Conceiving contraceptives: the involvement of users in anti-fertility vaccines development
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Chapter 1
Designing technology for everybody

1. Introduction

Users' involvement in the development of a technology should be studied over its entire life-cycle. Insight into the ways in which users are implicated from the earliest stages on might be helpful in understanding how research and development proceed, and the possibilities and limitations for changing the course of these developments. In this chapter I study whether and how ideas about future users have played a role in the incipient period of the development of anti-fertility vaccines in the 1970s, when a research group was organized and its agenda established.

In the late 1960s and early 1970s the growth of the world population was perceived as one of the major problems of society. In 1972, an international group of industrialists and scientists, known as ‘The Club of Rome’, published a report entitled Limits to Growth, which warned against the dire consequences of uncontrolled increase of population in interaction with economic growth and environmental pollution. The report argued for the achievement of a worldwide balance by, among other things, limiting population growth. Limits to Growth received extensive attention from the media and among policy-makers. Modern contraceptives were seen as a relevant technology to control the growth of population. In the same period, various national and international non-profit organizations were formed as an expression of these concerns about population growth. These organizations became important actors in the field of contraceptive development. The Contraceptive Development Branch of the National Institute of Child Health and Human Development in the United States was formed in 1969; the International Committee for Contraceptive Research of the Population Council in 1970; Family Health International in 1971; and the WHO’s Special Programme of Research, Development and Research Training in Human Reproduction in 1972 (Population Council 1990, 13). The Special Programme of Research, Development and Research Training of the World Health Organization (WHO/HRP) was the first institution to organize a research network for the
development of immunological contraceptives and continues to be a main actor in this field.

As the work of Akrich (1992, 1995) shows, a range of different user representations are produced in the process of designing a technology. Akrich has distinguished a number of implicit and explicit techniques that the designers employ to generate images of future users. These images have to be aligned in the course of the developmental process. In the early 1970s, many different representations of who the future users of immun contraceptives would be, and their disparate characteristics, and the contexts in which the technology would be used, were conceivable. What images were significant in establishing the initial research programme for anti-fertility vaccines? When the policy makers at the WHO/HRP began to organize research and development on anti-fertility vaccines, they were in a position to coordinate the many possible representations of future users. In this early stage of technological development, they invited a number of actors to have a say in shaping the research agenda. I will examine who was enrolled by the WHO/HRP in organizing the programme, and thereby became entitled to present representations of future users, and who was excluded.

A second issue that I want to address is how different representations of the future users of immunological contraceptives were construed by the actors involved, and what their content was. Images of future users of a technology are part of a complex of factors that coevolve with the developing artefact, along with research traditions, material possibilities, the availability of technologies, personal commitments, institutional contexts, ethical considerations, and political affiliations. While Akrich has analyzed the techniques by which such representations are created, she has not explored how the historical contexts of this work enable or constrain the emergence of certain images and not others. This issue is important, since it could shed light on ways to improve the involvement of users. We need to understand how certain perspectives are included in the developing product, while others are eliminated during the process. As an extension of Akrich’s approach, I will analyze the political and institutional specificities that situated the making of user representations for each of the actors involved. Configuring future users was part of the job of translating societal concerns about, e.g., population control into a biomedical research programme. In particular, users had to be represented in such a way as to appeal to the many actors involved in setting up the Programme, without inciting political controversy. Also, while the WHO traditionally has been composed chiefly of medical professionals, research into drug development was a new activity for the organization. The need to enroll biomedical researchers, oscillating between their basic research interests and their aspirations to be involved in the contraceptive development programme, also affected the ways in which future users were envisioned.
Because of these dynamics in the process of establishing a research agenda, it was likely that some images of users would be reinforced while others would disappear or simply never surface. In Akrich's elaboration of the script approach, this question of how certain representations of users become more influential than others is not addressed. I will examine how particular representations of users became embedded in the institutional context of contraceptive research and exerted a considerable influence on the development of new fertility-regulating methods. The need for reconciliation, for agreement upon a representation of users, conditioned the way in which the future users of anti-fertility vaccines were imagined.

In order to further demonstrate how representations of users can accomplish the (implicit and explicit) guidance of researchers' work, Joan Fujimura's concept of the doability of research (Fujimura, 1987) is very appropriate. Fujimura (1987) describes the achievement of doability by the alignment of three levels of work organization: the social world, the laboratory, and the experiment. Scientists make these levels fit together through a process of articulation: the organization and coordination of resources, the planning and allocation of tasks, and the structuring and labelling of problems. Fujimura asserts that by the creation of packaged pieces of work, such as physical apparatus or standard procedures, the amount of articulation work between levels decreases, and this in turn facilitates making research problems doable. I will argue that representations of users of the future technology can also be considered as packages of work, and that their alignment also facilitated the making of immunological contraceptives development into a doable research problem. The function of representations of users in reaching alignment between the various levels of work organization had consequences for the ways in which the users could be imagined. Finally, other functions of the representations of users will also be explored.

For this chapter, I will concentrate on the creation of a research group and its research programme on immunological contraceptives at the World Health Organization in the early 1970s. First, I describe the actors who brought their users' representations into the setting up of the Programme and I analyze how some of these spokespersons became more solidly embedded within WHO than others. Then I will characterize the nature of these representations. I conclude by analyzing the functions that representations of users accomplished in the emerging research on immunological contraceptives.
2. The WHO’s setting up of research on immunological contraceptives

2.1 Criteria for determining priorities

The birth of the Special Programme for Research, Development and Research Training in Human Reproduction (hereafter WHO/HRP or the Programme)1 can be dated in November 1971 when the first meeting of the Advisory Group to the Programme was held. Before then, the WHO had been primarily a policy-oriented organization, and conducting research would be a new kind of activity. At the request of member states of the WHO, a feasibility project was conducted between November 1970 and April 1971 to look into the viability of an international agency like the WHO undertaking research in the area of human reproduction. As Nelly Oudshoorn (1994) describes in her history of the making of the pill, the subject of family planning had been a controversial area of research. This was partly due to its relation with the taboo-laden subject of sexuality.2 In the 1960s, the status of family planning had begun to change. The governments of the United States and Europe came to recognize population growth as a problem in itself, and fertility-regulating technologies as a possible solution (Clarke 1990 and 1998). Research on fertility-regulating methods therefore began to receive increasing support and legitimacy. The WHO played an active part in achieving this transformation by defining the deficiencies in knowledge about human reproduction as a major public health problem and therefore an appropriate area for the attention of this organization (Oudshoorn 1997).

The feasibility project was financed by one of the member states, Sweden, and the Ford Foundation. For this project, staff and consultants at the WHO held discussions with scientists, research strategists, and administrators at 70 institutions in 23 countries (Kessler 1992, 47-48). Subsequently, the Special Programme was set up. An Advisory Group consisting of people with extensive experience in contraceptive-related research was invited to a series of consultations on the design and function of the Programme. The eleven biomedical scientists clearly outnumbered the one sociologist/demographer in the Advisory Group. Almost immediately after its foundation, the problem of determining priorities became acute for the WHO/HRP. The Advisory Group of the Programme specified the following factors to determine the suitability for inclusion in the Programme of any particular component or line of research:

1. Demand: explicit requests from the WHO Member States, donors, intergovernmental agencies other than WHO;
2. Need and scientific rationale: as perceived by the scientific community;
3. Applicability: extent to which the results of the activity could be expected to have an impact on family planning;
4. Rationale for WHO for being involved: distinctive contribution expected because of WHO’s intergovernmental and impartial nature;
5. Feasibility: given available knowledge, manpower, and facilities and, for institution strengthening, the extent of governmental commitment;
6. Time and cost: financial investment and length of time needed to complete projects;
7. Duplication of work: whether research was also being conducted by other agencies, industry, etc. (Kessler 1992, 51; WHO/HRP/AG 1979, 6-8).

This is an intriguing list. It shows us which spokespersons were enrolled into the WHO/HRP’s decision-making, and which other actors were not. The list indicates who was entitled to bring representations of users into the research on fertility regulation. Items 1 and 2 explicitly mention some of the spokespersons whose needs and demands were to be taken into account: member states and the scientific community. Item 3 does not mention a specific actor; on the contrary, it omits to indicate who is to speak for the impact on family planning. Would these be organizations in the field of family planning, providers of health care, or any other candidates? Items 4 to 7 are of a distinct order. That reflects the way in which the WHO perceives its role as an intergovernmental organization acting as a directing and coordinating authority for international health matters, with the HRP supporting research and institutional strengthening in the area of fertility regulation. These items also point towards the WHO/HRP’s position in the international field of research on fertility regulation.

Let us now examine more closely the two highest-ranking criteria on this list, and identify which other spokespersons the WHO/HRP enrolled to bring their user representations to the stage. Which spokespersons became dominant?

2.2 The WHO/HRP’s spokespersons

Demands of member states

The most important criterion was the demands of member states. Member states make their wishes known through the World Health Assembly, directly to the Programme, through the WHO’s Regional Committees, and through ad hoc consultations at national and regional levels (WHO/HRP/AG 1979, 4). The WHO is an intergovernmental organization, and the requests of member states are its raison d’être. Some member states are major donors to
the Programme, and it is therefore not surprising that their suggestions for areas of needed research received consideration. But to operationalize their demands was not an easy task. The member states differed widely in their requests. As the Programme states in its specification of this first criterion:

In a sense this is a political criterion. The difficulty lies in rating the political importance to the Programme of requests from different sources, e.g. one request only, but from a large country such as India, or five requests from small African Countries, or from the Vatican (WHO/HRP/AG 1979, 6).

There were considerable differences in the viewpoints of the member states. According to the introduction to the 1979 Annual Report:

The hardware enthusiasts consider that the answer to the problems arising in family planning lies in better birth control technology (...). The software advocates point out that, where motivation is high and the service infrastructure satisfactory, currently available methods are largely adequate. (...) The third group recognizes the shortcomings of both hardware and software, and their mutual interdependence.(...) All three viewpoints are represented among the Member States of WHO (WHO/HRP/AR 1979, 7-8).

This multiplicity of demands of member states had to be structured into the Programme. Within the Programme, a range of Task Forces was set up by the Advisory Group. A Task Force consisted of an international, interdisciplinary group of scientists and clinicians collaborating in research oriented towards a specific set of predetermined goals and objectives (Griffin 1991, 166). When new demands from governments and donors arose, such as the assessment of currently available fertility-regulating methods, or problems of delivering family-planning care, new Task Forces were set up (Kessler 1992, 50). In this way, consensus was maintained. As a consequence, separate Task Forces were created for the study of the safety and effectiveness of current methods of family planning and the development of new birth control technologies, on the one side, and the acceptability of different methods of fertility regulation on the other. Meetings for the coordination of the research with other agencies involved in family planning (such as UNFPA, the World Bank, the Population Council, etcetera) were convened along these same lines: one to deal with biomedical studies, and another for psychosocial and service delivery research (Kessler 1992, 56). To maintain its status as an apolitical agency, the WHO/HRP had to practice an encompassing strategy at the policy-making level. Different voices from the member states were addressed through separate working areas in Task Forces, so that confrontations between opposing forces could be avoided. The relative strength of biomedical
research and psychosocial and service research was by no means equal. For example: in 1976, of the US$ 10 000 000 available for research and development, only US$ 700 000 were set aside for the latter two areas (Kessler 1992, 56). The biomedical perspective of hardware enthusiasts acquired a better-equipped position than that of their psychosocially oriented colleagues.

Need according to the scientific community

The second item on the list of criteria for priority setting was the determination of need and scientific rationale as conceived by the scientific community. Who was included in this scientific community and what status did they enjoy vis-à-vis member states?

The research component of the Programme was structured in three broad areas: the safety and effectiveness of current methods of fertility regulation; the development of a variety of new methods; and the psychosocial aspects of family planning. The scientific community took the lead in the area of the development of new methods. This is reflected in the 1979 Annual Report of the Programme. The need for psychosocial and health-service research was underscored in general terms by referring to the wide recognition of its importance. Similarly, the research on currently available methods was reported to have been demanded by a whole range of actors, including the World Health Assembly, individual member states, multilateral organizations, national agencies providing contraceptives to developing countries, and lastly, clinicians and scientists. In the development of new methods, however, biomedical scientists were clearly in evidence. According to the HRP's 1979 Annual Report, in its section on 'Research and development of new methods':

The scientific community continues to be practically unanimous in pointing to the dangers and crudeness of presently available birth control technology, and of its failure to meet the wide range of individual needs, cultural requirements and service constraints. In the past year, this point of view has been expressed repeatedly and eloquently by such authorities as Diczfalusy (Diczfalusy 1979), Djerassi (Djerassi 1979), Segal (Segal 1979) and Short (Short 1979) (WHO/HRP/AR 1979, 69).

The scientific community was represented by a number of influential Western biomedical scientists. In contrast with the very general and dissenting demands of member states, these biomedical scientists readily agreed upon their far more specific needs. One of the scientists who became involved in the establishment of the Programme in 1972 was the physician Patrick Rowe.
Rowe had formerly worked for the pharmaceutical firm G.D. Searle, and had been in charge of the company’s clinical research. He said:

The donor countries never told us to have these specific Task Forces formulated. They agreed on the overall objectives of the Programme (...). We were looking at a number of different research leads. When you get into the more scientific and more sophisticated area, you have a steering committee that assesses these research lines (...). The recommendations of the committee were then endorsed by the Director of the Programme and by the Director General of WHO (interview with Rowe 1;3-4).

These steering committees consisted of mainly biomedical scientists. While the member states voiced a general demand to develop new methods for fertility regulation, the needs according to the scientific community were to provide an answer to the question of which methods should be developed. Therefore, they were in a favorable position to attune their interest in developing new methods to the needs that they perceived in the field of fertility regulation.

Immunological contraceptives were very attractive to both the WHO Programme and to scientists. In 1972 in Alma Ata, the WHO had adopted Primary Health Care as a general approach to achieve Health for All in the Year 2000. This Primary Health Care strategy included family planning as a basic component (Alma Ata Declaration 1972). Immunological contraceptives could be presented, on the one hand, as low technology, by emphasizing the method’s ease of provision by paramedical personnel in family-planning programmes, its simplicity of use, and the low costs (WHO/HRP/AR 1976, 6; WHO/HRP/AR 1978, 3). This profile of immunological contraceptives fitted the features of a Primary Health Care strategy. At the same time, the immunological approach to family planning was totally new. Therefore, on the other hand, the scientists could argue that a large number of basic research questions needed to be answered (WHO/HRP/AR 1974, 24; WHO/HRP/AR 1975, 11). Scientists of the Task Force on Immunological Methods for the Regulation of Fertility pleaded for the inclusion of this basic research in the Task Force’s research programme. For example, at their first meeting in July 1973, they stated:

It is apparent that we need additional information on the immune response to a variety of antigens as it is evoked in various components of the female reproductive tract (...). We propose a meeting of suitable workers and experts in the field to consider such topics (SC minutes 1973, 24).

Subsequently, the Programme did convene a Symposium, in which the scientists discussed the issue of their need for more fundamental research.
The veteran scientist and WHO consultant Egon Diczfalusy introduced the meeting and prudently addressed the importance of more basic research in the field of the two major disciplines involved, reproductive biology and immunology. According to Diczfalusy:

The role of these highly specific proteins in human endometrial function in general and in the process of implantation in particular remains to be established. Their continued study may perhaps offer a new lead for the development of an immunological method of fertility control (Diczfalusy 1975, 22).

And a little later he added:

Indeed, a better understanding of the underlying immunological phenomena might offer a promising lead for the development of new methods for interfering with implantation (Diczfalusy 1975, 25).

The different strategies that reproductive scientists involved in developing new contraceptive methods applied to maintain their professional autonomy has been extensively studied by the American sociologist Adele Clarke in her book *Disciplining reproduction: modernity, American life sciences and 'the problem of sex'.* (Clarke 1998). Clarke has examined the emergence of the field of reproductive sciences in the period up to the 1960s and analysed three related strategies. First, reproductive scientists distinguished reproductive from contraceptive research. This also was important in distancing their enterprise from the then socially ‘illegitimate’ birth control movement. Second, they argued in favor of basic instead of applied research as the foundation from which applications would ultimately flow. And third, they redirected contraceptive research from simple to scientific methods, as their interests were primarily scientific. On the basis of these strategies, reproductive scientists were successful in insisting that the culture of science be associated with contraceptive technology, and in negotiating an advantageous *quid pro quo* with the birth control/population policy movement. Reproductive scientists provided legitimacy to the field, as well as major modern scientific means of contraception. They could maintain their professional autonomy to go on doing what they thought was scientifically most challenging, and simultaneously gain considerable funding and support (Clarke 1998). Here we see that research into immunocontraception fitted well into these patterns, and that this way of doing reproductive science was perpetuated after the period studied by Clarke. The Australian gynecologist Warren Jones reflected precisely this need to match the interests of the biomedical scientists with the demand perceived in the field of family planning when he wrote on immunological contraceptives:

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This approach to fertility regulation must be translated from a philosophically and scientifically irresistible exercise to a goal-oriented programme capable of critical analysis in terms of feasibility, acceptability and cost-effectiveness (Jones 1982, 195).

The volatility of the non-existing method, prone to be presented simultaneously as low-tech and as requiring a lot of complex basic research, meant that immunological contraceptives could meet the wishes of scientists and the WHO/HRP alike. Moreover, doing research, especially biomedical research on a considerable scale, was a relatively new activity for the WHO (Kessler 1992, 50). This created a space in which biomedical scientists could become the backbone of the Programme, which depended heavily on their notion of promising research leads. The scientists were thoroughly aware of their position. As Robert Short, one of the biomedical authorities cited in the 1979 Annual Report of the WHO/HRP, said in his opening remarks to a joint symposium of the Society for the Study of Fertility and the WHO:

(... ) let us remember that WHO is us (Short 1979, 221). 8

This leads us to the third criteria for the WHO/HRP’s setting of priorities: applicability. Who was in charge of assessing applicability?

Comparable current methods

The third criteria of applicability that the Advisory Group formulated explicitly related the work of the Programme to the context of family-planning programmes. But the WHO/HRP did not specify who would elaborate this criteria. Strikingly, it was not organizations of family-planning programmes that would give voice to the criteria of applicability within the Programme. The Advisory Group had definite ideas of its own about what kinds of studies could be expected to have an impact on family planning:

For example, for current methods, high rating would be given to safety and effectiveness studies of methods practised on a wide scale or to studies removing fear from an otherwise highly acceptable method. For new methods, this rating reflects the extent to which the new method is an improvement over the most closely comparable current method and also the extent to which it would increase the number of family planning acceptors (WHO/HRP/AG 1979, 7).

Thus, current fertility-regulating methods provided standards for the applicability of research into a new method. Akrich (1995, 174) also describes this technique of representing users by "calling up the particular representation of the user incorporated in the comparable product.". But current
fertility-regulating methods cannot speak, and thus depended on actors entitled to "call up" users of products defined as comparable. By channeling the assessment of applicability through comparable existing products, the range of actors authorized to appraise this criteria was extended beyond family-planning programmes. Evaluating applicability no longer depended on experience in applying fertility-regulating methods, but on being able to call up a comparable product. In this way, the expertise of family-planning programmes was degraded and other actors could appropriate the assessment of applicability. The marginalizing of the expertise of family-planning programmes also had another effect: the supply of products that could be declared comparable was extended beyond fertility-regulating methods to include other products that could be defined as having something in common with the new method at hand, such as for example anti-disease vaccines. I will show later that the biomedical scientists who were designing immunological contraceptives relied extensively on the technique of representing users by reference to comparable other products.

What happened to the other actors who could have claimed competence in assessing applicability: social scientists?

Social scientists: a variety of needs

The Programme also employed an explicit technique to generate representations of users. The initial Advisory Group to the Programme foresaw a role for social scientists. Social scientists were expected to indicate what would make a fertility-regulating method acceptable for family planning. As the then director of the WHO/HRP, Alexander Kessler, wrote:

There was also to be a Task Force on the characteristics of different methods of fertility regulation that affect their acceptance in various sociocultural settings: social scientists were to provide specifications for desirable methods to be realized by their biomedical colleagues (Kessler 1992, 48).

Two of the Task Forces that were established involved social scientists. The Task Force on Psychosocial research in family planning focused on a range of cultural, social, economic, and psychological factors that influence couples’ decisions regarding the timing, spacing, and number of births, and their use of family-planning services (WHO/HRP/AR 1979, 89). And the Task Force on Health Service research in family planning developed strategies and approaches to the delivery of family-planning care and to the assessment of their efficacy and impact (WHO/HRP/AR 1979, 98).

One of the main findings of these Task Forces over the years was the great variability in users’ needs and preferences. For any of the contraceptive
methods studied, users’ expressed preferences varied widely among countries and specific settings. This finding, which could not conflict with anything or anybody, was readily adopted by the Programme:

The Advisory Group reaffirmed the objectives of the program:
- To provide Member States with a variety of safe, effective and acceptable fertility regulating methods to meet differing needs and different situations (...) (WHO/HRP/AR 1976, 6).

Note that the need for the availability of various methods does not necessarily imply the development of new methods. But the discourse on the diversity of users’ preferences in different settings provided by the social scientists reinforced the legitimation of the need for new methods. The biomedical scientists reasoned that a variety of methods was the appropriate solution to meet the diverse needs and preferences of users. They could therefore formulate the problem in terms of the need for new fertility regulating methods:

Improved and new methods. The search for an ‘ideal contraceptive’ has long been given up by those familiar with the field. What is needed is a wide variety of methods (WHO/HRP/AR 1977, 7).

In order to further legitimize the development of new methods, the biomedical scientists needed to define a product specification that would correspond to a demand. They therefore needed some clues about users’ needs and preferences. If the explicit techniques of the social scientists had been the only source of information on the acceptability of contraceptive methods, biomedical scientists could have selected from among the preferences that the social scientists identified. They could have ignored other users’ preferences noted by the social scientists, on the grounds that they were not developing the ideal contraceptive anyway. However, the biomedical scientists needed some reassurance that the new immunological methods they envisioned would indeed be acceptable. Therefore, an additional implicit technique became articulated through another actor in the WHO/HRP: the clinicians in the Steering Committees of the Task Forces.

Clinicians as spokespersons for users

Each Task Force had a Steering Committee. The Steering Committees would met approximately once a year to figure out what the precise research of that Task Force should be, to generate research proposals and identify appropriate people, and to discuss the results as they came in. The Steering Committee of the Task Force on Immunological Methods for the Regulation of Fertility was composed of reproductive biologists, immunologists, and
clinicians. The clinicians would advise the Task Force on the design and the execution of clinical trials, and interpret the results. But the clinicians in the Steering Committee had a dual task. As David Griffin, manager of the Task Force on Immunological Methods for the Regulation of Fertility since 1975, recalls:

They were expected to provide their own expertise, and many of them were research clinicians who knew what the research process was about and they were engaged in the research and so. But they were also looked to by the pure scientists, who are working in academic laboratories, who never come across patients in their work, as somebody who should be able to reflect the likely responses of people in their clinics if these methods were available. It was an interface, but it wasn’t (...) based on any valid data. The sort of things we would expect them to say is: ‘for God’s sake, don’t develop a vaccine that is going to inhibit ovulation or that is going to disrupt the menstrual cycle’. This kind of very broad issues. But they were never recorded in there [in the minutes of Steering Committee meeting, jvk] (interview with Griffin 1;86-87).

Thus, clinicians were expected by the other scientists to act as spokespersons for users. Various authors have pointed to the ‘dual mission’ of clinical practice in producing medical technologies and knowledge. Clinicians have both a professional and a scientific assignment: to care for their patients and to develop knowledge claims. They therefore can shift their framework and use both scientific arguments and arguments based on clinical experience (Gelijns 1991, Hiddinga 1995). In the development of immunological contraceptives, clinicians came to embody this reciprocal relationship between science and practice in the clinic. They alternated between representations of users without making them explicit, i.e. by setting down their statements on users in minutes or other texts. By providing minimal specifications, the clinicians made an important contribution to the alignment of the social worlds of clinical practice and technology development, by articulating their dual representations of future users.

In sum, I have described how member states, biomedical and social scientists, and clinicians were enrolled in the WHO/HRP. Spokespersons for family-planning programmes were not enlisted. Within the organizational structure of the WHO, biomedical scientists achieved an advantageous position to promote their perception of needs in the field of fertility regulation, i.e. to develop new methods. The clinicians held a special position in the Task Force. They owed this position to being able to give the scientists indications about whether a new method would be useful in the clinic. The representations of users of other candidate spokespersons became less well
embedded in the institution. Member states and donors to the Programme, although formally at the top of the organization, were in practice too divided to direct the course of the research programme. The social scientists were relegated to separate Task Forces from which their very general recommendations to offer a variety of methods were not threatening to the biomedical scientists. On the contrary, the biomedical scientists could mobilize these recommendations to justify the development of new methods. Importantly, no representatives of contraceptives users in what Akrich (1995, 168) calls the "political sense" were present in the establishment of the WHO/HRP. The obvious candidates to act as political representatives of users would have been people involved in the women’s health movement. But in the 1970s women’s health advocates were not yet enlisted by the WHO/HRP to contribute their representations of contraceptive users. Users were, however, brought into the setting of priorities for research areas by means of various representations. Here I will discuss the contents of these representations of future users that the various spokespersons of the WHO/HRP brought to the stage.

2.3 Representations of users in setting up the Programme

Both the social and the biomedical scientists made use of the opportunity to define new products in terms of their relation to comparable existing products. Both groups rated the speculative character of acceptability assessments of non-existing methods as a major methodological problem. Social scientists sidestepped this perceived methodological difficulty by studying the acceptability of the attributes of existing methods. They issued questionnaires to the clients of family-planning services. Their interviews dealt with attributes such as, for example, the timing and duration of use, perceived effectiveness, probable effects on menstruation, and the reliability of the methods (WHO/HRP/AR 1979, 91-94). By focusing on such characteristics, the social scientists further specified the level on which fertility-regulating products could be compared. Of course, studying the attributes of existing methods is not the only way to analyze the acceptability of new methods. If women’s health advocates had been enrolled at this stage, they might have proposed different ways to learn about users’ needs and preferences. On the basis of the critique of the development and provision of contraceptives that they had voiced since the 1960s, they might have pointed out the importance of studying the contexts in which contraceptives would be used, and the issue of women’s health and rights. From the perspective of women’s health advocates, other possibilities to generate representations of users might have emerged, such as focusing on the users, or pointing out repeating mechanisms in contraceptive use, or to defining relevant categories.
of users. The social scientists failed to examine the trade-offs between the attributes negotiated by the users. As a result of the specific way in which the social scientists studied the users, the technical artefact itself was highlighted, and not its uses or its contexts or its meanings. As against any of the other possibilities, the decontextualized attributes identified by the social scientists fitted nicely into the researchers’ framework of concentrating on the artefact. These attributes were exactly at the level of specification that the biomedical scientists required to conceive an appealing product profile for the non-existing immunological contraceptives. At most, the contraceptive developers announced that this novel method would be long-acting and easy to use (Diczfalusy 1975, 32; Talwar 1976, 129; Hearn 1976, 158). There was no need to specify to whom those attributes would be attractive.

Indeed, the lack of specification of intended users or contexts of use had a number of advantages for the researchers and the WHO/HRP. For if they had specified that the method was meant for a certain category of people of, for example, a certain sex, region of the world, or stage in their reproductive life cycle or socio-economic stratum, this could have diminished the versatility of the artefact that enabled them to address many audiences. In addition, for the WHO/HRP it was politically difficult to direct their endeavors explicitly towards the category of "people in developing countries". This had become very clear at the international government meeting on population in Bucharest in 1974. Here, the relation between control of population growth and development was vigorously debated. Government representatives of developing countries argued that the emphasis on population control was a means for rich countries to shirk their duty to provide substantive support for economic development. Development was the best contraceptive, they declared. Also, the fact that abusive situations in the testing and introduction of modern contraceptives had occurred particularly to poor women in Third World countries meant that the addition "particularly in developing countries" needed to be handled with care. In an interview in 1995, Griffin was cautious to explain:

When we say "particularly in developing countries", I think that on the occasions that we used that in the past, it was really meant to reflect what the overall goal of the WHO Programme is: to provide methods that are suitable for users in developing countries. In other words, which address the needs of developing countries, taking into account the expressed preferences of users as well as the capabilities of the health care delivery system. Now, that doesn’t mean to say that these are methods which would not be acceptable anywhere else in the world. When we develop methods we make sure that they are developed to the highest possible standards that would be acceptable anywhere in the world (interview with Griffin 1;27).
To say explicitly that a method would be especially suitable for users in developing countries was politically sensitive. It could be misunderstood as sanctioning the development of qualitatively inferior methods for this category of users. This interpretation was possible because a prior frame of reference existed, constituted on the basis of specific historical problems with contraceptive use and testing on poor women in developing countries. For the same reasons, the researchers and the WHO/HRP did not mention specific contexts in which a given method would be particularly useful or irrelevant. This explains why the continuity of work to develop immunological contraceptives was not affected by, e.g., the appearance of the HIV-pandemic in the 1980s. The contraceptive developers did not differentiate any specific category or context of users, and it could be argued that the new methods would serve "the betterment of mankind" (Segal 1976, 126) or "individuals worldwide" (Griffin 1992, 111). Focusing on certain attributes of contraceptive methods and leaving out the particular contexts in which these were to be used provided them with the space to construct, and if necessary to reconstruct, the universal acceptability of the new method.

The member states provided representations of users as well. The demands of member states were further specified in the 1978 Annual Report of the WHO/HRP, which stated that the research of the Programme

(…) aims to meet the expressed needs of Member States for technology for family planning and infertility cure that is safer, more effective, better adapted for the needs of their populations (WHO/HRP/AR 1978, 3).

In this early stage of the foundation of the Programme, the demands expressed by member states were understood to represent the needs of their population. Some states have a compelling interest in regulating the rate of increase of their populations. From the perspective of these states, the population at large would benefit from measures to bring down demographic trends. The product profile that the researchers proposed, a method that would be long acting and easy to administer, was therefore very attractive to them. Population policy programmes are apt to be directed towards women in developing countries (Hartmann, 1987). Betsy Hartmann pointed out that "emphasis on population control profoundly affects how family planning programs are organized and implemented in the field." (Hartmann 1987, 60). It also has a major impact on the way in which contraceptive technologies are developed.

One other representation of users had to be articulated in this process of reconciling different definitions of users: that of the clinicians in the Steering Committee on the Task Force for Immunological Methods for Fertility Regulation and the clinicians in the advisory board of the Pro-
gramme. Not surprisingly at that time, they were gynecologists/obstetricians and not andrologists.\textsuperscript{11} Traditionally, gynecologists have specialized in the reproductive functions of the female. Andrology, gynecology's counterpart for the male body, did not become an established profession until the mid-1970s and has remained a marginal field up to the present. With this particular medical specialty taking charge of indicating the practicality of new methods in the clinic, representations of female users were more likely to be put forward than representations of male users of contraceptives.

In sum, there was no need to be explicit about the intended end-users of the new methods. By being too specific about for whom and for what settings the new methods were being developed, the researchers could lose their highly desired flexibility. Instead, it was in their interest to imply that these methods would suit everybody in any context. The representations of users supplied by the social scientists were adopters and rejectors of existing contraceptive methods. The member states envisioned subjects of population policy. And the representations of users provided by the clinicians were visitors of family-planning clinics.

The number of Task Forces that the WHO/HRP established in this initial period fluctuated around twenty. Among them was the Task Force on Immunological Methods for Fertility Regulation. Now I will analyse what functions representations of users accomplished in the Programme. How did representations of users determine the organization of certain parts of the research and not others through this specific Task Force? And why did the Task Force concentrate on a certain type of immunological contraceptive?

3. The Task Force on Immunological Methods for Fertility Regulation

Biomedical scientists played a key role in the establishment of the Task Force on Immunological Methods of Fertility Regulation. Who were these scientists who introduced research on immunological methods to the WHO/HRP? What functions did their specific representations of users perform in the WHO/HRP's adoption of a major segment of the development of immunological contraceptives?

In the early 1970s, two scientists contributed decisively to the progress of research on immunological methods for fertility regulation: Vernon C. Stevens in Columbus, Ohio, in the United States, and Gursaran P. Talwar in New Delhi, India. By comparing the representations of users of these two scientists, I will illustrate the role of representations of users in defining the institutional workspace in which the research was carried out.
An alternative to the Pill

Vernon Stevens at Ohio State University (Columbus, U.S.A.) was trained as a reproductive biologist. In 1962, he received a grant from the pharmaceutical company G.D. Searle to test compounds for an alternative contraceptive pill. The U.S. Food and Drug Administration had approved the first oral contraceptive, Searle’s Enovid®, in 1960 (Gelijns 1991, 166). The acceptance of Enovid® as an officially approved drug did not mean that testing and developing had come to an end (Oudshoorn 1994, 134). Though initially Searle had the oral contraceptive market all to itself, by the mid 1960s Syntex - through its two licensees Ortho and Parke-Davis, as well as through its own sales force established in 1964 - had gained a major share of the U.S. oral contraceptive market (Djerassi 1979, 252).

In this context, the drug company G.D. Searle became interested in the use of contraceptive pills in other countries. In 1964 the company sponsored Stevens on a journey to visit clinics in various countries: Italy, Greece, Turkey, Lebanon, Pakistan, Egypt, Thailand, and Singapore. The trip ended in Sydney, Australia, at a symposium on the introduction of oral contraceptives. As Stevens said:

“I realized that the education and motivation of women in developing countries to take the Pill in the prescribed way was insufficient. Moreover, there were the costs; at that time the Pill could cost the equivalent of a whole years income.(...) At the symposium, the clinicians pointed out all the medical problems and the side effects; there were still a lot of problems at that time (interview with Stevens, 2;1).

(...) And that is when I became aware of the fact that, however tremendously new additions to the opportunities for birth control methods were made, that they weren’t going to satisfy all the needs, that there were more needs. And then I started looking for alternative ways, and that was how I got involved in immunological methods (interview with Stevens, 1;4).

From the initial testing of oral contraceptives in clinical trials onwards, the scientists had had a difficult task in disciplining women to take the pill in the prescribed manner (Oudshoorn 1994, 125-132). The costs of the then available compound and the occurrence of side effects prompted further research. Stevens saw the immunological means of birth control as an alternative to oral contraceptives: requiring less discipline from users than the pill, less expensive than the pill, and with fewer medical side-effects. In the late 1960s, Stevens was trying out different possibilities to develop an immunological method to regulate fertility.

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Oudshoorn pointed out that although the pill was developed as a universal, context-independent contraceptive, it nevertheless contained a specific user: "a woman, disciplined enough to take medication regularly, who is used to gynecological examinations and regular visits to the physician, and who does not have to hide contraception from her partner (...) This user is more likely to be found in western industrialized countries with well developed health care systems." (Oudshoorn 1996, 161). By the same token, less educated and motivated women with less purchasing power, for whom Stevens conceived his alternative approach, are more likely to be located in the setting of developing countries. Stevens’ representation of the users nicely matched the WHO’s mandate to direct its efforts especially to the needs of developing countries. Immunological methods were attractive to the WHO/HRP because the users that these contraceptives promised to address were the poor and less motivated women in developing countries. The WHO’s new Programme also became a first-rate option for Stevens. As Rowe remarked:

The company was uninterested. They were into hormonal contraception and they didn’t have any expertise in terms of immunology. (...) And it got at stages in Stevens’ work that he needed to get some external funding. Because baboons are expensive animals (interview with Rowe 1;1-4).

Like most pharmaceutical industries, the company concentrated on the safer strategy of improving oral contraceptives for the home market. Contraceptives are meant to be used by healthy persons for about 15-25 years of their lives. In comparison to drugs taken for acute disease conditions, the regulatory requirements for contraceptives are more stringent. Undesirable side-effects that may be considered admissible for drugs in life-threatening situations are not acceptable for contraceptives. As a consequence, developmental costs increase, while effective patent life decreases. This diminishes the pharmaceutical companies’ prospects of vast profits. In addition, the women’s health advocacy movement had raised concerns about the health effects of the Pill and the Dalkon Shield®. Also, the so-called "pro-life movement" was becoming more vocal, rendering the public climate inhospitable to innovation. The litigious public climate and the increased costs of liability insurance made this long-term high-risk research particularly unattractive to them (Djerassi 1979, 85; Bardin 1987; Gelijns 1991).13

Other suitable partners would have been any of the other major non-profit institutions that supported research on contraceptive methods especially for developing countries, like the Population Council, the U.S. Agency for International Development, or National Institutes of Health. However, these U.S. based and partly U.S. government-funded institutions refrained from

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supporting research that could be considered abortion-related. And this was the case with Stevens’ immunological approach using human Chorionic Gonadotropin (hCG). hCG is a hormone produced by the fertilized egg, i.e. it would be a post-fertilization method.14

**Immunological contraceptives gain access to the WHO/HRP**

In 1971 and 1972, the WHO/HRP organized a series of meetings at which biomedical scientists defined what kind of projects deserved support. At a consultation in August 1972 in Boston, the feasibility of interfering with specific placental proteins at the time of implantation was discussed as a method of contraception (SC minutes 1973, 6). Just before this, Patrick Rowe had moved from G.D. Searle to the WHO to set up the Programme, and he invited Stevens to this meeting (interview with Rowe 1;2, interview with Stevens 1;5). Here, Stevens presented his pioneering work on immunological interference with the placental protein hCG.15

Stevens’ contribution to developing potential human applications for immunological birth control required coupling a hormone (or body constituent) necessary for reproduction to another substance. The combined molecule appears foreign to the immune system and elicits an immune reaction, not only against itself, but also against the non-altered hormone (or body constituent) (Stevens, 1973).16

Stevens:

In the mid 1960s I established the fact, that by chemically altering substances that were yourself, you could make them so that your body would raise immunity against them.(...) And then for some years thereafter I was looking for a target to use this principle again. I studied a lot of antigenic materials that compose the reproductive system. (...I was just starting to focus in on hCG when the WHO Programme began in 1972 (interview with Stevens 1;5).

Stevens had generated some data that nobody else could yet equal. He had developed the theory and conducted early experimentation with his hCG-based preparation; he had done laboratory work and set up a baboon colony. In addition, Stevens presented the findings from a clinical study in the pharmacological properties of his preparation. According to Stevens:

The main thing was that we had preliminary data from a clinical trial to suggest that it would work (...I in 1972, I took to them some data that I had generated before, that convinced enough people who took part in the decisions that this was a viable approach to develop new methods (interview with Stevens, 1;52/2;2).
Stevens had conducted a clinical trial with female prisoners in the United States before he was invited by the WHO. The data obtained in this study had not been published. These results were presented at the consultation meetings where the Programme was set up (Stevens, personal communication 1996). Stevens had demonstrated that injection with the altered hCG effectively induced the formation of antibodies against unaltered hCG. The hormone hCG is necessary to preserve early pregnancy. It could be expected that antibodies against hCG would dispose of the hormone and thereby interrupt the establishment of pregnancy. This study suggested for the first time the applicability of an immunological approach to interference with human reproduction. This first clinical trial also had an unexpected and less desirable effect. Subsequent studies showed that the clinical trial participants did not ovulate, and that this could be an effect of the immunization with the altered whole hCG (Stevens 1975, 364-365). Next, a more carefully designed study with control data was conducted (Stevens and Crystle, 1973).

Stevens’ approach was not readily embraced by the Programme. Early in 1973, Stevens presented his data again, this time before a panel of expert immunologists at Rockefeller University in New York (SC minutes 1973, 6). In the audience were two Nobel laureates in immunology who were supportive of Stevens’ idea. The then director of the HRP, Alexander Kessler, had been working at Rockefeller University before he moved to the WHO to set up the HRP, and he therefore knew and greatly respected these scientists (interview with Stevens 1;52 and 2;2). After this presentation a definite plan of action for the Task Force was drawn up (SC minutes 1973, 6). In July 1973, Stevens received his first funding from the Programme and his work has been supported since then.

Shortly before, the Programme had agreed to place emphasis on research and development efforts likely to yield results within a reasonable period of time (Kessler 1992, 50). What was special enough in this new approach to change the recently established plans to give priority to short- and medium-term research?

The WHO expected that the projected immunological method would meet all the requirements of an alternative for the pill. In the 1976 Annual Report of the Programme:

A vaccine for fertility regulation has long held great appeal: it could provide long term protection, be relatively simply to administer by paramedical personnel and be manufactured probably at low cost (WHO/HRP/AR 1976, 18).

Moreover, the anticipated impact on family-planning programmes was invariably high.
Because of the large number of questions that requires to be resolved, this development effort may be considered high risk and fairly long term (10-15 years). However, the impact of a vaccine, to be used either by men or women, especially in developing countries, would be so great as to warrant this involvement (WHO/HRP/AR 1974, 24).

This expectation about the impact of anti-fertility vaccines on family planning programmes in developing countries was reiterated year after year in the WHO/HRP Annual Reports of 1975, 1976, 1977 and 1978.

The WHO’s change in philosophy to include long-term research was facilitated by the fortunate concordance between the user representations in Stevens’ projected method and the WHO/HRP’s concern to provide its member states with the means to have an impact on family planning. By allying his laboratory work with the concerns of the WHO, Stevens successfully made anti-fertility vaccine development into a doable research problem when alignment with the industrial world or with U.S.-based organizations had become unlikely. Convincing the Programme to engage in such a risky undertaking as to develop a completely new method would have been far more difficult if it had not been possible to correlate the new method to existing methods that were perceived to have the same use, particularly the Pill. In contrast with the Pill, this method would be long-acting. Its impact would not, like the Pill, depend on users’ willingness to take something every day, and it would not, like IUDs, depend on insertion by trained medical personnel. And, as distinct from hormonal contraceptives, its manufacture cost were expected to be low. The representation of users projected into existing contraceptives products facilitated the alignment between the laboratory and the social worlds of policy-making and financing. Representations of users could accomplish this role because they were packaged in other contraceptive methods. By contrasting the vaccine with the former methods, the users’ representation was transferred. Most packages Fujimura (1987) discusses are useful for aligning tasks at the level of the experiment with the laboratory. In the field of contraceptive development, representations of users also helped to articulate the work between the laboratory and the social world of policy-making and financing.

The alignment of the representations of users of Stevens and those of the WHO/HRP made the research on immunological contraceptives doable. I now will discuss Talwar’s representation of users. As we will see, Talwar’s research could not be incorporated into the programme of the Task Force on Immunological Methods for Fertility Regulation. Nor could the technical objects that both innovators in the field of immunological contraception were designing be made to converge.
Mobilizing the vaccine principle

The Indian biologist Gursaran Pran Talwar was the driving force in building up the research programme at the All India Institute of Medical Sciences in New Delhi in the 1950s and 1960s. The research and development work of the Institute, inventively carried out under very limited material circumstances, attracted the attention of the WHO. In the early 1970s, the Institute was assigned the status of WHO Research and Training Centre in Immunology for India and South East Asia, and Talwar was invited to become its director. In the early 1970s, first as Head of the Department of Biochemistry and then as Director of the Research and Training Centre in Immunology, Talwar was advancing the development of immunological methods of contraception (SC minutes 1973, 27; Diczfalusy 1975, 370; Talwar 1976, 129; Talwar paper 1996).

Immunological contraceptives were specified not only as opposed to the Pill, but also as comparable to anti-disease vaccines. This was possible only after the development of the new product had been partly detached from the context of family planning programmes. The summing up of reasons why a vaccine for fertility regulation would hold a great appeal in the 1976 Annual Report of the Programme contained one more item:

(...) It might also have great acceptability in view of the positive association that most people have with immunization (WHO/HRP/AR 1976, 18).

Where did this specification of immunological contraceptives originate?
In January 1974, Talwar received some βhCG from Stevens. (Talwar 1976, 130; interview with Stevens 1:15-16). By then it had become clear that the use of the whole hCG molecule could lead to potentially dangerous cross-reactions with other hormones. Stevens had abandoned the use of whole hCG and now used only the β-subunit of hCG. Talwar also strove to find a product with minimal cross-reactivity with other hormones, and he therefore purified and processed the βhCG. Additionally, in order to render the processed βhCG more antigenic, Talwar linked the preparation with tetanus toxoid (TT)(Talwar et al. 1976a, 218; Talwar 1976, 131). As Talwar reports:

The choice of tetanus toxoid as a carrier for the present purpose was based on a number of considerations: (1) it is one of the purest bacterial antigens available and has a very low incidence of local reactions, discomfort and fever; (2) it evokes immunity of a duration which is advantageous for health care programmes; (3) it is approved for human use; and (4) tetanus is an appreciable health hazard, especially in developing countries. The present studies show that processed
ßhCG-TT elicits antibodies not only to hCG but also against tetanus. It has thus a double benefit (Talwar et al. 1976a, 221).

This "double benefit" is repeatedly stressed by Talwar. By linking ßhCG to tetanus toxoid, Talwar had coupled immunological contraceptives to the principle of vaccination against disease. Tetanus toxoid was an effective immunogenic carrier. Conjugated with tetanus toxoid, the ßhCG could be made antigenic at lower doses than Stevens' hapten-conjugated preparation. This innovation of Talwar was adopted by the WHO's Task Force on Immunological Methods for Fertility Regulation. The Task Force scientists went on to develop a vaccine based on a fraction of ßhCG coupled with diphteria toxoid. Next, the Task Force on Immunological Methods for Fertility Regulation stressed that the new technology was a form of immunization. For example:

Immunization as a prophylactic measure is now so widely accepted that it has been suggested that one method of fertility regulation which might have wide appeal as well as great ease of service delivery would be an anti-fertility vaccine (WHO/HRP/AR 1978, 360).

This transfer of the definition of anti-disease vaccines as highly acceptable to immunological contraceptives is an example of what Rakow and Navarro call the process of "ideologically and technically bundling" technologies. (Rakow and Navarro 1993, 148). As Akrich (1995) indicates, defining the technologies under consideration as comparable implies the existence of relationships between the types of users incorporated into the equivalent products (Akrich 1995, 174). What did the user representations that immunological contraceptives could inherit from anti-disease vaccines look like? Vaccines against diseases are meant to be widely applied, long-acting, low-cost, and easy to administer. None of these characteristics contradicted the idea of creating an alternative for the Pill that the WHO and Stevens had envisioned. In addition, the vaccination principle was effective as a prophylactic measure against diseases, and could be effective not just on an individual level but on the level of whole populations.20

Population control: more and less outspokenly

In contrast to Stevens' search for an alternative to the Pill, Talwar's representation of the future users of immunological contraceptives was too outspokenly engaged with population policy to make it possible to align his research with that of the WHO/HRP's Task Force. For example, in July 1974, a special symposium was held on the contribution that immunology could make to the solution of some of the health problems of developing countries.
Here, Talwar pointed out that the most pressing of all problems facing his own and other developing countries was to stem the growth of their populations. And desperate situations justified desperate remedies, he said (Editorial Lancet 1974, 633). In the view of these drastic standpoints, the consensus-seeking WHO had to do a delicate moderating job in finding a way to endorse the work of Talwar’s team. Member state India was of paramount importance to the WHO/HRP. India had been the first country in the world to adopt a population policy to reduce the rate of growth by reducing fertility as part of the first five-year plan in 1950-1955. In 1951, India had been the first member state to ask the WHO for research on family planning (Kessler 1992, 43). The member state India had frequently expressed to the Programme its need for birth control vaccines (WHO/HRP/AG 1979, 101).

On March 12 1974, only a few months after he had received the βhCG, Talwar and his team initiated a clinical trial to test the immunogenicity of the processed βhCG conjugated with tetanus toxoid. Four sterilized women were injected with this conjugate (Talwar et al. 1976a, 220; Talwar et al. 1976b, 254). This experiment was contested. On the basis of Stevens’ problematic trials, the WHO/HRP had decided that the occurrence of cross-reaction taking place even between the ß-subunit of hCG and the chemically partly overlapping Luteinizing Hormone (LH) was too great to warrant studies in humans (Stevens 1975, 371). Anti-fertility vaccines were a novel type of drugs, and international guidelines for the evaluation of the safety and efficacy of these preparations were issued only in 1978 (WHO/HRP 1978). Even so, the WHO/HRP considered that the interval of a few months had been too short to conduct minimal safety and toxicology experiments in animals with the novel preparation. After this episode, the WHO/HRP’s funding for the Indian team was solely for animal studies to assess the immunogenicity, efficacy, and safety of the conjugate of processed βhCG with tetanus toxoid (WHO/HRP/AR 1976, 111; WHO/HRP/AR 1978, 144). Hence, the section on Collaborative Centers of the WHO/HRP’s Annual Report of 1975 mindfully says:

All Indian Institute. Research in this line [anti-hCG vaccine, jvk] has been carried out in parallel with, but separate from, the Task Force (WHO/HRP/AR 1975, 66).

Talwar had successfully put India on the map of research in reproductive immunology and vaccine development. Sheldon Segal, an eminent senior scientist of the U.S. Population Council, wrote an editorial comment introducing the 1976 report of Talwar’s first clinical trial in a theme number of the journal Contraception. He wrote:

(...) he [Talwar, jvk] may have advanced by several years at least the possibility of developing an hCG-derived vaccine for fertility regula-
tion (...) The scientific community recognizes this and will benefit from Talwar’s data as it turns its attention to the continual analysis, confirmation and extension of his work. The world at large stands to benefit by a successful outcome of this work, for at this junction in the World’s demographic pathway, a safe and effective vaccine for the regulation of fertility can be of the utmost importance (...) (Segal 1976, 126).

When the support of the WHO/HRP for the Indian research project was curtailed, Talwar sought and found other allies. Talwar’s representation of users as populations that had to be controlled massively and fast coincided with that of the Indian government. The Indian research team continued its work at the newly established National Institute of Immunology, where Talwar was the director. The Indian government supported biomedical research as an essential component of its high-priority family-planning programme (Segal 1976, 125-126). Talwar’s research was supported first by the Family Planning Foundation of India and then by the country’s Department of Biotechnology, where the project was awarded the status of one of sixteen high-priority missions. In addition, the research received funding from the International Development Research Centre (IDRC) of Canada and from the Population Council in New York (Talwar 1976, 130).

Two different prototypes

The representations of users of Stevens and Talwar could also not be reconciled in the technical object that they were designing. To overcome the problem of cross-reaction with LH, Stevens and his team went on to develop a vaccine based upon a small fraction of hCG. Warned by the unforeseen side-effects in the hurried first clinical trial, this Task Force scientist now preferred to err on the side of prudence. To render the preparation sufficiently antigenic, Stevens’ approach required a time-consuming and expensive research programme to identify suitable adjuvants, vehicles, and delivery-systems, that then had to be tested for their anti-fertility effect in baboons (WHO/HRP/AR 1979, 86).

In spite of Stevens’ conclusion that a vaccine based upon the entire βhCG would lead to cross-reactions with others hormones, Talwar and his team chose the entire β-subunit as the antigen. Talwar stressed the chemical differences between the β-subunit of hCG and the β-subunit of the most closely related other hormone, LH (Talwar 1978, 19). On the basis of their clinical trial with four women, the Indian group argued that there was no evidence of cross-reactivity with other hormones at physiological levels
(Talwar et al. 1976, 261). Both researchers claimed to develop an immunological method that would be safe and effective. And while Stevens consistently pointed out the potential hazards of the Indian approach, Talwar did not fail to express his doubts about the efficacy of the WHO preparation.

4. Conclusions

In setting up the Task Force on Immunological Methods for Fertility Regulation and its initial research programme, the WHO/HRP enrolled states, biomedical scientists, clinicians, and social scientists. Family planning organizations or members of the women’s health movement were not enlisted at this stage. The enrolled actors could argue for their representations of the potential users of the envisioned contraceptive.

The end-users of the new method were imagined in various ways by these spokespersons: as users of comparable methods, as populations, and as visitors of family-planning clinics. The representations of users were kept as loosely defined as possible without losing their function of justifying researchers’ work. Akrich (1995) found that implicit techniques for representing the user seemed to be more powerful than explicit ones. In this study, too, we saw that the only spokespersons who employed an explicit technique, namely the social scientists with their surveys, had little impact on the direction of the product development. But social scientists were important in structuring the conceptions of users (as undefinable) and of technology (as decontextualized things with definable attributes).

I have described three ways in which representations of users were involved in the researchers’ work. Firstly, the researchers needed representations of users to anticipate the usage of the technology that they were designing. The clinicians in the Steering Committee played a key role for this purpose. The researchers did not need too explicit and well-defined ideas about the future users. On the contrary, this precision would have constrained the researchers’ license to direct the process of technological innovation. The representations of users should therefore preferably not increase the complexity of the definition of the problem to be addressed. Not surprisingly, the two main protagonists of the furthest advanced research in anti-fertility vaccines, WHO/HRP Task Force scientist Vernon Stevens and Pran Talwar from The National Institute of Immunology in New Delhi, both appreciated and cherished the latitude that followed from this lack of articulation of who the future users of anti-fertility vaccines might be. In interviews conducted in 1995 and 1996, these scientists actively insisted that the methods they were developing would be available to anyone. As Stevens said:
I provide the technology. I want you to get that clear. I am not going to try to come out to say: well this should be used this way or that way, for these people and not those people. (...) It is just as much for Amsterdam middle-reproductive age women as it is for Australians or Zimbabweans or anybody else (interview with Stevens 1;20/36).

And as Talwar said:

(...) developing countries will probably be the biggest users. Although there is no reason why developed country women should not use it.

(jvk: So, it is especially appropriate for developing countries?)

Rather, I would say that there is no difference. Women are the same everywhere (interview with Talwar 1;22).

Scientists could keep the complexity of the social, cultural, and personal contexts in which users do or don’t plan their families out of view only by minimally specifying their representations of users. This was very useful. As the result of a consensus-seeking process, the accompanying product specification as low-cost, easy to administer, and long-acting proved rather stable. It was extended and elaborated in more detail in the following years, but it was not changed.

Secondly, representations of users were functional by permitting alignment among levels of work organization. Fujimura (1987) argues that transferable packages contribute to the alignment of different levels of work organization. Representations of users were brought into action in the same way. Stevens constructed the representation of users of immunological contraceptives as the mirror image of Pill-users, and this enabled the researchers to derive a product specification for the new method that they were designing. Talwar’s representation of immunological contraceptive users as an extension of anti-disease-vaccine users further complemented this product specification. The resulting product specification could be detached from the specific practices of these scientists, which thus facilitated the alignment of the laboratory level with the level of policy-making and financing in the field of contraceptive development. Fujimura (1987, 1992) describes the alignment of three levels of work organization: the experiment, the laboratory, and the world of policy-making and financing. In the case of medical technology development, a fourth level of work organization should be distinguished: clinical practice. Clinicians were appropriately staged to transfer their representations of users from their clinical practice towards the meetings of the Steering Committee. The clinical practice level also had to be aligned in making the development of a new contraceptive technology doable, and representations of users established the link. Moreover, representations of users had an impact on defining the institutional work space. The
WHO/HRP’s view corresponded with Talwar’s regarding the perceived urgency of bringing population growth down. But unlike Talwar and his group, the WHO/HRP did not adopt the representation of users derived from anti-disease vaccines: populations as level of intervention. The WHO/HRP’s ambiguity towards conceiving users of contraceptive methods as populations was relieved by concentrating their support on Stevens’ work, while not abandoning Talwar’s either. Standardized packages, such as specific representations of users, not only enable but also condition the doability of research problems.

Finally, the scientific community’s adherence to the variety of the individual user’s needs and of settings was important in legitimizing its research for the hardware and the software enthusiasts among the member states. When elaborating the needs for research, individual users and the variety of settings were not taken into account. The needs for research were phrased in terms of the attributes of the methods to be developed, and the basic research required to do so, and not in terms of users with specific needs and settings. An appeal to diversity could bridge political differences, but only as long as the technology was considered as detached from specific contexts of use.
Notes by chapter 1

1. The name of the programme from 1972 to 1976, the Expanded Programme of Research, Development and Research Training in Human Reproduction, was changed in 1977 to the Special Programme for Research, Development and Research Training.

2. Other arguments against the appropriateness for the WHO to engage in research on contraception were that "family planning would result in ageing of the population and cause a decrease in productivity", that over-population was "an economic and a not medical problem", and that "the duty of physicians is to preserve human life and not to stand in its way". (Work of the Fifth World Health Assembly, Population Problems. Chronicle of the World Health Organization, 1952, 6 (7-8). Cited in Kessler 1991, 43).

3. In the WHO/HRP’s Annual Report from 1974, the criteria are formulated more loosely: "The choice of methods under development is determined by several criteria: potential demand for a method, probability of success in development, likely time and cost, extent of research by other groups and industry, potential for collaboration." (WHO/HRP/AR 1974, 3). The criteria for priority setting for the Program in its early years evolved over the years and are formulated in detail in the document prepared for the meeting of the Advisory Group in September 1979 (WHO/HRP/AG 1979) (A.Kessler, personal communication, 14 February 1996).

4. For an analysis of the WHO’s strategic use of standardization processes in trying to achieve and maintain political neutrality see also De Bont (2000).

5. Egon Diczfalusy was head of the Reproductive Endocrinology Unit of the Karolinska Institute (one of the WHO Research and Training Centers) and consultant to the WHO. The chemist Carl Djerassi had been involved in the early work of the development of the Pill, and had just published his book *The Politics of Contraception*, in which he discussed birth control from the triple perspective of science, industry, and public policy (Djerassi, 1979). The biomedical scientist Sheldon Segal was the director of the Rockefeller Foundation’s Population Program, where he was one of the originators of contraceptive implants (Population Council/AR 1990, 12). Robert V.Short worked at the Medical Research Council Reproductive Biology Unit of the University of Edinburgh, United Kingdom.

6. See also contributions to the general discussion of the Karolinska Symposium by, for example, G.J.V.Nossal on the need to know more about
cellular and humoral sides of immunity in the female genital tract (page 436); O. Vyazov on the physiology and morphology of the blood-testis barrier (page 440); D.B. Amos on the causes of unexplained sterility (page 444); H. Goodman on the need for more fundamental research on the mechanisms of local immune responses and on sperm antigens (page 445); and C.A. Shivers on gaps in the knowledge on the surface of the egg and its accessibility (page 445) (Diczfalusy 1975). See also Jones (1982, 198).

7. See also Barzelatto (1991, 61).

8. On the dominance of the (Western) medical profession within the WHO, see also Sung Lee (1997).

9. See, for example, the results of the comparative studies reported in WHO/-HRP/AR 1979, 89-91, and in the overview provided by Shah, 1995. See also chapter 3.

10. See for example Concepcion, Mundigo, and Reeler (1991), who report that there seems to be little predictive value in users' statements about methods they have never used. According to Ellertson and Winikoff (1995) non-available technologies are typically greeted with ambivalence.

11. Oudshoorn (1994) has demonstrated that the successful making of the Pill in the 1950s and 1960s had reinforced gynecologists' networks in the field of contraceptive development. This gynecological infrastructure - the availability of medical practices and institutions and professions in which contraceptive development takes place - is gendered (Oudshoorn 1994, 138-141).

12. See also Pincus et al., quoted in Oudshoorn 1994, 112-137.

13. See also note 4 of the Introduction.

14. The medical definition of abortion is the interruption of pregnancy, and pregnancy starts after implantation of the embryo. The international anti-abortion movement accepts another definition of pregnancy, namely the moment of fertilization. See also chapter 2. The political lobbying of the powerful and sometimes violent anti-abortion movement has been extremely influential over the years. See also chapter 3.

15. Human chorionic gonadotropin (hCG) is released by the fertilized egg soon after fertilization and continues to be produced by the placenta. It stimulates the corpus luteum on the surface of the ovary to produce the hormone progesterone, which is necessary to prepare the uterus for the implantation of the fertilized egg and for the maintenance of pregnancy.
16. Until then most studies had been done on the effects of injecting gonadotropins (LH and FSH) and hCG from one species into another to raise an antigenic effect (active heterologous immunization). This had resulted in either cross reaction with other endogenous hormones, or in the attainment of high titers of antibodies against the antigen that did not neutralize the endogenous hormones. In addition, most adjuvants that could be used in animals to reinforce their antigenicity were unacceptable for human use. Stevens redefined the problem. He altered an isoantigen, that is, hormones or other body constituents from the same species, to render it more immunogenic. This was accomplished by hapten-coupling the hormone hCG with a diazonium salt (Stevens 1973, 496-505; Stevens 1975, 368).

17. The antibodies provoked by the altered hCG cross-reacted with Luteinizing Hormone (LH). This might have stopped the participating women from ovulating and was likely to result in amenorrhea and clinical symptoms of ovarian deficiency. Follow-up studies in four subjects of Stevens' clinical trial with whole hCG, approximately 6 months from the first immunization, suggested that they were actually rendered anovulatory. See Stevens 1975, 365.

18. For his first clinical trials in humans, Stevens had used altered whole hCG molecules. From fundamental research it appeared that the hormone hCG consisted of two subunits, denominated α-subunit and the β-subunit (Canfield et al., 1971). The α-subunit of hCG is identical with the α-subunit of several other hormones, among which is the Luteinizing Hormone. LH is a hormone secreted by the pituitary gland at the base of the brain, which stimulates ovulation in women and the production of testosterone in men. Therefore, antibodies against whole hCG did not discriminate between hCG and LH, neither biologically nor immunologically. This is called cross-reactivity.

19. For example: "The conjugate has the additional merit of conferring protection against tetanus in the recipients" (Talwar 1976, 130). "In addition, the (birth control, jvk) vaccines impart simultaneous protection against tetanus." (interview with Talwar by Sunny and Shah 1994, 23)

20. A microbe or virus cannot survive when more that eighty percent of the population has immunity against it (Burnet, 1972; Smit, 1995). If a person has not been immunized or a person’s immune system has not reacted strongly to the vaccine, that person is protected if most people around her or him are protected, because the person is less likely to be exposed to the virus or microbe. See also Richter 1993, 16.
21. The second International Congress of Immunology, held at Brighton, July 1974.

22. Also Stevens had hoped that the β-subunit of hCG as pure as possible might elicit antibody response to hCG but not to LH. When testing the β-subunit in baboons, the antibodies produced indeed reacted with baboon CG and not with baboon LH, and effectively reduced the baboons' fertility. These studies, therefore, indicated that in case an antigen could be prepared that elicited antibodies specific for hCG and not reacting with human LH, an immunological method for human fertility control might become feasible. However, the antibodies produced by injecting baboons with the β-subunit of hCG also reacted with human CG and human LH (Stevens 1975, 368). This indicated that even with the β subunit of the hCG molecule cross-reaction was taking place in the test tube. Stevens then went on to prepare smaller parts of the β-subunit of hCG, that could then be tested for their specificity in eliciting antibodies exclusively against hCG (Stevens 1975, 368 and 375).

23. The Task Force on Immunological Methods for Fertility Regulation published its first guidelines for the evaluation of the safety and efficacy of placental antigen vaccines for fertility regulation in 1978. According to the document: "Duration of the study before initiation of phase I trials in humans. It is proposed that these studies should have been conducted for a minimum of 6 months prior to initiation of phase I trials in humans." (WHO/HRP 1978, 370)