, however, require special attention on the part of service providers. Since the contraceptive protection offered by the hCG immunocontraceptive will be longer-lasting than the current injectables, users will need counselling to ensure that they understand fully the implications of using a long-acting method that is not reversible before the end of its expected duration of action (Progress 1997, 6).

In sum, I have analyzed two mechanisms at work in the encounter between women’s health advocates and reproductive scientists. One important mechanism was the specific way in which the concept of prototype was mobilized. Contextless prototypical vaccines were considered relevant for the assessment of the safety and efficacy of the new technology. But when the safety or efficacy of the evolving technology was questioned, the reproductive scientists would attribute these difficulties to the prototype status of the artefact. Crucially, the scientists would not attribute these problems to their understanding of safety and efficacy. As a consequence, the progress of their research based on this assessment would continue to get the benefit of the doubt. The effect of this boundary work was that a whole range of potential topics to be addressed from the women’s health advocates’ perspective on the situations of contraceptive users was erased, or postponed to later stages of development. Secondly, women’s health groups were concerned about some features which were directly related to the immunological nature of anti-fertility vaccines. The researchers also recognized the existence of these phenomena, but considered them only in relation to the application of the vaccine. The scientific work of the scientists was primarily concerned with what they perceived to be the vaccine itself, and not with its applications. This was only possible because the reproductive scientists assumed a distinction between their scientific work to develop immunocontraception and the applications of this method. This compartmentalization was reinforced in the encounter with women’s health advocates. The classification of issues such as the lag period, the unpredictable duration, and the reversibility-on-demand as external to the vaccine itself had consequences for the kinds of solutions that the contraceptive developers devised. The strategies they employed to align the proposed vaccine with eventual users included delegating the problems either to other technologies or to the service providers. These strategies seemed to put a strain on the representation of users implicated in anti-fertility vaccines. And importantly, this compartmentalization also had consequences for the part of the research in which the assessments of members of the women’s health movement could be taken into account. Much of what could be considered the technical part of immunological contraceptives was isolated from discussions involving alternative views on
users. The reproductive scientists did not allow the points of view of women's health advocates concerning technical characteristics to play a part in technology development. Next I will examine what happened in the encounter of differing assessments of the acceptability of the method.

### 4.4 Potential for abuse or acceptability

The contraceptive developers repeatedly emphasized those features of the future method that would make it attractive: it would be long-acting, easy to administer, and free from so-called user-failure risk. For example:

- **Advantages of fertility regulating vaccines**
  - (a) Long duration of effect from single injection or course of immunization.
  - (b) Absence of pharmacological activity.
  - (c) Absence of user-failure risk.
  - (d) Administration by method with high level of acceptability.
  - (e) Low cost (Ada and Griffin 1991, 18).35

This was the product profile that the researchers pursued. Stevens and his colleagues developed a delivery system to facilitate administration by a single injection. Both Stevens’ and Talwar’s teams chose to use bigger antigens that were expected to provoke a stronger and more prolonged immune response. Talwar’s team experimented with alternating carrier molecules, and Stevens tried different dosages of antigen and adjuvant to obtain a longer-acting formulation (Talwar *et al.* 1992, Talwar *et al.* 1994, Stevens 1992). Significantly, the characteristics of the new method that the reproductive scientists mentioned in relation to acceptability were those of the proposed artefact. As yet, immunological contraceptives were not long-acting: in clinical trials in Australia and India, the duration of immune response oscillated between some weeks and several months. Nor were they easy to administer: all the preparations that had been used in clinical trials were complex products that had to be prepared just before administration and required a scheme of multiple injections. (Jones *et al.* 1988, Talwar *et al.* 1994). As Griffin noted in the 1986-1987 Biennial Report:

The duration of the immunity elicited by the prototype vaccine used in the Phase I clinical trial, several weeks to several months, is well short of the 12-24 months sought by the Task Force. In addition, the complex composition of the vaccine, and the less than ideal nature of some of its constituents, would make this prototype unsuitable for wide-scale use (Griffin 1988, 177).
The researchers never mentioned the lag period or the unpredictable time-span of protective immune response in discussing the acceptability of the proposed method. The technical features of the proposed vaccine thus differed markedly from the prototype vaccine. And whereas the reproductive scientists had promoted the prototype vaccine for the safety and efficacy assessment, they brought the expected vaccine to the fore to anticipate its envisioned acceptability.

The role of expectations in technology development has been analyzed by Harro van Lente (1993). Van Lente has argued that the successful labeling of a certain technology as "promising" may have dramatic effects. If the promising status of a technology is recognized by the actors involved, they will define the requirements that justify this situation, which should be reflected in the technology. Next, they will perform the concerted actions that are needed to live up to this expectation. In this way, a self-justifying circle or spiral emerges: the technology is promising because work is done to make it meet certain requirements that justify the label of promising. According to Van Lente, a promising technology is typically specified in terms of novelty, next generation, and more advanced than existing technologies. Rip and Van Lente (1998) have outlined that such prospects may have a structuring effect upon the current activities of the actors involved in technological development. They will create a protected space, in which a process of trial and error is allowed for some time without the threat of the technology being considered a failure. Thus, once a technology has been assigned the status of "promising technology", an expectation-requirement cycle emerges, and this in turn helps to maintain a niche for the technological development.

Anti-fertility vaccines were a promising technology. The contraceptive developers portrayed the expected method as potentially better and more acceptable than existing methods. For example:

Safe, effective and reversible birth-control vaccines would be a significant addition to available methods of contraception and, in fact, may turn out to be superior to available methods in some respects (...) (Raghupathy and Talwar 1992, 597).36

And as Task Force Manager David Griffin wrote:

(...) If safe and effective fertility-regulating vaccines that meet this performance profile can be developed, they are likely to be highly acceptable to individuals who do not want to use, or who have discontinued the use of, existing contraceptives (Griffin 1996, 143).

Also, the reproductive scientists habitually expressed their expectation that anti-fertility vaccines would enlarge contraceptive choice and provide a means to curtail the increasing world population.37
While anti-fertility vaccines were a promising technology in the eyes of the reproductive scientists, they were not promising from the perspective of women's health advocates. Some of the requirements that the researchers viewed as potential advantages had been labeled as undesirable by the women's health groups. Specifically, the women's health advocates involved in the Campaign had argued that the methods' characteristics, such as long-acting and easy to administer in a "vaccine"-like approach, together with the impossibility to switch off an immune response once it has been triggered, were factors that contributed to the abuse potential of immunocontraceptives (Richter 1996, 68). Abuse potential was defined as "the likelihood of uninformed, disinfomed and coercive administration of a birth control method." (Richter 1996, 68). The same technical requirements that would lead to the expected acceptability in the eyes of reproductive scientists were markers of abuse potential according to women's health advocates. Further, both groups maintained that the acceptability/abuse potential that followed from the proposed product profile would occur particularly in certain sociocultural and economic contexts. The contraceptive developers mentioned the long duration and the ease of administration in particular in relation to developing countries. For example:

They will require only periodic intake. The injections can be given by paramedical personnel. Hospital and aseptic facilities are not required. Thus the approach is amenable for mass use even in countries without adequately developed health services. The efficacy of the approach, unlike oral contraception, is method-dependent and would not require day-to-day motivation (Talwar 1978, 414).

In the developing countries, a family planning preparation that needs to be administered at infrequent intervals and that requires little active participation by the user to remain effective, would have distinct advantages for both the providers and users of family planning services (Hjort and Griffin 1985, 271). This in turn aggravated the concerns of women's health groups that these proposed technical features would make the method susceptible to abuse. As the coordinator of the Campaign to Call for a Stop, Beatrijs Stemerding, asserted:

The characteristics of these methods reflect an aim to reduce population growth instead of meeting the needs of individuals (Stemerding 1995).

What happens if the same technical features are seen as a potential for acceptability by one set of actors and as a potential for abuse by another
group? To declare, for many years, that anti-fertility vaccines with certain expected characteristics would be highly acceptable to users, an advantage over currently available methods, and a contribution to curtail population growth was more than rhetoric. These statements were part of the expectation-requirements circle that constituted the new method as a promising technology. And this in turn had provided the contraceptive developers with the niche that they needed to continue of the lengthy and laborious innovation process. Conversely, the women’s health advocates’ expectations of the abuse of long-acting, easy to administer methods led them to call for an end to the protected space. Therefore, much was at stake for the contraceptive developers in sticking to the announced product profile of immunological contraception.

How did the contraceptive developers respond to the view of women’s health advocates on acceptability/abuse potential? Initially, Talwar and Stevens agreed with members of the women’s health movement that certain technical features might contribute to the potential for abuse of a contraceptive method. They seemed to share the view that a long-term method that could not be reversed on demand might be prone to abuse. But they distinguished this insight from their own scientific work. Talwar called up the prototype vaccine to refute the abuse potential of the method. He wrote:

(An) objection is that these vaccines may be administered to women (e.g., by a dictatorial regime) under false pretences, thereby rendering the recipients unsuspectantly infertile. Thus far, all the vaccines in trials are fully reversible, and the protection in the absence of booster is only 3-6 month duration. Therefore, these vaccines are not suitable for such nefarious purposes (Talwar 1994a, 701).

Stevens considered that addressing the problem of abuse was an issue outside the technological artefact itself, in the applications:

Any method of birth control that will induce long term infertility without any means by the user to reverse this state, such as anti-fertility vaccine, provides opportunities for ethical abuse. Such a method could be provided without or with inadequate informed consent or imposed by coercive governments or organizations. As control over reproductive function is a basic human right, stringent adherence to high ethical standards in the provision and promotion of vaccines must accompany their use (Stevens 1992, 142).

These reproductive scientists initially relied on the same mechanisms that I described in the preceding paragraph: by shifting between the proposed and the prototype vaccine, and maintaining a specific compartmentalization of the
research process. On this basis, Talwar and Stevens felt that to address potential for abuse was not part of their scientific work.

The Scientific and Ethical Review Group of the WHO/HRP took the position that the abuse of contraceptive methods was unrelated to specific technical features. In June 1994, the Programme convened a meeting between women’s health advocates and members of the SERG to discuss ethical aspects of the research, development, and introduction of fertility-regulating methods. Again, the case of anti-fertility vaccines was one of the main topics (SERG 1994). According to the report:

There was disagreement as to whether the vaccine has a higher abuse potential than other existing methods. Some people felt that the vaccine is no more open to abuse than currently available methods. (...) On the question of whether research should be stopped because of abuse potential, again sentiments diverged. Stopping immunological research in the field of human reproduction, some felt, would interfere with some of the most exciting leads currently emerging which hold promise for a whole host of new approaches in the future (SERG 1994, 5-6).

According to the SERG there was nothing specific in the product profile of anti-fertility vaccines that made them more prone to abuse than other methods. To assert that all methods could be abused was an important additional mechanism to protect the scientific domain from interference by non-scientists and to safeguard the continuity of the research. If all contraceptives were potentially open to abuse, this could not possibly be a reason to halt the research on anti-fertility vaccines. Subsequently, the researchers repeatedly stressed that any contraceptive method could be abused (Griffin, Jones and Stevens 1994, 113; interview with Stevens 1;8; Griffin 1996, 145).

The policy-makers at the WHO/HRP also affirmed that technical objects do not define any specific framework of action. Instead, they viewed contraceptive abuse as a result of political, socio-cultural, and economic situations. As Benangiano and Cottingham wrote:

Our position is that eliminating research on methods which might be abused will not, in fact, address the problem of abuse.(...) The problem of abuse needs to be tackled where it is happening, by unveiling abusive practices, by informing and educating all levels of the public about ethical requirements, and by extending and strengthening existing safeguards (Benangiano and Cottingham 1997, 43).

In other words, the Programme adhered to the view that abuse should be prevented by all means except technological design.41
Since the contraceptive developers rejected the view that abuse could be forestalled on the basis of the proposed characteristics of the artefact, it became increasingly difficult to maintain the promise of high acceptability of anti-fertility vaccines on the basis of these projected requirements. Therefore, to discuss either acceptability or abuse potential on the basis of the proposed product was deferred to later stages. The contraceptive developers claimed that the appraisal of the acceptability of the new product should wait until it was actually available. For example, as Task Force Manager David Griffin wrote:

> It is well accepted that it is not possible to do meaningful acceptability studies until a sufficiently large number of people are actually using the method in question (Griffin 1996, 143).

And Stevens confirmed:

> Despite the opposition to further development of hCG vaccines, it is my view that this research should be continued until suitable methods have been obtained before judgement of their acceptability is made (Stevens 1996, 149).

### 4.5 Modifications of the proposed method

Although it was taken up in a specific way, the women's health advocates had certainly been successful in putting the potential-for-abuse issue on the agenda. The projected duration, the technical feature that the women's health groups had related to abuse potential, was actually modified. In May 1995, women's health advocate Judy Norsigian, from the Boston Women's Health Book Collective, met with Philip Gevas from Apton Corporation, a small U.S. based pharmaceutical company which worked with the WHO/HRP on the development of an anti-hCG vaccine. They discussed the critique by women's health advocates of the vaccine design. Subsequently, Gevas wrote in a letter to Norsigian:

> We have already made a, perhaps, profound change regarding the duration of "protective period", which I am confident the WHO people will concur with. (...) I believe that the 12 to 18 months originally specified was a sincere attempt to determine what might be the best for people with limited access to physicians (e.g. the developing countries). However, the "abuse potential" (...) considerations convinced me that six months, instead, is far better (Letter by Gevas 31 May 1995).42
This change had been proposed by women's health advocates (WHO/HRP 1993, 20). Indeed, the WHO/HRP changed the objective of developing a vaccine with a duration of 12-24 months to the development of a 6- or 12-monthly hCG immunocontraceptive. According to Griffin, this change can be attributed to women's health advocates (interview with Griffin 1;23; Griffin 1996, 143). Stevens added:

I have been sort of told to make a short-acting as well as a long-acting thing. It was a loose kind of talking, not a formal meeting or group. It was centered on women's objections, their fears to lose control over their bodies. Company people considering taking a license said: 'Could you make it shorter?'. I said: 'How short?' They said: 'Six months?'. I said: 'No problem'. They wanted to make something more acceptable to those women who don't want to lose control over their fertility, their reproductive lives. We'll make a longer acting too, but also short-acting so that they will not complain (interview with Stevens 2;3).

In contrast to the other reconciliation work, this was not an attempt to align the product with the projected user-in-her-context. Instead, the modification was meant to reconcile the product with the political representatives of users.

Another aspect of the method that was modified under the influence of women's health groups was the use of the vaccine terminology. The researchers had anticipated that this would contribute to the acceptability of the contraceptive:

By virtue of its mechanism of action, its lack of effect on the menstrual cycle, its long duration of efficacy, and the positive health benefits perceived to be associated with other forms of vaccination, for example against infectious diseases, it is anticipated that an hCG vaccine will find wide acceptance as a new method of family planning (Griffin and Jones 1991, 178).

Women's health advocates, on the contrary, argued that the vaccine metaphor could contribute to its abuse potential, since it could lead to confusion (Call for a Stop 1993, Richter 1994). For example:

The "acceptability of the 'vaccine' principle" in developing nations could be considered a danger to women rather than an advantage. The widespread use of vaccines to prevent infectious disease opens the door for abuse and direct or indirect coercion by the state (Schrater 1992, 44).

Their concern for confusion had led them to put "vaccines" between quotation marks (see Note 5). They had emphasized the differences between anti-
disease vaccines and immunocontraception and proposed using a different terminology (Richter 1993).

In 1995, rumors were spread by anti-abortion organizations in Mexico, Tanzania, Nicaragua, and the Philippines that immunization campaigns providing tetanus toxoid vaccine were using women as guinea pigs to test an anti-fertility vaccine. These rumors affected the immunization rates in all four countries. In the Philippines, a court injunction even temporarily banned the use of tetanus toxoid in immunization campaigns (Milstien, Griffin and Lee 1995, TT Vaccine scare 1996, WHO press release 19/7/95). The women's health advocates involved in the Campaign issued a press release in which they emphatically distanced themselves from these rumors (Resistance on the Rise 1995). The Gender Advisory Panel was asked to propose an alternative terminology for anti-fertility vaccines. The Panel "suggested that the new name should include the concept of using the immune system, the idea that it is a temporary method, and should avoid words such as 'anti' or 'non' which give a negative impression" (GAP 1996, 14). Subsequently, the Programme adopted the term immunocontraceptive (GAP 1997) or 6/12 monthly injectable (Progress 1997(44)).

5. Conclusions

In this chapter, I have studied representations of users by women's health advocates and by the contraceptive developers, and the extent to which these were taken into account in the design of anti-fertility vaccines. Akrich (1992, 1995) was able to study the types of relations and the world inscribed in technical objects by going back and forth between the designers' projected users and "real" users. My approach differs from that of Akrich. I compared the projected users of two different social groups involved. I have demonstrated that scripts can be analyzed before "real users" appear on the scene, particularly when various social groups articulate their perspectives on users. This means that prospective technology assessments with a focus on users can be done at the incipient stage of technological design. Many authors have emphasized that in such assessments it is important to take into account the perspectives of different social groups (Rip, Schot and Misa 1995), but implicit and explicit ideas about the users of future technologies are usually not included in the analyses. This study in addition suggests the fruitfulness of studying representations of users constructed from different perspectives in the early stages of technological development. It also shows the difficulties that may arise in such an endeavour, even in an environment in which the potential benefits of such an approach are recognized. Involving the represen-
tations of users of both the contraceptive developers and women’s health advocates in this analysis provided me with a number of new insights.

I have examined the ways in which the women’s health movement has been involved with contraceptive technology, and its relation to users. The women’s health advocates did not represent contraceptive users in the sense of voicing their needs, or speaking on behalf of users. Instead, they represented a perspective on women using contraceptives that differed from that of the scientists involved in contraceptive development. This was important for three reasons. Firstly, it allowed the women’s health advocates to relate to users in ways different from those of a spokesperson. Their voice was not confined to expressing what users would want or need. Their critique could therefore encompass other issues, such as women’s health and their rights. For example, their critique of a contraceptive that would be long-acting and easy to administer was based not on their perception of the needs and preferences of users, but on their concern for the kinds of relations between users and providers that such a technology would imply. Secondly, thanks to their alternative perspective on users, the dynamics of the representations of both the women’s health advocates and the reproductive scientists involved became apparent. Women’s health advocates referred to the way in which their perspective was based upon certain experiences and an analysis of these experiences. By making explicit the situatedness of their perspectives, they revealed the situatedness of the perspectives of the reproductive scientists as well. Developing an alternative perspective on users also exposed the assumptions implicit in the techniques by which images of users had been generated. Users’ needs and preferences had been assumed to be identifiable at the level of the attributes of contraceptive methods. Women’s health advocates proposed that the array of techniques by which representations of users were generated should go beyond surveys and beyond the level of ideal product profiles. Thirdly, their perspectives on women using contraceptives also provided the underpinning for constituting themselves as credible partners in dialogue with the contraceptive developers. If women’ health advocates had presented themselves as voicing the needs and preferences of contraceptive users, their role would have been similar to that of the social scientists. They would have been advisors to the contraceptive developers on what attributes of contraceptive methods would be attractive to users. To take their advice (or not) would have remained the prerogative of the contraceptive developers. Now, instead, their contribution surpassed the level of women’s practical interests. They were able to provide a gender analysis of the activities of the Programme, for example by means of the Gender Advisory Panel and by means of the Technical Officer for Women’s Perspectives and Gender Issues. The alternative perspectives of women’s health advocates had implications for their representations of users, and for their
assessment of the way in which these were generated. Importantly, it also had consequences for their appraisal of anti-fertility vaccines and of the ways in which the research was carried out.

Gaining access to the scientific domain is not a one-sided process. Key mechanisms that social movements may use in order to gain access to the scientific domain have been studied by Epstein (1995), and I have discussed the differences and similarities between women’s health advocates and Epstein’s AIDS activists. In my analysis of the extent to which the perspectives of a social movement were taken into account in devising the script of anti-fertility vaccines, I have concentrated on the mechanisms at work amongst the scientists. I have shown how the scientists’ patterns of dealing with the differing perspectives of women’s health advocates were composed of attempts to align divergent representations of users in the sense that Akrich has analyzed, and of boundary work to preserve their scientific authority and the continuity of their research. These specific ways of dealing with representations of users had far-reaching consequences for the developing technology, in particular for determining which aspects of anti-fertility vaccines would be open to take into account the representations of users from other perspectives.

The assessment of the safety and efficacy of the vaccine was retained within the scientific domain by the mobilization of the prototype status of the product under development. Reproductive scientists could refer to the prototype status of the developing vaccine very selectively. Research conducted with the prototype vaccine could account for the safety and efficacy of anti-fertility vaccines, but this same research could not be cited in raising issues of the assessment of safety and efficacy. The double role of the prototype became apparent by comparing the perspectives of the reproductive scientists with those of the women’s health advocates concerning the way in which safety and efficacy should be assessed. This finding therefore underscores the importance of studying the representations of users provided by different actors at early stages of technology development. By contrast, in the case of other contraceptive technologies such as Norplant®, divergent understandings of safety and efficacy only became apparent once the user-script inscribed by the designers was acted out. This finding also points to the importance of studying in detail how the safety and efficacy of contraceptive technologies are assessed, the issue that I will address in the next chapter.

The researchers distinguished the ‘artefact itself’ from ‘its application’ in a context. By means of this compartmentalization, the development of the artefact fell within their scientific domain, while application problems were relegated to the domains of logistics and daily life. The distinction that these researchers made between the artefact and its use led them to envision specific strategies to reconcile the technology with its future users. The
researchers aimed at developing a method that would be long-acting and easy to administer. These purposes were pursued as part of the artefact. Other phenomena in the performance of immunological contraceptives were categorized as application problems, and the researchers looked for solutions outside the artefact itself to address these issues: an additional method was foreseen to bridge the lag period; the problem of the unpredictable duration of efficacy was addressed by a test kit; and the problem of the impossibility of reversing the contraceptive effect on demand was delegated to health care providers. Again, this mechanism became apparent by comparing the perspectives of the reproductive scientists involved with those of the women’s health advocates.

Madeleine Akrich has signaled that the strategy of delegating the work of reconciling the users and the artifacts to the technological hardware involves the risk "of ending up with a kind of technological monster, extremely sophisticated but finally quite ineffectual because it is unable to attract the users for whom it was intended" (Akrich 1995, 179). I have shown the relevance of this risk to anti-fertility vaccines by analyzing the emergence of a script in the making of this technology. The projected users of the proposed anti-fertility vaccines were women who would want to use a long-acting method, who do not have frequent access to specialized health care services, who either don’t want to or can’t use hormonal methods, and who may have to hide contraception from other members of the household. As Griffin wrote:

The intended performance profile of fertility-regulating vaccines, in particular anti-hCG vaccines, is that they would not cause endocrine and metabolic disturbances associated with contraceptive steroids, they would not require daily pill-taking, they would not present the storage and disposal problems of barrier methods, they would not require specialized insertion and removal procedures as with implants and IUDs, they would not depend on the strict self-discipline demanded by "natural" family planning, they would be naturally reversible unlike sterilization, and they would offer the woman or man personal confidentiality of use (Griffin 1996, 143).

The contraceptive developers repeatedly mentioned this ideal. These characteristics and the concomitant script are those of the imagined method. The method that was actually developing had a less coherent script. For example, a method to bridge the lag period could be an hormonal injection, barrier methods (condoms, diaphragms), or "natural" family planning (rhythm method, abstinence, withdrawal). A hormonal bridge method would exclude users who don’t want to or can’t use hormonal products. The other possible bridge methods might be unsuitable for users who look for personal confiden-
tially of use, or methods that do not require strict self-discipline. Similarly, a test kit to monitor the level of antibodies in the blood would make anti-fertility vaccines less convenient for those users who seek to avoid storage and disposal problems or who don’t have regular access to health care services. Thus, while the contraceptive developers attempted to align the developing technology with future users, the specific compartmentalization of the research process that they had adopted meant that certain problems which a user of the method might encounter remained implicit. One might expect that mechanisms such as discursively distinguishing the vaccine from its applications would cease to be effective once the methods enter the health care center, for example in clinical testing. In the next chapter I will explain how, indeed, other mechanisms were put in place in order to guarantee the continuity of anti-fertility vaccine development.

The imagined product profile of immunological methods of fertility regulation as long-acting, easy to administer by a vaccine-like approach, and free of the risk of user-failure has been remarkably fixed over the years. Other venues of immunocontraception, e.g., research into once-a-month, oral, or post-coital forms, were not explored. This profile has endured in spite of major technical problems in meeting these requirements. Also, no reference was made to studies indicating that this was indeed the kind of product that users wanted, or that would most readily expand contraceptive choice, or that significantly would contribute to population control. I have argued that to account for this stability, anti-fertility vaccines should be understood as a "promising technology" (van Lente 1993). The need to develop anti-fertility vaccines was justified on the basis of the expected acceptability of the foreseen product profile. As a result, these technical features were part of a circle in which the continuity of anti-fertility vaccine development was worthwhile against the odds. The women’s health advocates related their concerns about potential abuse to the same technical characteristics that had enhanced the promise of acceptability to the contraceptive developers. In the ensuing debate, the expectation of either acceptability or abuse potential following from these technical requirements was questioned. Consequently, some room for changing the product profile emerged.

The impact of women’s health advocates on the developing script of anti-fertility vaccines was modest. The extent to which their differing perspectives were taken into account in technological development was limited by the mechanisms that I have discussed above. One important technical feature of the developing method was changed as a result of their influence: the proposed duration of effectiveness. Women’s health advocates’ influence on contraceptive development was considerable in other respects as well. Their involvement in early stages of technology development had a number of significant effects on policy-making and on methodological issues. At the
WHO/HRP, the democratization of contraceptive research and development was thematized, as illustrated by the organization of the Creating Common Ground meetings and the ensuing participation of women’s health advocates in various other meetings and committees. The incipient institutionalization of gender-analysis took form through the Gender Advisory Panel and the Technical Officer for Women’s Perspectives and Gender Issues. The women’s health advocates were especially effective in putting topics on the agenda. The Campaign to Call for a Stop to the Research on Anti-Fertility "Vaccines" contributed to the visibility of many of these topics. The potential for abuse of certain contraceptives and other concerns of the women’s health advocates were discussed by reproductive scientists in their scientific articles in biomedical journals. Before the involvement of the women’s health advocates, the reproductive scientists never addressed these topics. The women’s health advocates also exerted some influence on the ways in which the research was done. They proposed different methodologies and a different scope for doing social scientific research, and actually carried out such research. They also proposed new areas for investigation, such as conducting social scientific research with participants of clinical trials. In the realm of biomedical research, their request to conduct long-term follow-up studies of participants in clinical trials was accepted. Faye Schrater was invited to participate in the Steering Committee of the Task Force, where it was decided what the precise research of the Task Force would be. In addition, the recommendation of the Gender Advisory Panel to involve women’s health advocates in the design, monitoring, and evaluation of clinical trials was adopted by the Programme. The extent to which their proposals and requests will be carried into effect remains to be seen.
Notes by chapter 3

1. In the U.K., the Committee on Safety of Medicines declared beagles inappropriate subjects for contraceptive testing and approved the method. During the 1970s and 1980s the drug was licensed for use as contraceptive in many developing countries as well as a few developed countries (Gelijns 1991).

2. Note that there is no similar history of men and contraceptives. Accordingly, men’s health advocacy groups in the area of reproduction have not developed.

3. These groups and organizations work independently in their own countries. They are active in campaigning and lobbying for better reproductive policies, provide reproductive health services and information, do research on reproductive health issues, and work in journalism, community organizations, trade unions, human rights organizations, etc. By means of the Network, these groups and individuals share knowledge, skills, and experience, and work together internationally to achieve their aims. Network members can request international solidarity through mobilization of the other Network members at crucial moments in their campaigns and activities on reproductive health and rights issues. The Network also publishes a Newsletter and organizes meetings and international actions (WGNRR Newsletter 1997, interview with Stemerding 1:8-15).

4. For example, they recalled this history in their background note to the Meeting between Women’s Health Advocates and Scientists to Review the Status of the Development of Anti-Fertility Vaccines convened by the WHO in August 1992 (WHO/HRP 1993). The 1993 report by women’s health advocate Judith Richter, Vaccination against Pregnancy: miracle or menace? (Richter 1993) also referred extensively to these experiences.

5. Stop Anti-Fertility "Vaccines": International Campaign against Population Control and Abusive, Hazardous Contraceptives. The women’s health advocates involved in drafting the Call for a Stop put "vaccines" in quotation marks to express their dissent from biomedical and social scientists and from policy-makers who suggested that the familiarity of people in developing countries with the vaccination principle would enhance the acceptability of immunological contraceptives (Jones 1986, Griffin and Jones 1991, Concepcion, Mundigo, and Reeler 1991). Women’s health advocates, in contrast, considered that use of this term would obscure the differences between anti-fertility vaccines and anti-disease vaccines (Call for a Stop 1993).
thought that the representation of the new contraceptive method as a vaccine could lead to confusion and eventually abuse (Richter 1993, Wieringa 1994).

6. One illustration of the Population Council’s insight into the relevance of consulting with women’s health advocates occurred in 1997, when the Population Council, together with a group of women’s health advocates, organized a symposium on practical and ethical dilemmas in the clinical testing of vaginal microbicides (Heise, McGrory and Wood 1998).

7. These were Judith Richter, a German pharmacist and women’s health advocate who had worked for many years on the issue of consumers’ rights in Thailand, and Anita Hardon, a Dutch medical anthropologist who had published widely on contested issues surrounding NorplantR and was a founding member of a women’s health advocacy organization.

8. Subsequently, four more Creating Common Ground meetings were convened in Latin America, Asia, and Anglophone and Francophone Africa in the period 1992 to 1995.

9. As the Foreword to the report of this meeting, signed by the then Director of the WHO/HRP, Mahmoud Fathalla, and Joan Dunlop, President of the International Women’s Health Coalition, says: "We are on the threshold of collaboration between the users of technology and the creators of it" (WHO/HRP/ITT 1991, 5).

10. See also the Declaration of the symposium on ‘Contraceptive development for the year 2000 and beyond’ (Declaration 1993) quoted in the Introduction.

11. See also Jones (1994b) and Jones (1996).

12. An impressive amount of social scientific research data is available on mostly women’s use of contraceptives. A wealth of data on patterns of contraceptive use involving a number of demographic variables has been generated by USAID-funded Demographic and Health Surveys. Shah (1995) analyzed the data from the DHS, which entailed findings based on nationally representative samples of 360,000 women of reproductive age in 44 developing countries of Africa, Asia, Latin America, and the Caribbean, in addition to a literature survey. The pharmaceutical industry has also done research on consumer preferences. For example, Ortho-McNeil Pharmaceuticals initiated an annual survey on contraceptive use patterns in 1969 among approximately 8,000 women (quoted in Report of Workshop, 1995). At the Population Council, social scientific research was carried out by its
Research Division, which published the results in its own bimonthly journal, *Studies in Family Planning*.

13. The representations of users that resulted from the surveys seemed to be very difficult to generalize. In addition, this research was repeatedly said to be extremely sensitive to the research methods employed, and to the questions that were asked and by whom (Cottingham 1997). This was generally considered as a methodological and not a political problem.

14. See also Ravindram and Berer (1994).

15. Of course this is one of the central insights of action-research approaches, and the comment has been made by other critical traditions in sociology as well.

16. This was left to the next meeting on Setting the Agenda for Research in Reproductive Health for the Next Decade. "Users' perspectives and needs" was one of the four main areas that this second meeting would consider in the ranking of the Programme's priorities for research and development. The other areas were: feasibility of service delivery; feasibility of the proposed product development; and the product's commercial potential (WHO/HRP 1996b). As compared to the agenda-setting process in the 1970s (see chapter 1), "users' perspectives and needs" figured significantly in the setting of the new agenda for research and development at the WHO/HRP. But the ways in which the users' perspectives of women's health advocates could be integrated into the work of the Programme was not discussed.

17. See chapter 4 for an analysis of the clinical trials with anti-fertility vaccines.

18. For a more encompassing analysis of the concerns of women's health advocates about anti-fertility vaccines, see Schrater (1992) and Richter (1993). See Richter (1995) for an overview and discussion of the activities undertaken by the campaign.

19. To convene such a meeting for scientists and women's health advocates had been one of the recommendations of the Creating Common Ground meeting in 1991. The need to discuss the development of contraceptive vaccines received special mention in these recommendations (WHO/HRP/ITT 1991, 41).

David de Ferranti (World Bank) 29 November 1994, Letter by Duff Gillespie (USAID) 2 December 1994. See also interview with Stevens 1:35.

21. Note that David Griffin acted as both a policy-maker and a scientist. On the one hand, as manager of the Task Force on Immunological Methods for Fertility Regulation, he was one of the central figures in preparing and making policy decisions on the research and development of anti-fertility vaccines. On the other hand, he published in important scientific journals in the field, such as *The Lancet*, *Human Reproduction*, and the *American Journal of Reproductive Immunology*, both alone and together with other scientists working in the Task Force. He also signed his letters as "David Griffin, scientist". This double role is a reflection of the unusual position of the Human Reproductive Programme within the WHO. The WHO is in the first place a policy-making institution, in charge of the development of international standards and norms on health issues. The HRP is to a large extent a research programme, but one that at the same time promotes, coordinates, and supports research, and also conducts and evaluate its own research.

22. See also Talwar et al. (1990): "Comparative phase I clinical trials were carried out in 5 centres with three formulations of beta hCG based vaccines inducing antibodies against hCG. The objectives of these trials were to determine their relative immunogenicity, duration, reversibility and safety". See also Talwar (1996) and Stevens (1997).

23. See also Hardon (1990), Richter (1993) and Schrater (1995).

24. See also Talwar (1996, 397).

25. Thanks to Rein Vos, who suggested this term.

26. See also Call for a Stop (1993) and Wieringa (1994).

27. The individual variation of immune responses was also discussed as "Special problem(s) raised" in Talwar (1994) and as "Application problem to be solved" in Stevens (1996).

28. See also Wieringa (1994).

29. See also Stevens (1996, 154).

30. This team added a stronger adjuvant substance to the injection. The researchers associated βhCG with another antigen, and the resulting, larger molecule, called HSD, would be more immunogenic. They also conjugated
HSD with two different carriers to be used in an alternating sequence in a women's immunization schedule (Talwar et al. 1992, 948; Talwar et al. 1994, 8532).

31. See also Griffin, Jones and Stevens (1994, 111).

32. See also Stevens (1996).

33. See also WHO/HRP 1993, 21.

34. See also Stevens (1990, 563) and Griffin (1990, 521, quoted in Richter 1993, 35).

35. See Jones (1982, 10 and 196), Griffin and Hjort (1985, 272), Thau et al. (1989, 237), Talwar and Raghupathy (1989), Stevens (1990, 344), Griffin and Jones (1991, 190), Griffin (1992, 112), and Brache et al. (1992, 1). These features figure in the same way in policy documents. For example: "The potential advantages of an immunological approach to fertility regulation can be summarized as follows: (a) possibility of infrequent administration possibly by paramedical personnel; (b) the use of antigens or antigen fragments, which are not pharmacologically active; and (c) in the case of antigens of known chemical structure, there is the possibility of large-scale synthesis and manufacture of vaccine at relative low cost" (WHO 1978, 360). See also WHO/HRP 1988 and WHO/HRP 1992.


37. For example: "Given the fact that the world population is increasing at an alarming rate, the development of effective and safe methods for birth control is an urgent and important problem" (Talwar and Raghupathy 1989, 97). See also Jones, Ada and Basten (1985, 288), Stevens (1986a, 162), Stevens (1986b, 374) and Mitchison (1991, 250).


39. See also Richter (1994, 219). Women's health advocates had documented that demographically driven family-planning programmes and contraceptive abuse had taken place especially in developing countries (Hanhart 1995, Sen, Germain and Chen 1994). Abuse of the hormonal implant Norplant also occurred in the United States. Hanhart (1995) mentions that there have been cases of judges offering women who receive social benefit payments a lighter criminal sentence if they agreed to use Norplant, and that legislation has
been proposed which would make welfare payments conditional on Norplant use.

40. See also for example: "Concerns have been expressed by the same womens’ groups about abuse potential of anti-fertility vaccines. (...) The solution to the potential problem of abuse lies in education, improved quality of care in health care service provision, responsible policies and practices by international agencies, governments and health service providers, and improved and increased dialogue between scientists, womens’ health advocates and consumers" (Griffin, Jones, and Stevens 1994, 113).

41. All the recommendations of the SERG meeting were directed towards the performance of clinical research and the provision of methods. The meeting recommended that the WHO/HRP should review the ethical guidelines for doing clinical research and formulate guidelines for the provision of fertility regulation methods. In addition, recommendations were made for implementing these guidelines, such as the organization of seminars and workshops and the installation of monitoring groups in the clinical trials and introductory stages of technology development (SERG 1994).

42. As a representative of Aphoton wrote in a description of its products: "The vaccine is designed to prevent pregnancy for one or two years (being modified to provide six-months protection to be more widely accepted)" (Lyles 1996, 5).

43. Stevens and Jones wrote that one of the potential advantages of the method was: "acceptability of the ‘vaccine’ principle - of particular importance in developing countries" (1983, 233).

44. See also Griffin (1994, 88) and Griffin, Jones, and Stevens (1994, 108).