Conceiving contraceptives: the involvement of users in anti-fertility vaccines development
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Citation for published version (APA):

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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

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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 assymetric 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.

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5. Women's health advocates' perspectives on users

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 legitimize 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\(^6\), 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).