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

Jessika van Kammen
Conceiving Contraceptives

The Involvement of Users in Anti-Fertility Vaccines Development

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## Contents

### Acknowledgements

### Introduction

1. Blaming the users in contraceptive development
2. Research on users in Science and Technology Studies
3. The script approach
4. Extensions to the script approach
4.1 The embeddedness of representations
4.2 Who is allowed to represent users?
5. The scope of this study
6. Outline of the thesis

Notes by the Introduction

### Chapter 1

**Designing technology for everybody**

1. Introduction
2. The WHO's setting up of research on immunological contraceptives
2.1 Criteria for determining priorities
2.2 The WHO/HRP's spokespersons
2.3 Representations of users in setting up the Programme
3. The Task Force on Immunological Methods for Fertility Regulation
4. Conclusions

Notes by Chapter 1
Chapter 2
Representing users' bodies

1. Introduction 59
2. Setting the stage for an accessible body 60
2.1 Negotiating male body boundaries 65
2.2 A cascade of target substances 66
3. Selecting proper target substances 69
3.1 The availability of hCG 69
3.2 "Politically correct targets" 70
3.3 'Androgyn' antigens 73
4. The reappearance of men 78
5. Conclusions 80

Notes by Chapter 2 84

Chapter 3
Involvement of the women's health movement

1. Introduction 89
2. The emergence of the discourse on users' perspectives 93
2.1 Women's health advocates gain ground 93
2.2 From population control to reproductive health 95
3. Different meanings of users' perspectives 98
3.1 Women's health advocates as spokespersons for users? 101
3.2 Various meanings of "users' perspectives" 104
3.3 Integration of users' perspectives into what? 108
4. The integration of users' perspectives into technological development 110
4.1 Women's health advocates' critique of anti-fertility vaccines 111
4.2 Demarcating the boundaries of science 114
4.3 Distinguishing between the vaccine and its application 118
4.4 Potential for abuse or acceptability 126
4.5 Modifications of the proposed method 131
5. Conclusions 133

Notes by Chapter 3 139
Chapter 4
Configuring the users in the clinical trials

1. Introduction
2. Clinical trials with anti-fertility vaccines: an overview
3. The enrollment of trial participants
   3.1 Selection of potential candidates
   3.2 Portraying women as supportive collaborators
   3.3 Obtaining informed consent
   3.4 Keeping them in the trial
4. Reporting of results: making the trials successful
   4.1 The construction of efficacy
   4.2 The construction of safety
5. Conclusions

Notes by Chapter 4

Conclusions

1. Conceptualizing users in technology development
2. The articulation of specific users' representations
3. Implicated (non)-users
4. The embeddedness of contraceptive development
5. Women's health advocates' perspectives on users
6. Alignment and boundary work
7. Abuse
8. Policy implications

Notes by the Conclusions

Bibliography

Summary

Samenvatting
Introduction

1. Blaming the users in contraceptive development

Women's health advocates and potential users should be represented in all decision-making mechanisms and advisory bodies that are established to guide the research process (Declaration 1993).

This recommendation was approved by the participants in the symposium on *Contraceptive research and development for the year 2000* and beyond, held in Mexico in 1993. The participants included senior managers of all international and some national public sector agencies that undertake contraceptive research and development, and programme directors and senior staff of national and international agencies that are otherwise involved in the field of fertility regulation research. The symposium was organized in preparation for the United Nations International Conference on Population and Development (ICPD) in Cairo in 1994, where the recommendation was seconded. Since the early 1990s, there has been a growing consensus among researchers, policy-makers, funding agencies, and women's health advocates that the future users of contraceptive methods should be involved in the developmental process. However, in practice the integration of the users' perspectives into contraceptive research and development has proved very difficult. Why?

The 1990s witnessed a major shift in the field of contraceptive research and development. In the Program of Action adopted at the ICPD in Cairo, for the first time people's reproductive health and rights were placed at center stage in the approach to family planning. The end-users of contraceptive technologies, virtually invisible in the previous paradigm of population control, came forcefully into focus. During this decade meetings between contraceptive developers and women's health advocates were organized, policy was formulated and social scientific research into the needs and
preferences of users was intensified in order to develop what was called the **integration of users’ perspectives**.¹

At the basis of this new strategy lay the conviction that users had not sufficiently been taken into account by contraceptive developers (Bruce 1987, WHO/HRP 1992, Population Council 1990, Cottingham and Benangiano 1997). Indeed, numerous problems and controversies have surrounded the introduction of modern contraceptive technologies. Well known examples include the first generation of oral contraceptives, the DalkonR shield, surgical sterilization, the hormonal injectable Depo ProveraR, and the hormonal implant NorplantR. The women’s health movement has played a pivotal historic role in documenting and exposing these problems. In the 1960s a growing number of reports signaled blood clotting disorders among women taking the Pill, which at that time contained more than one hundred times the amount of estrogen in current oral contraceptives. The DalkonR Shield intrauterine device (IUD) had to be taken off the market in 1974 because it caused pelvic inflammatory disease, leading to infertility and in a number of cases to deaths. There were documented cases of women being sterilized without their knowledge, especially in Third World countries. Depo ProveraR, an injectable hormonal method, was suspected of causing breast cancer. The fact that until 1992 it was available in many developing countries, but not in the United States, contributed to the perception that there was something wrong with the method. The hormonal implant NorplantR provoked controversy about the importance of side-effects such as irregular bleeding and headaches. Researchers and policy makers rated these side-effects as "non-life-threatening conditions", but women’s health advocates saw them as profoundly affecting women’s lives and daily well being. Women in Bangladesh, Brazil, and Indonesia faced problems because the expertise and sometimes the will to remove an implant after its expiration, or on demand, was not available (Boston Women’s Health Book Collective 1984, Hartmann 1987, Mintzes 1991, Hardon 1992, Briggs 1997, Cottingham and Benangiano 1997).

The fact that difficulties with these contraceptive technologies invariably arose once they began to be used seemed to suggest that the introduction of new methods needed more consideration. Two major organizations in the field of contraceptive development, the World Health Organization in Geneva and the Population Council in New York, developed new approaches to the introduction of contraceptive methods into family planning programmes. Henceforth, the introduction of new methods would ideally be accompanied by acceptability studies and research into the service delivery setting (Cottingham 1997, Simmons *et al*. 1997, Population Council 1990). Such an approach was implemented for the first time with the introduction of the hormonal implant NorplantR in the 1980s (Beattie 1991, Zimmerman *et al*. 2000).
But these acceptability studies and introductionary trials produced a peculiar effect: users became the problem, while the contraceptive methods remained unquestioned. The social scientists who studied the acceptability of contraceptive methods experienced great difficulty in defining who the (potential) users were, or specific views on what exactly should be studied. The results of users-studies were said to be extremely sensitive to the research methods employed, so that it was difficult to generalize (Shah 1995, Report of a workshop 1995, Cottingham 1997). A great many features of potential users and the contexts in which they plan their families could be studied, and were indeed studied. Crucially, the relation to technology development increasingly faded away. Instead of focusing on the user-technology interactions, attention shifted towards the users and away from the technologies. In the Norplant case, for example, the researchers found that the main reason why women discontinued the use of this method was menstrual disorders, such as frequent and long periods, or on the contrary, long intervals without bleeding. They then determined that there had been insufficient counselling to prepare women for such changes in their menstrual patterns. These studies concluded that Norplant was a very acceptable method, but that the method required that women be told on beforehand what side-effects they could expect, so that they wouldn’t worry (Hardon 1992, Hanhart 1993 and 1999, Fraser et al. 1998). As early as 1977, John Marshall from the WHO’s Task Force on Acceptability of Fertility Regulating Methods advocated "designing technology to fit people" (Marshall 1977) rather than the other way around, but this did not happen. Thus, two unforeseen tendencies evolved from the way in which studying users’ perspectives on contraceptives had been approached. First, the users and not the technologies were blamed for any mismatches. And second, earlier stages of technology development, and the possible involvement of users in the trajectories preceding introduction, were not questioned.

In this thesis I have turned the tables on the problem of integrating the users’ perspective into contraceptive development. Instead of focusing on users and their ideas about the acceptability of contraceptive methods, I will systematically trace the ways in which users were involved in the development of a new contraceptive technology, over its entire life cycle. Might it be that users are implicated in contraceptive development long before the methods appear in family-planning clinics? And couldn’t it be that problems have occurred over and over again, not because of the researchers’ lack of concern for users, but because of the specific ways in which users have been integrated into contraceptive development? Viewed this way, the issue becomes to make explicit the perspectives on users invoked in contraceptive development. My research questions are: What are the dynamics of users’
involvement in the development of anti-fertility vaccines? And what are possibilities and limitations for changing the ways in which users are implicated in this developmental process? In this thesis I will examine these issues empirically.

Various definitions of users have been suggested in the realm of medical technology development (Rose 1999). The demand structure for medical technologies is multi-layered. For example, Stuart Blume (1994) has argued that in the area of diagnostic imaging the demand for new medical technologies responds to the shared interests of both its industrial producers and the professional users of medical technology. Annetine Gelijns (1991) has proposed that in relation to demand for medical technology the term "user" should include various groups, among them patients, clinicians, hospital administrators, and the families of patients. However, this broad definition of users makes the dynamics between these diverse groups invisible. In this study I will examine the involvement of end-users, defined as those who potentially will be actually injected with anti-fertility vaccines to regulate their fertility. The situation of contraceptive innovation and marketing can be characterized by a relatively large number of intermediaries between the developers and the end-users. According to Charlotte Ellertson and Beverly Winikoff (1997), this is the case firstly because in prescribing drugs or medical therapies to end-users, doctors play an intermediary role. The views of these intermediary users are important to the developers of medical technologies, who often have little opportunity to gain a thorough knowledge of the situations in which their novel methods might be used. But the perspectives of the doctors can differ from those of the end-users. In providing contraceptives, doctors have historically played a policing role to regulate women's sexuality. Secondly, contraceptive development increasingly takes place in the public sector rather than in the private sector. The withdrawal of industry has led to increasingly significant investment by the international and U.S public sectors and by nonprofit foundations (Djerassi 1989, Bardin 1987, Gelijns 1991, Vemer and Bergink 1994). Notably, many of these public and nonprofit organizations are major players in the distribution and provision of contraceptives, especially to poor women in developing countries (Gelijns 1991, Zeldenrust, de Haan and Smit 1994). Ross and Frankenberg (1993) have estimated that ca. 80% of the contraceptive users worldwide are supplied by public sector programmes. This is the third reason why a focus on end-users' involvement in contraceptive development is especially important, according to Ellertson and Winikoff (1997). As compared to other consumer goods and even compared with other medical devices, contraceptive users have relatively little power to make their preferences known, not even by voting with their wallets. Contraceptives are often
donated to family-planning programmes. Decisions about which methods or brands to donate may be made for reasons unrelated to the end-users, such as the price, existing surpluses, or on political grounds. Among these political grounds are demographic concerns. Owing to this special institutional embeddedness, the involvement of end-users in contraceptive technology development requires special consideration. In addition, to label all these intermediary groups as users of medical technology might distract attention from the patients or end-users whose lives and well-being are very much affected by the medical treatment or therapy.

Since contraceptive methods are developed mostly by public agencies, the early and middle stages of the developmental trajectories are relatively open to scrutiny. In drug development by the pharmaceutical industry these stages are usually cloaked in with secrecy. Anti-fertility vaccines provide a particularly suitable occasion to study the ways in which users are implicated in the development of a novel contraceptive technology while it is still in the making. In the late 1980s and early 1990s, when women’s health advocates first learned about the development of these new methods, their introduction was still far away. Nonetheless, many women’s health groups were concerned about the development of anti-fertility vaccines. These groups also began to sense that the developmental trajectories preceding the introduction of contraceptive technologies needed further analysis. One major women’s health group in India stated: "First it was NET-EN [an injectable hormonal method, jvk], now it is Norplant and the next is going to be the anti-fertility vaccine (...) we have to stop reacting in a piecemeal fashion to every new method that is being introduced (...) [we have to] critically examine the research processes and methods (...)" (Forum for Women’s Health 1994, 40).

The German women’s health advocate Judith Richter wrote: "This is a unique opportunity to take part in a scientific and socio-political discussion about a new contraceptive while it is still being developed, drawing from experiences with long-acting contraceptives, such as hormonal implants or injectables" (Richter 1993, 7). The involvement of women’s health advocates with anti-fertility vaccines development, in the same period when the contraceptive developers became committed to taking their concerns and those of potential users into account, makes this case especially interesting. Anti-fertility vaccine development was at the forefront of experimenting and learning about different ways to accomplish "the integration of users’ perspectives" into earlier stages of technological development.

The development of anti-fertility vaccines began in the 1970s. Unlike hormonal methods, the immunological mechanism of action causes temporal infertility by provoking the production of antibodies against substances necessary to human reproduction, such as certain hormones and molecules of the sperm and the ovum. About ten percent of the public funding available
for research on new contraceptives is spent on anti-fertility vaccines (WHO/HRP 1993). The researchers involved are located in various contraceptive research institutions, predominantly in India and the United States. Their activities are coordinated by the World Health Organization (WHO), the Indian National Institute of Immunology, the Population Council in the U.S, and the American National Institute for Child Health and Development/National Institutes of Health (NICHD/NIH), which sponsors a consortium of university-based research groups in the U.S. The research is supported by national and international public resources, and by philanthropical private foundations, most notably the Rockefeller Foundation (Richter 1996). Funding from the pharmaceutical industry for research on contraceptives in general, and for immunological methods in particular, is rather small. Research institutions do seek collaboration with pharmaceutical companies, especially at the time of phase II clinical trials when production needs to be scaled-up.

Those engaged in health care technology assessment and forecasting have much to learn from the case of immunoncontraception development. Recently, Stuart Blume (1998) has signaled changes in the relations of patients and users vis-à-vis medical innovations. Influenced by demographic developments and the concomitant increasing prevalence of chronic and disabling conditions, patients increasingly organize and demand to be taken into account in decision-making processes surrounding the development and implementation of medical technologies. The role of the state in technology development has also changed, from a generally benevolent and distant posture to actively introducing new regulatory requirements and demanding proof of the need for new treatments. These changes affect both the medical innovation processes and the study of these processes. Therefore, Blume has argued, it is no longer sufficient to look at medical innovation through the eyes of scientists. According to Blume, health care technology assessment should no longer ignore the social and political issues, the multitude of actors involved, and the complexities that arise from the changing involvement of the state and the end-users. Many of the dynamics in anti-fertility vaccines development that I will discuss might be exemplary for these tendencies. The discussion by Arie Rip, Thomas Misa, and Johan Schot in their book Managing technology in society (1995) points in the same direction. These authors signal that most current assessments of medical technologies are done only after they are ready for introduction into clinical practice, or later. To be able to produce desirable technologies and positive impacts, design practices should be broadened. They suggest that "Realistic strategies for managing technology in society (...) must consider impacts already during the development of technology, involve users and other impacted communities, and a certain element of societal learning on how to coproduce technology and its
impacts" (1995, 5). In contraceptive technology development, precisely because it has been such a contested area, a number of initiatives have been undertaken to promote broader participation and dialogue on social aspects in earlier stages of technology development. Therefore, this study provides important insights into the effects of such endeavors upon technological development.

In the remainder of this introduction, I will first discuss the literature on users in Science and Technology Studies. In particular, I will outline the script approach, developed by the French sociologist Madeleine Akrich as an analytical tool to study user-technology relations. Subsequently, I will introduce my contributions to this approach, which I will elaborate in this thesis. And next I will describe the scope of this study and provide an overview of the following chapters.

2. Research on users in Science and Technology Studies

Users have become an area of mutual interest for both Science and Technology Studies and for Gender Studies. In recent years Science and Technology Studies have contributed convincingly to the view that technological development is a sociotechnical process (Bijker, Hughes and Pinch 1987, Law 1991). Technologies are constructed by actors with particular perspectives, at certain historical places and moments. In traditional approaches to technological development, technological innovations were thought to evolve linearly, automatically, and as if inevitably from advances in scientific knowledge. Social constructivist approaches emphasize the non-linear character of technological developments, and the agency of the people involved. Technologies are developed by actors who actively take decisions and make commitments towards some technological developments and not towards others. These actors also include the users, and many recent studies include an analysis of the roles of users. In particular, feminist Science and Technology scholars have suggested placing the end-users at the analytical center of their work. Initially this was proposed as a strategy to enhance the visibility of women's contributions. The extent to which women had become invisible in technological development was succinctly summarized by the American historian Jan Zimmerman, who remarked that "Technology is everything that women don't do" (Zimmerman 1986). According to the Dutch historian of technology Ruth Oldenziel (1995), the focus predominantly on the work of innovators and engineers in the design and production stages of high-tech, capital intensive technologies, and the relative neglect of studying end-users' involvement in technological development has led to an unintended genderblindness in much of the work in Science and Technology Studies.
Many feminist authors have noticed that merely conforming to Bruno Latour's famous methodological adage to "follow the actors" (1979) may lead to following only the most powerful and visible actors (Star 1991, Fujimura 1991, Clarke and Montini 1993, Summerton 1996). Susan Leigh Star has called this "the executive approach" (Star 1991), and it has its gender implications as well. Star has signaled that such an approach negates the work of less visible actors, and reflects only one perspective among many. The work of "invisible actors" such as technicians, wives, and secretaries is obscured (Star 1991, Shapin 1989). These invisible actors also include "actors that are silenced but implicated" by the practices of the designers (Clarke and Montini 1993). The users of technologies are an outstanding example of such invisible but implicated actors. Aspiring to retrieve the users, Ruth Schwartz Cowan proposed that the analyst should study technological development from the users' point of view. In her programmatic 1987 article on The consumption junction: a proposal for research strategies in the sociology of technology, she argued that the success or failure of technological development depends to a large extent on a positive decision at the consumption junction, the place and the time at which the user does or does not employ the technology. Focussing on the consumption junction invites the analyst to think through the considerations of users and the contexts in which they adopt, modify, or reject a technology. Therefore, Schwartz Cowan suggested, this junction might provide an excellent strategic research site for understanding technological development.

The fruitfulness of such a user-centered approach to technological development was subsequently illustrated by various authors (Callon 1986 and 1987, Cockburn and Omrod 1993, Chabaud-Rychter 1994, Berg 1994 and 1996, Pinch and Kline 1996, Bergman and Frissen 1997, Lie and Sorensen 1996). Roger Silverstone and Eric Hirsch (1992) have coined the term "domestication of technology" to highlight the processes of cultural appropriation by which users make technologies meaningful in their everyday lives. Drawing upon the methods of history and anthropology, these authors examined various instances in which users were genuine co-producers of technological artifacts, in ways sometimes overlooked by previous analyses. For example, Ronald Kline and Trevor Pinch (1996) have described how rural people in the first half of the twentieth century in the United States were active participants in the social construction of the automobile. Farm men and women defined the car as more than a transport device; they saw it as a general source of power. These families used the car for many different purposes, such as running agricultural machinery, grinding, sawing, and pumping, and for powering washing machines. In the usage stage, they adapted the car and thereby became agents of technological change. Partly in response to these novel interpretations of the car, manufacturers developed
new artifacts such as tractors and pickup trucks. Kline and Pinch (1996) have demonstrated how the usefulness of the concept of interpretative flexibility can be extended to the usage stage. Interpretative flexibility is a core notion from the initially design-oriented Social Construction of Technology approach (Bijker and Pinch 1987). According to this approach, different social groups attribute different meanings to the same artifact. Therefore, what counts as a working artifact or what counts as a problem to be addressed is subject to different interpretations among different social groups. Also, certain meanings that specific social groups assign to an artifact can become embedded in new artifacts, and this process can help us understand technological development, as in the above-mentioned example of the car. Of course, not all flexible interpretations are consequential.

As Nelly Oudshoorn (1998) has noted, it is no coincidence that the role of users in the area of reproductive technologies such as contraceptives has become an important theme in feminist Science and Technology Studies. Many of us have our own histories of engagement with the women’s health movement, a node in the network that seems to be situated close to, and have a complicated relation to, Schwartz Cowan’s consumption junction. In addition, current contraceptive technologies have a special relevance to women’s health and lives. They are designed to prevent a condition that can be both intensely desired and profoundly resisted. Indeed, the analysis of users’ roles in the field of reproductive technologies has contributed greatly to our insight into the diverse ways in which users, far from being victims, incorporate these technologies into their understandings and adopt, modify, or reject them correspondingly (Hardon 1992, Franklin 1997, Saetnan 1997, Rapp 1998). One example of users acting as agents in the realm of reproductive technologies is the development of the so-called Yuzpe-regimen for fertility regulation. The Pill was designed to be taken daily as an oral contraceptive. Women in countries where abortion is not safely and legally available started to use the Pill improperly: post-coitally in a different dosage, as an emergency method of fertility regulation. The safety and efficacy of this use of the method was tested, and in 1995 experts on fertility regulation from around the world produced a consensus statement in which they encouraged this use of hormonal contraceptives (WHO/HRP 1996, 40-41). Thus, end-users put the Pill to an alternative use and thereby became co-producers of technology. In sum, studies of the domestication of technologies have confirmed that users as a social group engage in processes of attributing meaning and modifying technologies. There is a growing body of scholarship supporting the claim that users are a relevant social group that co-construct technologies in the usage stage.

The above-mentioned studies have analyzed the ways in which end-users in their encounters with technological artifacts adopt or reject them,
submit them to alternative uses, and insert them into frames of meaning that are radically different from those foreseen by the designers. But what about users’ involvement in the preceding stages of technological development? How can we study the involvement of users in the development of a technology that is not (yet) ready for use, such as anti-fertility vaccines? The Social Construction of Technology approach does not suffice for dealing with these questions. In a SCOT analysis, users come into view as a relevant social group only *ex post*. Other forms of involvement of users, for example the effect of ideas about the envisioned users in earlier stages of technological development, are not systematically included in such an analysis.

3. **The script approach**

The script approach, proposed by the French Science and Technology scholar Madeleine Akrich, seems very promising for studying other forms of users’ involvement (Akrich 1992, Akrich and Latour 1992, Akrich 1995). In her analyses, Akrich presents innovators as deeply interested in the future users of the developing technology from the very beginning. They inscribe their hypotheses about users into the technical content of the new artefact:

Designers thus define actors with specific tastes, competences, motives, aspirations, political prejudices, and the rest, and they assume that morality, technology, science, and economy will evolve in particular ways. A large part of the work of innovators is that of "inscribing" this vision of (or prediction about) the world in the technical content of the new object. I will call the endproduct of this work a "script" or "scenario" (Akrich 1992, 208).

Technologies, she has affirmed, contain a *script*: together with the actors and the settings in which they are supposed to act, technical objects define a framework of action. Technical objects can distribute responsibilities and assign positions to other participants in the sociotechnical network. Crucially for my purpose, these participants also include potential users. The designers’ projected users are anticipated in the script. Steven Woolgar (1991) has introduced the term "configuring the user" to indicate this process of defining the identities of potential users and setting constraints upon their likely future actions. In the realm of contraceptive technologies, Oudshoorn (1998) has analyzed one example of a script that assigns a specific position to the users: that of the hormonal implant Norplant®. This contraceptive consists of a number of small hormone-releasing rods that have to be implanted under the user’s skin by the means of a small operation by a trained health worker in aseptic circumstances. The same conditions are needed for removal of the
contraceptive. According to Oudshoorn, this form of administration entails a prescription for use that is incorporated in the artifact. The script of Norplant enforces a specific relationship between the user and the health care provider, namely one of dependency. This example also nicely illustrates the simultaneously social and technical character of the links between users and technologies. The script approach allows one to analyze and describe the contraceptive method as both a constructed and an embedded technology and as a social phenomenon.

Akrich (1992) developed her approach by searching for a way to analyze the structuring action of technical objects that would be neither deterministic nor voluntaristic. If a set of prescriptions for use are solidified in a technical object, artifacts definitely may have politics that affect potential users. Of course, as Akrich (1992, 208) has noted, "it may be that no actors will come forward to play the roles envisaged by the designer. Or users may define quite different roles of their own". For example, Akrich (1992) has described how the photoelectric lighting kit was designed to provide cheap electricity and to work under all circumstances, without people interfering with and potentially damaging the kit. Therefore, the designers decided to make a kit with direct current, a standard length of wiring, watertight batteries, and nonstandard plugs. A specific role and responsibility was allocated to the users, namely not to tamper with the artifact. But in spite of this inscription, some users found ways to adapt or modify the kits. Another example that Akrich has described is the use of electricity meters in Ivory Coast. These were designed to control and measure the users' consumption of electricity. But some users found ways to block the meters and to establish illicit connections. Another way of putting this is that not all electricity users matched the representations of users inscribed in the kit or in the meter (Akrich 1992). In such situations of mismatch between the foreseen users and the actual (non)users, the designers' representations of users, solidified in the artefact by their design decisions, will become especially apparent. This enables the analyst to de-scribe the script. Another example of such "subversive use" is provided by Oudshoorn (1994). A contraceptive hormone preparate was developed in the 1950s. The preparate was marketed as a drug to stabilize irregular menstrual cycles. One of the side-effects mentioned in the package insert of these pills was that women would not ovulate when using these preparates. In practice the pills were soon prescribed and used as a contraceptive method. Thus, these users did not conform to the formal script of this technology. Characteristically, the extent to which the possible actions and relations of users were inscribed into the design became apparent in its use.

Clearly, the potential future users of anti-fertility vaccines exist in an infinite variety of social, cultural, and personal settings. Ruth Schwartz
Cowan has signaled that the fact that users "come in many different shapes and sizes [is] the single most worrisome complicating factor" (1987, 263) of focusing on users. And Akrich (1995, 174) has noticed that "(...) ‘the user’ is not a single entity taken on board when the project is launched, but a set of disparate characteristics which will not necessarily merge into a tight configuration ready to accommodate the definitive end-user". In what ways are representations of users constructed, and how do they come to bear upon technological development? Technology developers and their associates had to do a lot of - more or less visible - work to represent users in such a way that they can properly accomplish the function of guiding the innovators in the process of developing new technologies. Akrich (1995) has described different techniques by which representations of users are generated. She has distinguished explicit techniques, legitimized by a formal scientific and conceptual basis, from implicit techniques of a more empirical kind, lacking such a basis. Explicit techniques include marketing surveys, consumer testing, and feedback on experience through after-sales services. The less formal techniques that Akrich has described include: the designers’ reliance on personal experience, the reliance on expert consultants, and the adoption or rejection of representations present in products considered to have something in common with the innovation at hand. These representation techniques produce a whole set of particular aspects of "users", each of which may or may not be displayed in specific situations. For the successful development of a new technology, these disparate representations should be combined and superimposed to achieve alignment. Akrich found three strategies that technology developers employ for the purpose of reconciling the various facets of users. The first is the strategy of delegating the reconciliation function to the artefact itself. This can be done by endowing the artefact with a number of features that would enable it to cope with different situations, expectations, and requirements of users. One variant of this is the ‘range of products’ strategy: developing a number of similar, but not identical, products tailored for a specific user type. In the area of family planning, this would equal the ‘cafeteria approach’: the differentiation of contraceptive methods offered to users. The second strategy that Akrich found was to delegate the reconciliation work to intermediaries, who then make the necessary adjustments between the technological system and disparate representations of users. An example of such intermediaries in the area of reproductive technology would be the service delivery system or the providers of family planning. This happens, for example, when health care providers instruct and counsel the visitors of family-planning clinics on how to use condoms. In this way methods and users are brought together. The third strategy that Akrich describes is partly to omit the need for reconciliation by creating a new user together with the new technology. One example is the prescription of hor-
effective in medical technology development, as illustrated by the Dutch physician and philosopher Rein Vos in his book with the telling title *Drugs looking for diseases* (Vos 1991). Vos developed a model for understanding drugs development in which he highlights the importance of medical practices. According to Vos, drugs development can be conceived as a process of *rapprochement* between profiles of drugs on the one hand and profiles of diseases on the other. Vos does not point out the eventual role of representations of users in drugs development or in medical practices. Paraphrasing Vos, Akrich’s third strategy would be that of drugs (or medical technologies) looking for users.

In sum, the script approach assigns an important role to the representations of future users, the implicit and explicit images of prospective users held by the developers of a technology. The studies of Akrich (1992, 1995) make very clear that a range of different user representations are produced in designing a technology, and that these representations have to be made compatible in the course of the developmental process. In order to study the making of the script, the analyst has to elucidate what these representations look like, and examine how they are inscribed. In other words, the approach does indeed provide me with methodological tools to study the ways in which representations of users are involved throughout the technological development process. Other scholars who have adopted Akrich’s script approach and confirmed its appropriateness for studying interactions between users and technology include Nelly Oudshoorn (1996), Margo Brouns (1998), Marta Kirejczyk (1999), Els Rommes (1999), Jelsma and Popkema (1998) and Jaap Jelsma (1999), and Anne Jorum Berg (1996). However, using this approach is not sufficient for answering my research questions. Akrich does not analyze how some specific representations of users become more powerful than others in certain circumstances. Insight into this last issue is important in the light of my research question about the possibilities and limitations for changing the ways in which users are actually integrated into contraceptive technology development. In addition, problematic scripts are identified only once a technology was already being implemented. Might it not be possible to study the script set out by the designers before it is acted out? Could the inscription of representations of users be influenced at earlier stages of technology development? In the following paragraph I propose two extensions to the script approach that enable me to address these issues.

13
4. Extensions to the script approach

4.1 The embeddedness of representations

Why were certain representations of future users of anti-fertility vaccines adopted while others were excluded? And why did certain representations persist while others disappeared? These are important questions for understanding the development of immunocontraceptives, and for a perspective on change. Representations of users are not free-floating entities hovering above the real world. The ability of researchers to generate representations of users and to integrate these into their technical choices is not merely contingent. The material and political specificities of research practices both enable and constrain the range of possible configurations of users. Representations of users are produced and reproduced in specific historical situations, that have evolved over years of doing reproductive science. Nelly Oudshoorn (1991, 1994) has investigated the search for male and female sex hormones and the development of the Pill. She has analyzed how the availability of research methods and materials for female sex hormones, and the existence of a powerful institutional context of gynecological clinics to care for the reproductive functions of the female body, resulted in the making of hormonal drugs for women and not for men. Oudshoorn has called this "the power of structures that already exist" (1994, 138-151). Pre-existing power structures also have a cognitive dimension. For example, Oudshoorn (1991) has argued that the conceptualization of certain hormones as male or female sex hormones echoed common-sense notions on masculinity and femininity, and conformed to pre-scientific ideas about the localization of sex in the testis and the ovaries. This dualistic categorization was by no means self-evident. Oudshoorn has shown the uncertainties scientists faced in trying to bring their experimental findings, such as the discovery of oestrogenic hormones in the urine of stallion and ovaries secreting male hormone, into line with their ideas concerning sexual duality. Many studies confirm that gender has been a remarkably persistent feature of such pre-existing structures (van der Ploeg 1998, Brouns 1998). The American sociologist Adele Clarke has also noted, in her comprehensive cultural history of the reproductive sciences in twentieth-century America, that earlier occurrences delineate the possibilities for future developments in the field. The availability of laboratory techniques, the structure of the funding of the field, and the strength of social movements such as the birth control movement and the eugenics movement, turned out to have definite consequences, and to be deeply gendered. The development of the reproductive sciences was also culturally prestructured by the "controversial status" of the discipline, due to its association with sexuality (Clarke 1998). These pre-existing power-structures not only co-produce specific
technological developments; they also affect the cultural construction of user representations and the likelihood of their alignment. The researchers' room for manoeuvre is constituted by factors including earlier choices, the availability of research material, institutional constellations, the political climate, and cognitive notions.

For a perspective on change, it is therefore necessary to include a detailed analysis of the room for manoeuvre in which certain representations of users are conceivable, and in which they come to bear upon technological development (van Kammen 1999). The reproductive researchers involved in anti-fertility vaccine development did not start from scratch. One should examine where certain representations came from, who articulated them, and under what circumstances. Such an analysis, in addition, will shed light upon representations of users that were not adopted, and on path for technological development that were not taken. Indeed, it will elucidate how "things could have been otherwise" (Star 1991), or not. For example, when the initial research programme for immunocontraception was set up, the development of such a brand-new approach to fertility regulation promised to be a lengthy, expensive, and uncertain process. The contraceptive developers therefore had urgently to agree on a proper definition of the problems to be addressed. Not all representations of future users were equally adequate for this purpose. What kinds of representations of users were suitable for making immunocontraception into a "doable research problem" (Fujimura 1987), and what kind of representations were not? Answering these questions requires a detailed account of who was entitled to bring representations to the fore, what these representations looked like, and where they originated. Another striking feature of immunocontraceptives is that, according to the researchers involved, they could be developed for both men and women. But representations of male users have faded, and most current research involves the development of methods to be used by women. Why? To explain this phenomenon requires an analysis of the material and political contexts in which the contraceptive developers took their decisions. These questions are addressed in this thesis.

Although the script approach has the potential to address the questions I just raised, Akrich does not take these issues into account. To be sure, Akrich (1995) has indeed observed that not all representations of users are of equal force, and that different ways of generating representations of users correspond to different circumstances; but she has not stipulated how the specificities of particular circumstances produce and reproduce certain representations. She has enlisted various strategies for achieving the alignment of divergent representations, but does little to explain what makes them succeed or fail. She concludes with the recommendation that
To strengthen the design process by incorporating a multiplicity of user representations, the main challenge is to coordinate the application of the various methods and reconcile their results (Akrich 1995, 182).

This conclusion leaves open the question of who is to do this coordination, what situates the reconciliation work, and what differences might be involved. In the contested field of contraceptive technology development, these are capital issues.

4.2 Who is allowed to represent users?

The other extension to the script approach that I propose responds to the wish to make explicit the representations of users inscribed in a developing technology before it is put into use. Madeleine Akrich (1992) has developed the concept of script by studying technologies after they were already in use. In such a situation we can follow Akrich's methodological recommendation to trace the negotiations between the innovators and potential users, and

(...) to go back and forth continually between the designer and the user, between the designer's projected user and the real user, between the world inscribed in the object and the world described by its displacement (Akrich 1992, 209).

As noted before, in earlier studies it was especially in situations of divergence between the projected users and the real users that the representations of users inscribed in the script became apparent. Does this mean that we have to wait until technologies go awry in their use before we can discern a script for users? That would seriously foil the practicality of the concept, but fortunately this is not the case. Akrich (1995) has also brought to the fore her view of the importance of users in the debate on Constructive Technology Assessment. CTA aims to develop instruments for managing technological change in its interaction with society. Akrich's advice to people engaged in forecasting is that they should try to obtain an overview of the array of already existing user representations in order to assess their coherency. She also points to the role of CTA "to find ways of ensuring that certain user representations - which would otherwise not be considered by the innovators and entrepreneurs - are taken into account" (1995, 183). But how can this be done? How can we learn about the prevailing representations of users before they are inscribed in the script, and before the script is performed? In this book I seek to demonstrate that evolving scripts can indeed be made explicit in earlier stages by contrasting the representations of users of the involved scientists with those of other actors concerned in technology development. In
anti-fertility vaccine development, the international women’s health movement provided me with a suitable contrast-point. Since the late 1980s, members of women’s health groups have become actively involved with anti-fertility vaccines. Women’s health advocates are a diverse group of individuals, organizations, and informal groups all over the world who share the common goal of empowering women to control their own fertility and sexuality with maximum choice and minimum health problems, by providing information and alternative services, and by campaigning for a woman’s right to make informed choices about her fertility, for improved services, and for appropriate technologies (WHO/HRP/ITT 1991, 6, Hardon 1992). By sharing "commitments to certain activities and sharing resources of many kinds to achieve their goals" they compose a social world (Clarke 1990, 190). Of course, the experiences and perspectives of both the reproductive scientists and the international women’s health advocates vary widely. No monolithic women’s health advocates’ perspective exists nor does that of reproductive scientists as a whole. At the same time, however, the situated knowledges (Haraway 1991) of the women’s health advocates and the reproductive scientists are sufficiently different to render comparison fruitful.

The women’s health advocates do not claim to be able to speak in the name of users, nor are they expected to do so by the contraceptive developers; yet they do claim to be entitled to a voice in contraceptive development. In chapter three I explain how women’s health advocates acquired this political position in contraceptive development, and how their status remains contested. Their contribution has been justified on the basis of a mixture of normative and instrumental arguments, claiming e.g. that listening to different voices was good in itself, and that it would help to better identify the needs of users. The relation of this social movement to contraceptive development is comparable to the involvement of the AIDS movement in the United States in the development of new treatments, as analyzed by the American sociologist Steven Epstein (1995). In his study, AIDS activists ceased to be "real users" in their own eyes and in those of the biomedical researchers, as soon as they acquired the language of the experts and gained access to the relevant institutions. At the same time, they gained recognition as political representatives of people with HIV/AIDS. Members of women’s health groups have also gained credibility to voice their perspectives on contraceptive users in their encounters with reproductive scientists. This contact makes such social movements particularly interesting for elucidating scripts in the making. Instead of studying the negotiations between the innovators and the potential users, I was able to study the representations of future users that the scientists and women’s health advocates invoked in their negotiations about what the technology and its concomitant script would look like.
Actor-network theorists such as Bruno Latour (1987) do not distinguish between the political and the semiotic meaning of a given representation. This is helpful to illuminate the ever political sense of signs, things, and people speaking and acting on behalf of signs, things, and people. While recognizing the potential politics of any of these relations, I want to be more careful by not assuming beforehand that these relations involve the same types of politics and the same kinds of representations. One crucial difference between representations of users in a semiotic sense, and political representatives of users, is that the latter are endowed with human agency. Unlike the illustrations and descriptions of users in the texts of contraceptive developers and women’s health advocates, or a biochemical substance in a tube that might cause temporal infertility, the members of the women’s health movement can literally talk back to the scientists. Moreover, these human agents are endowed with intentionality and the ability to make choices, and they are fully accountable for their role as political actors. It is on this basis that they engage in negotiations with the contraceptive developers, and thus I can compare their notions about potential users with those of the contraceptive developers.

Akrich’s analyses (1992, 1995) have concentrated on the designers who inscribe their representations of users into technologies. She does not explore the role of user representations of other social groups in the design of technologies. This is a pity, both for theoretical and for political reasons: theoretically, because Akrich’s emphasis on the ways in which images of future users mediate in technological development offers a promising means to gain insight into the creation of successful and unsuccessful artifacts, and to study the politics embedded in a given script. Social movements concerned about technological developments also construct representations of future users of these technologies, and perhaps these representations can also be integrated into technological designs. The political relevance of including women’s health advocates in the analysis lies further in the normative project of formulating ways to steer technology development with the participation of all the various actors involved.

There is another group of actors with a seemingly ambiguous status vis-à-vis the process of representing future users: clinical trial participants. In clinical research, the safety and efficacy of the potential method is tested in humans. The participants in the clinical tests are the first embodied agents who are actually injected with an anti-fertility vaccine. The clinical testing of immunocontraceptives provides me with another opportunity to study an evolving script before the method is introduced. Clinical trial participants "represent" users in two ways: in a statistical sense and as embodied agents. In this latter role, they can act as co-producers: just like real users, they possess agency. These ‘test-users’ may adopt, modify, or reject the technology,
or assign meanings to it that no one has anticipated. In addition, the results produced in clinical trials are meant to be generalizable for future users, but the carefully selected participants by definition differ from these future users. The effects of this inherent dilemma in testing on the configuration of future users has been described by Woolgar (1991). Woolgar has examined usability trials with a new type of microcomputer, meant to assess the responses of potential users. Company employees typically thought of real users as "others", as "outsiders", and as unknowable entities. People participating in the trials were, by the mere fact that they were trial subjects, no real users. This same dilemma is the subject of ongoing discussions among clinical researchers, biostatisticians, social scientists, and policy makers (Hansen and Launso 1989, Sherman, Temple and Merkatz 1995, Meinert 1995, Heise, McGrory and Wood 1999). In these debates, the issue becomes how the researchers in anti-fertility vaccines development constructed the clinical trial participants so as to represent the future users. How did their configuration work affect the development of the script of the contraceptive? Also, given the potential agency of the test-users, it is interesting to see what we can learn from their encounters with the foreseen users inscribed in the anti-fertility vaccines. Clinical testing thus provides yet another occasion in which evolving scripts may be distinguished early on.

5. The scope of this study

My approach also has its limitations. I have not been able to study actual end-users of anti-fertility vaccines, persons who potentially will be injected with preparations designed to regulate their fertility. No opportunity existed to examine what the technology might have meant to them, or how they might have incorporated it into their lives, or not. As I have explained, awaiting the introduction of a new contraceptive technology is not always the best option if we want to influence the course of its development. If representations of users are inscribed in a technology from the beginning, there are good reasons for users and their political representatives to try to have a say in technology development over its entire life cycle. This requires additional analytical tools. My analysis of these inscription processes with their constraints and possibilities, and the extensions to the script approach that I propose, might be helpful in meeting this need. If anti-fertility vaccines development had already reached the stage of implementation, I would have had the opportunity to study real end-users, e.g. by attending consultations at family planning clinics or by interviewing them about their use of the method. This would have been very interesting, and certainly may be a subject for further investigation. Examination of the unfolding of the script of
anti-fertility vaccines in the context of actual use would have enabled me to compare these dynamics with the processes of inscription. Examples of research that do include an analysis of both the inscription of representations of users by the designers, and the subsequent domestication of the technology by real users are provided by Akrich (1992, 1995) and by Rommes, Van Oost and Oudshoorn (1999). My study focuses instead on the making of the script, the processes of inscription. In order to gain insight into the mutual construction of the technology and its users at this stage, I proposed to use additional contrast points, and to examine the room for manoeuvre of different actors to construct and integrate their particular notions of future users.

Where can representations of users be found? I examined the texts of scientists, policy-makers, and women’s health advocates. My analysis is based on more than 100 articles published in major scientific journals such as the American Journal of Reproductive Immunology, Fertility and Sterility, and Human Reproduction, which report on the identification and selection of candidate antigens, animal studies, and clinical work in anti-fertility vaccine development. These articles were identified by a Medline search for the period 1975 to 1995 using the key words "vaccine", "fertility", and "immuno-contraceptive", as well as the names of authors. In addition, I have read some of the key references in the early phases of anti-fertility vaccine development. I also analyzed policy documents from organizations and institutes that conduct contraceptive research (WHO, the Population Council, the Indian National Institute of Immunology, and the National Institutes of Health), and minutes of the meetings of steering committees that hold an intermediate position between science and policy. In particular, I analyzed the policy documents on the integration of users’ perspectives and the reports of encounters between scientists and women’s health advocates. I collected and analyzed many of the relevant documents accompanying the clinical research, such as protocols, information brochures, and consent forms. In addition, I interviewed the principal researchers involved from the United States and from India, policy makers at the WHO and the Population Council, and a number of international women's health advocates.

6. Outline of the thesis

The chapters in this book follow the developmental trajectories of anti-fertility vaccines. Anti-fertility vaccine development started in the early 1970s, when the concept of immunological approaches to fertility regulation became articulated in an initial research programme. Chapter 1 is about this agenda-setting stage. In order to develop a research programme, agreement had to be reached about a doable research problem (Fujimura 1987).
describe who was entitled to bring representations of future users to the fore, and examined what their content. The actors involved believed that these potential methods would suit everybody in any context. This outcome was not as politically neutral as it might appear at first sight. It reflected the impossibility of the contraceptive developers to deal with diversity and with contextualized representations of users. This representation of future users as everybody in any context cleared the way for the forces of habit. In chapter 2 I analyze the selection of biochemical substances that were considered suitable for the development of anti-fertility vaccines. In spite of the scientists' claims that anti-fertility vaccines could be developed for either males or females, the representation of men as future users became less dominant than representations of female users. I argue that the remaking of women's bodies as the site of contraception was enabled and constrained by specific material and political factors. Of central importance from a perspective on change, I explore the circumstances under which the contraceptive developers could diverge from the beaten track and develop an anti-fertility vaccine for men. In the following chapter, I examine how the main design characteristics of anti-fertility vaccines evolved. The contraceptive developers aimed to develop a long-acting, easy to administer injectable method. Members of women's health groups were concerned about the potential for abuse of anti-fertility vaccines, and disputed the proposed product profile. I distinguish the mechanisms that define the limitations and possibilities for taking into account such alternative perspectives on the developing technology. Chapter 4 is about the testing of the safety and efficacy of the new method in clinical trials. I study under what conditions and with what consequences clinical trial participants were selected, and examine the ways in which they were to represent the future users of anti-fertility vaccines. I also analyze when agency is ascribed to clinical trial participants, and the extent to which the agency of clinical trial participants affects the testing. In the Conclusions, I summarize the highlights of my findings and suggest possible broader implications.
Notes by the Introduction

1. See for example the President’s message of the Population Council’s annual report with the telling title "Contraceptive development and introduction with user satisfaction in mind: twenty years of learning." (Population Council 1990), and the WHO/HRP discussion paper "Perspectives on fertility regulation: past and present work by the Special Programme and other agencies." (WHO/HRP 1995). See also Talwar (1994), Griffin, Jones and Stevens (1994), and Call for a Stop (1993).

2. See also Von Hippel (1988) for an identification of areas where the separation between developers and users is relatively unclear.

3. According to Mastroianni, Donaldson, and Kane (1990), thirteen large pharmaceutical firms became involved in contraceptive research and development in the 1960s. At present, only Ortho and Wyeth-Ayerst in the United States, and three large European companies, Schering AG, Organon and Roussel Uclaf, have substantial contraceptive research and development programmes. Syntex, Searle, Parke-Davis, Upjohn, Mead Johnson, Eli-Lilly, and Merck, Sharpe & Dohme have all abandoned new contraceptive research. There are several reasons for the fact that there are so few large companies left to work on contraceptive innovation. The Program for Appropriate Technology in Health, an international nonprofit health research organization, carried out a survey among executives of fourteen drug companies. These businessmen believed that the market was well served by the current contraceptives. According to the report, industry has determined that it can spend fewer resources and achieve greater profit by modifying existing contraceptive products than by developing new contraceptives. Product modifications are often given the same patent protection as new products. Industry also worries about product liability, regulatory demands, and the high costs and long time needed to develop new contraceptives. In comparison to drugs taken for acute diseases, regulatory requirements are more stringent for compounds that are meant to be used by healthy persons for 15-25 years of their lives. U.S. executives believed that contraceptive vaccines pose special liability and regulatory challenges, since they are both a vaccine and a contraceptive, the two riskiest products for a pharmaceutical manufacturer in that country (PATH 1993, Service 1994).


6. A similar critique has been voiced by Amsterdamska (1990).

7. See also Oudshoorn (1998) about the role that representations of users by journalists play in technological innovation.

8. Statistically spoken, the selected participants in clinical trials embody the dilemma between the internal and the external validity of the testing.
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 immunococontraceptives 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/demo- grapher 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).³

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 Diczfalussy (Diczfalussy 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:
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 meet 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
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 contraceptive 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. 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.
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).

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
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.\(^\text{14}\)

**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.\(^\text{15}\)

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).\(^\text{16}\)

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 (…) 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 require to be resolved, this development effort may be considered high risk and fairly long term (10-15 years). However, the impact of a vaccine, to be used either by men or women, especially in developing countries, would be so great as to warrant this involvement (WHO/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.18 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
\( \beta \text{hCG-TT} \) 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 \( \beta \text{hCG} \) 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 \( \beta \text{hCG} \) 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 \( \beta \text{hCG} \) coupled with diphtheria 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.

**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 β-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-
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 specifi-
cation 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 research-
ers 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 repre-
sentations 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)
Chapter 2

Representing users’ bodies

1. Introduction

In the process of setting the agenda for anti-fertility vaccine research and development that I have described, users were involved by means of the implicit and explicit images of prospective users that were envisioned by the member states of the WHO, biomedical scientists, and social scientists. The eventual target group for immunological contraceptives was conveniently kept vague: the method would be for everybody. This indetermination of the envisioned users included their sex. The fact that anti-fertility vaccines could be developed for either male or female users was repeatedly emphasized by scientists and policy makers in the field of immunocontraception. In this chapter I will examine why, in spite of the constant reiteration that immunological methods for both sexes could be developed, most work has been done to develop a vaccine to be used by women. For this purpose, I will explore how representations of users were involved in the next stage of the development of immunological contraceptives: the selection of appropriate substances against which people could be immunized for the purpose of regulating their fertility.

Akrich’s studies (1992, 1995) show that innovators were very interested in the future users of their product from the beginning. But are technology developers always interested in their future users? Or are they just concerned with such matters as resolving their technical problems and making the artefact work? As I have argued in the Introduction, even if innovators do not always have users in mind, we cannot conclude from this that users don’t matter. The technical trade-offs that the innovators make in the earliest stages of technology development have consequences for who might use the artefact, and how. Therefore, the absence of articulated ideas about future users highlights the need to focus on the ways in which users are implicated in technology development.1

How were ideas about future users involved in the initial research of the biomedical scientists? In order to select an antigen and develop an anti-fertility vaccine, biomedical researchers needed a representation of their
object of intervention: the users' body. Users' bodies are of paramount importance in the development of medical technologies. Therefore, in the first part of this chapter I will analyze the provenance of representations of users' bodies that were brought into the process of defining opportunities for immunocontraception. In the emerging field of reproductive immunology, a wide variety of representations of users' bodies was possible. How did all the different scientists agree upon a particular representation of users' bodies, and what did this body look like? In this chapter I will answer these questions by focusing on the disciplinary backgrounds of the scientists who became involved in the research on anti-fertility vaccines. The newly formed Task Force on Immunological Methods for Fertility Regulation of the World Health Organization enrolled scientists from different disciplinary backgrounds in its attempts to develop anti-fertility vaccines. According to Richard Whitley, scientists belonging to the same discipline share a general approach to the analysis of similar issues. This is called disciplinary styles, and refers to a coinciding conceptual framework for defining problems and solutions and for preferring certain methods and techniques (Whitley 1974). The concept of disciplinary styles encompasses both discursive and material elements of scientific approaches. I suggest that it is useful for understanding the contribution of reproductive biologists, immunologists, and clinicians in reaching agreement upon a representation of users' bodies.

But studying representations of users' bodies, the disciplinary styles from which they arose, and the ways in which they were made to align, is not sufficient for understanding the development of anti-fertility vaccines with a particular script. Although a whole range of possibilities were depicted, only a few types of anti-fertility vaccines were actually developed. How, then, can we understand this narrowing down to a few particular types of vaccines? The ability of researchers to generate representations of users and to integrate these into their technical choices is not merely contingent. The range of possibilities is both enabled and constrained by specific (inter)national or institutional policies, and by material practices that have evolved over years of doing reproductive science. The extent of the researchers' room for manoeuvre to develop certain technologies and not others will be explored in the second half of this chapter. A gendered pre-existing infrastructure characterized the field of the reproductive sciences, and this had important consequences for which types of vaccines would be developed and which not.

2. Setting the stage for an accessible body

In 1972, the World Health Organization in Geneva took the lead in research and development of anti-fertility vaccines by establishing a Task
Forc ee  o  Immunologica l Method s  fo  Fertilit y  Regulation. One of the first activities of this Task Force was to organize a symposium in 1974 in which sixty prominent reproductive biologists, immunologists, and clinicians from fifteen countries came together to discuss the prospects of immunocontraception (Diczfalasy 1975). Each discipline favored its own particular approach to the question of how immunological contraceptives could be developed, and the meeting was an occasion to debate their views and proposals. Which representations of users’ bodies emerged from each of these approaches?

Clinicians: mobilizing nature’s experiments

At the symposium, the clinicians argued that immunization against fertility was likely to be possible, because part of naturally occurring infertility in otherwise completely healthy persons is due to immunological factors (Diczfalasy, 1975). This experience in the treatment and study of infertility guided the clinicians in devising immunocontraception. Their approach consisted in taking serum from women patients with infertility who visited their clinics, and trying to identify the implicated antibodies.1 The Australian clinician Warren Jones had tested several methods for the detection of anti-sperm antibodies in the sera of women with infertility (Jones 1975, 376-401). Jones presented his work at the 1974 symposium. He was readily invited to participate in the Steering Committee of the WHO’s Task Force on Immunological Methods for Fertility Regulation.

From the analogy with naturally occurring infertility, the clinicians considered anti-fertility vaccines development as mimicking the so-called "experiments of nature". The notion of mimicking nature’s experiments was gratefully adopted by the scientific community involved in vaccine development, and facilitated making anti-fertility vaccines conceivable.2 As the Indian scientist Pran Talwar wrote in a review article:

Is it possible to prevent fertility immunologically? The answer to this question has been provided by nature’s experiments. (...) Although the way in which immunologic response developed in the infertile patients is not clear, the very fact of its existence indicates that it is producible (Talwar 1979, 62).

Also adopted from the parallel with infertility research was a certain representation of future users. Infertility has traditionally been located, investigated, and treated in the female body, and the clinicians - or more precisely: gynecologists - encountered women in their clinics (Pfeffer 1985, Oudshoorn 1994, van der Ploeg 1995). Anti-sperm antibodies were also found in men with infertility. But research into the immunological variety of infertility had
mostly been done in women. As two American researchers wrote in a review article:

That reproductive processes in women are vulnerable to immunologic intervention has been best documented by the numerous reports of natural infertility in women with anti-sperm antibodies and anti-zona pellucida antibodies (Anderson and Alexander 1983, 566).

The experience of gynecologists in the field of infertility pointed to the female body as the natural site for intervention. The representation of users’ bodies that these clinicians adopted with this practice was that of the infertile woman.³

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**Immunologists: women’s permeable bodies**

The way in which the clinicians had made anti-fertility vaccines thinkable, by detecting antibodies against sperm in women, fitted the immunologists’ common-sense intuition as well as their practical traditions. According to immunologists, any substance that was not part of the self would be recognized by the immune system and elicit an immune response. Therefore, that the sperm and the fetus, which are immunologically foreign to a woman, should be tolerated in the womb was (and to a certain extent still is) highly problematic for immunologists. It was precisely in this immature area of immunology that anti-fertility vaccines were intended to act. The immunologists were ambivalent about the development of anti-fertility vaccines. On the one hand, studying the effects on fertility of antibodies against specific antigens was clearly within their domain. On the other hand, the reproductive processes in women violated their paradigmatic self/non-self boundary. As one of the immunologists commented:

There is no need to emphasize either the importance of the ultimate goal - the control of fertility - or the difficulty of assessing the possible contribution of immunology to that goal (Celada 1975, 419).

The concept of anti-fertility vaccines, at the intersection of immunology and reproduction, was closely linked to a major theoretical problem in immunology. But in the practical realm there were glimmers of hope. Since sperm and placental extracts are relatively easily available, experiments to study the formation of antibodies by injecting these substances had been carried on since the turn of the century.⁴ Immunologists could therefore rely on some experience with immunological techniques using these substances.

The immunologists supported research into interference with sperm and with the placenta, both in the female body, as the most promising approach to anti-fertility vaccine development. These substances which, moreover, they
knew how to handle, were not unambiguously part of the immunological self. Sperm was obviously foreign to a woman, and its transient presence was predominantly restricted to her reproductive tract. The placental hormone hCG did circulate in a woman’s blood stream after conception had taken place, but it was produced by a not completely self-structure: the fertilized ovum. Therefore, only sperm and placental antigens in women were acceptable targets for the immunologists, since they could be categorized as non-self and thus fit into the existing immunological paradigm. As Voisin stated at the symposium:
I think that all immunologists in the audience agree that immunization against an antigen pertaining to an organism must be expected to lead to dangerous consequences (...) The only way to have some means that would not be expected to lead to dangerous consequences is to immunize against a substance that is not part of the body. The only two types of such substances are coming from the placenta or, rather, from spermatozoa that have a short lifetime in the female body (in Diczfalusy 1975, 35).

This was a fascinating manoeuvre: the immunological discomfort with women’s reproductive bodies was made into a virtue for anti-fertility vaccine development. The immunologists’ inability to explain the occurrence of pregnancy became their logic to prevent it. Placental substances and sperm in a woman’s body were considered appropriate targets because of their ambiguous state in terms of the immunological selfness of females.

What did this mean for the representation of users’ bodies that circulated amongst immunologists? Their representation of possible future users of the new method had been women with problematically ill-defined body boundaries in the field of reproduction. Now, body boundaries were reinterpreted as being permeable, as admitting non-self, and thus permitting immunocontraceptive intervention in women.

Reproductive biologists: the chain of reproductive events

Reproductive biologists did not yet have specific practices for developing anti-fertility vaccines, but they had a long-standing tradition in the pursuit of reproductive science. For these scientists, anti-fertility vaccines provided a new opportunity for doing reproductive research. They began by summing up the steps in the human reproductive process. According to the reproductive biologists, each of the following steps was in principle susceptible to intervention:

spermatogenesis, epididymal sperm maturation, ovulation and the menstrual cycle, sperm transport in the female organism, capacitation,
fertilization, tubal transport of the fertilized ovum, implantation and early embryonic development (Diczfaszy 1975, 13).

The reproductive biologists represented their object of contraceptive intervention as a chain of reproductive events with two steps localized in the male and seven in the female body. Each of these steps could perhaps be intercepted immunologically. Because it was not bound by the immunological self/non-self paradigm, their representation greatly extended the number of possible sites of immunointerference, and thereby the number of possible research leads. In the first chapter I discussed the analysis by the American sociologist Adele Clarke (1998) of the strategies that reproductive scientists had used to maintain their professional autonomy vis-à-vis the world of family planning while at the same time gaining support and funding. In particular, they had insisted upon distinguishing research into contraception, associated with sexuality and the socially illegitimate birth control movement, from the more decent and scientific research into human reproduction. And they had insisted that the study of human reproduction should include basic research (Clarke 1998). It is within this framework that we can understand the emergence of the reproductive biologists’ representation of users’ bodies. An all too explicit representation of contraceptive users’ bodies was displaced by a suitable object of intervention for the reproductive sciences: a chain of steps. This representation of users’ bodies, in addition, entailed an extension of opportunities for immunointerception, and thereby of possible research leads. Notably, the strategy of extension could only work because users’ bodies were represented in this particular way. For other thinkable representations of users’ bodies (for example as occurring in a variety of socioeconomic and personal settings or as experiencing a range of different meanings of family planning) increasing the number of possible research leads might not have been an attractive option, as this would have added to the complexity, deferring the thinkability of a quick and universal technological fix for fertility control. Representing users’ bodies in terms of steps in the reproductive process was a very effective strategy in gaining support for a wide range of research in reproductive science.

In sum, on the basis of their specific material and cognitive resources, each discipline preferred a different approach to developing anti-fertility vaccines, and their approaches were accompanied by different, gendered representations of users’ bodies. The clinicians viewed future users through an analogy with their infertile patients. Therefore, male users were not explicitly excluded, but in accord with the pre-existing gynecological infrastructure, female users received more emphasis. In the conceptualization of the immunologists, women’s reproductive bodies could possibly respond to immunological intervention. Male users were inconceivable for them, as their
bodies did not contain foreign target substances. For the reproductive biologists, both male and female bodies were involved in reproduction and were therefore in principle amenable to intervention.

### 2.1 Negotiating male body boundaries

According to the reproductive biologists' representation of users' bodies, immunological contraceptives could potentially be developed for either men or women. But if the criteria of the immunologists for the selection of antigens were upheld, male bodies were at risk of disappearing completely. It was the American reproductive biologist Vernon Stevens who explicitly articulated the issue of male or female users. As the originator and protagonist of the most promising approach to the female body (see chapter 1), Stevens was beyond suspicion of merely speaking on behalf of his own interests in developing a method for men. During one of the first discussions at the symposium, he said:

If this position is adopted and followed by the investigators in the field, i.e. the prohibition of using any self-antigen as an approach to immunological fertility control, then does anyone have any suggestion for attempts to establish a male immunological fertility control method? As far as I can determine, this excludes the male (in Diczfalussy 1975, 35).

In an apparent attempt not to surrender the extensive range of steps that he and other reproductive biologists had proposed, Stevens brought male users back onto the stage. But the selfness of male bodies had never been called into question by immunology. How could the steps in the male reproductive body be rendered susceptible to immunological interference? The reproductive biologist Erwin Goldberg, who had been working on an anti-sperm antigen, reasoned that sperm could be envisioned as foreign to males as well: sperm is sequestered from the immune system by one of the toughest barriers of the body, the blood-testis barrier. Therefore, Goldberg reasoned, molecules of sperm could be a target in male as well as female bodies:

The logical basis for such experimentation derives from two primary considerations. In the first place, spermatozoa are cells foreign to the female. Therefore, any unique macromolecule constituents of sperm would be expected to induce antibody formation which, in turn, could be followed by reduced fertility. (...) Similarly, in the male the germinal epithelium is isolated from the body's immune system, presumably by the blood-testis barrier. This suggests that antibody formation could be provoked by sperm specific proteins (Goldberg 1975, 203).
In addition, it was argued that spermatozoa could be considered foreign to the male immune system because their production starts at puberty. Sperm could therefore bear molecules which had not been ‘seen’ by the immune system when built up in the fetal stage, and could therefore be recognized as ‘foreign’:

After realizing (...) that the immune system will exercise by acting only on late developing antigens to which the body is not tolerant but not to the rest treated as ‘self’, our group has of late become interested in devising new ways and means of harnessing the autopotential against sperm antigens to achieve aspermatogenesis (Talwar 1979, 66).

The immunologists and clinicians had first rendered women’s reproductive bodies susceptible to immunological interference with fertility. Subsequently, the reproductive biologists successfully challenged the immunological selfness of the male reproductive body. The immunologists did not have to cede their criteria that less-self substances were more appropriate for the development of harmless immunological contraceptives. Instead, men’s reproductive bodies were redefined as being not completely immunological selves. Now male bodies were endowed with the same ambiguity as female bodies. This redefinition of male body boundaries meant that men could become conceivable as users of immunological contraception.

Note that the means by which male users were made conceivable are historically specific. Anti-sperm antigens were portrayed as having an "autopotential" for achieving something in the male. This stands in remarkable contrast to the way in which the female body was represented, as vulnerable to immunological interference. The redefinition of the male body did not contradict the ancient dichotomy: in contrast to the female reproductive body, the drastically reinterpreted male body did not lose its capabilities.

2.2 A cascade of target substances

The researchers involved had to reach agreement about the possibilities for immunointerception. Their common understanding of the site where immuncontraception would work was reflected in scientific papers as a picture. The researchers found their greatest common denominator in representing users’ bodies as a cascade of target substances. The reproductive immunological body that emerged from this fusion of the reproductive biologists’ and immunologists’ bodily representations was made possible by its articulation through target substances. All the steps in the human reproductive process proposed by reproductive biologists were now presented in
immunological terms: as possible antigens or target substances. As Jones wrote:

For the purposes of fertility control, immunological influences may be brought to bear most logically on the stages of the human reproductive process up to and including implantation (Fig.1.1) (...)

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**Fig.1.1** Schematic representation of the reproductive process. (Jones 1982, 2)

Once this simplified representation of users’ bodies as a cascade of opportunities was established, all possible target substances could be added to the figure without seriously affecting its elegance. The opportunities for immunological interference were further extended to include the pituitary and hypothalamus hormones involved in the production of sperm, ova, and sex steroids, i.e. LHRH, LH, and FSH. LHRH from the hypothalamus regulates the synthesis and release of the pituitary hormones, LH and FSH, in both male and female bodies. LH and FSH control spermatogenesis and the production of testosterone in men, and of estrogen and progesterone and follicular development in women.

Scientists inevitably have to simplify and select what is considered relevant and important for their work. The convenience of this specific representation of users’ bodies in terms of target substances can be understood as the result of two dynamics: the merging of disciplinary styles, and the propensity of scientists to extend rather than limit their possibilities for exploring new research leads. Various scholars who have studied representational activity in science have emphasized the importance of visual depic-
tions (Lynch and Woolgar 1990, Fyfe and Law 1988, Beaulieu 2000). The scheme that they proposed was not "just a picture". The centrality of target substances has become firmly anchored in research practices. Target substances have been a structuring factor in research on immunological contraceptives. The 1974 program of the WHO Task Force on Immunological Methods for Fertility Regulation was organized in terms of target substances (Diczfalusy 1975). Subsequent meetings and review articles classified the developmental work on anti-fertility vaccines by target substance. Target substances also informed the way in which the scientists involved referred to each other. For example:

(jvk: Who, in your view, are the other main researchers?) Well, in the zona pellucida thing there is A, and B and C. And at the sperm side there is D, who works with E, he is also a sperm fellow (interview with Stevens 1;43-44).

The representation of users' bodies as a cascade of target substances was adopted by the major actors in the field, including the team under the direction of Pran Talwar at the National Institute for Immunology in New Delhi, and the research carried out under the auspices of the World Health Organization (Talwar 1979, 64; Gupta and Koothan 1990, 48; WHO/HRP 1993, 12; Talwar et al. 1993, 208). The captions that accompanied this depiction indicated "possible points of intervention to prevent pregnancy" (WHO/HRP 1993, 12) and "possible sites of immunointervention" (Gupta and Koothan 1990, 48), suggesting that from the picture we can learn where the interventions will be located.

Of course, processes of selection and simplification are never neutral (Star, 1992; Law and Whittaker, 1988). Simplification of what would otherwise be unworkable complexity implies at the same time a process of production of new objects and relations. In emphasizing or making visible certain elements and setting aside as trivial other parts of the scientific object and endeavor, some elements get lost. Apparently, in the representation of opportunities for the immunological interception of fertility, recognizing the boundaries of what once used to constitute male and female bodies was not necessary, or even meaningful. In this representation, the distinction between the bodies of male and female users had disappeared completely. In the schematic outline, testes and ovaries are grouped together under the heading gonads and depicted as producing gametes and sex steroids, undifferentiated by sex. The bifurcation between sperm and ovum is depicted in the same way as that between FSH and LH, substances that occur in both bodies. A body with a sex seems to be implicit as a source of target substances: the ovum and the early embryo occur only in women. But the sex of the body of who might use the vaccine is absent. This is an intriguing finding. As against the intuitive notion that the sex of bodies might be more central to reproductive
science than to any other science, it seems to be irrelevant to the scientists involved.

Thus far I have shown how the scientific community involved in the research and development of anti-fertility vaccines constructed a common representation of users' bodies. The opportunities of the scientific community in making this representation were defined by their disciplinary styles, their access to material and cognitive resources, and their willingness to further the enterprise of developing anti-fertility vaccines. This work to reach agreement on where the vaccines might act was crucial in developing the prospect of immunological contraception. However, the emergence of the representation of reproductive immunological bodies outlined here cannot reveal the whole story. The scientists had reiterated all the time that anti-fertility vaccines could be made for both males and females. They worked hard to include the bodies of male users, and they depicted a sexless cascade of possible sites of intervention. One would rather expect that now a vaccine to be used by either men or women could be made. This was not the case, however. The representation of users as either male or female was not inscribed in the artefact that they developed. Instead, a technology with a clearly gendered script evolved. The overwhelming majority of the work on anti-fertility vaccines is aimed at women. Why? What can account for the asymmetric presence of male and female users' bodies in anti-fertility vaccines research and development? For example, how did the development of an anti-hCG vaccine become and continue to be the most advanced line of research? Why are anti-sperm vaccines mostly developed for women? And how could some research on male immunocontraception still be carried on? To answer these questions I will now turn towards the research practices in which anti-fertility vaccines were developed against certain substances and not against others.

3. Selecting proper target substances

3.1 The availability of hCG

The availability of a substance was a very important criterion in selecting appropriate antigens. The placental hormone hCG satisfied the availability criteria (WHO/HRP 1973, 23). In the early 1970s, when research on anti-fertility vaccines began, hCG was also used in the treatment of infertility. Therefore the WHO's principal investigator, Stevens at Ohio State University, could obtain purified hCG from companies that collected pregnancy urine for this purpose (interview with Stevens 2;3). Also for Talwar and his group at the National Institute of Immunology in New Delhi, the plentiful availability of hCG in family planning clinics was a consideration in focusing
on its derivates (Talwar 1976, 129). The hormone hCG was embedded in the
gynecological infrastructure, which contributed to its becoming a favorite
target substance in the early developmental stage of the vaccine in the 1970s.
The notion of a gynecological infrastructure was introduced by Oudshoom
(1991), who has analyzed how the availability of research methods and
materials for female sex hormones, and the existence of a powerful institu-
tional context of gynecological clinics for the reproductive functions of the
female body, resulted in the making of hormonal drugs for women but not
for men. The absence of such a network in the field of male reproduction in
part accounts for the lack of success in developing male hormonal drugs. The
successful development of hormonal contraceptives further strengthened the
gynecologists’ networks in contraceptive development (Oudshoom 1991, 127-
172). As a consequence of this asymmetry in the institutionalization of male
and female reproduction, target substances in women were more likely to
circulate and be available in reproduction research than those in men. The
convenient availability of abundant quantities of hCG was an advantage. In
the 1978 Annual Report of the WHO:

Other lines [than hCG, jvk] which continue to show promise but which
are pursued at a lower intensity include vaccines based on sperm
antigens and antigens of the zona pellucida. Several lines have been
discontinued during the past year either as the result of disappointing
data being obtained regarding anti-fertility efficacy or because of
technical problems preventing sufficient quantities of material being

3.2 "Politically correct targets"^11

The appropriateness of the antigen hCG was also conditioned by
specific moral and political cultures. HCG is produced by the fertilized ovum
and vaccines based on hCG could be considered abortifacient. In an article
reviewing different vaccine candidates, two American researchers commented:
Physicians introducing large scale contraceptive vaccination programs
should be sensitive to the ethical and moral views of the population.
HCG vaccines and other early abortifacient will not be accepted by
many societies. (...) Because of the convenience of vaccines and the
need for improved methods of birth control, many people will accept a
safe contraceptive vaccine that interferes solely with prefertilization
reproductive processes (Anderson and Alexander 1983, 568).

While the medical definition states that pregnancy begins only after implan-
tation, U.S. policy was guided by the notion that fertilization is the key
moment. In the Reagan era, funding for population programs were cut^12 and
special mandates were initiated to prevent the principal U.S. government funding agencies, the National Institutes of Health (NIH) and the Agency for International Development (USAID), from funding this research (Djerassi 1989, 358; Roush 1994, 1165). As Nancy Alexander, who had become head of the contraceptive development branch of the U.S. National Institute of Child Health and Human Development of the NIH (NICHD/NIH), said of the hCG vaccine:

"Our Congress would think of it as an abortifacient." (Alexander, quoted in Aldous, 1994).

These politics profoundly affected the research of the U.S. Population Council. The Population Council’s International Committee for Contraception Research had joined the work of Talwar and his team at the National Institute of Immunology in New Delhi on the development of an hCG-based vaccine and invested many years of work in this effort. Encouraged by the results of Talwar’s clinical trial with four women in 1974, investigators under the auspices of the Population Council carried out phase I clinical trials with a similar preparation in Sweden, Finland, Chile, and Brazil in the period 1976 to 1980 (Nash et al. 1980, 329). In 1986, the ICCR of the Population Council initiated an additional phase I clinical trial in Finland, Chile, and the Dominican Republic (Brache et al. 1992, 2). In 1991 a representative of the Population Council reported to the meeting of the Steering Committee of the WHO/HRP that

Although plans had been made to carry out a phase II clinical trial with this vaccine, lack of funds and lack of interest by two of the three centers, which are predominantly Catholic countries, have led to a delay in initiating this study (SC minutes 1991, 25).

Their effort to develop an anti-hCG vaccine diminished and finally stopped completely in the course of 1994. The strong political opposition against abortion-related technology in the United States was a major reason to redirect their research program. As the former director of the Contraceptive Development Programme of Population Council, Rosemarie Thau, said in an interview:

I could not get funds for the hCG vaccine. The government considered it as an abortifacient, because it works probably after fertilization. But I could get money for the LHRH vaccine, so this also influences it (interview with Thau 1993;12).

Also for the pharmaceutical industry, the extent of abortion-relatedness was a factor in selecting a target substance for anti-fertility vaccine development. According to Stevens:
A long time ago, two scientists [from the Dutch pharmaceutical company Organon, jvk] visited here for two or three days. And they were enthusiastic about the data, went back and made very positive recommendations for Organon. But then we got up to the top level and they considered these sociological factors and said: we can’t do it. They have been supporting research at the University of Edinburgh though, developing a vaccine against the zona pellucida antigens (interview with Stevens 1:31-32).13

On the other hand, the WHO/HRP, committed to the avoidance of duplication of efforts, persistently carried on its work on hCG. The WHO and the Task Force researchers used a twofold strategy to justify the political acceptability of their option. First, they pointed out that the mechanism of action of the hCG vaccine, especially the precise moment of its activity, had not yet been determined. The vaccine therefore could be portrayed as a "peri-implantation" method (Stevens 1990, 347; Dirnhofer et al. 1993; Benangian 1994). Second, the researchers emphasized that, independently of the mechanism of action, menstrual bleeding would appear around the expected time. Therefore, women wouldn't even notice the difference between normal menstruation and an immunologically intercepted fertile cycle (Jones et al. 1988, 1295; Griffin and Jones 1991, 178; Griffin 1992, 169; Griffin, Jones and Stevens 1994, 71; Griffin 1994, 89). Historically, the maintenance of menstrual regularity has been a major motive in developing new contraceptive methods.14 Since there was a great deal of agreement on the significance of not disturbing menstrual patterns, emphasizing its maintenance was appropriate for asserting the methods’ acceptability. The development of an hCG vaccine had started some years earlier than research on other antigens. It had gained momentum and maintained an advantage over the other research leads of the WHO/HRP (interview with Griffin 1:38). However, Task Force researcher Stevens was essentially excluded from receiving NIH financial support due to political pressure from lobbyists to deny government funding to anyone associated with abortion-related research (Stevens, personal communication 1 July 1997). The Australian gynaecologist Warren Jones, who under the auspices of the WHO conducted a clinical trial with anti-hCG vaccine in 1986-1987, also received abusive letters from anti-abortion lobbyists. Questions about the precise mechanism of action of the anti-hCG vaccine were asked in the Australian Senate in October 1987 (Minutes Estimate Committee D 1987, 58-59).

For the research team at the National Institute of Immunology in India, where abortion was legalized in 1976, the abortion-relatedness of their research into anti-fertility vaccines never seems to have been an issue (Kalpana Viswanath, personal communication 16 December 1996).
3.3 ‘Androgyn’ antigens

For the U.S.-based researchers who depended on U.S. funding, developing an anti-hCG vaccine was no longer an option. They therefore turned towards the politically impeccable pre-fertilization antigens, such as molecules of sperm and the outer layer of the ovum, the zona pellucida. In 1986, the American National Institute of Health began to fund applied research on pre-fertilization immunoc contraception. Grants and contracts were awarded to two consortia of collaborating university-based scientists in the United States working on zona pellucida antigens and on various sperm antigens (McClure, 1994).

Like hCG, ovum antigens occur only in women; but vaccines based on sperm antigens could be a target substance in both sexes. This was repeatedly stressed by the researchers involved:

Sperm antigens comprise one possibility for both males and females, as they are present only transiently in the female reproductive tract and are sequestered in the male, where their expression is restricted to testicular germ cells and sperm (Jones, Ada and Basten 1985, 289).

Compared with anti-egg or anti-fetus immunoc contraception, an anti-sperm vaccine has two theoretical advantages. First it would work in both males and females; second, it would not raise problems of auto-immunity in the female if a sperm-specific protein is used (Isahakia and Bambra 1992, 118).

A promising approach for a contraceptive vaccine is to use a sperm protein as immunogen and to develop a vaccine for either men or women. The idea is that the vaccine would act to block some required sperm function and thus induce infertility (Primakoff 1994, 208).

Sperm antigens thus gave rise to a representation of users’ bodies that fitted the visual depiction that the involved scientists had assembled: as either male or female. That anti-sperm vaccines could be developed for either men or women was portrayed as an attractive feature by the researchers. But the undifferentiated sex of future users of anti-sperm vaccines envisioned by the researchers did not coincide with their practice: most anti-sperm vaccines are developed for women. The ‘androgyneity’ of these antigens makes it possible to explore how research practices shaped the choice of male or female users.

The development of modern molecular biological techniques in the mid-1980s changed the availability of potential target substances. This was especially relevant to sperm antigens: earlier, only abundant components of sperm could be tested, but now antigens that were short-lived or scarce could
also be studied (Naz, Alexander, and Isahakia 1984, 342; Griffin 1991, 171; Primakoff 1994, 210). From the early 1980s on, several laboratories developed monoclonal antibodies to define and characterize a whole range of different sperm antigens which could be made available and studied for contraceptive purposes (Anderson and Alexander 1983, 561; Talwar and Gaur 1987, 1077; Naz 1990, 748).

To be appropriate for either male or female contraception, the sperm antigen must be located on the surface of the sperm cell and not inside. Only sperm surface antigens could actually be developed into a vaccine for users of either sex. In researchers' texts on the biochemical work of identification and chemical characterization of sperm surface antigens, the sex of future users of an eventual vaccine based on that antigen is not discernible. Nor is there any mention of the sex of future users in research on the tissue specificity of the antigen. Its role in fertilization is also studied in isolation from male or female bodies: the extent to which antibodies against a certain antigen inhibited fertilization could be studied in in vitro experiments (Naz 1988, Primakoff et al. 1988, McClure 1994, Griffin and Hendrickx 1989). The first bodies to appear in the research reports were those of laboratory animals. What difference did the sex of test animals make?

Two antigens on the surface of sperm - and therefore potentially a basis for both male and female methods - seemed promising: FA-1 and PH-20. FA-1 was found by the NIH-supported research team of Rajesh Naz at the Albert Einstein College of Medicine in New York. They conducted tests in female rabbits and male mice. In female rabbits they found a significant reduction of fertility after immunization with FA-1. The male mice experiments were also encouraging. The researchers then commented:

These results, using FA-1 as a model antigen, indicate that an anti-sperm contraceptive vaccine may be effective in both males and females. In males, it will act by binding to spermatozoa in epididymis and vas deferens, probably without percolating into the testes. Once bound, the antibodies can show their effects at the time of fertilization in the female genital tract (Naz and Menge 1990, 512-513).

That antibodies did not percolate into the testes was important to avoid problems of autoimmune testicular inflammation, called orchitis. Naz and his colleagues found additional evidence of the possible safety and efficacy of FA-1-based vaccines in the involvement of the antigen in clinical infertility in men and women (Naz 1988, 24; Naz and Menge 1990, 513). This seemed to enhance the possibility that an anti-sperm vaccine for both women and men could be realized:

Nature has provided a human model to illustrate how an immunological contraceptive would work through the occurrence of infertility
in some men and women with anti-sperm antibodies (Menge 1980, quoted in Naz and Menge 1990, 515).

For an anti-sperm vaccine to be effective, it is not sufficient that antibodies against a sperm antigen circulate in the bloodstream: anti-sperm antibodies should be present in the male or female reproductive tract to encounter sperm:

Ideally, antibodies against the antigen should be present throughout the reproductive tract at concentrations sufficient to result in a complete inhibition of fertilization. As yet, little is known regarding the male tract and the induction of local antibodies that would effectively bind to and inhibit sperm function without also possibly causing immune orchitis. Good experimental animal models duplicating the condition in man have still to be found. In the female, however, there is a rather extensive literature concerning (...) the various sections of the genital tract (Naz and Menge 1990, 515).

Naz and his colleagues chose the female rabbit as a model to study the effects of immunization with FA-1 on fertility (Naz 1988, 24). Although the sperm antigen FA-1 had been an ‘androgy nous’ antigen, the structuring of the research practice was not gender-neutral. The idea of developing immunological contraception for either males or females was actively considered by the researchers involved. However, this representation of future users could not be objectified in the technical choices of the researchers. Instead, a user with a definite sex was inscribed in the developing technology. The development of modern molecular biological techniques in the mid-1980s changed the availability of potential target substances (Naz 1990, 748). In contrast to hCG, the availability of sperm antigens was largely independent of the existing gynecological infrastructure as a result of advances in molecular biology. But now the availability of suitable male animal models became an obstacle in developing an anti-fertility vaccine for male users. The sex of future users of an FA-1-based vaccine became relevant to researchers in the light of the unequal level of knowledge from animal models of the male and female reproductive tracts. Thus the appearance of embodied laboratory animals in the developmental trajectory of the FA-1 vaccine did help to determine whether this method would be developed for men or women. This was not because of essential differences between male and female bodies, nor did I find any indication of these researchers explicitly preferring to develop a method for one or the other category of users. On the contrary, the idea of a vaccine to be used by either males or females had been amply lauded. But the development of this vaccine was embedded in an already existing and
historically specific infrastructure of contraceptive development, characterized by the underdevelopment of knowledge about male reproductive functioning.

Another research team working on an ‘androgy nous’ sperm antigen was the NIH-supported group at the University of Connecticut, led by the husband-and-wife team of Paul Primakoff and Diana Myles. These researchers also tested their preparations in both male and female test animals. The sperm protein PH-20 was reported to be an effective contraceptive in both male and female guinea pigs. In 1988, they published in the journal *Nature* a letter headed:

> Fully effective contraception in male and female guinea pigs immunized with the sperm protein PH-20 (Primakoff *et al.* 1988, 543).

This finding greatly encouraged the anti-sperm vaccine researchers (Aldous 1994). Unfortunately, PH-20 also caused autoimmune testicular inflammation. As one of the researchers involved, Gary Hunnicutt, commented:

> Unless some new technology was going to come about where one could block testicular inflammation from happening, it just didn’t look as though the anti-PH-20 vaccine for men was going to be feasible (interview with Hunnicutt 1:15).

But the possibility of developing such a new technology was not further explored, and research into an anti-PH-20 vaccine for men was abandoned, although the relevance of the testicular inflammation found in the guinea pigs for assessing the possibility of developing an anti-PH-20 vaccine for men remained contested. At a conference on the immunological control of fertility in 1994 in Australia, the findings of the PH-20 experiments were discussed once more. One reproductive scientist observed that guinea-pigs are very sensitive to such conditions compared with other animals: the observation had only been reported in the guinea-pig (Dunbar 1994, 359). Another researcher, who had collaborated in the project, observed that the experiments had been done with PH-20 antigen purified from guinea-pig testes and not recombinant PH-20. Such native PH-20 might be expected to be more biologically active, and could therefore perhaps account for the side-effect, he said (Tung 1994, 359). Nevertheless, research into this vaccine has been followed up for females only.

But the findings of Primakoff and Myles and their colleagues on contraceptive effectiveness in male and female laboratory animals had a distinct effect on the further course of anti-fertility vaccine research. While more closely observing the processes in the male genital tract, researchers noticed that PH-20 on the sperm surface undergoes a molecular transformation after the sperm leave the testes but before they are ejaculated (interview with Hunnicutt 1:19). Immunological inhibition of these changes in the
sperm at the time of passage through the epididymis would affect their ability to function in fertilization. Primakoff and Myles identified a second sperm antigen, Fertilin, that was involved in these changes. Post-testicular interception of sperm in men would remove the danger of autoimmune testicular damage (see Aldhous 1994, McClure 1994). Thus, the work on the ‘androgy nous’ antigen PH-20 helped to focus attention on the male reproductive tract for investigation. Remarkably, in the research on Fertilin, one of the most advanced studies on sperm antigens for men, female test animals were used:

Another approach being taken is to develop strategies for immunoc contraception in males. These strategies involve immunization with fragments of Fertilin (PH-30) with the aim of achieving contraceptive efficacy while eliminating orchitis and other inflammatory responses. In particular, female monkeys and mice immunized with protein domains containing the active site of Fertilin β are being tested for contraceptive efficacy (McClure 1994, 4).

Here we see another example of reproductive scientists rendering irrelevant the sex of the bodies they work with. Even in the human stage of experimentation, sex is not necessarily bracketed out. In order to perform at short notice a small clinical trial in Sweden with the WHO’s anti-hCG vaccine, it was proposed that the involved researchers - both men and women - would themselves be the participants (interview with Griffin 1:55). As the aim was to evaluate the safety of the vaccine and not its efficacy in preventing pregnancy, researchers found no reason to exclude male bodies. However, both of the ‘androgy nous’ sperm antigens FA-1 and PH-20 ended up being developed for female users only. To overcome the established practice was not easy. Seemingly, given the availability of research materials, animal models, and knowledge and experience of reproductive functions, it was more self-evident to go on developing methods for women. There was, however, one other ‘androgy nous’ antigen which has led to the furthest progress in developing an anti-fertility vaccine aimed at use in the male body. This is the Luteinising Hormone Releasing Hormone (LHRH), also called Gonadotrophin Releasing Hormone (GnRH). This research and development was done at the Population Council. What permitted he Population Council to act as "gender bender" (Oudshoorn 1996) and develop a method for men? What was necessary to include males in reproductive science?
4. The reappearance of men

Confronted with the lack of possibilities for funding and the lack of interest on the part of their collaborating centres in an anti-hCG vaccine, the Population Council reconsidered its research leads in the early 1990s. In 1992, the NIH invited the Population Council to apply for a grant. The Population Council submitted their project to develop a pre-fertilization vaccine against LHRH for male users. The choice of LHRH as a target substance in males was shaped by a number of historically specific political, economic, material, and social factors.

Immunization against LHRH in women would disrupt ovulation and the menstrual cycle. In men it suppresses not only spermatogenesis but also the production of testosterone and therefore libido. To compensate for the suppression of sex steroid hormones both in men and women, a replacement had to be administered concomitantly. According to the Population Council, an LHRH vaccine for women would therefore have no advantage over other (hormonal) contraceptives. The then Director of the Contraceptive Development Program of the Population Council, Rosemarie Thau, commented:

In females, immunization against LHRH appears less promising, since the processes which are interrupted are more complex and steroid replacement would be more difficult. Moreover, in women several more desirable approaches for contraceptive vaccines are available (Thau 1992, 128).

In 1992, the Population Council determined to develop this method for men. This decision was not predetermined by male and female reproductive biology. The team at the National Institute of Immunology in New Delhi, by contrast, made a different trade-off. These researchers argued that an anti-LHRH vaccine could be used by women whose menstrual cycles are usually disrupted temporarily anyway due to the suppression of LHRH: breastfeeding women (Talwar et al. 1992a, 948). But this line of research was short-lived. The clinical trial that this team carried out in 1992 with an LHRH vaccine to postpone the return of fertility and menstruation in women who had just given birth raised concerns of other scientists in the field and of international women’s health advocates, who considered this research unethical (Minutes SC 1991, 31; Talwar et al. 1992b, 7; Richter 1996, 96-97).¹⁹

A number of additional factors were involved in the Population Council’s decision to focus on an anti-LHRH vaccine to be used by men. Since an anti-LHRH vaccine would suppress the production of testosterone, it could also play a part in the treatment of patients with testosterone-dependent cancer of the prostate. This relation between the contraceptive and cancer
treatment had various advantages. First, on the basis of this relation, the anti-LHRH vaccine could be portrayed as not just another contraceptive but as promoting reproductive health. According to the Director of Reproductive Physiology, James Catterall:

We are reproductive health oriented. So conditions that come to mind that fit in that broader context are prostate hypertrophy, prostate cancer, breast and cervical cancer, and menopause (...). And these are all things that our contraceptive products may help to alleviate, if given in a slightly different dosage regime. So rather than be blind to those other potential uses, we try to broaden our scope a little bit and not just focus on contraception (inter-view with Catterall 1;2).

According to the scientists involved, the anti-LHRH vaccine fitted well into this new profile. Second, patients with cancer of the prostate were an opportune and accessible test population. The United States Food and Drug Administration guided the Population Council scientists to initiate a clinical trial in this population, since men with prostate cancer stood to benefit most from reducing circulating testosterone (Catterall, personal communication 8 July 1997). This opportunity was most welcome. Men are not habitual visitors to family planning clinics, and are therefore relatively more difficult to recruit for enrollment in a contraceptive trial. Talwar and his team had already conducted clinical trials in patients with prostate cancer in two centers in India and in one other center in Austria (Talwar 1992, 3). The Population Council’s first clinical trial to test the safety and performance of their anti-LHRH vaccine was carried out in twelve patients with prostate cancer (Thau 1992, 128). And third, the reorientation of the Population Council’s focus also entailed an attempt to get industry involved in an early stage of the research process. One contributing factor to the low incentive for industry to work in the field of contraceptive research and development was that the major expanding market was in developing countries, where pharmaceutical sales were generally less profitable (Fathalla, Diczfalusy and Spieler 1995, 2). But as cancer of the prostate is the second most frequent form of cancer in men, there were prospects that the anti-LHRH vaccine might attract research funding from the pharmaceutical industry. As Catterall said:

I think that broadening our focus was an interactive event that had to do with our examination of our mission and the Cairo Conference. And the vision of people in this field of how needs of population research were changing. And also the Foundations and other people that fund us let us know that they were interested in these other issues as well (interview with Catterall 1;4-5).
Reflections about the sociocultural feasibility of male contraceptives were invoked as well. As one of the researchers involved, Anna Ladd, observed in a review article:

In the past 20 years, there has been a definite social trend towards shared responsibility for family planning, and many men desire to exercise control over their own fertility. This has led to an increased interest in the development of new means for regulating male fertility (Ladd 1993, 189).

To be sure, according to the scientists involved, this newly embraced male desire to control their fertility did not in the least contradict the Population Council's primary mission to encourage the control of population growth. The senior staff scientist in charge of conducting clinical trials with the anti-LHRH vaccines, Claude Aguillaume, asserted:

(...) emphasizing male contraceptive responsibility is a key to getting men both to fulfill their broader obligations and to contribute to population stabilization (Aguillaume 1994, 2).

In sum, an anti-LHRH vaccine for men permitted the Population Council to develop a non-abortion-related vaccine of potential interest to industry. This antigen was simple to make and some knowledge of its performance was available from the Indian research. Whether or not a vaccine for either men or women could be made on the basis of this antigen was not a consideration in selecting this target substance. But in the context of the above-mentioned historically specific factors, the Population Council made an explicit choice in favor of male users.

5. Conclusions

In this chapter I have explored the reasons why most immunological contraceptives are being developed for female users, in spite of the researchers’ claims that the method could be developed "for either men or women". One explanation could have been that scientists stressed the ‘androgy nous’ possibility just to highlight the scientific novelty of the method, or to please the policy-makers at WHO who hoped to support the development of a method that would be appealing to a broad array of member states. However, I found that the absence of a distinction between the development of a method for male or for female users was deeply rooted in the research practices of the reproductive scientists. The question of whether the method would be for male or female users was in fact not a relevant consideration for the biomedical scientists. Yet, the choice of molecules of the zona pellucida,
sperm antigens involved in fertilization process, or hCG as the antigen against which a vaccine would be developed had implications for the sex of the future users of the method. Another obvious explication for the scanty research into male immunological methods could have been that the male body simply provides relatively little opportunity for contraceptive intervention. Immunological contraceptives were an excellent occasion to explore the tenability of this argument. While a number of possible target substances were present in only the male or the female body, a few of these substances were present in both, such as surface molecules of the sperm and LHRH. I have examined the course of the research on these ‘androgynous’ antigens, and I have argued that the lack of research into male immunological methods does not follow automatically from male physiology. Yet, the distribution of opportunities for developing anti-fertility vaccines for male or female users was not merely contingent, but embedded in a certain context that evolved over years of doing reproductive research.

I have approached the question about the asymmetric situation in anti-fertility vaccine development by analyzing the ways in which the bodies of future users were implicated in the early developmental work of the biomedical scientists. Representations of users’ bodies played an important role in making anti-fertility vaccines feasible. Clinicians, immunologists, and reproductive biologists constructed a representation of users’ bodies on the basis of the material and cognitive resources of their various scientific disciplines. In the newly constituted area of reproductive immunological research, users’ bodies were represented as a cascade of target substances. In this representation, the sex of future users was disregarded by the researchers. The disappearance of the notion of two stable and opposite categories might have facilitated the prospect of exciting new ways to develop reproductive technologies. But the sexless representation of users’ bodies could not be integrated into the technological design. The sex of future users was an important characteristic of the evolving technology, and predominantly female users would be supplied whereas male users tended to be ignored.

Anti-fertility vaccines with a clear gender script evolved, and from a perspective on change it was important to understand why. How could it be that the sexless representation of the users’ bodies was so prominent in the accomplishments of the researchers, and yet was not inscribed in the developing technology? This finding seems to diverge from Akrich’s work (1992, 1995), in which the users’ representations of innovators play a key role in the way a script evolves. Here we see that the emergence of a joint representation of users’ body was of central importance in envisioning the possibility of immunological approaches to contraception. But the work of reaching agreement about the sites where immunocontraceptive intervention could take place was more important than the content of the picture. This is in line with
my finding in the first chapter: that representations of users fulfill more functions than simply that of directing the work of innovators. The main function of the cascade of target substances was that it permitted the fusion of different disciplinary approaches, and not that it led researchers towards developing one vaccine or another.

How, then, can we understand that anti-fertility vaccines were developed against some antigens and not against others? The study of researchers’ work, with a focus on the gendered bodies of future users, yielded insight into the fact that most anti-fertility vaccines are developed for female users. Material and institutional factors have played an important role in facilitating the development of certain types of anti-fertility vaccines and not of others. The impact of materiality was clearly illustrated by the availability of the hormone hCG in the 1970s, which allowed this research lead to become the most advanced one. The availability of animal models and the access to male or female patients also affected the continuation or discontinuation of research into methods for men or women. But even so, researchers were able to bracket out sex, as was illustrated by the use of female test animals in the development of an immunological contraceptive to be used by men. Researchers decisively influenced the course of their research when they decided to discontinue it once they had detected side-effects from immunizing with PH-20 in male guinea-pigs, or when they considered their knowledge of the male reproductive tract to be insufficient. In addition, funding policies and political discussions have played an important role. The far-reaching consequences of national and institutional funding policies were exemplified by the effects of the ban on abortion-related research in the U.S. Without this ban, research on anti-hCG vaccine might have proceeded faster, and research on pre-fertilization antigens might have received considerably less attention. Ironically, fewer NIH-supported opportunities to explore ‘androgynous’ or male antigens might have emerged. Another example of the influence of funding policies is when the Population Council sought a rapprochement with the pharmaceutical industry, which in turn favored a particular approach to the development of the new product. Importantly, political discussions pursued at international conferences have resounded in contraceptive development. Funding opportunities have been closely linked to political and cultural notions such as the political viability of the moment of interrupting fertilization, the desirability of male responsibility in contraception, or the urgency of population control.

The unequal distribution of sex in reproductive matters has been remarkably persistent over time and in different contexts. But these recurrent patterns do not simply unfold along a historical trajectory under their own momentum. Rather they are reproduced and remade in situations which could have been otherwise. I have shown how researchers have defined, redefined, or ignored male and female bodies, yet the female body nevertheless became
the reproductive body. The considerable room for manoeuvre that researchers encountered in their endeavours to develop new contraceptive methods suggests that a medical technology does not necessarily have to develop as it actually does.
Notes by chapter 2

1. The concept of implicated actors was introduced by Clarke and Montini (1993). See also the Introduction to this thesis.

2. Following the reports of antibodies against reproductive tract antigens in infertile patients, the WHO Task Force for Immunological Methods for Fertility Regulation set up a Reference Bank for Reproductive Immunology in 1974 (Hjort and Griffin 1985). Sera of infertile persons were collected, examined and compared with those of fertile controls. Major problems soon arose, particularly in trying to standardize the assignment of sera to one of the 16 clinical categories of donors. The project generated all kinds of variations between the results of participating laboratories, between different types of tests and between samples of sera. This approach was postponed in 1977 (Griffin 1991, 167; Jones 1994, 112).


4. There is a striking similarity with the early history of the development of the Pill: the contraceptive potential of oral progestines was first tested in those who visit gynecologists: women with infertility (Oudshoorn 1994, 119).

5. Contemporary practitioners in the field of reproductive immunology tend to date the history of their field from 1899, when E.Metchnikoff at the Pasteur Institute in Paris and M.Landsteiner in Vienna injected (human and guinea pig) sperm into the peritoneal cavity of guinea pigs and described the formation of antibodies (Metchnikoff 1899, Landsteiner 1899). Although Metchnikoff mentioned the possibility of other applications of these sera, apparently his primary interest was to use them as a medium for his physiological studies. However, the question was raised of what effects, if any, were produced by spermatozoa invading the female tissues, and these and slightly different experiments were repeated over and again. The authoritative Journal of the American Medical Association devoted an Editorial to the subject in 1921 (Editorial, 1921). In 1926, S.Rosenfeld injected three women with semen, following vague reports of birth-control clinics which seemed to show that this could avert pregnancy for about twenty months (Katsch 1959, 950; Jones 1974, 377). In 1937, U.S. Patent number 2,103,204 was awarded to M.J.Baskin from the Department of Gynecology, University of Colorado (Denver), for a nonspecific spermatoxic vaccine and for the process involved in producing the vaccine. Baskin had studied the practical applications for preventing pregnancy by injecting twenty women with fresh human sperm
(Baskin 1932). The patent claimed the invention of "a determinant (...) usable as a vaccine or antigen in vaccination of human female to produce spermatoxic condition in her blood and secretions", but was never put into use (cited in Katsch 1959, 950). The history of the study of placental antibodies is presented as a different research line than the work on sperm. This lead originated in 1903, when M.S.Dobrowolski described the production of sera against an extract of the placenta of guinea pigs and rabbits and demonstrated their capacity to interrupt pregnancy. He then explicitly speculated about human application of his finding (Dobrowolski 1903). As with the anti-sperm antibodies, similar reports continued to appear occasionally.

6. One exception has been described by Catherine Waldb (1995). She has analyzed the discursive construction of permeable male immunological body boundaries, in particular of the receptive partner in anal sex, in relation to the emergence of the AIDS epidemic in the 1980s.

7. See for similar reasoning Talwar, Naz and Das (1979, 5882) and Anderson and Alexander (1983, 564).

8. The quote continues: "The female is biologically tuned to limited reproduction. She ovulates only once a month and rarely is more than one egg shed. The fertile life of the egg is fairly limited. After shedding, the ovum has to be taken up by a functional fallopian tube and retained for a defined period to permit the uterus to gain receptivity for implantation. (...) It is tempting for the biologist to formulate strategies for intervention at any of these numerous points in order to achieve control of fertility. Besides biological considerations, the female is also more highly motivated to practice family planning methods, for she bears the brunt of maternity" (Talwar 1979, 67). This gender-stereotypical metaphor in reproductive science has been comprehensively analyzed by, among others, Emily Martin (1991). See also Irma van der Ploeg (1995) for an analysis of the unequal distribution over male and female bodies of abilities for In Vitro Fertilization for the treatment of male infertility.


10. In the period from 1974 to 1979 the Task Force on Immunological Methods for Fertility Regulation of the WHO/HRP worked on vaccines against a range of antigens: the C-terminal peptide of the β-subunit of human Chorionic Gonadotropin (CTP-BhCG), human Placental Lactogen (HPL), non-hormonal trophoblastic antigens (SP1 and PP5), antigens of sperm (acrosin,
hyaluronidase and LDH-X), and antigens of the zona pellucida (WHO/HRP 1973, 13; Diczfalusy 1975, 448-451; Griffin 1991, 167-169). As had been foreseen in the research program of the Task Force, a progressive reduction was made in the number of leads supported. From the early 1980s on, by far the greatest amount of work carried out by the Task Force has been concerned with the development of a vaccine against the placental antigen hCG, to be used by women. The research team at the National Immunological Institute in New Delhi worked on a great many different vaccines both for male and female users, but concentrated on a preparation directed against hCG. University-based research groups in the United States worked on the development of immunological contraceptives against a range of sperm antigens, mostly to be used by women, and against antigens of the outer layer of the ovum, the zona pellucida. The Population Council developed a prototype vaccine against hCG but, abandoned this lead in the early 1990s to concentrate research efforts on the development of an anti-LHRH vaccine.


12. The Clinton Administration restored these programs in 1993 (Roush 1994, 1165).

13. A similar reaction by the pharmaceutical industry happened in the United States concerning the emergency contraceptive pill RU 486R. The then director of the Center for Biomedical Research of the Population Council, Wayne Bardin, said "every pharmaceutical industry in the country turned it down" when it came to testing and marketing the drug, for fear of being targeted by a political backlash. (quoted in Service 1994, 1485). Anti-abortionists in the U.S. threatened boycotts and other actions and received front-page treatment in the New York Times. The Reagan Administration supported these protesters (Djerassi 1989, 359). See Clarke and Montini (1993) for a comprehensive account of the reception of RU 486R in the U.S.

14. Note for example, the remarkable parallel with the establishment of the regimen of medication in the development of the contraceptive Pill, which was also guided by an attempt to mimic normal menstrual periods (Oudshoorn 1994, 112-135). In the 1970s and 1980s, cultural anthropologists extensively documented the social, cultural, and religious importance of menstruation. After the introduction of two other long acting contraceptives, the hormonal injectable Depo ProveraR and the hormonal implant NorplantR, acceptability studies in the 1980s indicated that disturbances of the menstrual cycle were the main reason for women to discontinue their use. Also women’s health advocates stressed the effects of menstrual disturbances on women’s daily well-being and their ability to monitor their reproductive
health. Physicians considered that heavy bleeding and more or longer periods could lead to anaemia and that other disturbances could disguise a number of adverse health conditions (Hardon 1992, Wolffers, Hardon and Jansen 1989).

15. Thanks to Anita Hardon, who suggested this term.

16. See also Jones (1994, 323), and Jones (1996, 73).

17. The sperm antigens found with monoclonal antibodies were identified and characterized to see if they were specific for sperm and had a function in fertilization. Then they were tested in laboratory animals such as mice, rabbits, and guinea pigs. If the antigen elicited a sufficiently strong immune response in these animals, the next step was to obtain a large quantity of the antigen. Subsequently, the immunogenicity and anti-fertility effects of the antigen in primates could be evaluated. Substances that were regarded as safe and effective in primates would then eventually proceed to clinical trials (Primakoff 1994, Naz and Menge 1990, Naz 1988, Naz 1990).

18. The principal investigator of this clinical trial, Marc Bygdeman, described this plan in a letter to the German women's health advocate Judith Richter (quoted in Richter 1996).

19. The international ethical guidelines for biomedical research involving human subjects of the Council for International Organizations of Medical Sciences states: "As a general rule, pregnant or nursing women should not be subjects of any clinical trials except such trials as are designed to protect or advance the health of pregnant or nursing women or fetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable subjects" (CIOMS 1993). When Talwar presented the clinical work in breast-feeding women at the 1991 meeting of the Steering Committee of the Task Force for Immunological Methods for Fertility Control, concern was expressed about the possible transfer of anti-LHRH antibodies to suckling infants and the adverse effects that this might have (Minutes SC 1991, 31).

20. Note that in this interview Catterall gave a very specific interpretation to the term "reproductive health" by understanding it as the extension of the use of contraceptive products to other conditions. Another interpretation is, for example, phrased in the document signed at the United Nations Conference in Cairo: "Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of infirmity, in all matters relating to the reproductive system and to its functions and processes (...)" (United Nations 1994).
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 Cyclofem® (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 Spicehandler 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).

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? Beatris Stemmerding, 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 Stemerding 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 Iqbal 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).

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. 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
groups 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.20 And as WHO/HRP Task Force Manager David Griffin wrote in a response to Beatrijs Stemerting 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).21

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
influenced 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 immunocontraception 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 immun contraception, 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 utilizable 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).  

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).32

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). 33

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).34

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).

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).38

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).39

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 Aptton 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).44

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-
tiality 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 enters 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). They
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 Norplant® 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 \bhCG 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 Apton 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).
Chapter 4

Configuring the users in the clinical trials

1. Introduction

In the previous chapter I analyzed the central role of prototype vaccines in safeguarding the scientific development of anti-fertility vaccines from interference by non-experts. Prototype vaccines were mobilized by the scientists to account for the safety and efficacy of the developing product. The safety and efficacy of prototype vaccines are examined extensively in laboratory experiments, in animal studies, and ultimately in clinical trials. Clinical trials are the first occasions on which anti-fertility vaccines are injected into a human body, when a real, embodied user of anti-fertility vaccine is finally constituted.

Controlled clinical trials to test medical therapies and drugs were first introduced in the 1940s. Wartime conditions, and the availability of more science-based medical interventions, such as antibiotics, encouraged the systematic evaluation of treatments. In a clinical trial, a group of people is treated with the new technology or therapy and then compared with another group that receives a placebo or a standard treatment. In the 1970s, the methodology had become standard for clinical practice, and the U.S. Food and Drugs Administration had adopted clinical trials as a core requirement for the registration of a new drug. Currently, clinical trials occupy an important place in the drugs development process (Marks 1998). The clinical trial stage is a time-consuming and relatively expensive element of the research and development process, involving considerable administrative and organizational effort. The research protocol has to be approved by national drugs controlling agencies, institutional review boards, and ethical commissions before a clinical trial can be carried out, and these procedures can last for many months or even years. Clinical trials are generally divided into three or four phases. Phase I trials are to test the safety and the biological effects of the product and to find optimum dosages in 20-50 participants. For new contraceptive products, phase I trials are done with sterilized volunteers to lessen risk. Phase II clinical trials are carried out to assess the efficacy and side effects in 100-200 people. In contraceptive technology development, the
efficacy of the new product is compared with the 95% efficacy of e.g. the Pill. In between phase I and II trials, additional toxicology and teratology studies in animals have to be carried out. In phase III trials the number of participants is greater, and so also the chance of discovering rare side-effects. When the new preparation has been licensed for general use, in some countries the monitoring of side-effects and efficacy continues in phase IV or post-marketing trials (Mintzes 1991). In anti-fertility vaccines development, three different formulations of an anti-hCG vaccine have been tested in phase I clinical trials, and for one of these formulations in addition a phase II clinical trial was completed. Phase I clinical trials also have been carried out with an anti-FSH vaccine and with anti-GnRH vaccines.

In what ways are users represented in clinical trials? Clinical trials are expected to yield results that can be generalized to future users. Trial participants therefore have to represent users at least in a statistical sense. This representation is not straightforward: clinical trial participants differ by definition from end-users, and frequently intentionally so. Trial participants are selected by means of giving their informed consent to the use of an experimental drugs, and on the basis of inclusion and exclusion criteria. The methodological and epistemological limitations of the clinical trial methodology, and of the generalizability of the results, have been comprehensively discussed by medical practitioners, biostatisticians, and social scientists. For example, Hansen and Launso (1989) have shown that there are major differences between the controlled setting of a clinical trial and the future users’ everyday lives. The trial participants are never fully representative of the potential user population at large. The controlled setting of clinical trials is not adequate for predicting problems connected with the daily-life use of the product, such as non-compliance, interactions with other drugs, and abuse. Rare or long-term problems are not detected by clinical trials. In general, the investigators decide which parameters will be monitored. Unexpected or unknown side-effects, or side-effects that are considered irrelevant by the researchers or difficult to measure, are not taken into account (Hansen and Launso 1989). A similar critique has been formulated by Morgall (1991), Hardon (1992), Snow (1994), and Koch (1995). In short, clinical trial participants represent end-users according to certain criteria that always may be disputed. Given the ongoing debates, the issue then becomes: how did the researchers configure the clinical trial participants so as to represent the future users?

There is another sense in which clinical trial participants stand in for future users. Epstein (1995) has described how AIDS activists in the United States successfully countered the roles foreseen for them in clinical trials to test new treatments. They combined methodological and moral arguments to plead that the trial participants should be more fully representative of dif-
different groups affected by the disease. Methodologically, they embroidered on the ongoing debate amongst biostatisticians that a more randomly selected group would generate more generalizable data on the safety and efficacy of the experimental treatment, i.e. they contested statistical representativeness. In addition, for the morally informed line of the argument, they presented participation in clinical trials in terms of access to possibly life-saving treatment, "a social good that must be distributed equitably." In other words, according to these AIDS activists, the clinical trial participants should also represent future users in a political sense, to ensure that the health needs of different groups affected by the disease would be taken into account. As Epstein (1995) has indicated, this political sense of representation involves different roles for clinical trial subjects and a more active form of participation, "to become a full-fledged partner in the experimental process". Instead of merely making their bodies available to enable the researchers to produce clean and generalizable data on efficacy and safety, room was created for the goals and ambitions of these "test-users". Viewed from this perspective, other aspects of clinical trial participants than merely those considered relevant for their statistical representativeness come to the fore. In their role as test-users, clinical trial participants also may represent users as early adopters or as the forerunners of those who eventually might use the vaccine. Trial participants typically appear in the scientific reports of the researchers under the heading "materials and methods". But clinical trial participants differ from some of the other materials involved. Characteristically, clinical trial participants - 'subjects' in the words of the scientists - may talk back. These test-users are embodied agents who, like future users, may become co-producers of the technology. One way in which both users and trial participants can be expected to enact agency is by "voting with their feet". Ann Saetnan (2000) has analyzed the introduction of sonographic examination of the fetus as a standard procedure for pregnant women in Norway. She has described how physicians interpret the fact that women visit the clinic for a sonogram as a foot-vote for continuation of the development the technology, regardless of the reasons that might bring these women to the clinic. Conversely, women could simply not use a technology, or not present themselves as clinical trial participants, or drop out after they have been enrolled. Authors such as Nelly Oudshoorn (1994), Ineke Klinge (1998), and Lara Marks (1996) have also looked for ways to conceptualize the agency of the sometimes overlapping categories of clinical trials participants, users of medical technologies, and women. The question is how to analyze women's continual participation, or dropping out, without degrading them by portraying them as passive victims of the situation, or by underestimating the constrains placed upon them by their lack of resources and by existing structures.
As I mentioned in the Introduction, no opportunity existed to study the women who took part in the clinical trials. The voices of these participants are absent from my account. Instead, I have examined how the researchers handled the potential agency of clinical trial candidates. What roles were foreseen for the participants in the clinical trials with anti-fertility vaccines? Clarke and Montini (1993) reported how, at a conference of researchers and family-planning organizations in San Francisco that was part of the Planned Parenthood Campaign for New Birth Control, "some speakers seemed to imagine that women would tie themselves to the doors of the local federal building demanding new contraceptives (...) as people with AIDS have done to push for access to particular drugs". This never happened. As the head of the contraceptive branch at the National Institute of Child Health and Human Development (NICHD/NIH), Nancy Alexander, remarked: "There isn't really any constituency that is talking to their congressmen saying 'we need new research in contraception'." (quoted in Service, 1994). As against people with HIV/AIDS, the likely benefits to healthy women of applying for the testing of a new contraceptive are not obvious. Oudshoorn (1994) has also described how the researchers involved in the early development of the Pill in the late 1950s had to work hard to create what she calls "a laboratory in the field" for testing the contraceptive potential of their hormonal preparations. The first field trial was carried out in Puerto Rico, in collaboration with its Family Planning Association. The island guaranteed relatively controlled conditions with little chance that trial participants would be lost for follow-up. An organizational infrastructure was provided by the Family Planning Association, which had a widespread network of family-planning workers and clinics. Trial subjects were found in a new public housing project for poor families, who were used to relying upon the public health system. Oudshoorn concluded that even in this favorable context selected for testing the Pill, researchers encountered many difficulties in trying to discipline the participants to abide by the test protocols. The women had to take the Pill in the prescribed way, submit themselves to interviews and physical examinations, and continue to comply with their appointments to visit the clinic. (Oudshoorn 1994). In other words, clinical trial participants may resist being disciplined in the ways inscribed by the researchers in the technological script. In addition, since the time that the Pill was first tested and introduced, alternative means of family planning had become available, regulatory requirements had become more rigorous, and ethical standards had been raised. To enroll and maintain women in the trials to test anti-fertility vaccines entailed a number of problems.

In this chapter I will examine these problems. I divided the clinical trials into three stages: the recruitment and selection of participants, the actual enrollment and conduct of the trials, and the reporting of the results. How
were clinical trial candidates portrayed in the texts of researchers so as to facilitate their recruitment? When was agency ascribed to the clinical trial participants and when not? What else did the researchers in different countries do to enroll and maintain a sufficient number of women in the trials? Once the researchers had enrolled sufficient and suitable women, they could measure antibody levels in the blood of the trial participants and monitor side-effects. But more than measurements was needed to make the trials successful. The scientists hoped that the anti-fertility vaccines would be effective and safe. What representations of users did they invoke in their scientific reports to portray the testing as successful? What were the effects and the limitations of their representational strategies?

The structure of this chapter is as follows. First, I provide a short overview of the clinical trials that have been carried out with anti-fertility vaccines. The rest of the sections refer to these trials. Next, I analyze the ways in which the clinical trial participants were configured, specifically in the inclusion and exclusion criteria. Subsequently, I discuss how the researchers dealt with the agency of the participants in attempting to recruit and keep them in the trials. Finally, I examine how clinical trial participants were represented in the assessment of the efficacy and safety of anti-fertility vaccines.

2. Clinical trials with anti-fertility vaccines: an overview

Three prototypes of βhCG vaccine have undergone at least phase I clinical trials to test their safety and performance in humans. A whole βhCG vaccine was first tested by Stevens and his colleagues in six female prisoners in the early 1970s (Stevens 1975, personal communication by Stevens 26 December 1996) and in six other women in the United States in 1973 (Stevens and Crystle 1973). The β-hCG-CTP vaccine that Stevens developed for the WHO/HRP Task Force for Immunological Methods for Fertility Regulation was tested in 30 trial participants in the Flinders Medical Center in Adelaide, Australia in 1986-1987 (Jones et al. 1988). In 1994, a phase II trial with this vaccine was started in two hospitals in Uppsala and Stockholm, Sweden. But this trial was suspended after a few months, because the first seven participants all experienced severe and unexpected side-effects. The researchers went back to the laboratory to find out the causes of these side-effects and to do additional animal studies.

Talwar and his colleagues at the All India Institute of Medical Sciences in New Delhi tested a whole βhCG vaccine in four sterilized women in 1974 (Talwar et al. 1976a). This trial was extended by the Population Council to 15 more women in Finland, Sweden, Chile, and Brazil (Nash et al. 1980). In
1990, another phase I trial was carried out with whole βhCG vaccine by The Population Council in Chile, Finland, and the Dominican Republic in 24 sterilized women (Brache et al. 1992).

The researchers at the All India Institute of Medical Sciences extended their 1974 trial to eight non-sterilized women (Hingorani and Kumar 1979). Another trial in 23 non-sterilized women was carried out in Bombay (Shahani, Kulkarni and Patel 1979, Shahani et al. 1982). These trials were sponsored by the International Committee for Contraception Research (ICCR) of the Population Council in New York. In contrast, the Population Council researchers had included sterilization as a criterion in their extension of Talwar’s 1974 trial, because of the lack of knowledge of contraceptive effectiveness, and as they fairly add, "the desire to observe antibody response and health effects without the complication of pregnancy" (Nash et al. 1980, 329). The fact that the researchers in Bombay selected fertile women in this stage of research was criticized both in India and abroad. The concerns were not only about the testing in women before adequate safety tests had been carried out, but in particular about the fact that the women were recommended to have abortions in the event they became pregnant. According to the Indian science journalist Jayaraman:

> Although Talwar was the first to put hCG vaccine into human trials in 1974, he lost the race because of controversies that cropped up after he jumped the gun. In a hurry to beat his competitors, he vaccinated six unsterilized women with hCG-IT vaccine in 1976 when its efficacy was still in doubt. Two of the women became pregnant, World Health Organization withdrew support, and questions of ethics raised by the Indian scientific community forced him to go back to the laboratory (Jayaraman 1986, 661).²

Next, the Indian research team at the National Immunology Institute in New Delhi proceeded to develop an hCG-based vaccine that was expected to be more effective, called the Hetero Species Dimer-hCG vaccine (HSD-hCG). Three slightly different versions of this vaccine were tested in 101 women in India in a phase I clinical trial in 1988 (Talwar et al. 1990). And in 1991-1992, 148 more women were vaccinated at the All India Institute of Medical Sciences and the Safdarjung hospital in New Delhi, and the Post Graduate Institute of Medical Education and Research in Chandigarh, in a phase II trial to investigate efficacy (Talwar et al. 1994). In 1995, the director and founder of the National Institute of Immunology, Pran Talwar, retired and his successor critically reevaluated the progress of the anti-fertility vaccine development. In 1997, the projects’ annual grant from the Indian Department of Biotechnology was halved, and a planned phase III trial was not begun. The
researchers went back to the laboratory to study the long-term safety aspects of the preparation.

Phase I clinical trials were also carried out with an anti-FSH vaccine in men in India (Moudgal et al. 1997a and 1997b), and also with an anti-GnRH vaccine in post-partum women (Talwar 1992) and in men with cancer of the prostate (Ladd et al. 1988, interview with Talwar 22 June 1996). Currently, a phase II clinical trial of the anti-GnRH vaccine is underway in healthy men in Chile (interview with Catterall 18 October 1996).

3. The enrollment of trial participants

The clinical trial protocols for the testing of anti-fertility vaccines were very demanding. Typically, the women would first undergo a thorough clinical examination, including a gynecological examination and a Pap smear. Urine would be collected and blood would be drawn. They were required to keep a menstrual record during the whole test period of about a year. Then they would receive two to four injections in the gluteal muscle, at fortnightly or monthly intervals. Subsequently, the protocol prescribed that they had to visit the clinic monthly for physical examinations, blood and urine tests, and interviews on side-effects. The women in the phase II trial in Sweden were asked to keep "coital diaries". In the 1990 phase II trial in India, eight women visited the clinic for an early morning examination after intercourse in mid-cycle. (Kumar et al. 1976, Talwar et al. 1976b, Nash et al. 1980, Shahani et al. 1982, Jones et al. 1988, Thau et al. 1989, Talwar et al. 1990, Brache et al. 1992, Protocol WHO/HRP 1992 version, Technical Report NII 1991-1996, Talwar et al. 1994). There were no clear rewards for the sterilized participants in phase I trials. The investigators preparing the Swedish phase II trial in fertile women anticipated that the requirements of three injections, close monitoring, and the provision of frequent blood and urine samples may make recruitment difficult and may lead to poor subject compliance in respect to follow up visits (Protocol WHO/HRP 1992 version).

For a successful course of the trials, it was centrally important that enough women would enter and continue to participate. What did researchers do to promote this situation? How could a sufficient number of women be enrolled and maintained in the trials?
3.1 Selection of potential candidates

Clinical trial participants in all the trials were selected on the basis of inclusion and exclusion criteria. These criteria were reflected in the trial protocols. Based on these lists, the research physicians would admit or reject candidates. In this selection the particularities of who might fit the technology was defined, and the process thus entailed the configuring of trial participants. Most of the inclusion and exclusion criteria were medically informed. In general, the trial participants had to be healthy women of reproductive age. For the phase I trials candidates needed to have been surgically sterilized, since the efficacy of the method was unknown. Women with any immunological disorders, such as allergies or a personal or family history of diseases with an autoimmune component, or with sensitivity to the specific components of the vaccine, were excluded. The researchers anticipated that these conditions might interfere with the safety or efficacy of the new vaccine (Griffin and Jones 1991, 181). Other inclusion and exclusion criteria were introduced in order to ensure that the clinical trial population would, in a statistical sense, faithfully represent the intended user population of ovulating women. Candidates had to be pre-menopausal and to have had regular menstrual cycles for at least three consecutive cycles prior to the treatment (Griffin and Jones 1991, 182; Protocol NII 1990).

The inclusion and exclusion criteria were not only medical but also sociocultural. Criteria such as age limits and family situations were based on legal, ethical, and cultural considerations. For example, in the Australian phase I trial in sterilized women, initially a lower age limit of 18 years was proposed by the researchers (Project description WHO/HRP 1984). This was revised and raised to over 29 years, because at that time the researchers reckoned with the possibility that the vaccine might induce irreversible immunity. Irreversibility was considered a potential ethical problem even in sterilized young women, because they might request a reversal of sterilization (Griffin and Jones 1991). Another example of socially informed inclusion and exclusion criteria were family situation requirements. Participants in the phase II trial in India had to be 20-35 years old, of proven fertility, and "exposed to the risk of pregnancy (cohabiting with husband)" (Protocol NII 1990). Also, participants should have at least two living children (Talwar et al. 1992a, 124; Talwar et al. 1993, 210; Talwar et al. 1994, 8533). This last requirement clearly echoed the Indian national population policy of promoting two-child families, and the social importance attached to having children. In contrast, candidates for the Swedish phase II trial were required to "have completed their families" (SC minutes 1991, 5). Not to demand any specified number of children echoed the cultural notion of women's right of self-determination.
From the lists of inclusion and exclusion criteria we can also learn that certain aspects of the participants were deemed irrelevant in making them representative of future users. Race, ethnicity, class, religion, or educational background did not figure on the lists.

The selection of women on the basis of inclusion and exclusion criteria reduced the number of potential candidates. In Australia, women were recruited by means of press releases in national newspapers and announcements in the medical centers (Press release WHO/HRP 1986, Press release Flinders Medical Centre 1986). The chief investigator in the first clinical trial with the WHO/HRP’s anti-hCG vaccine in Adelaide was Warren Jones, Head of the Department of Obstetrics and Gynecology at the Flinders Medical Center at Flinders University. Jones described the Australian phase I trial:

Subject recruitment was initiated in late 1985. There were 181 telephone enquiries from female volunteers of whom 89 were potentially suitable, that is they were surgically sterilised, over 29 years of age and pre-menopausal. Of these 57 were interested in participating in the trial and the final group selected for screening numbered 43 (Jones 1986, 185).³

One way to raise the number of potential candidates was to modify the socioculturally informed inclusion and exclusion criteria, such as age and family situation. In the Australian phase I trial the lower age limit of 29 was changed to over 25 years when additional participants were needed. This was after ten of the selected clinical trial participants had received unstable emulsions, and additional participants had to be recruited to replace them (Press release Flinders Medical Centre 1986, Jones 1986, Jones et al. 1988, 1297).

A similar pattern occurred in the phase II trial with the WHO/HRP’s anti-hCG vaccine in Sweden. The original recruitment target for both centers in the Swedish trial was 50 subjects. A total of 61 women contacted the Karolinska Hospital in Stockholm in response to its initial publicity about the trial, and 17 of them remained potentially available after the interview and the screening. In the Uppsala University Hospital, a total of 16 women expressed interest, of whom three passed the interview and the screening stages (SubSC minutes 1994). The representative of one company involved, Mats Ehrnebo, wrote in September 1994 in a progress report to Task Force Manager David Griffin:

There has been a slower than expected patient recruitment. (...) It is planned then for a more extensive patient recruitment. (...) every aspect that could raise the number of patients that could be screened should be encouraged (Ehrnebo 1994).
The researchers involved in preparing this trial had chosen wider age limits: 18-39 years. The selection criteria for the phase II trial in Sweden were discussed at a 1991 meeting of the Steering Committee of the WHO/HRP Task Force. The lower age limit of 18 seemed to be inconsistent with the requirement of "having completed their families". According to the minutes:

It was recommended that if the age range of the subjects was to be kept at 18-39 years, then the requirement that they should have completed their families should be deleted (SC minutes 1991, 5).^4

This requirement was then changed into "having had one proven pregnancy" and being "engaged in a stable relationship with a non-vasectomized male partner of proven fertility", while the age limits were not changed (Protocol WHO/HRP version 1992). Requirements involving completion of the family were no longer specified. In this way the pool of eligible women was maximized. Later, the lower age limit for the Swedish phase II trial was raised to 25, after the Ethics Committee of the hospital in Stockholm received a letter from the women's health advocates involved in the Campaign to Call for a Stop. The Ethics Committee then reexamined the previously approved application in depth and insisted on raising the minimum age (SubSC minutes 1994, Letter by Stemerding 31 March 1994, Letter by Hjemdahl 6 February 1995).

The socially informed criteria had reflected the researchers' ideas of who might be the future users of the method. Initially, because of uncertainty about the reversibility of the method, these were women who had completed their desired family size. At the 1974 Karolinska Symposium in Stockholm, where the first WHO/HRP research programme on immunological contraception was announced, Egon Diczfalusy said:

(...) the present philosophy is (...) that there is a section of population, say, for instance, women who completed their desired family size, who would certainly be willing to accept an immunological method even if it is irreversible, provided it is safe (Diczfalusy 1975, 31).

And in 1982, Jones wrote:

Such a method ideally would provide a 'buffer period' of potentially reversible contraception for the parous woman who no longer wishes to use oral contraception or other methods, but who is not yet ready to undergo surgical sterilization (Jones 1982, 196).

Next, as I explained in chapter 1, the researchers insisted that the method was not meant for any specific category of users: it would be for everybody. The changes in the inclusion criteria to enhance the number of potential candidates made more specified types of users thinkable, e.g. young women.
Now the researchers under the auspices of the WHO increasingly portrayed the new method as "suitable for delaying a first birth, for spacing birth, and for providing a reversible alternative to surgical sterilization after childbearing has been completed" (Griffin, Jones and Stevens 1994, Griffin 1994, Griffin 1996). The changes in the age criteria, prompted by the need to maximize the number of trial candidates, reinforced the representation of future users as women at all stages of their reproductive lives.

In the Indian trials, women were enrolled through the family-planning clinics of public hospitals. The organizational infrastructure of the health-care system in India helped the researchers at the National Institute of Immunology to recruit women in this way. The Indian researchers encountered fewer problems in finding sufficient potential trial candidates than the WHO/HRP Task Force scientists. For the trials with non-sterilized women carried out in India, women's willingness to participate was seen to be rooted in their need for alternative methods for family planning. In one interview, Talwar spoke about the trial participants as agents who actively sought to become involved. About the enrollment of participants in the phase II trial in the early 1990s, he said:

They were happy. Many of them had problems with IUD's and other methods. (...) We had no difficulty. In fact whenever you stop the trials, people where coming time and again to the clinics, asking [for the vaccine]. You know the original trials were designed for 750 cycles and it continued to 1224. Because some clinics said: you cannot stop all of a sudden. In recognition of the participation, if people are asking, you have to offer it for a limited period (interview with Talwar 1:25-26).

Also the researchers from the Nair Hospital in Bombay reported that participants in their early phase II trial had a need for alternative contraceptive methods:

These subjects did not desire any more children but were reluctant to undergo surgical sterilization (Shahani et al. 1982, 422).

Next to the prescriptions in the protocols, the array of options available to the potential candidates and country-specific institutional arrangements played a part in selecting and thereby configuring the trial participants. Public hospitals provide care for the poorer part of the Indian population, who have fewer alternatives in planning their families. Apparently aware of the selective effect that this setting might have, Talwar repeatedly stressed that:

The number of literates in our trials is more than one could expect considering the average literacy level in our country (Talwar, in Sunny and Shah 1994, 23).
The WHO/HRP Task Force researchers did not comment on the educational background of the participants in Australia and Sweden.

3.2 Portraying women as supportive collaborators

What about the second sense in which women selected for the testing are cast to represent future users: as early practitioners of the new method? Indeed, the researchers did ascribe the role of forerunners of future users to the trial participants. As the researchers at the NII wrote in the information brochure:

These volunteers may be the future users of the vaccine when it is available in the market (Information brochure NII, 3).

The researchers in Sweden, India, and Australia assigned trial participants to the role of supportive collaborators in the technology development process. In Sweden, the information brochure for trial candidates in the phase II trial said:

What are the benefits of participation? (...) By taking part in this trial, participants (...) will be performing an important role in the development of a new method of birth control that may benefit women throughout the world (Information brochure WHO/HRP).

Similarly, in India the information brochure for phase II trial candidates mentioned, among other benefits of participation:

By participating in the trial, the volunteer will benefit from the antifertility effect of the vaccine and she will be involved in an important event in the development of a novel birth control method, which in the future would benefit other women (Information brochure NII, 9).

Two sociologists from Delhi University, Kalpana Viswanath and Preeti Kirbat, conducted fieldwork to study the setting of the phase II clinical trial with HSD-hCG vaccine in New Delhi. They interviewed several of the medical doctors, social workers and participants involved. Viswanath and Kirbat reported that whenever visitors from abroad arrived, certain trial participants were asked to come to the clinic to meet them. The women would dress up with formal sarees and jewelry for such occasions, and the visiting doctors and researchers would take their photos (Viswanath and Kirbat 1997). Thus, the image of women committed to supporting the development of the new birth control technology was confirmed and conveyed to the world.

In Australia, additional participants were needed a few months after the trial had started. In their second press release, the researchers stressed the
commitment and the motivation of the participants who had already been enrolled:

Women volunteers participating in the trial are motivated by a desire to see a more acceptable form of contraception become available for their own and future generations. They have also expressed a wish to help overcome the critical problems of overpopulation in developing countries where a vaccine method is likely to be very acceptable (Press release Flinders Medical Centre 1986).

In other words, here also women participating in the trials were portrayed as agents who actively supported the development of anti-fertility vaccines, if not in their own interest then for the benefit of their children. As in Saetnan's (1996) study of pregnant women visiting the clinic for sonograms, their many possible motives for participation in the trials were equated with support for the development of anti-fertility vaccines. As the Australian chief investigator Jones wrote in the acknowledgement section of a 1986 article:

The trial subjects were unique in their motivation and commitment to assist in the establishment of a new era of contraception (Jones 1986, 187). 6

The configuring of trial participants as supportive of the researchers' project made it easy to understand their readiness to abide by the demanding protocols. This portrayal of the trial participants as distinctively motivated potential users had implications for the researchers' depiction of future users of anti-fertility vaccines as well. The researchers of the WHO/HRP Task Force mobilized women's participation in the Australian clinical trial to underscore the acceptability of the method for future users. In 1994, three of the researchers involved wrote:

It is not possible to do meaningful acceptability studies on new methods of fertility regulation until a sufficiently large number of people are actually using the method in question. However, all 200 volunteers for the Phase I clinical trial in Australia, including the 43 women who actually participated in the trial, expressed support for the development of this method largely because of its characteristics (Griffin, Jones and Stevens 1994, 112).

While admittedly speculative in tone, these researchers were suggesting that women's actual participation in the clinical trial was indicative of the acceptability of anti-fertility vaccines to future users. 7 They could mobilize the trial participants in this way because of their ascribed role as early adopters.

157
3.3 Obtaining informed consent

The enrollment of participants followed informed consent procedures. Candidates received information about the experimental drugs and about what their participation would involve. They then could sign an informed consent form to express their voluntary decision to participate. The aim of the informed consent procedures was to enroll women in an ethical manner. Internationally endorsed guidelines to regulate informed consent procedures were recorded for the first time in 1964 in the Declaration of Helsinki, prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, and they have been updated several times since then. Worldwide, ethical review committees at research centers and funding agencies scrutinize research proposals, information brochures, and final reports on the basis of these guidelines. Ethical guidelines for biomedical research involving human subjects are centered on the dual purpose of respect for a person’s right to make decisions, and protection of vulnerable persons in biomedical research (Cook and Dickens 1991). The provision of comprehensive information to candidates and free decision making were considered essential for ethical enrollment (CIOMS 1993). In other words, to ascribe agency to women in the informed consent procedure was necessary to ensure ethical enrollment.

The women in the Australian phase I trial received verbal explanations from the research physicians and an information sheet (Project description WHO/HRP 1984). The informed consent form stated:

I have read and understood the above information and consent to my inclusion as a subject in the proposed Clinical Trial (Subject Consent Form WHO/HRP 1984).

Women were seen as actively taking the decision to become research subjects and to submit their bodies to the research protocol on the basis of the information provided to them. The informed consent form for the phase II trial under the auspices of the WHO/HRP Task Force in Sweden was accompanied by an extensive information brochure. Again, women were addressed as if they would give their consent or not on the basis of a process of careful communication and individual decision-making. The introduction to the brochure stated that the information was "in order for you to reach a decision". The brochure was written to provide answers to questions likely to be asked by "individuals who volunteer to be in the study", and she was "free to ask questions at any time before and during the study". It was stressed that if she decided to participate in the trial this would be "of your own free will" and that she might "decide to withdraw from the study, for any reason and at any time" (Information brochure WHO/HRP). This mode of addressing
assumed that women had different options for action. Participation in the trial was envisioned as one option for women, the informed consent as a communication process, and women were seen as decision-makers.

A different picture of women's options for action emerged from the performance of the informed consent procedures in the phase II trial in India. The German documentary-maker and women's health advocate Ulrike Schaz filmed the recruitment of some women for this trial. The film showed a room in a public hospital in New Delhi where dozens of women were standing in line waiting to see a doctor. The doctor was sitting behind her desk and told a patient:

We have got a new injection. The effect of the injection stops children for one year. You need not be afraid about this. The injection has no side-effects. You see this injection is absolutely 100% effective. We will also put in a copper-T [IUD, jvk]. Continuous copper-T is not very good. If you have it three years, six years, then there is the risk of cancer. That is why we want you to change (Schaz and Schneider 1991).

The information that this doctor gave to the patient diverged from the protocol. The doctor said that the anti-fertility vaccine was a new injection instead of explaining that this was an experimental method. The duration and the efficacy of the vaccine were yet to be established. And there is no evidence to suggest that three or six years of copper-T would enhance the risk of cancer. This documentary was shown to members of the Steering Committee of the Task Force on Immunological Methods for Fertility Regulation of the WHO/HRP at their meeting in August 1992. It was also presented to scientists and staff of the Population Council at their 1992 meeting of the International Committee of Contraception Research, which collaborated with the National Institute of Immunology. These organizations discussed the issue. The research protocol for this phase II trial had been approved by the Drugs Controller of India, the institutional ethics committees, and the Ethics Review Committee of the Canadian International Development and Research Centre, one of the funders of the clinical research at the NII (Talwar 1994 et al., Letter by Maureen Law 28 March 1995). As a part of the international Campaign to Call for a Stop, women's health advocates discussed the film with the staff at the IDRC (Resistance on the Rise 1995). The film caused concern. This representation of a trial participant differed from the one that the Task Force researchers had been addressing. The woman on the screen was no free-floating agent who could freely decide to consent or not on the basis of her understanding of the complete and accurate information provided to her, but an embodied trial candidate in a specific situation. While the scene underscored the importance of proper infor-
mation, the candidate’s options for action seemed to depend on more than communication processes. Informed consent therefore appeared not as a communication and decision-making process, but as a form of social intervention in a specific context, producing and reproducing power-relations.

At the suggestion of women’s health advocates, some of the researchers from the WHO/HRP Task Force concluded that providing more and better information to women might not be sufficient to ensure her voluntary participation. These researchers proposed that women’s health advocates could play a role in monitoring the conduct of clinical trials. As I described in the previous chapter, women’s health advocates had gained credibility as representatives of an alternative perspective on users in contraceptive development. In the minutes of the August 1992 meeting of the Steering Committee:

The need for involvement of representatives of women’s health advocacy groups at the earliest stages of clinical protocol design and throughout the clinical evaluation of new family-planning methods was recognized and endorsed by the Steering Committee (SC minutes 1992, 6).

But the principal investigators of the forthcoming clinical trial in Sweden felt that there was no need to involve women’s health advocates in their particular trial (SC minutes 1992, 6). Following the proposals of women’s health advocates, the IDRC also suggested to the researchers at the NII that a witness from a local women’s organization should be present at all future clinical trial recruitment sessions (Letter by Maureen Law 28 March 1995). However, the NII did not request any additional funding from the IDRC after their grant expired in 1995, and they did not carry out further clinical studies with anti-fertility vaccines.

The question remained of what the international organizations involved in contraceptive development should do about the obviously unethical situation of providing inaccurate information, as the film demonstrated. As the women’s health advocates had urged in their meeting with IDRC staff in July 1995, the IDRC asked the researchers in India to send them information regarding the longer-term follow-up of the women who had been involved in the study and of any children who were born of these women (Letter by Anne Philips 14 April 1998). The WHO and the Population Council did not publicly undertake any activity. The political sensitivity of criticizing this research partly lay in North-South relationships. In a 1994 guest editorial in the journal *Current Opinion in Immunology*, Talwar wrote:

In the past, most of the new developments in contraceptive vaccines originated from research in industrially developed Western countries. The BHCG and HSD vaccines have emerged from research in a developing country. Apprehensions have been expressed as to whether trials
can be carried out in a developing country in compliance with the ethical principles enshrined in the Helsinki declaration. Economically developing countries, such as India, are not intellectually and professionally underdeveloped (Talwar 1994a, 702).

In addition, the national character of the Indian achievements was often stressed. For example, the announcement of the launching of clinical trials in India in the News section of *Nature* starts:

Clinical trials of two locally developed birth control vaccines have started in India (Jayaraman 1986, 323).

And the researchers involved stated that

The leading work for these vaccines has been done in India, though laboratories in other parts of the world are also engaged in similar studies (Talwar et al. 1992b, 947).

Under the heading 'India's Birth Control Vaccine', an interview with Talwar was introduced with a reference to "the world's first birth control vaccine, being pioneered at New Delhi's National Institute of Immunology". A 1991 photo of Talwar at an international congress of immunopharmacology in conversation with Jonas Salk, the inventor of the polio vaccine, is reproduced with the article (Sunny and Shah 1994, 20-27). In this context, to denounce this research of the National Institute of Immunology would imply criticism of the Government of India. India has been an very important partner for the WHO and for the Population Council. As I described in chapter 1, the Government of India was among the first to introduce family planning as an official policy in the 1950s. Contraceptive research was strongly encouraged by the Government.

To be sure, the clinical research in the Indian centers yielded results that were highly relevant to the other contraceptive vaccine developers. The Indian phase II trial for the first time generated information on efficacy, such as the antibody titre necessary to prevent pregnancy (Talwar et al. 1994b). According to the minutes of the Steering Committee meeting of September 1991:

It was recommended that Dr. Talwar and his co-investigators should obtain as much information as possible about the levels and affinities of the anti-hCG antibodies in the serum at the time of implantation in those subjects who got pregnant, as these data would be extremely valuable for estimating the actual efficacy threshold of immunity to hCG (SC minutes 1991, 31-33).
These trials also provided important data for assessing certain safety issues, such as the clinical relevance of potentially harmful cross-reactions. As the chairman of the Steering Committee wrote:

The cross-reactions elicited by the intact β chain vaccine are worrying but that concern diminishes as the number of women who have been vaccinated without adverse consequences increases (Mitchison 1990a, 726).

On the basis of the Indian human trials, the WHO/HRP Task Force scientists also decided to omit some of the safety testing in baboons. As the Steering Committee observed:

The value of a homologous baboon CG vaccine model becomes less important as the amount of more relevant data from clinical trials increases (SC minutes 1992, 13).

In 1993, Talwar was back in the WHO/HRP Steering Committee.

3.4 Keeping them in the trial

Agency was not solely an attribute that researchers could ascribe or not to clinical trial candidates. Therefore, it cannot be expected that the women actually relinquished their agency by signing a form and becoming research subjects. From the trial reports it turns out that women maintained at least their capacity to foot-vote, and to either continue or stop visiting the clinic after they had been enrolled and selected. Sarah Franklin (1995), who studied women’s determination to undergo In Vitro Fertilization, has also pleaded for a more processual perspective on women’s involvement in ongoing procedures instead of focusing only on their initial motivations. It is therefore important to study the role of clinical trial participants and the agency ascribed to them after their enrollment.

Indeed, women in Australia, India and Sweden continued to drop out after they had been selected. For example, the WHO researchers wrote that of the 37 selected and medically screened subjects for the Australian trial, 11 dropped out. The reasons mentioned by the researchers included one case in which the "husband was opposed" to the trial, and another with "domestic problems". One woman dropped out because of "work commitments". Another, recently returned from south-east Asia, had a recurrence of a parasitic intestinal disorder. Two women dropped out in this stage because they "decided to seek sterilization reversal" (Jones 1986, Jones et al. 1988).11 Again, the Indian researchers encountered fewer problems in maintaining a sufficient number of women in their trials. In the phase I trial in India with the three HSD-hCG vaccines fifteen of a total of 116 subjects
ceased to participate, among whom were two subjects who were "excluded from the trial due to non-adherence to the study protocol" and one who was "lost to follow-up". Only three of the 116 subjects discontinued "owing to personal reasons" (Talwar et al. 1990).12 Drop-out was a problem for the researchers. It meant the loss of prudently selected participants, and it rendered useless the work of enrolling them and the measurements done on them. How did the researchers handle women’s capacity for foot-voting in order to prevent drop-out? There were important differences between the life and health of women in India and of women in Australia and Sweden. These differences had affected the ways by which they had been recruited, and also influenced their options for action once they had become research subjects. Accordingly, the researchers devised different means to prevent drop-out.

In the Indian trials, the daily life situations of women facilitated their enrollment and perpetuation in the trial. The sociologists Viswanath and Kirbät have described how the most frequently mentioned advantage of participation for clinical trial participants was that it improved their access to medical care. Since they could not afford to go to private clinics, asking for medical treatment meant leaving all work and queueing for hours in long lines outside the public hospitals. As clinical trial participants, they and their families received priority treatment. It might be difficult to overestimate the importance of this benefit for poor women of childbearing age in India. Moreover, Viswanath and Kirbät have described how the researchers actively tried to make participation attractive to the participants so that they would not drop out.13 They mentioned that most of the hospitals where the trials were conducted had separate rooms for the trials. According to these authors, at one of the hospitals the trial center was a very pleasant room with posters and photos and a place to sit around. The clinical trial provided an opportunity for the participants to come and spend time at the trial center chatting while being served cold drinks and snacks. The women received reimbursement for their travel expenses and time lost from employment (Kirbät 1998, 4-5). Kirbät concluded:

(...) women participating in clinical trials often use it as a means for improving their existing situation. They are in their own way getting access to an extra income, improved health care, and a sense of identity and social space outside their homes (Kirbät 1998, 5).

In other words, according to Kirbät, the researchers made special efforts to make participation attractive and discourage participants from abandoning the trial. As Kirbät’s analysis has indicated, women’s performance of agency was not limited to the enrollment stage. This author regarded women’s continued participation in the trial as their able and knowledgeable performance in a
specific situation. Accordingly, the ethics (and politics) of the clinical trial were not confined to the enrollment stage. Kirbat continued:

On the other hand, one can argue that these motivations provided by the research center in some ways take undue advantage of the situation of low income, uneducated women by providing them with opportunities they would otherwise not have (Kirbat 1998, 5).

Thus, this author has described a tension between women as actively seeking to become research subjects in a specific situation, and women as victims of those circumstances and power relations. Importantly, the provisions that the researchers made were effective only in the light of the daily-life situations of poor women. In contrast, the provision of a social space outside the home might not have been of significant to men, and access to good-quality health care was not an issue for richer people. The arrangements that the researchers made suited a specific category of clinical trial participants.

The difference that social contexts and relational factors made in recruiting and keeping women in the trials can be illuminated by comparison with the Swedish phase II trial. Researchers had fewer opportunities to make participation in this trial attractive to women in Sweden. Improving their access to good-quality health care was not relevant for these women. Just as in the Indian phase II trial, participants were reimbursed for travel expenses, time lost for employment, and other trial-related expenses. But as in any country, offering payments as an inducement to take part in the trial was considered unethical, since it would limit the candidate’s ability to consent freely. Apart from the eventual anti-fertility effect during the efficacy stage of the trial and a thorough medical examination, there were no personal benefits for the participants (Information brochure WHO/HRP). The researchers encountered various problems in enrolling and keeping a sufficient number of trial participants.

4. Reporting of the results: making the trials successful

To enrol enough and suitable trial participants was a necessary but not a sufficient condition for successful clinical trials. The researchers hoped to find a long-lasting and high level of antibodies against hCG in the blood of the participants, and they hoped that the women would display no side-effects. To substantiate the safety and efficacy of the vaccines in a successful clinical trial would provide an ardently needed basis to encourage further development (WHO/HRP 1985, 55). The field of immunological contraceptives had enjoyed the status of "showing promise" for over fifteen years now (WHO/HRP 1978, WHO/HRP 1988, Shegal 1976, Talwar 1976, Talwar 1993,
Mitchison 1990b, Griffin 1991, Griffin and Jones 1991, Jones et al. 1988), and as I discussed in chapter 3, this had been vital for the continuity of the research. Yet the efficacy of an anti-fertility vaccine had never been established in humans. It was high time to show result for these efforts.

As I described in chapter I, the 1974 Indian trial had prompted a bitter competition between the anti-hCG vaccine developed by the NII team and the one developed by the American-Australian team under the auspices of the WHO, and the split was aggravated when Indian researchers tested the vaccine in fertile women. The ongoing competition between the American, Australian and Swedish researchers under the auspices of the WHO on the one hand, and the Indian team at the NII on the other contributed to the pressure to produce favorable outcomes. From both sides, doubts were expressed about the extent to which the published results indeed reflected the trial findings. As Talwar said about the report on the efficacy of the CTP-hCG-vaccine by the Task Force scientists:

It will not work and they know that it won’t. On paper it looks good, but many people have tried that. But you see people don’t publish the negative results. Furthermore, you don’t want to displease WHO. Because, you know, you want to receive money or invitations and so on (Interview with Talwar 1:21-22).

And as Stevens said about the published results on the safety of the HSD-hCG vaccine tested by the team at the NII:

Talwar’s vaccine, using [two large antigens] creates some concerns. But you can only believe what they report, and they say that there is not any notable disruption of ovarian function (Interview with Stevens 1:46).

These researchers thus seem to suggest that part of the production of promising results took place in the reporting about the work. Also constructivist STS scholars such as Latour (1987), Oudshoorn (1994), and van der Ploeg (1998) have described how the reporting of scientific results is more than a formalized account of the accomplishments achieved in the laboratory or the clinic. Scientific writing can be considered as part of the work itself, partly constitutive of the results. Therefore, I will have a closer look at the reporting of the trial results in scientific articles, in particular at the ways in which the participants figured in these texts. In what ways were clinical trial participants represented in the reporting of safety and efficacy results? Which efficacy and safety problems could not be resolved by the means of textual representation, and how were these issues dealt with?
4.1 The construction of efficacy

The first step in showing that anti-fertility vaccines would be effective was to generate a sufficiently high and sustained level of antibody response to hCG in phase I trials. As I have described in the former chapter, the scientists had made various modifications to the vaccine in order to achieve this goal. But the phase I trials with anti-hCG vaccines continued to produce substantial variation in the duration of the immune responses among women (Talwar et al. 1976b, Nash et al. 1980, Jones et al. 1988, Talwar et al. 1990, Brachet et al. 1992). The results were not reassuring. What did the researchers do when the trials did not produce the results they were looking for? In so far as the problem of variation in the duration of immune responses had remained unresolved by modifications to the vaccine, it was remedied in the textual representations of the results. Notably, the clinical trial participants were invoked in these representations, but they were unable to talk back.

In the trial reports from India the attainment of a sufficiently high and sustained immune response was attributed to the participants and not to the vaccine. The subjects could fail, but not the vaccine. According to the report of the trial with fertile women in India in the late 1970s:

The results of this study indicate that Pr-beta-hCG-TT vaccine was immunogenic in the majority of subjects except for one subject who was totally unresponsive and another 2 who developed very low titers (Shahani et al. 1982, 432).

In addition, the researchers rated the findings in these "unresponsive" women as insignificant in evaluating the efficacy of the vaccine:

The occurrence of 10 pregnancies in 8 subjects during the trial need not yet be taken as a failure of antibodies to block the implanting blastocyst. (...) the pregnancy occurrence could be attributed to failure of contraceptive supportive measures, ovulatory cycles, and the high fertility of this group (Shahani et al. 1982, 433).

These researchers thus concluded that the technology had not failed. Instead, the women had failed by not using the mandatory supportive contraceptives and simply by being too fertile. Once the capacity to fail was assigned, a distinction was made between good and poor responders. In the 1974 phase I clinical trial report:

All subjects gave a positive response to this vaccine. (...) N.D. was the best responder and A.M., the poorest in the group (Talwar et al. 1976b, 239).
And in a 1979 article Talwar wrote:

There is (...) one other variable which every immunological approach has to face, and this is the difference from individual to individual in immunological responsiveness to a given antigen. There are good, moderate and poor responders (Talwar 1979, 464).

This same distribution of competencies was adopted by the Population Council. In the trial of the Population Council in the Dominican Republic and Chile in 1990, various dosages of vaccine were given to the participants. In the trial report the subjects are classified in terms of low, intermediate or high response to the vaccination, and not by dosage. Subjects with a low level of antibodies were referred to as "poor responders" who "did not achieve titers sufficiently high" (Brache et al. 1992).

The distinction in the textual representation of the results between good responders and women who failed to produce a sufficient antibody response was not without consequences. In this line of reasoning, the finding of variation in the duration of effective immune responses was not considered prohibitive for the further development of anti-fertility vaccines. Instead, the method was redefined as unsuitable for poor responders. In an interview with medical anthropologist and women’s health advocate Anita Hardon, Talwar said:

The main disadvantage, as I see it, is that you have to be a responder. Around 20% of the women were poor responders (Talwar, quoted in Hardon 1997).

Another textual representation technique to resolve the problem of individual variation was by giving mean levels of antibody concentrations and mean durations. The report of the phase I clinical trial with anti-hCG vaccine developed under the auspices of the WHO in Adelaide in 1986 presented the mean concentrations of anti-hCG antibodies attained by each dose group. The researchers at the Bombay hospital did the same, and also in the 1990 report of the comparative clinical trial in India the results are presented in a table with mean peak titers and also mean duration of antibody levels above a certain threshold (Shahani et al. 1982, Jones et al. 1988, Talwar et al. 1990). In each of these studies, mean values were calculated even when the data had been obtained using of different batches of vaccine. In the case of the comparative trial in India, even data generated by different formulations of anti-hCG vaccines were pooled. All reports concluded that although the individual variation in immune responses required further examination, the results were promising, so that further trials could be undertaken.

The second step to assess the efficacy of the anti-fertility vaccines involved phase II trials. In the phase I trials, researchers had been able to
handle the problem of individual variation in immune responses by means of specific modes of reporting the results. But in phase II trials in fertile women, these textual representation techniques were no longer sufficient. Weak or short immune responses would inevitably fail to protect individual trial participants against pregnancy. As a result, this problem placed special demands on the phase II trials.

In the phase II trials in both India and Sweden, a participant would be advised to have her IUD removed, or to stop using other barrier methods, as soon as the anti-hCG antibody level in her blood would rise above the level estimated to provide protection against pregnancy (Talwar et al. 1994, Protocol WHO/HRP 1992 version). The duration of a protective immune response could not be predicted for an individual trial participant, and therefore her antibody level had to be carefully monitored. The researchers had envisioned that easy-to-use test kits for home or clinic use would be an appropriate way to address this problem (see chapter 3). But such test kits were not yet available. Moreover, knowledge and expertise required for the use of these assay techniques was not widely available. As Griffin and Jones, from the WHO Task Force on Immunological Methods for Fertility Regulation, put it:

In view of the genetically controlled variations in individual immune responses, frequent blood sampling for antibody titres estimations and rapid provision of the titre information to the clinical trial investigator will be needed. Access to a reliable assay facility, in which rapid and accurate estimations of the hCG antibody levels can be made, is therefore essential for a satisfactory outcome of the study (Griffin and Jones 1991, 187).

The efficacy of the anti-hCG vaccine could not properly be estimated just anywhere, but required a suitably equipped. The prestigious Karolinska Institute in Stockholm, Sweden, was selected. The principal investigator of the phase II trial, Marc Bygdeman, confirmed:

The capacity to do such analyses was one of the prerequisites for doing the phase II study on the contraceptive efficacy of the treatment (Bygdeman 1996, 322).

In addition, information about whether the antibody level in her blood was still sufficiently high had to be made available to participants on a short notice. For the phase II Swedish trial it was foreseen that:

Failure of a subject to be present on the specified day will necessitate a home visit to ensure that all blood and urine samples are obtained (Protocol WHO/HRP version 1992).
The phase II trial with fertile women in India also had to take into account the need to inform women quickly if their antibody levels should fall. The Information Brochure for the Indian phase II trial mentioned that

All participants will have to give their contact addresses and/or phone numbers so that the health workers can contact them anytime during the trial. In case they wish to leave town, they must inform the centre well in advance so that adequate measures can be taken by the clinical investigators (Information Brochure NII).

And the Indian sociologists Kirbat explained that for the Indian phase II trial:

(...) there was a whole team geared towards following the women's level of antibody titres, and blood tests were carried out every two weeks. When a booster vaccine was required for a participant, she was contacted - sometimes by going to her house at night in the hospital van. This kind of a follow up would be impossible in typical public hospitals (Kirbat 1998, 7).

In other words, the phase II trials in Sweden and India had to be organized in such a way as to counteract the individual variation in immune responses, involving accessible trial participants, frequent blood sampling, well equipped laboratories, and highly motivated health personnel.

To inform the women in time was one of the main problems that the scientists preparing the Swedish phase II trial foresaw:

To obtain the maximum number of study cycles in each subject and to ensure that subjects are not exposed to the risk of pregnancy against their wishes, it will be necessary to obtain reliable estimate of anti-hCG antibody levels within as short a space of time as possible, and preferably within 72h. Providing this information within the time constraints imposed by the assay procedure may prove difficult (Protocol WHO/HRP 1992 version).

There were thus two reasons why the women had to be informed as soon as possible about their antibody levels. First, to safeguard the women from unwanted pregnancy. And second, this was crucial to maximize the number of cycles that would be relevant for the assessment of efficacy. "Study cycles" meant menstrual cycles in women with a sufficiently high immune response. Menstrual cycles in women with a low level of antibodies would not be study cycles. As Griffin and Jones wrote in a description of their approach to calculating the number of trial participants required for the Swedish phase II trial:

This approach assumes that the different cycles contributed by each woman are independent (...). Because of the independence assumption
it is immaterial whether these (approximately) 750 cycles be observed on 125 women having six cycles of contraceptive immunity, or 250 women each with only three month immunity (Griffin and Jones 1991, 188).

In her analysis of the testing of the Pill in the 1950s, Nelly Oudshoorn (1994, 128-131) has described how veteran researcher Gregory Pincus represented the trial participants as menstrual cycles in his scientific reports. The researchers had experienced persistent problems of recruitment and of drop-out of women in the conduct of the trials, but these were made invisible by the means of this technique of textual representation. As Oudshoorn pointed out, referring to the number of menstrual cycles created the effect of impressive grand totals and thriving trials. Since then, menstrual cycles have become an established method of reporting in contraceptive research. More than replacing women with their "immaterial" menstrual cycles would be needed for the testing of anti-fertility vaccines, with their drawback of causing differing responses. Not all menstrual cycles could be treated as equal. Analogous to the distinction between good and poor responders, the researchers distinguished good and poor cycles. Only the good ones were study cycles.

In the phase II trial in India, the only completed study to assess the efficacy of anti-hCG vaccines, a distinction was also made between the cycles of women with a high antibody response and of those with a low antibody response. According to the trial report, 148 women completed the schedule of three injections. Of these, 119 (80%) generated antibody levels that were above 50 ng/ml, the estimated threshold necessary to prevent pregnancy. In approximately 60% of these 119 women, the protective level was sustained for six months or more. One pregnancy occurred in a woman having an antibody titer of over 50 ng/ml in 1224 cycles. Twenty-six pregnancies occurred in the other 29 women who had titers below this level and were not given booster injections, or who had not used alternative contraception effectively (Talwar et al. 1994). The researchers refer to these results in a 1997 article:

Observations recorded over 1,224 cycles showed only one pregnancy occurring above 50 ng/ml. The efficacy imparted by the vaccine at this threshold titre was thus very high (Talwar et al. 1997, 155).

Without the distinction between cycles with immune response above or below the threshold, the efficacy of the anti-hCG vaccine in the phase II trial would have been a relatively disappointing 60 to 80%. 
The promising efficacy results produced in the Indian phase II trial were significant and influential. The 1994 report of the phase II trial was hailed as a landmark by other researchers in the field of contraception:

‘Bravo to Talwar’, says gamete biologist John Herr of the University of Virginia, who is working to develop an anti-sperm contraceptive vaccine. ‘It’s the result that says "go".’(...) That ‘go’ signal is sorely needed, say contraceptive vaccine researchers, who argue that their field, which shows great promise, has long suffered from sparse funding (Aldous, 1994).

As the managing editor of the *American Journal of Reproductive Immunology*, Carolyn Coulam, wrote in an editorial:

This milestone is very important in justifying further research and development of hCG vaccines and providing hope of social and economic progress in the developing world (Coulam 1997, 151).

In sum, to make the efficacy trials with anti-fertility vaccines successful, the researchers needed a suitable location and organization: frequent access to the participants for blood sampling and additional injections, centers where information on antibody levels could be generated, and ways to keep the participants promptly and regularly informed. The assessment of the efficacy of the vaccine would have been far less satisfactory if the personnel in the Indian trial had not put a great effort into giving booster injections in time. This efficacy also depended on specific textual representations of the results, such as the classification of menstrual cycles either as study cycles, or as those in which antibody titers were below the threshold.

In the construction of efficacy, the clinical trial participants were assigned the passive role of contributors of study cycles. There was one exception. The clinical participants could not possibly control their antibody responses, but they might be able to regulate their exposure to pregnancy. In this way they would be actively involved in the efficacy assessment. In preparation of the phase II trial in Sweden, Griffin and Jones wrote:

In order to demonstrate the efficacy of the vaccine, it is necessary to observe a minimum number of cycles in which intercourse took place at a time when there would be a high chance of pregnancy in the absence of effective contraception. Without recording the timing of acts of intercourse, the impact of couples deliberately or subconsciously avoiding intercourse at mid-cycle could not be assessed (Griffin and Jones 1991, 188).

The request that trial participants keep coital diaries was an attempt to account for this effect.
4.2 The construction of safety

The construction of safety is of special concern. Betsy Hartmann (1992) has signaled that contraceptive safety is defined in relative terms. She cited from a contraceptive study by the U.S. National Research Council:

All active drugs cause adverse effects in some users. If safety were understood as the total absence of adverse effects, then no drug could be called "safe". Safety of a drug is conceived as a favorable ratio of benefits to risks for the population of users of the drug as a whole (Mastroianni, Donaldson and Kane 1990, 102).

As Hartmann has concluded, given this definition, the question of how contraceptive safety is assessed becomes particularly relevant.

As I explained in chapter 3, researchers in fertility regulation successfully retained the assessment of safety within their scientific domain. The safety of the vaccine in humans was measured on the basis of parameters in the blood of the participants, clinical examinations, and the participants’ reporting of side-effects (Talwar 1976, Nash et al. 1980, Jones et al. 1988, Talwar et al. 1990). The involvement of the clinical trial participants in the first two aspects consisted of presenting themselves to the clinic to undergo the investigations by the research physicians. But by giving notice of side-effects the participants could play a more active role, and I will therefore concentrate on this aspect of the safety assessment. In what ways were the clinical trial participants portrayed in the scientific reporting of side-effects?

By reporting side-effects or not, the participants could influence the safety assessment of anti-fertility vaccines. But appraising the significance of side-effects was beyond their competence and control. The clinical investigators were entitled to make these assessments. For example, to affect the safety assessment of anti-fertility vaccines, observed side-effects had to be attributed to the method and not to the participants. In the phase I trial of the Population Council a distinction was made between the problems described by the trial participants, and other medical conditions. The researchers wrote:

Complaints voiced by subjects during the interval from first vaccination to the present, and conditions detected by physical examination, are summarized in table 2 (Nash et al. 1980, 332).

The conditions expressed by the participants were portrayed as "complaints" (Nash et al. 1980, Talwar et al. 1990). The use of the term "complaints" in describing the side-effects reported in clinical trials is not restricted to anti-fertility vaccines. But the use of this term was entrenched in a context in which complaining women were granted dubious legitimacy. Kirbat (1998) reported about one woman who told her that:
After she kept complaining for a few weeks she was told by the social worker that it was in her nature to complain. (...) Later this woman was asked to leave the trial (Kirbat 1998, 7).

The researchers were also entitled to interpret and report on the seriousness of the side-effects in their scientific papers. In an article about the Indian phase I trial, this led to the following counterintuitive characterization of the problems. The researchers wrote:

(...) Out of 88 subjects who were immunized with different formulations of the hCG vaccine, 63 did not have any complaints following first injection. The remaining 25 subjects (28%) had minor complaints such as erythema, pain at the site of injection, fever, oedema, generalized rash, transient joint pain, nausea, muscle pain and giddiness. (...) Thus, further work can be undertaken to study the efficacy of these vaccines in humans for preventing pregnancy (Talwar et al. 1990, 302-306).

In an analysis of acceptability studies of Norplant®, Anita Hardon found this same tendency to qualify the side-effects that women reported as "minor" and "transient", and to stress that their relation to the new method had not been proven. As many women's health advocates have observed, from the perspective of women these so-called "minor" complaints might interfere deeply with a women's daily life and well-being. The "non-life threatening" side-effects of Norplant®, such as menstrual disturbances, headache, and dizziness, were the main reason for women to discontinue the use of drug (Hardon 1992). Outside the realm of contraception research, in his study of the development and testing of non-steroidal anti-inflammatory drugs to treat rheumatoid arthritis, John Abraham (1995) found a similar pattern. Scientists developing these drugs for the pharmaceutical industry tended to minimize side-effects and to exaggerate efficacy, in systematic accord with their commercial interests. In anti-fertility vaccines development, such interests are less apparent than the researchers' concern with maintaining the promising status of their field of technology development. Again, this labeling of the side-effects was significant. The conclusions about the degree of side-effects facilitated the further development and testing of anti-fertility vaccines. In the protocol for the phase II trial, the Indian researchers observed that in the phase I trials:

No notable side-effects of immunization were observed (Protocol NII 1990).

The other research groups as well invariably concluded that they found "no significant adverse effects (...) on health" (Nash et al. 1980, 328) and "no
serious adverse reactions" (Brache et al. 1992, 8), or that "no serious or unacceptable side-effects were observed by the investigators nor reported by the trial volunteers" (Griffin 1988, 177).

So far it seems that the trial participants’ complaints about side-effects made little difference for the safety assessment and the further development of the vaccines. But there was another way in which the trial participants could express their grievances: they could leave the scene. One of the side-effects that was noted by the trial participants in the Australian phase I trial was muscle and joint pain following the injection. As Griffin wrote:

The only side-effects considered significant by the resident physician, were transient muscle and joint pains reported by a few subjects. These symptoms (...) were satisfactorily controlled with analgesics and did not cause any of the volunteers to withdraw from the trial (Griffin 1988, 182).20

The researchers counted on the participants’ capacity for foot-voting. The fact that women did not abandon the trial was regarded as an indicator of the weight of the side-effects. The pain was eased with analgesics. No further research into the causes of the pain was undertaken at this stage.

Side-effects turned out to be a very important indicator in the interrupted phase II trial in Sweden. Recruitment for this trial was started in December 1993, and the first women were vaccinated in March 1994. In June 1994 the trial was stopped. According to the newsletter of the WHO/HRP, Progress:

After consultation with Task Force advisers, and with the clinical trial investigators and trial monitors, the phase II clinical trial of the prototype anti-hCG vaccine developed with support from the Programme’s Task Force on Vaccines for Fertility Regulation was suspended in June 1994 following the occurrence of unexpected but transient side-effects in the majority of the first seven women volunteers admitted to the trial (Progress 1994, 8).

The principal investigator of the Swedish trial, Marc Bygdeman, wrote a progress report to Task Force Manager David Griffin.21 The adverse events that were considered to be related to the vaccination included sterile abscesses in two women, pain at the injection site, muscle and joint pain, fever in two women, and menstrual disturbances in three women, including a too early onset of menstruation and an episode of prolonged menstruation (Bygdeman 1994). Apart from the reported severity of the pain, the side-effects found in the Swedish phase II trial were not uncommon as compared with those in the earlier trials with anti-hCG vaccines. The nature of the side-effects was not different from that described in the reports of the Indian phase I trial (Talwar
et al. 1990) and that of the trial under the auspices of the Population Council (Nash et al. 1980, Brache et al. 1992). As Stevens and Crystle wrote in their report about their 1973 trial with six women in the United States:

After the initial injection (…) some itching and swelling at the injection site occurred. This was significant in 3 women and 1 had a sterile abscess at the injection site (Stevens and Crystle 1973, 488).

Stevens and Crystle ascribed these reactions to the adjuvant substance, which then was changed (Stevens and Crystle 1973). In the phase I trial in Australia by the Task Force scientists, several women in the higher dose group also experienced muscle pain, which was reported to be "mild and transient", and pain-killers had been provided. Two participants reported redness and itching at the injection site (Jones et al. 1988, 1297, Griffin 1988). In this Australian trial several women also had menstrual disturbances: three participants reported intermenstrual spotting and one had very heavy periods. In a 1994 article the Task Force scientists Griffin, Jones, and Stevens mentioned these disturbances:

There was nothing unusual about these events in a group of 40 previously sterilised women and none of these events was considered to be related to the vaccine (Griffin, Jones, Stevens 1994, 110).

But in the Swedish phase II trial the clinical investigators reported that the side-effects were serious, and they characterized the reactions as vaccine-related. This was in contrast to the dominant tendency of characterizing the side-effects of new contraceptives for women as minor, transient, and of unknown relation to the product. Why were the side-effects evaluated differently in this trial, resulting in the interruption of the vaccine development?

The clinical investigators attempted to control the side-effects by various means. Task Force manager Griffin wrote a letter to inform the Scientific and Ethical Review Group of the WHO/HRP of the interruption:

All 7 subjects experienced unexpected side-effects, such as transient fever, injection site pain and in two instances, sterile abscesses. Although these side-effects were reduced to a tolerated level by reducing the dose and splitting the injections, they could not be eliminated completely. The trial was stopped, therefore, and the cause of these side-effects was investigated (Letter Griffin n.d.).

While the side-effects were reduced to tolerable levels according to the researchers, some of the trial participants made a different assessment. Two of the seven women discontinued their participation on their own account because of the pain created by the vaccine. The report by Bygdeman men-
tioned that the pain of one of these women, and in the two women with the abscesses, was so severe as to prevent them from working. One of the seven, the only one who had received a second injection, became pregnant (Bygdeman 1994). By leaving the trial, the participants decisively influenced the course of research on anti-fertility vaccines. When the trial was stopped, the Task Force members proceeded with research to identify the causes of the side-effects, and undertook additional laboratory and animal studies for further vaccine development.

Another reason why the assessment of the side-effects in the Swedish trial differed from that in earlier trials might have to do with the international campaign to Call for a Stop on this research that had been launched in November 1993, one month before the start of the trial. The Task Force Manager, clinical investigators and members of the Steering Committee who took part in the decision to interrupt the trial were well informed that their work was being watch-dogged. The campaigners had sent their petition, the Call for a Stop to the Research on Anti-Fertility "Vaccines", to the press and to the research centers and funding agencies involved. In March 1994, the coordinator of the campaign, Beatrijs Stemerding, also sent a letter to the ethics committees of the hospitals were the trial was carried out, in which she asked them to reconsider their decision to proceed with the trial (Letter by Stemerding 31 March 1994). At the meeting of the Steering Committee Clinical Trials Subcommittee on 29 June 1994 in Uppsala, Sweden, both "the exchange of correspondence" between the campaigners and the researchers, and "the current status of the trial" were discussed (SubSC minutes 1994).

5. Conclusions

In this chapter I have traced the ways in which trial participants have been involved in the clinical research stage of anti-fertility vaccines development. Trial participants represented users in two ways: in that the trial findings would be extrapolated to users, and as the first embodied agents to be injected with the product. I analyzed the texts of contraceptive developers in order to explore the ways in which clinical trial participants figured at the selection stage, in the actual conduct of the trials, and in reporting about the efficacy and the side-effects of anti-fertility vaccines. For the Indian phase II trial I had access to some additional sources, namely the reports of Viswanath and Kirbat (1997) and Kirbat (1998), and the film by Schaz and Schneider (1991).

As I mentioned in the introduction to this chapter, analyses of clinical trial methodology often includes discussions about the capacity of the trial participants to represent future users in a variety of real-life circumstances. In
the former chapter I described how the reproductive scientists successfully insisted upon assessing the safety and efficacy of the developing artefact detached from such circumstances. In the same vein, the issue of selecting trial participants who would represent future users of different races, ethnicities, classes, and the rest, was not raised in organizing the trials. Instead, the efforts of the researchers were directed towards finding and keeping enough women in the trials. As against the AIDS treatment trials narrated by Epstein (1995, 1997), and similar to many other trials, the researchers in Australia and Sweden encountered difficulties in enrolling a sufficient number of suitable subjects. Another difference from the AIDS trials was therefore that the arguments to minimize the restrictions for participation were not so much methodologically or morally inspired as they were practically informed. In particular, the inclusion and exclusion criteria contained prescriptions for who might participate in the trials. Practical considerations relating to the wish to maximize the number of eligible women and to the institutional settings in which the trials took place influenced ideas about who might use the vaccine. As a result, the representation of future users as women at any stage of their reproductive life was established.

Examination of the roles assigned to the clinical trial participants permitted me to gain a number of new insights. The clinical trial methodology contained a script and the appropriate acting out of their roles by the participants was central to the researchers’ success. Their prescribed role in the conduct of the trials was to visit the clinic repeatedly, to submit their bodies to medical examination and blood tests, and to report side-effects. At all stages of the trials, the researchers from the WHO/HRP Task Force and from the NII also cast the participants as early adopters, and as important contributors to technology development who shared with the researchers the goal of making a new contraceptive available to the women of the world. In the enrollment stage they emphasized this role in the information they issued to women. Some participants were specifically assigned this role in the conduct of the Indian phase II trial, and the trial participants’ endorsement of the method was again reiterated in the acknowledgement sections of the published reports. The researchers brought the active involvement and commitment of the trial participants to the fore in order to promote the acceptability of the method. From this it appears that not only the efficacy and safety of anti-fertility vaccines were on trial, but also the legitimacy of the research. Indeed, one of the main conclusions reached on the basis of the completed trials was that the research should continue.

To make the trial participants actually perform their roles as reliable allies necessitated additional work in carrying out the trials. In the enrollment and conduct of the trials, the participants were present as embodied agents. Their embodiment endowed them with the capacity to foot-vote. It also
endowed them with vulnerability to pain and ethical abuse. It was at this stage that international differences between women’s options for action came most clearly to the fore. Because of women’s different spectrum of options for action, it was easier to recruit and keep women in the trials in India than in Sweden. For poor women in India, the clinical trials could provide a welcome opportunity to obtain better access to superior health care, an extra income and a social space outside their homes. This illustrates how the politics and ethics of clinical trials are not confined to obtaining women’s informed consent to become a research subject. Women’s participation and continuation in the trial depended not only on their understanding of the information provided to them, but also on the contexts and the power relations in which they were engaged.

Much of the work that the scientists did to find and keep women in the trial was invisible in their scientific publications. As compared to oral contraceptives, anti-fertility vaccines were designed to avoid difficulties in the administration of the method, such as expecting women to take the Pill daily. But this technology faced different problems in the encounter with women, such as the pain of the injection and the unpredictable duration of efficacy in individual women. In the reports there was no mention of home visits to administer booster injections to participants, provision of analgesics for pain, or an attractive room where participants could sit around. Such efforts on the part of the researchers decisively contributed to making the trials successful, because they encouraged women to enter and remain in the trials, thus enabling researchers to collect sufficient "study cycles". The published reports included representation strategies definitely designed to support the conclusion that the development of anti-fertility vaccines should continue. The efficacy and safety measurements were reported as if detached from the embodied agents from whom they had been taken. In order to achieve an effective method, embodied agents were replaced by study cycles: menstrual cycles in which the immune response was deemed adequate. Since Pincus first introduced the representation of women as cycles in the 1950s, this has become an established procedure in the reproductive sciences. These cycles are treated as immaterial and contextless, and therefore easy to handle. As Oudshoorn (1994) has described, representing women as menstrual cycles in the early testing of the Pill had the effect of emphasizing similarity among women, while obscuring diversity. In anti-fertility vaccine development, reporting in terms of cycles had precisely the same effect: it camouflaged the variations among individual women in the duration of an effective immune response. But this was not sufficient to make the vaccine effective. In the efficacy trial with anti-fertility vaccine carried out in India, the researchers therefore introduced a new distinction between good responders and poor ones. The chance that the method might fail was thus minimized. On this
basis, the trial results were announced as promising. In the words of Franklin (1995), "a belief in the technique in general, 'it does work'" prevailed over the fact that in many practical respects it did not work.

Not all efficacy and safety problems could be resolved at the level of textual representations. The Swedish trial participants were unwilling to endure the side-effects that they experienced, and two of them left the trial. Next, because of the researchers’ concerns about the side-effects, the trial was stopped. Thus, even in the testing of a technology designed to leave little room for the enacting agency of women, in this case they decisively affected the course of technological development. Once they were assigned a role in legitimating anti-fertility research and development, the foot-voting of clinical trial participants sent the researchers back to the laboratory bench.
Notes by chapter 4

1. In his book *The progress of experiment: science and therapeutic reform in the United States 1900-1990*, Harry Marks (1998) traces the history of clinical trial methodology, including the ongoing debates about its methodological and epistemological shortcomings. Trudy Dehue (1997) analyses how the randomized groups design should be understood as a late nineteenth-century accomplishment in experimental psychology rather than as a methodological inheritance from the natural sciences. Armstrong (1977) showed how the advent of the clinical trial upset the balance between "clinical sense and clinical science". Taubes (1995) reports on the discussion about tensions between the methodological and ethical requirements of trials. Pocock, Hughes, and Lee (1987) analyzed 45 clinical trial reports published in the *British Medical Journal, The Lancet*, and the *New England Journal of Medicine* and identified numerous statistical problems that may lead to problems of interpretation. The dilemma of controlled representativeness versus unconstrained heterogeneity, refueled by the 1993 FDA Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, is discussed by Sherman, Temple and Merkatz (1995) and Meinert (1995). The critique of Evelleen Richards (1988) goes beyond the methodological and epistemological level. This author has made a comparative analysis of the unresolved controversy between Noble laureate Linus Pauling and orthodox oncologists about the potential value of vitamin C in cancer treatment. This author concludes that the assessment of medical therapies is inherently a social and political process. She concludes that methodological reforms cannot resolve disputes over contentious therapies or technologies. These must be treated as essentially political issues, where there are no impartial experts.

2. This research helped to create and maintain a niche for the continuation of contraceptive vaccine development. For example, the WHO researchers discussed the early testing in non-sterilized women in India in the protocol for their trial in Australia. While mentioning that the Indian trial had many unsatisfactory features, the protocol commented: "The results and implications of these human trials provided encouragement for (...) the principle of hCG vaccination" (Project description 1984 version).

3. Six of these 43 women were not included due to medical reasons.

4. Another way of enrolling more women proposed by the researchers in the Steering Committee was via collaboration with women's health organizations (SC minutes 1991, 43), but this was never taken up. A third way to gain
access to a larger number of women discussed by the WHO/HRP Task Force Steering Committee was to extend the number of centers (SubSC minutes 1994).

5. See also Saheli (1998) and interview with Talwar 22 June 1996.

6. See also Jones et al. (1988, 1298). Scientists from the Population Council wrote in the report of their phase I trials in Chile, Dominican Republic, and Finland: "Our deepest gratitude to the women who participated in this trial for their dedication, cooperation and commitment" (Brache et al. 1992).

7. See also Griffin (1992, 116).

8. Cultural anthropologists have observed that the meaning given to autonomy is not universal, and that many cultures are inspired by values that may be contrasted with individual autonomy, such as communalism or interdependency.

9. Interview with Schrater, 22 October 1996.

10. The Indian science journalist K.S.Jayaraman opens a news item in Nature Medicine with: "Researchers in India appear to have the edge in a keenly watched race to develop a vaccine that will provide protection against pregnancy" (Jayaraman 1995, 609).

11. Two women dropped out because of (pre)menstrual problems; in one case the husband died; and one woman became sensitive to one of the vaccine components (Jones 1986, Jones et al. 1988).

12. Five women dropped out for medical reasons unrelated to the trial (Talwar et al. 1990).

13. Especially in the Postgraduate Institute of Medical Education and Research in Chandigarh, trial participants received more time and attention from the doctors than other patients, and also in this hospital the drop-out rate was lower (Preeti Kirbat, personal communication 10 December 1998).


15. In the interview Talwar referred to an article published by a research group consisting of Austrian, German, French, and Dutch researchers, in which questions are raised about both the efficacy and the safety of the CTP-hCG vaccine developed under the auspices of the WHO (Dirnhofer et al. 1993, Dirnhofer, Wick and Berger 1994).
16. Capabilities were attributed to antibodies: "The antibodies are not only capable of reacting immunologically with the whole hCG molecule but are also competent for neutralizing the biological activity of hCG in radioligand receptor assay" (Talwar 1976, 242).

17. As Nash et al. wrote: "Only one subject (...) failed to show a response" (1980, 333).

18. The four women who dropped out due to reactions following injections, such as erythema, redness, and itching, are not included in these 28% of participants (Talwar 1990 et al., 305).

19. Also Mitchison commented on this trial in a review article saying that "No important adverse reactions have occurred" (1990a, 726). See also Talwar and Raghupathy (1989).

20. See also Griffin, Jones and Stevens (1994, 110).

21. Patient no. 1: sterile abscess at the site of injection (16 O4 94) was incised and drained (27 O4 94); Until then patient was unable to work due to severe pain; Recovered fully.
Patient no.2: attack of unconsciousness due to alcohol intoxication; Menorrhagia of unknown causes, possibly drug related; Positive skin test against vaccine; Dysmenorrhea, possibly drug related; Abdominal pain, not drug related.
Patient no. 3: discontinued on her own account after first vaccination because of the pain created by the vaccine; Severe myalgia which made her unable to work, vaccine related; Episode of prolonged menstruation more than 12 days, possibly vaccine related.
Patient no. 4 (got pregnant): Vaccinated 2X, second vaccination made in split doses; After first vaccination slight fever and severe myalgia for about 48 h. after vaccination, vaccine related; After second vaccination intense pain and lump at the site of earlier vaccination. Fever. Myalgia in both legs, severe enough to prevent patient from working; Dysmenorrhea and too early onset of menstruation, vaccine related, bleeding possible vaccine related; Pain at injection site. (hereafter trial stopped)
Patient no. 5 vaccinated once, then trial stopped; Soreness at injection site as well as myalgia and anthralgia, vaccine related; Acute cystitis, not vaccine related.
Patient no. 6: vaccinated once, got split injections; Discontinued on her own account due to severe pain at first vaccination; Anthralgia and myalgia; Fever.
Patient no 7: Vaccinated once; Mild myalgia and fever, vaccine related.

22. The reports of the early phase I trial with six women in India (Talwar 1976) and of the completed phase II trial (Talwar et al. 1994) do not include a description of side-effects.

23. One woman from the control group, who had received an injection with adjuvant and vehicle only, had an early menopause (Jones et al. 1988).
Conclusions

1. Conceptualizing users in technology development

In this thesis, I have traced the various ways in which the end-users of anti-fertility vaccines are involved in contraceptive development. I set out from the idea that in order to change design practices and make them more responsive to the users of contraception, one first needs to make visible the ways in which users are actually implicated in current practices. My research questions were: What are the dynamics of users’ involvement in the development of anti-fertility vaccines? And what are possibilities and limitations for changing the ways in which users are implicated in this developmental process? I approached these issues by analyzing the representations of users that reproductive scientists construct along the developmental trajectories of anti-fertility vaccines, and by examining how users were implicated in their developmental work.

Many studies in the realm of users and technological innovation regard technology as a means to solve problems, and users’ involvement as a way to solve problems better. In this view, the question is one of understanding users’ needs earlier and better, by gathering information from the expected users. Once adequate information on users has been collected, it can be used to guide the technology developers. Or technological innovations, especially radical ones, are seen as completely unrelated to eventual users. Since innovators are unable to forecast the eventual demand for their products, and users may not know in advance that they have certain needs and preferences, users are of no interest to technological development until the product enters the market. What these views have in common is that they ignore the interrelatedness of technological development and social processes such as (envisioning) the use of technologies. Drawing upon contemporary insights from Science and Technology Studies, I have explored the possibility of a two-way relationship between users and newly developing technologies from the very beginning. As I stated in the Introduction, scholars in Science and Technology Studies have shown how technologies and the people who use
these technologies once they have been introduced are engaged in a process of mutual shaping. According to this view, technological change and new social practices emerge together. New technological artefacts create new possibilities and limitations for users, who at the same time actively participate in the construction of technologies by adopting or rejecting them, submitting them to alternative uses or modifying them. But how are users involved in the early, pre-market stages of technological development? This question had remained underexplored in Science and Technology Studies.

Akrich's script approach (1992, 1995) vividly draws attention to the significance of user representations in early stages of technology development. Akrich has convincingly shown how designers' images of future users affect their technical choices and thereby the script of the evolving artefact. Especially illuminating is her analysis of the different techniques that innovators use to construct images of the future users. This enabled Akrich to point out and systematize forms of users' involvement that had not yet been articulated explicitly before, such as the designers' reliance on personal experience, on expert consultants, and on products considered to have something in common with the developing product at hand in imagining future users. Akrich developed the script approach in order to understand the success or failure of artefacts to respond to the needs of end-users. But what if the technical choices of innovators have consequences for who might use the technology in the absence of any articulated representation of future users? It seemed to me that these choices are relevant for understanding the co-production of users and technologies as well. My contribution in this thesis therefore has been to demonstrate that the co-production of users and technologies starts before technologies are introduced, from the very beginning. Future users of technologies are defined not only by the representations of users that designers bring into the process, but also by early technical choices that in turn are shaped by existing institutional infrastructures, material possibilities, international policy-making, etc. This is why I have introduced the concept of implicated users. Implicated users, like Clarke and Montini's implicated actors (1993), are absent from the immediate arena of technology development, and representations of them are not necessarily articulated clearly by any of the actors involved. But the technology development matters to them, because its outcome has consequences for their eventual use of the technology. I propose that implicated users are an important new addition to the existing instrumentarium for conceptualizing users in the pre-market stage of technology development. In this thesis I have explored various methodological tools to study such implicated users: first, by examining the proposed product profile and considering through its consequences for users of the artefact, on the basis of, e.g. historical experiences with comparable other products; second, by focusing on a specific category of
users that I as an analyst define, e.g. male or female users, and monitoring what certain technical choices would mean to them; third, clarifying who the implicated users in researchers’ work are by contrasting them with the representations of users that other involved actors have articulated, e.g. in their encounters; and fourth, by analyzing how test-users are selected and how they are portrayed, e.g. by recontextualizing the findings reported in clinical trial reports. To make visible how users are implicated in the technical choices of the innovators is particularly important for understanding the possibilities and limitations for changing user-technology relations in early stages of development.

In this chapter I will summarize the conclusions of the preceding chapters and survey the various ways in which users were involved in anti-fertility vaccine development. I will indicate the broader relevance of my findings to develop a perspective on more user-centered practices of contraceptive technology development.

2. The articulation of specific users’ representations

Technological innovation projects have usually been inspired by speculations about possible futures. Anticipations related to future users are among those speculations. Drawing upon the work of Madeleine Akrich (1992, 1995), I have argued that part of the work of contraceptive innovators consists of inscribing representations of future users into the developing artefact. The resulting technology in turn prescribes specific uses and excludes other modes of use. From a perspective on change, it is worthwhile to examine who was involved in imagining the future users, and who was excluded from this process, and also to consider what other possible futures could have been imagined.

Everybody or nobody

According to the contraceptive developers, anti-fertility vaccines were meant to be for everybody. In chapter 1 I described how in the formulation of the initial research programme on anti-fertility vaccines by the WHO/HRP in the early 1970s, the idea of future users was emphatically left vague. Nobody was forthrightly excluded as a potential user of anti-fertility vaccines. This certainly was convenient from a political and strategic point of view. I have explained that the perception of future users as practically anyone was the outcome of a consensus-seeking effort on the part of the various actors involved in setting up the research agenda. The WHO/HRP and the member states wanted to avoid the suggestion that research into this particular method
could be interpreted as a statement about the politically sensitive relation between population growth and development. Therefore, they did not explicitly acknowledge that the method was thought to be particularly suitable for developing countries. The biomedical scientists wanted to include as many basic and applied research leads as possible, both for male and female users. Family-planning organizations, social scientists, and women's health advocates were not in the institutional position to bring to the fore alternative or more specific representations of users in setting up research into immuncontraception.

The future method was characterized not in terms of the expected users, but in terms of a few design characteristics. Making a contraceptive vaccine that would be low-cost, long acting, and easy to administer appeared to be a "doable research problem" (Fujimura 1987). This foreseen product profile properly aligned the social worlds of funding and policy-making with those of biomedical scientists from different disciplines. The scanty definition of future users was very helpful in defining the problem as doable. Suppose instead that the scientists had defined a more contextualized and explicit image of the future users. For example, they might well have argued that anti-fertility vaccines would respond to the needs of healthy women between 15-45 years, of any race, with limited access to health care, and wanting to practice family planning surreptitiously. However, such an explicit characterization would have raised many sensitive questions. What are the actual features of the service delivery systems in which the method will be introduced? How many healthy women with limited access to health care wanting to use contraception confidentially are there, and where are they? What if someone other than the woman herself wants to plan her family surreptitiously? These questions might have urged the biomedical scientists to align their work with that of family-planning organizations, social scientists, and women's health advocates. To render the research doable would then have been considerably more difficult.

In order to substantiate the need for developing new methods, users were represented in a different, but equally unspecific manner: as individuals worldwide, planning their families in a vast variety of settings, and expressing a variety of needs and preferences. The imprecise nature of the idea of future users of anti-fertility vaccines allowed the biomedical scientists and policy-makers to shift between emphasizing now the diversity of users, and now their similarity. Just like the idea of developing a new method suitable for everybody, representing users as diverse did not provoke political contestation. However, none of these representations was politically innocent. While the idea of users as anybody in any context obscured the differences among users, the emphasis on infinite diversity tended to make invisible what many users might have in common.
This way of representing future users is in contrast to participatory technology development approaches, e.g. in agriculture, in developing sustainable technologies, and in the field of information and communication technologies. In these approaches, analysts try to extend design practices by making linkages between technology development and the application of technologies in specific contexts (Rip, Misa and Schot 1995, Bunders, Haverkort and Hiemstra 1996, EC report Leslie Haddon et al. 1998, EC report Pim Hertog et al. 1996). In participatory technology development it is considered that the inclusion of a different range of social groups and forces in the process of shaping technology will result in the design of alternative products and alternative impacts. This encompasses the involvement of concrete groups of users, or persons who act as representatives of specific groups of users. Innovators involved in a participatory research project cannot maintain that their technology is developed for everybody. Even in the earliest stages of design, they will have to identify the users with which they will align their research, and create such groups. To overcome the problem of oversimplified or overdiversified representations of users, participatory design approaches often make use of classifications of future users: e.g., "small, medium and large farmers", or "female headed households" in agricultural technology development, or "the elderly" or "people with disability" in information and communication technology. These classifications are based on characteristics of the users that previous research has shown to make a difference for technological practices, such as access to land, water, and labour in agricultural technology development, or vision, memory, and motorial precision in information and communication technology. Analogously, contraceptive users could be classified along parameters such as, e.g., sex, stage in reproductive cycle, access to health care, health, and control over reproduction. Once the contraceptive developers begin to envision the users more specifically and more concretely, notions about users such as "everybody in any context" may no longer be taken for granted. Instead, the ways in which similarity or diversity is constructed can be interrogated.

Of course, any classification of future users is problematic. Imagine again that the contraceptive developers had stated explicitly that this method would respond to the needs of healthy women from 15 to 45 years, of any race, with limited access to health care, and wanting to use family planning surreptitiously. Should a user's access to health care be assessed on the basis of country, geographical distance to the health care center, legal access to health care, or cultural and economic position? Does being healthy or not include a person's genetic predispositions, and how do we rate health risks, e.g. exposure to HIV? Is the health care system prepared to include a category women using contraception confidentially? Any classification denotes a simplification, and thereby creates phenomena and relations, and make
specific aspects more or less visible (Star and Griesemer 1989, Star 1991 and 1992, Law and Whittaker 1988). The global categories of "everybody" or "individuals worldwide" are no exception. These notions have the effect of obscuring and foregrounding specific aspects of users as well. Pointing out diversity that had been concealed historically in monolithic or dualistic ways of thinking has played an important role in postmodern social theory and not least in Gender Studies. For example, Sandra Harding (1994, 1996) has challenged the universalistic (and euro-centric) notion of scientific knowledge and proposed the development of a multicultural view of the global sciences. Anne Fausto Sterling (1985) has deconstructed the dualistic notion of sex and proposed a classification system that allows for five sexes. But while the notion of diversity has played an enormously important role in proposing alternatives to dominant categorizations, we should not lose sight of the constructed character of diversity. Contrary to what certain social scientists involved in studying contraceptive use seem to assume, diversity is not a pre-existing entity that can be mapped out with increasing precision using ever more sophisticated social scientific research. Nor is it an inherently emancipatory notion; instead, it can be tamed, co-opted, and reappropriated.¹ In particular, in developing new contraceptive methods, the difficulty in current policy-making practices of dealing with the image of future users as endlessly varied has had a paralyzing effect upon the development of user-centered approaches. Therefore, it might be timely to go one step beyond the statement that the practices of people regulating their fertility differ widely. The question rather is: which dimensions of difference are relevant for user-centered contraceptive development, and according to whom, when, and how? In other words, I argue that the problem is not one of obscuring or constructing differences per se, but of doing so in ways unrelated to users' practices of regulating their fertility.

The representations of users as everybody or as infinitely diverse are hard to align with contraceptive development. For example, in chapter 2 I have argued that sex of the future users is one important parameter to specify. I analyzed the representation of the future user's bodies adopted by the reproductive scientists: a sexless cascade of target substances, together with the confirmation that anti-fertility vaccines could be developed for either men or women. This lack of diversification was problematic, because it obscured the fact that in anti-fertility vaccine development the dominant pattern of women as contraceptive users was reproduced. Here we have seen that the category of "everybody" was far too simple. In the same vein, other dimensions that are relevant for linking contraceptive technology development to family-planning practices can be defined, such as stages in the reproductive life-cycle, access to health care, health status, and users' control over their reproduction. How would such specific categories of users affect the doability
of contraceptive research and development? Surely, such an approach would entail the need to align contraceptive development with, e.g., family-planning organizations, social scientists, and women’s health advocates to achieve doability, and this might defer the doability of a quick and universal technological fix for fertility control. Yet, I would argue that there are a number of advantages to be found by invoking better-defined user profiles. One such result might be that users would become thematized at an early stage, as opposed to the volatility of a user representation such as "everybody". Users would then acquire more visibility vis-à-vis the needs and preferences of the technology developers, and vis-à-vis logistic, economic or political considerations for particular product concepts or technological choices. Also, formerly hidden assumptions about the similarity or diversity of users might become obvious, and lead to further consideration and discussion. In other words, an explicit definition of the end-users of new technology might well provide a point of departure for a more user-centered approach to technology development.

3. Implicated (non)-users

There are reasons to doubt the claim that anti-fertility vaccines could be made suitable for everybody. This representation of users articulated by the designers was not inscribed in the developing technology. Yet the very absence of a more precise definition of who might use the method, and in what contexts, allowed for the development of immunocontraceptives with a peculiar user-script. As I described in chapter 3, the work of the research groups of Stevens and Talwar to develop an anti-hCG vaccine was mostly directed to making the method longer-acting and easier to administer. I have argued that the method that the researchers proposed to develop contained a script: a low-cost anti-hCG vaccine that would provide long-acting protection against pregnancy following a single injection, and that could be used surreptitiously, would be suitable for women with poor access to low-quality health care and relatively little decision-making power over their reproductive lives, in casu poor women in Third World countries. It is here that the concept of implicated actors (Clarke and Montini 1993) becomes particularly useful. Poor women in developing countries were absent from the arena of contraceptive development, and representations of them were not articulated as a notion to be inscribed in the artefact. They are, however, implicated by the actions in the field of contraceptive development, in that these actions will have consequences for their fertility-regulating practices. By understanding poor Third World women as implicated users in anti-fertility vaccine development, I can make them visible and analyze their involvement before
the technology is put into use. This is helpful to provide early warning against possible problems that might come with a vaccine with the proposed product profile, on the basis of experiences with other fertility regulating technologies. Such problems could then be prevented from happening. Thus, making visible what has been hidden, obscured or deleted, but implicated (Star 1991, Clarke and Montini 1993) has been an important methodological strategy in this research project. Similarly, in chapter 2 I showed that the bodies of male and female users had become invisible in the dominant representation of users’ bodies that the reproductive scientists had generated. From a perspective on change it was important to reintroduce the bodies of male and female users into my analysis to study their fate, and so I did. This enabled me to understand why most research leads in immunocontraception are directed towards female users, and to get some clues about what would be needed to change this. The concept of implicated users is therefore an important addition to making the script approach relevant for assessing technologies in early stages of development, and for finding means to influence the developmental process. It enables the analyst interested in change to capitalize on the lessons learned from earlier (problematic) experiences, such as situations of abuse and the asymmetric situation of contraceptives for male and female users.

Describing the script of anti-fertility vaccines

There are also reasons to doubt that the method being developed in the laboratories of Stevens and Talwar would meet the needs of poor women in the Third World looking for a low-cost, long-acting, and easy to administer method. The developing method required a bridge method to cover the lag period of three to six weeks before an effective immune response would have built up. The researchers suggested that another contraceptive method should be used during these weeks, such as hormonal injections, condoms, diaphragms, abstinence, withdrawal, or the calendar method. The dependence of anti-fertility vaccines upon these methods raises the question of the extent to which they constitute an alternative to women looking for a non-hormonal, non-barrier, and not natural way of planning their families. In addition, the need for continuous monitoring of a person’s level of antibodies limited its appropriateness for people with poor access to health care facilities. The use of a home kit to test if the antibody response was still effective would exclude users who wanted to avoid the storage of contraceptive devices in their homes. These incoherencies in the evolving script were obscured by the vague ideas about users, defined as "everybody" and "many differing individuals worldwide". One would expect that a more coherent idea of who the future users might be would surface when anti-fertility vaccines were
introduced into a clinical setting for testing, but this did not happen. All the preparations that were clinically tested required four- or six-weekly injections, a bridge method, and regular monitoring of each woman’s immune response. In chapter 4 I have described how the clinical trials were organized so as to make the participants fit the technology, and not the other way around. This involved well-equipped laboratories, adequate communication procedures, and frequent access to the trial participants. In order to make the method more suitable for use in family-planning clinics, the researchers under the auspices of the WHO/HRP worked on the development of an alternative delivery system, and the Indian team worked on a single injection preparation. But the problems for users that might proceed from the need for a bridge method and the unpredictable duration of a person’s immune response to the vaccine were hardly addressed by these researchers.

4. The embeddedness of contraceptive development

Constructing more specific representations of future users might not be enough to achieve a more user-centered approach to contraceptive development. As I mentioned before, anti-fertility vaccines with a script for use evolved in the absence of well-defined notions about the method’s eventual users. Technological development is structured not only by imagined notions about envisioned futures. It is not enough to study how various representations are constructed and how these can be reconciled. Therefore, I have proposed that Akrich’s script approach should be extended to include an analysis of what enables and what constraints certain technical choices with implications for the eventual users. Chapter 2 focused on the importance of the contextual embeddedness of technological development and its implications for whoever might use the artefact. Anti-fertility vaccines directed against specific antigens developed according to the room for manoeuvre that the biomedical scientist had at their disposal, and not solely in anticipation of representations of users. I have shown how the preferred ways of developing anti-fertility vaccines of reproductive biologists, immunologists, and clinicians was accompanied by specific representations about the bodies of the future users. Together, these biomedical scientists drew a sketch of possible places where the anti-fertility vaccines would intervene: a cascade of target substances. This representation was not ”just a picture”; it had evolved from their disciplinary styles, their material and cognitive resources, and their willingness to further the enterprise of developing anti-fertility vaccines. However, the sexless representation of users’ bodies was not inscribed in the developing artefacts. As a result of the embeddedness of contraceptive development in a specific historical context, most leads in immunocontracep-
tive research were followed up for female users. I found that access to research materials and the availability of animal models greatly influenced the course of immunocontraceptive research and development. These issues of access and availability were not simply contingent, but had evolved from a reproductive research practice of many years’ standing. Institutional arrangements and policy debates decisively structured the development of immunocontraception as well. From a perspective on change, it is important to emphasize that international policy debates, in particular the discussions about the abortion-relatedness of the anti-hCG vaccines and about male partnership in contraception, forcefully impinged on the co-construction of anti-fertility vaccines and the future users. The development of male methods had been on the international research agenda since the 1970s, and was resuscitated in the preamble of the UNDP Conference in Cairo in 1994. The anti-abortion climate in the U.S. had led the National Institutes of Health to exclude work on anti-hCG vaccines from their 1986 research programme in immunocontraception. In the early 1990s, when their work on an anti-hCG vaccine got stuck, the Population Council explicitly included research into a contraceptive vaccine for males in its portfolio. They did so despite many technical and physiological constraints, and despite ongoing uncertainty about the cultural feasibility of a male method. This shows the importance of international policy-making for what ultimately happens in the laboratory. In particular, it nicely illustrates the difference that an explicitly articulated policy on the (sex of the) future users can make. A similar conclusion on the importance of global patterns and developments for understanding local practices has been made by Nelly Oudshoorn (1997). Oudshoorn has analyzed the role of the WHO as an intermediary organization in the development of hormonal contraception for men. The choices and constraints confronting the WHO could not be understood without working across the macro-, meso- and microlevel, and included population control and development politics, the dominance of hormonal approaches to fertility regulation, the availability of certain compounds, along with concerns about patents, litigation, and the acceptability of the new method. Following Oudshoorn, I would like to emphasize the importance of including analyses of larger social and political currents in the study of local science and technology practices. These structural elements are central to an understanding of the dynamics of representing users as well. Such a focus enabled me to illuminate what was necessary to incorporate certain representations in the developing technology, what the effects were, and what possibilities were excluded.
Analyzing the dynamics of users’ involvement from a perspective on change led me to employ yet another methodological strategy: to include the user representations of the women’s health movement. As I set out in the Introduction, I propose this strategy as an important addition to the script approach, for making visible the actors implicated in technological development. If I had not started from an interest in understanding contraceptive development in order to prevent further problems and contentions, I might have studied the dynamics of users’ involvement by following only the contraceptive developers, and by analyzing only their explicit ideas about who the future users might be. Now, instead, I was concerned to unravel how users are implicated in representations such as target substances (chapter 2), immune responses and menstrual cycles (chapter 4), and to study more closely the representations of users envisioned by the women’s health movement, and their impact on contraceptive development.

The policy shifts in the early 1990s under the banner of reproductive health and rights influenced the course of research on anti-fertility vaccines. As I have described in chapter 3, on the eve of International Conference on Population and Development in Cairo in 1994, members of the international women’s health movement succeeded in making reproductive health and rights into a central issue in contraceptive policy-making. In particular, the value attached to "integrating users’ perspectives" brought the scientists involved in contraceptive development and concerned women’s health advocates together at the negotiating table at the WHO in Geneva. Women’s health advocates were invited to voice the "users’ perspectives" on the basis of their extensive experience, and collective analysis of the situation of women worldwide wanting to plan their families. I have pointed out that the fact that women’s health advocates do not speak in the name of users provides them with the possibility to present a reproductive health-based analysis instead of a collection of views on the contraceptive needs of women worldwide. Also concerned with enhancing the visibility of users in contraceptive development, the women’s health advocates presented their more contextualized representations of who might use the vaccines. Their analysis of what the developing immunocontraceptive product would mean in users’ daily-life situations led to alternative assessments of the safety, efficacy, and acceptability of the new method.

Not by coincidence, there is a striking analogy between the women’s health advocates’ proposal of more contextualized representations of the future users, and my analytical work of elucidating how clinical trial participants are invoked when depicted in terms of antibody responses and menstrual cycles. Both the women’s health advocates and I draw upon the feminist instrumen-
tarium of situating any perspective on users (Haraway 1989, Star 1991). This approach led me to look at situations in which the involved actors constructed their particular representations of users. It explained the contextualized depiction of potential users of anti-fertility vaccines that provided the basis for the women’s health advocates’ critique of the new method. It also led both me and the women’s health advocates to explicate the historically problematic experiences in the field of contraception as the contexts in which our concerns about anti-fertility vaccines emerged.

Extending the approach proposed by Akrich (1992, 1995), by contrasting the representations of users put forward by women’s health advocates with those of the contraceptive developers, provided an important means to reach a better understanding of the processes of co-construction of the users and the technology previous to usage, and the possibilities and limitations for altering these dynamics. The encounters between the contraceptive developers and the women’s health advocates were very relevant occasions for studying the representations of users held by both groups, which were brought to the fore in their meetings. Comparing the views expressed by women’s health advocates and those of the reproductive scientists enabled me to distinguish the specificities of both perspectives. This method of making explicit representations of users by various relevant social groups by comparative analysis might also be very helpful in studies on the domestication of technological artifacts. For example, if anti-fertility vaccines proceed to be developed beyond phase II clinical trials, the making and remaking of its script for usage will continue. Then the user images of health care providers, and their role in the unfolding script of the new method, will become very interesting. This might be an interesting theme for further investigation.

Safe and effective?

Safety and efficacy measurements were done on prototype vaccines that were specified as different from the preparations that would ultimately enter the clinics. Occasionally, scientists mobilized work on the contextless prototype vaccines to accomplish the conflicting role of underscoring the feasibility of the immunocontraceptive approach in family-planning practices. The women’s health advocates’ alternative assessments of safety and efficacy, based upon contextualized representations of users, were excluded from the debates. The scientists succeeded in maintaining control over the appraisal of safety and efficacy. Still, measuring safety and efficacy was not as clear-cut as the scientists suggested, and representations of users certainly played a role in the assessment of safety and efficacy in clinical trials. To construct a vaccine that would be safe, effective, and moreover wanted, demanded enormous organizational efforts from the researchers and health personnel.
involved. Because of the different daily-life situations of women in India and in Australia or Sweden, the scientists in India had a larger repertory of actions to enroll and keep participants in the trials. Part of the work to achieve the safety and efficacy of anti-fertility vaccines was in the reporting of clinical trial findings in scientific texts. The scientists concluded that the efficacy of the anti-hCG vaccine was very high. To accomplish this result, the researchers determined the antibody responses to hCG on the basis of menstrual cycles, regardless of who had contributed the cycle. Next, they made a distinction between the good cycles, in which the antibody level had surpassed a threshold value, and the bad ones in which the threshold was not attained. Only the good cycles constituted the basis for the calculation of the vaccine’s efficacy. The safety of anti-fertility vaccines was achieved by laboratory and clinical measurements, and by characterizing the side-effects that the trial participants reported as not serious, not significant, or not unacceptable. This is not to say that "the real truth" about anti-fertility vaccines is that they are ineffective and perilous; but if user-centered concerns had been taken into account in the clinical trials, the assessments might have been otherwise. For example, it is difficult to imagine that the question of how, when, where, and by whom the good and the poor responders amongst women visiting the family planning clinic can be distinguished would have been overlooked so plainly. And the relevance of, e.g., pain following the injection for a women’s daily well-being might have been noticed as an important subject for further investigation before it made two of the seven Swedish women leave the trial.

In an article in *Science* on *Patients in research: not just subjects, but partners* (1995), the American researcher Jody Heyman from Harvard Medical School discussed how research would change if patients were included in the design of clinical studies. She indicated that there would be more research on the side-effects of treatments, that efficacy outcomes would be presented in terms relevant to the patients, and that patients’ concerns about long-term effects would be more fully addressed. Strikingly, the lack of research into these issues was exactly the reason why the development of anti-fertility vaccines was ultimately suspended. The scientists in India were asked to do more studies on the long-term effects of the method, and the Task Force scientists went on to scrutinize the side-effects. Note that these were also precisely the kinds of concerns that the women’s health advocates had expressed. Possibly, if people voicing alternative perspectives on users had been involved in the preparation of the past clinical studies, they could have signaled these and other concerns, and the socially costly, expensive, and time-consuming detour of the scientists might have been prevented.
6. Alignment and boundary work

The researchers continued their endeavors to develop a long-acting and easy to administer method in spite of many technical problems. Other thinkable venues for immunocontraception, e.g. an oral formulation or a menses inducer, were not explored. Neither the AIDS pandemic, nor women’s health advocates’ alarming assessments of the side-effects and abuse of a number of existing contraceptive methods, changed the course of their research for many years. Throughout this thesis I have argued that this was possible because of the incessant efforts of the researchers to keep the developing artefact isolated from its use by specific groups of users, and to keep their research disconnected from the insights of social scientists, family-planning organizations, and women’s health advocates. Once seated together around the negotiating table, the interactions between the contraceptive developers and the women’s health advocates could best be understood as a mixture of attempts by the former to align their work with the users’ representations brought to the fore by the advocates, and continued boundary work to safeguard their scientific development work from intrusions (Akrich 1992 and 1995, Gieryn 1983 and 1995, Jasanoff 1987). As against the contextualized assessments of the developing artefact provided by the women’s health advocates, the reproductive scientists adhered to a compartmentalization of the vaccine and the application of the vaccine. Assuming a distinction between the vaccine and the application of the vaccine entailed a specific politicization of the technology: the problem of abuse was located outside the artefact itself. This compartmentalization also led them to envision a specific way of aligning the technology and the users. The work of making users and anti-fertility vaccines fit was delegated to additional technologies. The test-kit to monitor the level of anti-bodies, and the bridge method to cover the lag period, were both intended to align the (application of the) method with the representation of a contextualized user. The consequence of these alignment efforts was that the researchers could go on developing the artefact that they had in mind. Simultaneously, some key concerns of the women’s health advocates, most notably their safety concerns stemming from what the method would mean in a user’s daily-life situation, came to fall outside the range of issues on which their users’ perspectives were considered relevant and could be taken into account.

Too early or too late?

At what stage in the technological development process should alternative perspectives on users be taken into account? Contraceptive developers maintain that first there should be a product before its acceptability to users
can be sensefully assessed. On the basis of the many problems with contraceptive technologies, and in particular the Norplant® experience, this seems to be too late. The Population Council developed Norplant® and assessed its acceptability in a number of so-called "introductionary trials" in the 1980s. Some of the problems that were signaled have been addressed since then. For example, the Dutch pharmaceutical company Organon has developed an alternative hormonal implant method which seeks to evade the insertion and removal problems that Norplant® displayed. Other problems, notably the side-effects of Norplant®, have not been addressed, and in 1995, the second-highest number of notifications of adverse drug reactions reported to the U.S. Center for Drug Evaluation and Research were on Norplant®. This is remarkable for a drug with a small number of users (Scrip 1997, Hanhart 1999). Also, the publication in 1998 of a "Consensus Statement", signed by the Norplant® developers and their associates (Fraser et al. 1998), bears testimony to the continuing problems surrounding Norplant®. In what ways could user-centered concerns be brought into contraceptive development at earlier stages to prevent such situations?

It would be important to explicate the envisioned users of the actors involved in setting up the research agenda, and to bring in alternative and more user-centered perspectives, e.g. like those expressed by social movements. The opposition against involving different voices in the stage of discussing the concept for a new product has been framed in methodological terms. The contraceptive developers referred to social scientific research in which users' stated preferences appeared to have little relation to future uptake. The opinions of users about imaginary contraceptive methods or products that they have not yet used seemed to have little predictive value. From this, the contraceptive developers concluded that no meaningful acceptability studies could be done before the product was available. According to them, taking the users into account should wait until later stages of development. While the contraceptive developers might be right that users' views on non-existent methods are necessarily speculative, to conclude from this that alternative perspectives cannot be taken into account until the introductionary stage is premature. My analysis suggests that the assertion that users cannot be involved as long as there is no tangible product to talk about is not so much a methodological issue as it is a form of boundary work. It is a way in which the contraceptive developers can confirm their scientific authority as opposed to, e.g., politics, and acquire and preserve control over their work. (Gieryn 1983 and 1995, Jasanoff 1987). But as I have argued throughout this thesis, speculations on possible futures are part and parcel of any technological development. On methodological grounds, the speculative character of imagined users therefore cannot serve as a basis for excluding the envisioned futures provided by some actors and not those of
others. The conclusion that more than a methodological issue is at stake is supported by my analysis of the role of the prototype in chapter 3. After a more or less tangible prototype of an anti-fertility vaccine had been developed, the researchers still insisted that it was too early to take into account alternative perspectives on users. The critique by women’s health advocates of certain technical features of the developing artefact were attributed to the prototypical status of the product. Women’s health advocates’ concerns for the vaccine’s safety and efficacy that followed from these characteristics were therefore postponed, once more, until later stages of development. At the same time, the researchers based their claim that anti-fertility vaccines were safe and effective on these same products. The proposal of women’s health advocates to include a social scientific research component in the clinical trials was cautiously accepted. But it was not carried into effect, again due to the methodological consideration that it might affect the biomedical testing. And, ironically, the proposal was said to have come too late for inclusion in the organization of the trial. To put it simply, according to the researchers, it is always either too early or too late for the involvement of other perspectives on users. While taking into account alternative users’ perspectives might at no moment be convenient for the contraceptive developers, this does not mean that it is impossible. In other fields of technological development, e.g. in information and communication technology or in sustainable technology development, a number of initiatives exist in which the initial concept for a new technology is discussed with various stakeholders, including representatives of future users and social movements (Haddon et al. EC report 1998, Pim den Hertog et al. EC report 1996). Of course there should be something for the stakeholders to interact with, but this could be a proposal for a new approach to family planning or the concept for a new product as well as it could be a description of a prototype. For the contraceptive developers, there is a risk that an approach to family planning or a product profile that has been recommended by women’s health advocates will not succeed or will not be well received. But this risk is not necessarily greater than for those suggested by the contraceptive developers themselves. In fact, one would expect that the more contextualized approach to understanding users’ needs and preferences proposed by the women’s health advocates would render more coherent representations of users than the disparate collection of facets of users that the developers of anti-fertility vaccines have co-produced.

7. Abuse

The concern of women’s health advocates that on the basis of certain design characteristics anti-fertility vaccines would have a higher potential for
abuse than other methods was circumvented as well. The scientists maintained that eventual abuse of anti-fertility vaccines in family planning practices fell outside their scientific domain of developing the novel artefact. From my interest in making contraceptive development practices more responsive to concerns stemming from a more contextualized view on users, this postponement of the discussion about the relation between technical characteristics and abuse is a missed opportunity. For years, the assessment of the side-effects of contraceptives and situations of abuse have been contested issues, and this situation seems to perpetuate itself. What possibilities and limitations for changing this situation can we identify on the basis of the preceding? That the scientists were able to transgress the boundaries of scientific discourse was exemplified by their shifting to a different discourse in order to legitimate the need to develop additional methods. Apparently, to affiliate their developmental work with the politics of population control seemed less problematic to them than with the politics of reproductive health and rights. The prevailing representation of users in population control discourse as women in need of contraceptives with a number of singular attributes fitted well with their developmental practices. The question thus becomes: under what conditions would the reproductive scientists be able to align their work with more contextualized perspectives on users?

Part of the answer lies in clarifying the concept of technology held by the actors involved. For constructivist science and technology scholars, the distinction that the contraceptive developers assumed between the artefact and its application, abusive or not, is not self-evident. The script approach that I have adopted and elaborated in this thesis makes it possible to see, without recurring to technological determinism, how certain effects of technologies are defined in their design. Whether or not a technology will be abused cannot be predicted, but some designs make abuse more likely than others. Anti-fertility vaccines contain a script that, as I have shown, has evolved from a composite of population control ideology, the workings of the immune system, funding opportunities, the availability of certain target substances, scientific rivalry, measurements made in the lab and in the clinic, health care infrastructures, international policy debates and campaigns, and more. A contraceptive technology evolved with a particular script, that could have been otherwise. It seems to me that according to this understanding of technology, responsibility must be shared among the actors involved in the funding, policy-making, (re)design, testing, and implementation of anti-fertility vaccines. Throughout this thesis I have pointed out some of the ways in which these actors were involved in making immunocontraception. Actions to prevent abuse should also involve all the actors mixed up in the co-production of sociotechnical (dis)order. That is, as against the position taken by the anti-fertility vaccine developers, there is a role for them to play.
One consequence of this view is that immunological approaches to fertility regulation are not inherently wrong or abusive, as some women’s health advocates have occasionally suggested. On the other hand, it remains possible to point out some specifics features that have actually been inscribed into the design of anti-fertility vaccines and that support the concerns for abuse. The second consequence is that the researchers should no longer shy away from the politics of working in a largely publicly funded area, in doing research into human reproduction, and in the specific technology that they are developing. In particular, they should not selectively avoid unwelcome sociotechnical issues such as abuse. Over the years, women’s health advocates have collected a lot of insights into the problem of the uninformed, disinfomed, and coercive administration of birth control methods. The reproductive scientists might benefit from their expertise. Greater understanding might occur if the reproductive scientists were prepared to learn more about feminist concerns with reproductive health and about the daily-life situations in which people plan their families, much in the same way as many of the women’s health advocates have learned the language of biomedicine and the logic of scientific research. This would be helpful to create linkages between technological innovation and contraceptive practices. Third, policy-makers should no longer treat reproductive science and technology, scientists and contraceptive artefacts, as politically neutral. The actions of the WHO/HRP can be characterized by continuous efforts to achieve consensus and pacification, and the portraying of science as an impartial authority has been of central importance in their accomplishments. For example, in chapter 1 I discussed how in setting up the research programme, separate Task Forces were formed to address the interests of member states interested in the development of new technologies, and to respond to the concerns of member states asking for more acceptability studies and research into service delivery systems. These preoccupations reflected the political conflict between Member States who thought that development was the best contraceptive, and followers of the opposite thesis. The WHO/HRP came to be dominated by biomedical scientists, at the expense of experts in the fields of family planning, women’s health and rights issues, social scientists, and policy-makers themselves. The policy-makers at the WHO/HRP attempted to avoid politics when they hosted the encounters between scientists and women’s health advocates. The women’s health advocates voiced their concerns about the safety and efficacy of anti-fertility vaccines when assessed from a women’s daily-life situation point of view. These concerns were either referred back to the scientific domain, entailing the need for additional research, or labeled as application problems and therefore deemed irrelevant to technological development. The contextualized representations of users that the women’s health advocates upheld were troublesome to the WHO/HRP because res-
toring the contexts in which people plan their families meant restoring the politics. And lastly, the possibility that the technological artefact might have a politics of its own was rejected by the policy-makers. According to them, the problem of contraceptive abuse should vigorously be addressed by guidelines, ethics courses, and monitoring systems, but not by changing technological development.

Admittedly, many of the WHO/HRP's successes have been achieved on the basis of their presenting themselves as an apolitical agent maintaining consensus. But on the basis of the preceding I would argue that any approach or any position that policy-makers in the field of contraception take is necessarily and inevitably political in its consequences. In addition, some contestation might actually be healthy for the quality of technology. Many of the concerns that women's health advocates brought to the fore on the basis of their more contextualized view of users were not superfluous luxuries. Examples include their insistence upon rethinking the practicality of test-kits to monitor a person's immune response, research into the possible interactions between anti-fertility vaccines and the required bridge method, the need for long-term follow-up of the children born in the Indian trials, and the problematic product profile of anti-fertility vaccines in the light of the contraceptive abuse taking place.

8. Policy implications

What kind of policy framework should be developed in order to make contraceptive development more responsive to users? As against technology development in agriculture or in information and communication, the possibilities for experimenting with users are limited, for obvious ethical and legal reasons. This underscores the importance of gaining insight into the dynamics of representing users. What follows are some preliminary suggestions.

A number of initiatives "to integrate the users' perspectives" have already been developed at WHO/HRP. These include the organization of meetings to stimulate dialogue between women's health groups and scientists, the establishment of a Gender Issues and Women's Perspectives Unit, the installation of a Gender Advisory Panel, enhancing women's health advocates' participation in scientific and policy-making committees, and rethinking the kind of social scientific research that would meet the requirements of a user-centered approach to technology development. These and other efforts have already resulted in, for example, a renewed interest in barrier methods at the WHO/HRP, the consolidation of a user-centered approach to contraceptive introduction, and a new framework for determining
the Programme's priorities in developing new contraceptives. Thus, it seems that the creation of linkages between technological development and user-centered considerations has in effect started to change contraceptive development practices. The institutionalized positions that have already been created to allow women's health advocates to enter into dialogue with reproductive scientists and to voice their perspectives on users constitute a major achievement for furthering a user-centered approach to contraceptive technology development, and should become more firmly anchored in the institutional structure of the WHO/HRP and other organizations.

The WHO/HRP has been a very interesting location for studying users' involvement in medical technology development. Compared to the pharmaceutical industry, the communication channels of this publicly funded institution are more open. Transparency remains a key issue in drug development. As the sociologist John Abraham concludes quite rightly on the basis of his inquiry into secrecy and the development and regulation of new drugs: "A pharmaceutical product worthy of being put on the market should be able to withstand such public exposure and any ensuing investigation into its therapeutic value" (1995, 253). Openness is a basic requirement for allowing taking into account alternative perspectives on users into contraceptive development. But the provision of information is not sufficient. Contrary to what has been suggested by the contraceptive developers, the protest of women's health advocates against anti-fertility vaccines is not simply an information problem. It is not that they simply misunderstand what the reproductive scientists seek to develop and how. Instead, the experiences and perspectives of women's health advocates differ from those of the contraceptive developers, and lead to a different understanding of immunocontraception. Similarly, the contraceptive developers do not simply lack information or misunderstand users' needs. This became apparent in the WHO/HRP 1995 Meeting on Women's and Men's Perspectives on Fertility Regulating Methods and Services, which proceeded to address the notion that the reproductive scientists and policy-makers required more information on users' needs. But, as I have described in chapter 3, there was an additional problem, namely the differing perspectives on users' needs and on how to take these into account in contraceptive development. Therefore, additional means to "integrate the users' perspectives" into contraceptive policymaking are warranted. It is not sufficient "to add users and stir", to borrow a phrase from feminist writings.

My analysis of contraceptive technology development provides indications on how user-centered perspectives can be included from the early stages onwards. First, it is important to thematize the foreseen users of a contraceptive method from the very beginning. In this way, the lack of guidance for the reproductive scientists that ensued from representations of
users as "everybody" or as "individuals worldwide" can be avoided. Second, this study shows that visions about the future, including implicit and explicit prospects about the needs and preferences of envisioned users, form an essential part of the technological construction process. The question of who can participate in the forecasting is therefore not so much a methodological as it is a political issue. And third, I have demonstrated that the labeling of safety and efficacy as purely technical characteristics that can adequately be measured using prototypes is no longer tenable. Nor is it viable to portray abuse potential as an issue unrelated to technological design.

Whether their characteristics and situations are articulated or not, users are implicated from the very beginning. For policy-makers, there might be various advantages in specifying more clearly the representations of users that they prefer to be seen inscribed into a developing technology. Once an explicit point of reference has been defined, prevailing but as yet implicit ideas about future users can be discussed with different actors, and thus inform the decision-making. The biomedical researchers can be asked to consider these representations in their developmental work. Also, the images of the future users held by the different actors involved should be examined for their correspondence with the results of social scientific studies on contraceptive users, and with the findings of other experts such as women's health advocates and family planning organizations. In this way, the looming incoherencies in the foreseen future users of a developing method can be detected early on, and then dealt with.

According to my analysis, key roles in bridging the gap between the representations of users held by the biomedical scientists and those provided by the women's health advocates were played by actors who in one way or another simultaneously belonged to different social worlds, and can therefore be considered "bilingual". Jane Cottingham is both a policymaker and a women's health advocate, and she played a role in important initiatives at the WHO/HRP to make contraceptive development more open to alternative perspectives on users, such as the series of dialogue meetings, the Gender Advisory Panel, and the nomination of more gender-sensitive persons in all kind of committees. The feminist immunologist Faye Schrater could operationalize the concerns for long-term and exceptional side-effects by advocating the most rigorous testing possible in the Steering Committee. Various women's health advocates were social scientists and thereby able to work to translate their concerns for a user-centered approach into terms more acceptable to the contraceptive developers. And Task Force manager David Griffin was in the unenviable position of speaking the languages of both policy-making and biomedicine, and in addition having to learn that of the world of women's health and rights. In other words, actors who are members of multiple social worlds seem to be well-situated to align the representations of
users shared by the members of one world with those prevalent in another. Policy-makers might exploit this finding, for example by creating more intermediating positions.

Until now, social scientific studies of users have mainly been in the realm of contraceptive acceptability. On the basis of chapters 3 and 4 I would suggest that users’ perspectives should be taken into account not only in order to enhance acceptability, but also to promote more user-centered understandings of safety and efficacy. One way to achieve this goal might be the involvement of women’s health advocates in the planning, conduct and evaluation of clinical research, as they have suggested. This would be helpful to construct alternative indicators of safety and efficacy that make sense from the perspectives of women’s daily life situations. The presence of women’s health advocates in clinical testing might also produce a more systematic monitoring of the quality of the enactment of informed consent procedures.

In addition, the contraceptive developers might further capitalize on the different roles assigned to the participants in clinical testing. I have described how clinical trial participants were not only made to represent the population of future users in a statistical sense, but also performed the role of pioneer test-users. This assignment could be further exploited, and the trial would then become an opportunity to see if different facets of the user have been satisfactorily reconciled in the technology: first, by making this role an explicit one, and, second, by involving the participants in the assessment of the method’s acceptability. This could be done by analyzing their reproductive life histories, in a series of focus group discussions or surveys. This data could be compared with that of non-participants. It is interesting to note that, under the auspices of the WHO/HRP, social scientific research on contraceptive acceptability has been carried out during clinical testing among the participants and their partners in a new hormonal method for men (Oudshoorn 1999).

Finally, my analysis leads to important conclusions for women’s health advocates trying to make contraceptive development more responsive to users. Particularly helpful is the insight from Science and Technology Studies that contraceptive technologies contain a script that is not preordained by the nature of immunology and the reproductive system, nor is it a purely social construct. Anti-fertility vaccines with a problematic users-script evolved not because of the researchers’ lack of concern for users, nor was it inherent in the immunocontraceptive approach to family planning. Rather, anti-fertility vaccines with a certain script were made in situations that could have been otherwise. I have examined these situations and the mechanisms that contributed to the way in which the new method developed. From this analysis we can learn that the technical choices made in contraceptive development should certainly remain on the feminist agenda.
Notes by Conclusions

1. See Jenny Reardon (1999) for a similar line of thought.

2. See Els Rommes (1999) for an analysis of the workings of the category "everybody" in information and communication technology.

3. See also Saetnan, Oudshoorn and Kirejczyk (2000).


5. See also De Bont (2000).

6. When one of the funders of the Indian phase II trial, the Canadian IDRC, decided to not provide any more funds for the development of anti-fertility vaccines and to close their file on the project, women’s health advocates insisted upon longer term follow-up of the women who had been involved in the study and the children who were born of these women (Letter by Laxmi Murthy 30 May 1998, Letter by Karen Seabrooke, Shree Mulay and Beatrijs Stemerding 21 May 1998).
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Summary

Since the early 1990s, a consensus has been growing among researchers, policy-makers, funding agencies, and women's health advocates that the future users of contraceptive methods should be involved in the process of their development. However, in practice the integration of the users' perspectives into contraceptive research and development has proved very difficult. Most studies of users and contraceptives have focused on the introductory stage, where problems generally surface. Earlier stages of technology development, and the possible involvement of users in the trajectories preceding introduction, have not been questioned. In this thesis I have traced the ways in which users were involved in the development of a new contraceptive technology over its entire life cycle. The research questions are: What are the dynamics of users' involvement in the development of anti-fertility vaccines? And what are the possibilities and limitations for changing the ways in which users are implicated in this developmental process? The character of the relation between representations of users and technology development is subject to debate. This study provides an empirical and theoretical contribution to this discussion. In contraceptive technology development, precisely because it has been such a contested area, a number of initiatives have been undertaken by international organizations to promote broader participation and dialogue about social aspects in earlier stages of technology development. Therefore, those interested in technology assessment may find that this study provides important insights into the effects of such endeavors upon technological development.

In the Introduction, the literature on users and Science and Technology Studies is discussed. The Social Construction of Technology approach conceptualizes users as a relevant social group, but the effects of ideas about the envisioned users in earlier stages of technological development are not systematically included in such analysis. The script approach proposed by Akrich (1992, 1995) assigns an important role to representations of future users held by the developers of a technology. Technologies, she has affirmed, contain a script: together with the actors and the settings in which they are
supposed to act, technical objects define a framework of action. Technical objects can distribute responsibilities and assign positions to other participants in the sociotechnical network, including the potential users. The innovators’ projected users are anticipated in the script. In this thesis, I have adopted this approach in order to understand how anti-fertility vaccines evolved with a particular script. Akrich’s procedure has been to examine situations of mismatch between the anticipated users and the actual (non)users, and in this way she has made visible how the designers’ representations of users had been solidified in the artefact by their design decisions. But I am interested in understanding users’ involvement in the preceding trajectories, before they are solidified or go awry. And I am concerned with developing a perspective on changing the ways in which these technologies evolve in the pre-market-stage, so that problems might be prevented. Therefore, I have proposed two extensions to the script approach. First, it is important to analyze where certain representations came from, who articulated them, and how some of the implicit and explicit images of prospective users became more powerful than others in certain circumstances. Second, I have explored various ways to learn about the prevailing representations of users before the script is performed. I have examined how evolving scripts can be made explicit in earlier stages by contrasting the representations of users held by the scientists involved with those held by other actors concerned in technology development. In anti-fertility vaccine development, the international women’s health movement provided me with a suitable point of contrast. I was able to study the representations of future users that the scientists and women’s health advocates invoked in their negotiations about what the technology and its concomitant script should look like. The clinical trials with immunococontraceptives provided me with another opportunity to study the evolving script before the product is introduced. Given the potential agency of the trial participants, it is interesting to see what we can learn from their encounters with the expected users inscribed in the anti-fertility vaccines.

The chapters in this book follow the developmental trajectories of anti-fertility vaccines. Immunococontraceptive development started in the early 1970s, when the concept of immunological approaches to fertility regulation became articulated in initial research programmes at the Human Reproduction Programme of the WHO and at a national research institute in India. Chapter 1 is about this agenda-setting stage. From a perspective on change it was interesting to examine who was entitled to bring representations of future users to the fore, and what their contents were. The WHO/HRP enrolled its member states, biomedical scientists, and clinicians in framing the research programme. Social scientists, family-planning organizations, and women’s health advocates were not involved in the process in this stage. I have discussed how representations such as populations, non-Pill users, and finally
"everybody" were generated and came to bear upon the initial research programme in immunocontraception. Importantly, representations of users had more functions to accomplish than that of simply guiding the innovators in their technology development, such as legitimizing the research and development. In order to develop a research programme, agreement had to be reached about a "doable research problem" (Fujimura 1987), involving the alignment of the laboratory work, the clinical practice, and the world of policy-making and financing. In this endeavor, ideas about who might use the methods were left implicit. The WHO/HRP and the member states wanted to avoid the suggestion that research into this particular method could be interpreted as a statement about the politically sensitive relations between population growth in Third World countries and development. The idea of users as "everybody" was not as politically neutral as it might appear at first sight. Aligning the technology development with more specific user profiles might have deferred the doability of a quick and universal technological fix for fertility control.

In chapter 2 I have examined the circumstances in which appropriate antigens were selected, and the concomitant representation of users' bodies that evolved. The scientists' indeterminacy about the envisioned users included their sex. Users' bodies came to be represented at the level of target substances. However, the sexless representation of users' bodies did not correspond with the work that the reproductive scientists carried out in practice. A technology evolved with a clearly gendered script. Therefore, I have argued that even if innovators do not always have users in mind, we cannot conclude from this that users do not matter. The concept of "implicated users" (see Clarke and Montini 1993) is meant to make this form of involvement visible.

Next, in order to account for the asymmetric presence of male and female bodies in anti-fertility vaccines development, I have analyzed the researchers' room for manoeuvre to develop certain vaccines and not others. The distribution of opportunities for developing anti-fertility vaccines was not merely contingent, but embedded in a certain context that evolved over years of doing reproductive research. The availability of research materials decisively structured the course of the research and development of immunological contraception. The purified placental hormone hCG was readily deliverable, and animal models of proven utility existed for studying the female reproductive tract. This "gynecological infrastructure" (Oudshoorn 1994) for doing reproductive science encouraged the development of vaccines to be used by women more than research into male methods. International policy debates also forcefully impinged on the co-construction of anti-fertility vaccines and future users. Particularly influential were the policy debates on abortion, on male partnership in contraception, and on reproductive rights. I
have also examined the factors conducive to research into male immuno- 
logical contraceptives.

The involvement of the international women’s health movement with 
anti-fertility vaccines development is analyzed in chapter 3. The inclusion of 
women’s health advocates in the analysis of contraceptive development raised 
the question of whether and how women’s health advocates could be con- 
sidered spokespersons for future users of anti-fertility vaccines. I have 
approached this issue by analyzing how the question was handled by the 
actors involved. The women’s health advocates did not claim to speak in the 
name of users; but based on their differing experiences and analysis, women’s 
health advocates could contribute more contextualized images of future users 
to the discussions with contraceptive developers. Influenced by the policy 
shifts in the early 1990s under the banner of reproductive health and rights, 
their alternative perspectives were recognized as valuable by the contraceptive 
developers. Crucially, for members of the women’s health movement this 
meant that they were not restricted to the essentially impossible task of 
voicing the supposed needs and preferences of people wanting to plan their 
families. Instead, they could relate to contraceptive technology in other ways, 
as researchers or as advocates. Room was created for women’s health 
advocates to introduce different frames of meaning, such as exploring the 
kinds of relations that one or another technology might constitute.

I also have examined the possibilities and limitations involved in 
inTEGRating women’s health advocates’ alternative perspectives into the design 
of anti-fertility vaccines. The scientists aimed to develop a contraceptive that 
would be long-acting and easy to administer, and they expected that such a 
method would then meet users’ needs and preferences. From their perspective 
on users-in-their-contexts, the women’s health advocates questioned the 
practicality of certain features of immunocontraceptives. In particular, they 
were concerned about the occurrence of a lag-period of three to six weeks 
after injection to build up sufficient immune response, the unpredictable 
duration of effectiveness, and the impossibility of switching off the immune 
response on demand. Given the history of recurrent situations of coercive and 
not fully informed administration of contraceptive methods, they also were 
concerned that these methods might be prone to abuse in population-control- 
driven family-planning programmes. According to the researchers, these 
issues were not part of developing the vaccine itself, but should be addressed 
in family planning programmes in the application stage. The researchers 
proposed providing a bridge method to cover the lag period, a test-kit to 
monitor the antibody response, and thorough counselling by health-care 
providers on the possible duration of effectiveness. I have analyzed these 
proposals as a mixture of "boundary work" (Gieryn 1983 and 1995, Jasanoff 
1995) and the attempts of the scientists to align the developing artefact with
the users (Akrich 1992, 1995). Women's health advocates also questioned the efficacy and safety of the developing product for users with differing genetic dispositions, or suffering from stress, malnutrition, or disease that might affect immune responses, or in contexts of marginal health care. The researchers argued that these concerns of the women's health advocates were irrelevant, since what they had developed was only a prototype and not a product that would be used by users-in-their-contexts. But at the same time, measurements made on the basis of these prototype vaccines in clinical trials were cited in support of the safety and efficacy of the new method. As a result of this way of mobilizing the prototype status of the developing method, the women's health advocates' different understanding of safety and efficacy could not be taken into account. All of their concerns were postponed to later stages of technology development.

Users' involvement in the clinical testing of anti-fertility vaccines is studied in chapter 4. I have examined the roles that were assigned to the clinical trial participants in the researchers' papers. The scientists viewed trial participants as "test-users" and referred to the trial participants as the forerunners of the future user population (see Epstein 1995). In the enrollment and in the conduct of the trials, the participants were present as embodied agents. Their embodiment endowed them with the capacity to foot-vote. It also endowed them with vulnerability to pain and ethical abuse. It was at this stage that international differences between women's options came most clearly to the fore. Because of women's differing possibility for action in various countries, it was easier to recruit and keep women in the trials in India than in Sweden. For poor women in India, the clinical trials could provide a welcome opportunity to obtain better access to superior health care, an extra income, and a social space outside their homes.

In the clinical trials in India and Sweden in the 1990s, special organizational efforts were required to overcome the problem of unpredictable individual variation in immune response, involving well-equipped laboratories, motivated health care personnel, and frequent access to the trial participants for blood tests and booster injections. Part of the effort to make the vaccine work was in the reporting of the trial findings in scientific texts. The researchers applied a specific distribution of competencies, in which high antibody responses were attributed to the vaccines, while side-effects and lesser immune responses were assigned to the women. In the Indian trial, the efficacy results were expressed not in terms of the number of pregnancies among the trial participants, but of the number of pregnancies per menstrual cycles in which the immune response was above the threshold value. The outcomes produced in this way played an important role in legitimizing further research. I have indicated that the status of "promising technology" (Van Lente 1993) that had been assigned to anti-fertility vaccines helps to
explain how the new contraceptive method could continue to receive the benefit of the doubt for many years.

In 1994, the WHO discontinued their clinical trials in Sweden, when two of the first seven participants left the trial because of the severe side-effects they experienced. The scientists then proceeded with research into the causes of these side-effects. At the same time, the research group in India postponed their clinical research and continued with additional laboratory work to make their preparation more suitable for wide-scale use in family-planning clinics. Concerns about the side-effects of anti-fertility vaccines and the practicality of the method had been among the issues raised by women’s health advocates before the trials had begun. I have therefore concluded that if people voicing user-centered perspectives had been involved in the early stages of anti-fertility vaccine development, the socially costly, expensive, and time-consuming detour of the scientists might have been prevented.

In the concluding chapter the highlights of this story are summarized and some implications for policy-making in the field of contraceptive development are outlined. The method that the researchers proposed to develop contained a script: a low-cost anti-hCG vaccine that would provide long-acting protection against pregnancy following a single injection, and one that could be used surreptitiously, would be suitable for a particular category of users: women with poor access to low-quality health care and relatively little decision-making power over their reproductive lives, in casu poor women in Third World countries. I have therefore proposed that "implicated users" is an important addition to the instrumentarium for conceptualizing users in the pre-market stage of technology development. To make visible how users are implicated in the technical choices of the innovators is particularly important in understanding the possibilities and limitations involved in changing user-technology relations in early stages of development.

My analysis of who was entitled to represent future users, and in what circumstances, enabled me to understand the power of implicit and unarticulated notions of users, such as "everybody". From the perspective provided by the women’s health advocates, of users attempting to plan their families in their daily lives, a number of incoherences became apparent in the script of anti-fertility vaccines. Women’s health advocates doubted that the method being developed would actually meet the needs of poor women in developing countries. I have argued that the lack of definition of those for whom the method is deemed suitable allowed the technology to develop in this inefficient way. I propose that invoking better defined user profiles from the beginning would help one to thematize users and to detect dysfunctional user-scripts early on.

Constructing more specific representations of future users might not be enough to achieve a more user-centered approach to contraceptive develop-
ment. Technological development is structured not only by imagined notions about envisioned futures; and future users of technologies are defined not only by the representations of users that designers bring into the process, but also by early technical choices that in turn are shaped by existing institutional infrastructures, material possibilities, international policy-making, etc. Therefore, the script approach should be extended to include an analysis of what enables and what constrains certain technical choices with implications for the eventual users.

A contraceptive technology evolves with a particular script that could have been otherwise. I have shown how the script of anti-fertility vaccines has evolved from a composite of population-control ideology, the workings of the immune system, funding opportunities, the availability of certain target substances, measurements made in the lab and the clinic, health-care infrastructures, international policy debates and campaigns, and more. I have argued that, according to this understanding of technology, contraceptive abuse is not a problem of application, but one related to technological design. Abuse can therefore not be addressed satisfactorily in the health-care delivery system alone. Action to prevent abuse should involve all the actors involved in the coproduction of technology and social (dis)order, including the contraceptive developers.

To policy-makers in the field of contraceptive development I have suggested that, in addition to the initiatives already undertaken by the WHO/HRP, strong linkages should be created between technological innovation and the practices in which contraceptives are used. Contraceptive developers have asserted that users cannot be involved as long as there is no tangible product to talk about. While they might be right that views on users’ involvement with non-existent methods are necessarily speculative, it does not follow from this that alternative perspectives cannot be taken into account before the introductionary stage. Speculations on possible futures are part and parcel of any technological development, and the hypothetical character of imagined user-technology relations cannot serve as a basis for excluding the envisioned futures provided by some actors and not those of others. Taking into account user-centered perspectives is a major challenge, because restoring the contexts in which people plan their families means restoring the political dimension to technological development.
Conceiving contraceptives
The Involvement of Users
in Anti-Fertility Vaccines Development

Samenvatting

Vanaf de jaren '90 groeide de consensus onder onderzoekers, beleidmakers, financieringsinstanties en vrouwengezondheidsactivisten dat de toekomstige gebruikers van anticonceptiemiddelen betrokken zouden moeten worden bij het ontwikkelingsproces. Maar in de praktijk blijkt het heel moeilijk te zijn om gebruikersperspectieven te integreren in het onderzoek en de ontwikkeling van anticonceptiemiddelen. De meeste studies naar de relatie tussen gebruikers en anticonceptie waren gericht op de fase waarin de problemen gewoonlijk aan de oppervlakte komen: de invoering van anticonceptiemiddelen in family-planning programma's. Naar de stadia van technologie ontwikkeling die daaraan vooraf gaan, en naar de wijze waarop gebruikers daaraan deel uit maken, werd geen onderzoek gedaan. In dit onderzoek ben ik nagegaan hoe gebruikers verwikkeld zijn in de ontwikkeling van een bepaalde nieuwe anticonceptie-technologie, en dat gedurende het hele ontwikkelingstraject. Twee onderzoeksvragen stonden daarbij centraal. Op welke wijze zijn gebruikers betrokken in het ontwikkelingsproces van antivruchtbaarheidsvaccins? En wat zijn de mogelijkheden en beperkingen om dit te veranderen?

De aard van de relatie tussen technologie en gebruikers staat ter discussie. Met deze studie wil ik zowel een empirische en als een theoretische bijdrage leveren aan dit debat. Anticonceptie ontwikkeling is onderwerp van voortdurende onenigheid, en internationale organisaties hebben daarom een aantal initiatieven ontplooid ter bevordering van een bredere participatie en van een dialoog over de sociale aspecten in eerdere stadia van de technologie ontwikkeling. Voor mensen die geïnteresseerd zijn in technology assessment levert dit onderzoek belangrijke inzichten op over het effect van deze inspanningen.

In de Inleiding wordt de literatuur op het gebied van gebruikers en Science and Technology Studies besproken. In de Social Construction of Technology benadering worden gebruikers geconceptualiseerd als relevante sociale groep. Maar van dit type analyse maken de effecten van voorstellingen over gebruikers in eerdere stadia van technologie ontwikkeling niet systematisch deel uit. In haar script benadering wijst Akrich (1992, 1995) een belangrijke rol toe aan de voorstellingen over toekomstige gebruikers die technologie-ontwikkelaars er op na houden. Technologieën, zegt Akrich, bevatten een script: samen met de actoren en de setting waarbinnen zij
worden verondersteld te werken definiëren technische objecten de handelings-mogelijkheden. Technische objecten behelzen een verdeling van verantwoordelijkeheden en wijzen posities toe aan andere participanten in sociaal-technologische netwerken, onder wie de potentiële gebruikers. In het script lopen de ontwerpers vooruit op de door hen veronderstelde gebruikers. In dit proefschrift maak ik gebruik van Akrich’s benadering om te onderzoeken hoe antivruchtbaarheidsvaccins met een bepaald script tot stand kwamen. Haar werkwijze bestond er uit dat zij situaties onderzocht waarin er een discrepantie was tussen de beoogde gebruikers en de uiteindelijke (niet) gebruikers. Zo kon zij zichtbaar maken hoe de voorstellingen die de technologie-ontwekkelers zich maakten van de gebruikers vaste vorm hadden aangenomen in het artefact middels hun ontwerpbeslissingen. Maar ik was geïnteresseerd in het voorafgaande ontwikkelingstraject, voordat technologieën in het gebruik ofwel geaccepteerd ofwel afgewezen werden. En ik had belangstelling voor het ontwikkelen van een perspectief op verandering van de wijze waarop technologieën tot stand komen in deze eerdere stadia, zodat problemen misschien voorkomen zouden kunnen worden. Ik stel daarom twee uitbreidingen van de script benadering voor. In de eerste plaats is het belangrijk om te analyseren waar bepaalde representaties van gebruikers vandaan zijn gekomen, wie ze onder woorden heeft gebracht, en hoe het komt dat sommige impliciete en expliciete beelden over toekomstige gebruikers onder bepaalde omstandigheden meer invloedrijk krijgen dan andere. In de tweede plaats heb ik verschillende methodes verkend om inzicht te krijgen in de aard en inhoud van representaties van gebruikers. Ik heb onderzocht hoe zich ontwikkelende scripts in eerdere stadia expliciet gemaakt kunnen worden door de ideeën over gebruikers van de betrokken onderzoekers te contrasteren met die van andere belanghebbenden. Voor de ontwikkeling van immunologische anticonceptie voorzag de internationale vrouwengezondheidsbeweging mij van een bruikbaar contrast. Ik kon onderzoeken welke voorstellingen over toekomstige gebruikers naar voren werden gebracht door enerzijds de onderzoekers en anderzijds de vrouwengezondheidsactivisten in hun onderhandelingen over hoe de technologie en het daarmee samengaande script er uit moesten gaan zien. De klinische proeven met antivruchtbaarheidsvaccins vormden een andere gelegenheid om het zich ontwikkelende script te bestuderen voordat de methode zou worden geïntroduceerd. De aanwezigheid van deelnemers aan de proeven maakt het interessant om na te gaan wat we kunnen leren van hun treffen met de gebruikers zoals die waren ingeschreven in het script van antivruchtbaarheidsvaccins.

De volgorde van de hoofdstukken in dit proefschrift komt overeen met het ontwikkelingstraject van antivruchtbaarheidsvaccins. De ontwikkeling van deze vorm van anticonceptie startte in de jaren ’70, toen het idee van een immunologische benadering van vruchtbaarheidsregulering onder woorden werd gebracht in onderzoeksprogramma’s van het Human Reproduction Programme van de World Health Organization (WHO/HRP) en van een
nationaal onderzoeksinstituut in India. Hoofdstuk 1 gaat over het opzetten van de onderzoeksagenda. Om meer zicht te krijgen op de mogelijkheden tot verandering was het van belang om na te gaan wie gevraagd werden om representaties van toekomstige gebruikers naar voren te brengen, en hoe die voorstellingen eruit zagen. De WHO/HRP nodigde de lidstaten, biomedische wetenschappers en klinici uit voor het opstellen van het onderzoekprogramma. Sociale wetenschappers, organisaties voor family planning, en vrouwengezondheidsactivisten werden in deze fase niet bij het proces betrokken. Onder de representaties van gebruikers die de uitgenodigde actoren naar voren brachten en die van invloed waren op de totstandkoming van het eerste onderzoekprogramma waren noties als bevolkingen, niet-pilgebruikers, en uiteindelijk "iedereen". Ideeën over toekomstige gebruikers hadden meer functies te vervullen dan alleen het richting geven aan de technologie-ontwikkeling, ze moesten bijvoorbeeld ook het onderzoek en de ontwikkeling legitimeren. Om een onderzoekprogramma op te kunnen zetten moest overeenstemming bereikt worden over een doable research problem (Fujimura 1987), en daarvoor moesten het werk in het laboratorium, in de kliniek en in de wereld van beleid en financiering op één lijn gebracht worden. In een poging om dit te bereiken werden de denkbeelden over wie de methode zouden kunnen gebruiken vaag gehouden. De WHO/HRP en de lidstaten wilden voorkomen dat het onderzoek naar immunologische anticonceptie geïnterpreteerd zou kunnen worden als een uitspraak over de politiek gevoelige relatie tussen bevolkingsgroei in de Derde Wereld en ontwikkeling. De opvatting over gebruikers als "iedereen" was politiek niet zo neutraal als op het eerste gezicht leek. Het in overeenstemming brengen van de technologie met specifiekere profielen van toekomstige gebruikers zou ten koste zijn gegaan van de doability van het onderzoek, en daarmee zou de mogelijkheid van een snelle en universele technologische oplossing voor vruchtbaarheidscontrole zijn opgeschort.

In hoofdstuk 2 laat ik zien in hoe de situatie was waarin de selectie van geschikte antigenen plaatsvond, en hoe in samenhang daarmee een bepaalde representatie van het lichaam van gebruikers tot stand kwam. De onbepaaldheid van de denkbeelden die wetenschappers hadden over de toekomstige gebruikers betrof ook hun sekse. De lichamen van gebruikers werden beschreven in termen van substanties waartegen mogelijk een vaccin ontwikkeld zou kunnen worden. Maar deze sekseloze voorstelling van de lichamen van gebruikers was niet in overeenstemming met de praktijk van de wetenschappers die zich bezighielden met de menselijke voortplanting. Er ontwikkelden zich een technologie met een duidelijk gender-script. Ik heb daarom betoogd dat zelfs als technologie-ontwerpers geen gebruikers voor ogen hebben, we daaruit niet de conclusie kunnen trekken dat gebruikers er niet toe doen. Het concept geïmpliceerde gebruikers (zie ook Clarke en Montini) is bedoeld om deze vorm van betrokkenheid zichtbaar te maken.
Om de asymmetrie in het voorkomen van mannelijke en vrouwelijke lichamen in de ontwikkeling van antivruchtbaarheidsvaccins te begrijpen heb ik vervolgens een analyse gemaakt van de speelruimte die de onderzoekers hadden om bepaalde vaccins wel en andere niet te ontwikkelen. De mogelijkheden om de nieuwe methodes te ontwikkelen waren ingebed in een bepaalde context, die zich had ontwikkeld gedurende vele jaren van onderzoek naar de voortplanting. De beschikbaarheid van onderzoeksmateriaal structureerde op doorslaggevende wijze het verloop van het onderzoek en de ontwikkeling van immunologische anticonceptie. Het placenta-hormoon hCG was gemakkelijk verkrijgbaar in zuivere vorm, en voor onderzoek naar het voortplantingsstelsel van de vrouw bestonden al gevestigde diermodellen. Deze gynaecologische infrastructuur (Oudshoorn 1994) voor het doen van onderzoek op het gebied van de voortplanting stimuleerde het onderzoek naar middelen voor vrouwen meer dan dat naar middelen voor mannen. Ook waren internationale politieke debatten van grote invloed op de co-constructie van antivruchtbaarheidsvaccins en de toekomstige gebruikers, in het bijzonder de discussie over abortus, over de rol van mannen bij de anticonceptie, en over reproductive rechten. Ik ben ook nagegaan welke factoren mogelijk maakten dat er toch enig onderzoek naar een immunologisch middel voor mannen werd uitgevoerd.

In hoofdstuk 3 ga ik in op de rol van de internationale vrouwenbeweging in de ontwikkeling van antivruchtbaarheidsvaccins. Dat zij betrokken waren bij het proces roept onder meer de vraag op of en hoe vrouwengezondheidsactivisten zouden kunnen worden beschouwd als woordvoerders voor de toekomstige gebruikers. Dit heb ik onderzocht door te analyseren hoe de betrokken actoren deze kwestie zelf behandelden. De vrouwengezondheidsactivisten claimden niet in naam van de gebruikers te spreken. Maar op basis van hun andere ervaringen en hun analyse van die ervaringen waren vrouwengezondheidsactivisten in staat om in de discussies met anticonceptie-ontwikkelaars een meer gecontextualiseerd beeld van de toekomstige gebruikers te geven. Onder invloed van de verschuivingen in het internationale beleid op het gebied van anticonceptie ontwikkeling in de jaren '90 in de richting van meer aandacht voor reproductive rechten en gezondheid, werd hun alternatieve perspectief erkend als waardevol. Van groot belang is dat hierdoor de leden van de vrouwengezondheidsbeweging zich niet hoeftden om te beperken tot de in wezen onmogelijke taak stem te geven aan de veronderstelde behoeften en voorkeuren van mensen die hun familie willen plannen. In plaats daarvan konden zij zich verhouden tot anticonceptie op andere manieren, bijvoorbeeld als onderzoeker of als pleitbezorger. Er was ruimte gecreëerd waarin vrouwengezondheidsactivisten andere verbanden en betekenisissen konden inbrengen in het debat, zoals inschattingen van wat voor soort relaties door een technologie worden vormgegeven.

Vervolgens heb ik onderzocht wat de mogelijkheden en beperkingen waren om de alternatieve perspectieven van de vrouwengezondheidsactivisten
in te brengen in het ontwerp van antivruchtbaarheidsvaccins. De wetenschappers stelden zich ten doel een anticonceptiemiddel te ontwikkelen met een lange werkingstijd dat eenvoudig toe te dienen zou zijn, en zij verwachten dat zo'n methode tegemoet zou komen aan de behoeften en voorkeuren van gebruikers. Vanuit hun perspectief van gecontextualiseerde gebruikers vroegen de vrouwengezondheidsactivisten zich af in hoeverre een aantal eigenschappen van antivruchtbaarheidsvaccins wel praktisch zouden zijn. Zij waren met name bezorgd over de lag-periode van 3 tot 6 weken na de injectie die nodig is om een voldoende immuun-respons op te bouwen, over de onvoorspelbaarheid van de werkingstijd, en over de onmogelijkheid om de immuun-respons desgewenst uit te schakelen. Tegen de achtergrond van het steeds terugkerende verschijnsel van het toedienen van anticonceptie onder dwang of zonder dat de gebruikers volledig zijn geïnformeerd, maakten zij zich zorgen dat deze methode zich zou lenen voor misbruik in familie planning programma's die beheerst worden door bevolkingspolitiek. Volgens de onderzoekers maakten deze punten geen deel uit van het vaccin zelf, maar moesten ze aan de orde komen als de middelen toegepast zouden worden in familie planning programma's. Ze opperden dat een ander anticonceptiemiddel gebruik zou kunnen worden om de lag-periode te overbruggen. Ze ontwikkelden een speciale test-kit om de immuun-respons te volgen. En ze stelden voor dat het personeel in de gezondheidszorg de gebruikers goed zou moeten voorlichten over de mogelijke werkingstijd. In mijn analyse heb ik laten zien dat deze voorstellen begrepen kunnen worden als een mengeling van boundary-work (Gieryn 1983 en 1995, Jasanoff 1995), en pogingen van de wetenschappers om het zich ontwikkelende artefact toch te laten aansluiten bij de gebruikers (Akrich 1992 en 1995). Vrouwengezondheidsactivisten zetten ook vraagtekens bij de effectiviteit en de veiligheid van het middel voor gebruikers met een verschillende genetische constitutie, of die onderhevig zijn aan omstandigheden die de respons op het vaccin beïnvloeden zoals stress, ondervoeding en ziekten, of in situaties waar de gezondheidszorg gebrekkig is. De onderzoekers betoogden dat deze zorgen van de vrouwengezondheidsactivisten niet relevant waren, omdat wat zij ontwikkeld hadden nog maar prototypes waren, en niet het middel dat uiteindelijk gebruikt zou worden in het dagelijks leven. Maar ondertussen werden deze prototypes gebruikt in klinische proeven, en werd op basis daarvan verslag uitgebracht over de effectiviteit en veiligheid van het nieuwe middel. Door de prototypes van het middel op deze manier in te zetten kon geen rekening gehouden worden met de andere invulling van de begrippen veiligheid en effectiviteit die vrouwengezondheidsactivisten hanteerden. Al hun zorgen werden verwezen naar latere stadia van de technologische ontwikkeling.

Over de betrokkenheid van gebruikers in de klinische proeven met antivruchtbaarheidsvaccins gaat hoofdstuk 4. Ik heb onderzocht welke rollen de onderzoekers in hun verslagen toeschreven aan de deelnemers. De wetenschappers zagen de deelnemers als "test-gebruikers" en refereerden aan hen
als de voorlopers van de toekomstige gebruikerspopulatie (zie ook Epstein 1995). In de werving en in de uitvoering van de testen waren de deelnemers in levende lijve aanwezig. Daardoor hadden ze de mogelijkheid om wel of niet deel te nemen, en zo een *foot-vote* uit te brengen. Het maakte hen ook kwetsbaar voor ethisch misbruik en voor pijn. Het was in deze fase, waarin de middelen klinisch getest werden, dat verschillen tussen de keuzemogelijkheden van vrouwen wereldwijd het duidelijkst naar voren kwamen. In India was het gemakkelijker om vrouwen te recruteren voor de tests dan in Zweden. Aan arme vrouwen in India boden de testen een welkome gelegenhuid om toegang te krijgen tot betere gezondheidszorg, om extra inkomen te verwerven, en om buitenshuis te kunnen verkennen.

In de klinische tests in India en in Zweden in de jaren '90 werden speciale organisatorische maatregelen getroffen om het hoofd te bieden aan het probleem van de onvoorspelbare individuele variatie in immuun-respons. Daar waren goed uitgeruste laboratoria voor nodig, gemotiveerd gezondheidszorgpersoneel, en veelvuldige toegang tot de deelnemers voor bloed-tests en *booster*-injecties. Een deel van de inspanningen om het vaccin te laten werken bestond uit het rapporteren van de bevindingen in wetenschappelijke rapporten. De oorzaken voor hoge en lage immuun-respons die de onderzoekers daarin aangaven vertoonden een specifieke verdeling: hoge immuun-response schreven zij toe aan het middel terwijl zij lage immuun-respons en bijwerkingen toeschreven aan de vrouwen. In de tests in India werd de effectiviteit van het middel niet uitgedrukt in het totale aantal zwangerschappen onder de deelnemers, maar werden alleen de zwangerschappen geteld die voorkwamen in de menstruatiecyclus waarin de immuun-respons boven een bepaalde drempelwaarde was geweest. De uitkomsten die op deze wijze werden bereikt speelden een belangrijke rol in het legitimeren van vervolgonderzoek. Ik heb aangegeven dat de status van veelbelovende technologie (Van Lente 1993) die aan antivruchtbaarheidsvaccins was toegeschreven kan helpen verklaren hoe deze vaccins gedurende zo’n lange tijd het voordeel van de twijfel kregen.

In 1994 onderbrak de WHO/HRP de klinische tests onder haar auspiciën in Zweden, toen twee van de eerste zeven deelnemers van verdere deelname afzagen vanwege de ernstige bijwerkingen die zij ondervonden. De wetenschappers gingen toen verder onderzoek doen naar de oorzaken van de bijwerkingen. In dezelfde periode werd het klinische onderzoek in India voorlopig opgeschort en gingen de onderzoekers er toe over hun middel met aanvullend laboratoriumonderzoek eerst geschikter te maken voor groot-schalig gebruik in family-planning klinieken. Precies deze punten, de vraag naar de praktische bruikbaarheid van het middel en zorgen over de bijwerkingen, waren door de vrouwengezondheidsactivisten naar voren gebracht voordat de klinische testen begonnen. Ik heb daarom geconcludeerd dat de dure, in sociaal opzicht kostbare, en tijdverspillende *detour* van de wetenschappers voorkomen had kunnen worden als vrouwengezondheidsactivisten
hun perspectief op gebruikers naar voren hadden kunnen brengen in eerdere fasen van de technologie ontwikkeling.

In de Conclusie vat ik de hoofdpunten van mijn betoog samen, en schets ik de implicaties voor beleid op het gebied van de ontwikkeling van anticonceptie. Het middel dat de onderzoekers wilden ontwikkelen bevatte een script. Een goedkoop anti-hCG vaccin dat met een enkele injectie langdurige bescherming zou bieden tegen zwangerschap, en dat heimelijk gebruikt zou kunnen worden, was geschikt voor een specifieke categorie gebruikers: vrouwen met gebrekkige toegang tot kwalitatief slechte gezondheidszorg en met relatief weinig zeggenschap over hun gezondheid en geboorteregeling; met ander woorden arme vrouwen in de Derde Wereld. Ik stel daarom voor dat geïmpliceerde gebruikers een belangrijke toevoeging is aan het instrumentarium om gebruikers van een technologie te conceptualiseren voordat deze op de markt wordt gebracht. Het zichtbaar maken van hoe gebruikers verweven zijn in de technische keuzes van technologie-ontwikkelaars is in het bijzonder van belang om inzicht te krijgen in de mogelijkheden en beperkingen om de verhouding tussen gebruikers en technologie in de vroegste stadia te veranderen.

Mijn analyse van wie hun representaties van gebruikers naar voren mochten brengen in welke omstandigheden, stelde mij in staat om in te zien hoe invloedrijk impliciete en ongearticuleerde noties van de gebruiker - zoals "iedereen" - kunnen zijn. Vanuit het perspectief van de vrouwengezondheidssactivisten, van gebruikers dus die in hun dagelijks leven hun familie proberen te plannen, vertoonde het script van antivruchtbaarheidsvaccins een gebrek aan samenhang. Vrouwengezondheidssactivisten betwijfelden of het middel dat werd ontwikkeld eigenlijk wel tegemoet zou komen aan de behoeften van arme vrouwen in ontwikkelingslanden. Ik heb betoogd dat het ontbreken van een duidelijke omschrijving van de beoogde gebruikers een situatie creëerde waarin de technologie zich zo heeft kunnen ontwikkelen. Van daaruit stel ik voor dat de gebruikers profielen van het begin af aan scherper worden gedefinieerd. Zo komen gebruikers centraal te staan en kunnen disfunctionele gebruikers-scripts tijdig worden opgespoord.

Het vormen van meer specifieke beelden over gebruikers zou wel eens niet afdoende kunnen zijn om gebruikers een centraltelere rol te geven in anticonceptie ontwikkeling. Technologie ontwikkeling wordt niet alleen gestructureerd door ideeën over toekomstige gebruikers. En toekomstige gebruikers van een technologie worden niet alleen gedefinieerd door de voorstellingen die de ontwikkelaars in het proces inbrengen, maar krijgen ook vorm door de bestaande institutionele infrastructuur, materiële mogelijkheden, internationale beleidsdiscussies, etc. Ik heb daarom voorgesteld dat de script benadering zou moeten worden uitgebreid met een analyse van de ruimte die beschikbaar is voor bepaalde technische keuzes, en de implicaties hiervan voor mogelijke gebruikers.
Antivruchtbaarheidsvaccins ontwikkelden zich met een bepaald script en dat had anders kunnen zijn. Ik heb laten zien hoe het script van dit middel tot stand kwam in een samenspel van bevolkingspolitiek, de werking van het immunologische systeem, financieringsmogelijkheden, de beschikbaarheid van bepaalde grondstoffen, metingen die gedaan werden in het laboratorium en in de kliniek, de organisatie van het gezondheidszorgsysteem, internationale beleidsdiscussies en -campagnes, en nog meer. Ik heb betoogd dat vanuit deze opvatting van technologie het misbruik van anticonceptiemiddelen gerelateerd is aan het technologisch ontwerp, en niet uitsluitend beschouwd kan worden als een toepassingsprobleem. Daarom kan niet volstaan worden met het aanpakken van misbruik in het gezondheidszorgsysteem. Bij activiteiten om misbruik te voorkomen zouden alle actoren die figureren in de co-produktie van de technologie en de sociale (wan)orde betrokken moeten worden, dus ook de technologie-ontwikkelaars.

Ik stel voor dat beleidsmakers op het gebied van anticonceptie ontwikkeling, naast de initiatieven die al zijn ontwikkeld door de WHO/HRP, sterke verbanden zouden moeten creëren tussen technologisch innovatie en de praktijken waarin anticonceptie wordt gebruikt. De technologie-ontwikkelaars stellen dat gebruikers niet in de ontwikkeling van anticonceptie betrokken kunnen worden zolang er geen tastbaar product is om over te praten. Ze hebben daarin in zoverre gelijk dat de ideeën over gebruikers van niet-bestaande produkten noodzakelijkerwijs speculatief zijn. Maar om hieruit af te leiden dat alternatieve gezichtspunten geen rol kunnen spelen is voorbarig. Speculaties over mogelijke toekomsten maken altijd deel uit van welke technologische ontwikkeling dan ook. Het hypothetische karakter van ideeën over gebruikers kan dus geen reden zijn om toekomstbeelden van sommige actoren wel en van andere niet in de technologie ontwikkeling te betrekken. De gebruiker daarin een centralere plaats toekennen is een enorme uitdaging, want als we de contexten waarin mensen hun families plannen terugbrengen in de ontwikkeling van anticonceptietechnologie kunnen we niet langer heen om de politiek.
ERRATUM

Onderaan pagina 12 is de volgende regel weggevallen:

...(hor-)monal drugs that were once developed for contraception, in different dosages, for problems associated with menopause. This last strategy might be very...