

The brief life of Norplant® in Brazil: controversies and reassemblages between science, society and State

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Abstract *Norplant® is the brand name of the world's first registered subdermal hormonal contraceptive implant, developed by the laboratories of the Population Council, an international organisation working in the area of fertility and population growth. The article revisits the trajectory of this contraceptive in Brazil from its arrival through clinical trials to its eventual ban in 1986 by the Brazilian regulatory agency responsible for approving medications at the time. Its circulation generated controversies related to research practices, side effects and political uses of the drug as a birth control method. This article focuses its analysis on the divergences related to research practices. It uses a controversy analysis technique, reviewing the versions of those involved, investigating their understandings and the effects that this object generated in their networks. Norplant® provoked displacements and associations between civil society groups, State authorities, scientists and physicians, industry, pharmaceutical products, research procedures, bureaucratic instruments, and the female users of the contraceptives. Scientific styles of medical thought were shaken up and new forms of thinking about scientific autonomy began to be discussed in the country.*

Key words *Science, society and State, Ethics in research, Sexual and reproductive health, Contraception*

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Introduction

Norplant® is the brand name of the world's first registered subdermal hormonal contraceptive implant. The drug was developed by the laboratories of the Population Council, an organisation set up in 1952 by the Rockefeller Foundation for the purpose of improving understanding of the relations between fertility, population growth and socioeconomic development, and intervening in the so-called 'demographic crisis'¹.

Hormonal contraception was first inaugurated with the contraceptive pill, use of which quickly spread globally from the 1960s on. In the mid-twentieth century, new contraceptive technologies (hormonal products and intrauterine devices or IUDs) appeared to offer a solution to the ancient problem of preventing pregnancy and the more recent problem of containing the 'population explosion'². Reproductive scientists invested in the development of new methods that, as well as being more efficacious and safer, were also more effective.

In 1970, Howard Tatum, director of Population Council, came to the conclusion that the low number of professionals and the difficulties in disseminating methods were compromising the effectiveness of demographic control programs. He therefore devised a contraceptive method that was highly efficacious, easy to use, independent of the user's motivation, long-lasting, dispensed with the need for regular professional follow-up, reversible and cheap. Having established the concept of long-acting reversible contraception, Tatum could declare that the "era of implant contraception has begun"³.

After fifteen years of research, scientists in 1980 developed the levonorgestrel implant, registered as Norplant. 'Pre-introductory trials' then began with the objective of generating the local acceptability, expertise and conditions needed to introduce the method into family planning programs⁴. Brazilian trials of Norplant began in 1984 following the authorization of the Ministry of Health and were coordinated by the Campinas Reproductive Health Research Centre (CEMI-CAMP)⁵. Norplant was officially in circulation in Brazil until January 1986 when the research was cancelled after a series of denunciations.

This article revisits the brief social life of Norplant in Brasil. It analyses the controversies provoked by the circulation of this particular implant and discusses the conditions that led to the cancellation of clinical trials in the country. Although the Norplant episode dates from the 1980s, it strikes us as *bon à penser* contemporary

aspects of the relations between science, technology, society and public policies in Brazil.

The study of scientific controversies can be extremely useful to the field of collective health, providing theoretical-analytic tools still seldom used in the study of the development of medical research and scientific innovations in Brazil, the incorporation of health technologies, and, in particular, the sphere of reproductive health, which has been an arena for so many disputes.

Theoretical and methodological aspects

According to Latour⁶, modern scientificity conceives sociotechnical artefacts as mere products that circulate neutrally between subjects and groups, reproducing pre-established social effects, related to the meanings intended by their producers. This process is related to the broad project of 'purification' of the things that separate reality into entirely distinct spheres, such as the realms of the human and the non-human, nature and culture, subjects and objects (ibid).

In this work we take a different interpretative approach. Our starting point is the impossibility of separating science, technology and society into clearly defined domains, dimensions that are in fact coproduced and interconnected by human and non-human agents. From this viewpoint, nothing specific exists that can be picked out as the 'social dimension of science.' The social is not given, rather it is continuously made and remade through dynamic and heterogenic connections between humans and non-humans, persons and groups. Hence the production of science and of biomedical objects is always from the outset a production of the social⁷.

In this sense, biomedical objects cannot be reduced to entities that remain limited to the fate imagined by their creators and reordered by society. Biomedical objects act and transform, producing networks and associations. Their actions are contingent, situated and relational: in sum, they too are social actors, or *actants* in Latour's⁸ reworking of sociological terms.

Recognizing that biomedical objects have a social life⁹, we explore the trajectory of Norplant, track down the controversies generated by it, the ideas, values and norms that were disputed, legitimized or discarded, and examine its agency in the constitution of associative networks and interactions.

The method adopted in this work is the study of controversies. This enables the estrangement of the diverse viewpoints and ways of making

of the subjects involved, a distancing from the self-evidence of events, the scrutiny of what has been constructed as 'correct,' the revisitation of competing explanations – not only those that were victorious, but also those that were rejected – and the revelation of the unstable, contingent, political and historical character of a 'scientific truth'¹⁰.

We have used both written and oral sources. Our work included compiling scientific articles published between 1970 and 1983 in the journals *Contraception* and *Studies in Family Planning* by researchers from the Population Council, accessed via the CAPES periodicals website. Using the US on-line library Popline – focusing on reproductive health matters – we obtained research reports, technical notes and various other kinds of documents containing information on the development of Norplant – in other words, the 'grey literature' related to the topic under study. We also tracked down reports produced by Brazilian newspapers and magazines published in the 1980s: *O Globo*, *Jornal do Brasil* and *Veja*. Searches in digital archives were made using the terms 'Norplant,' 'contraceptive implants' and 'hormonal implants.'

The oral sources consisted of interviews with researchers and feminists involved in the Norplant controversies, conducted in 2013 and 2014. A dossier provided by the coordinator of the Norplant research in Brazil, Anibal Faúndes, filled with documents and research reports, was a precious source of information, clues and insights for our analysis.

We utilized controversy analysis techniques, revisiting the versions of those involved, investigating the understandings each had of the situation, and the effects which the disputed object produced in their networks, tracing the ways through which they sought to enlist allies, and following the assemblages and associations that the thing under dispute provoked – or in sum, how social life was generated in this process.

Diving into these materials, we are left dealing with a puzzle: we never really know whether they are sufficient. The notion of saturation is unsuited to this type of study. We are guided by clues, seeking to join pieces together and approach the history gradually from various angles. This is why the controversies surrounding Norplant can and should be revisited still, new aspects, documents and testimonies should emerge and, with this, show more clearly how its history has genealogical connections to contemporary dilemmas that pervade the relations between the sciences, the State and society.

The making of Norplant

Norplant is a subdermal hormonal implant composed of six flexible silicon capsules containing levonorgestrel, a synthetic derivative of progesterone. Inserted under the skin of the forearm using an anaesthetic, the capsules slowly release the chemical compound. Its effect lasts for five years and the recommendation is for the capsules to be removed afterwards since they are not biodegradable¹¹.

Scientists from the Population Council were responsible for introducing the concept of a contraceptive implant, which combined three core principles: the diffusion of biological materials through the walls of silicon capsules; the continual and long-lasting release of chemical substances via these recipients; and the possibility of preventing pregnancy with low doses of progestogen. The association of materials-techniques-scientists enabled the design of subdermal hormonal contraceptive implants. Recruitment of pharmaceutical companies – Wyeth (United States) and Leiras (Finland) – cleared the way for the search for a reversible contraceptive with a long-lasting effect¹¹.

The first clinical trials with implants were conducted in Chile, India and Brazil in the 1960s. In 1970, following the Population Council's creation of the International Committee for Contraception Research (ICCR), the multicentred international trials were expanded^{11,12}. Variables like the size, thickness and number of silicon capsules, the type and quantity of hormone, collateral effects, and the time that the contraceptive effect lasted all formed part of the jigsaw puzzle of attaining the idealized method: safe, efficacious, acceptable and low-cost, and effective in responding to the demographic problem¹¹.

Brazil was an important field for the clinical trials of contraceptive implants. Since 1968 different substances had been tested in the Clémério de Oliveira Maternity Clinic of the Federal University of Bahia, headed by the physician Elsimar Coutinho. By 1970 Coutinho had already published articles on the research¹³.

By 1978 Coutinho had tested eight hormones on 5,000 women. He concluded that the methods had a high level of acceptability and effectiveness; the side-effects were well tolerated and amenorrhea, the main alteration, could be advantageous in underdeveloped countries where malnutrition and anaemia were common¹⁴.

Coutinho's links to the Rockefeller Foundation date from the end of the 1950s. Its support enabled him to spend three decades investigat-

ing injectable, oral, vaginal and implanted hormones, as well as vaccines, intrauterine devices, male pills and other methods. Scientific and political motives were intertwined in his work with Coutinho (self)identified with the ideas and strategies of the global establishment concerning population control¹⁵. In Brazil, the Bahia group was the only team involved in the contraceptive implants project during the 1960s and 1970s.

Unlike the pills and intrauterine devices, subjects of controversy in the 1960/1970 period¹⁶, the trials with hormonal implants were conducted silently and unperturbed at the Climério de Oliveira Maternity Clinic. In the years prior to the research with Norplant, reproductive scientists and the Brazilian public seldom communicated. The Brazilian State was either unaware of the research or judged that it had no role to play in the laboratories. Contemporary conceptions of the ethics of research involving human beings were still rudimentary and the idea of scientific autonomy was shaped along traditional lines.

In 1978, researchers from the ICCR published the findings of the international multicentred study with two implants: levonorgestrel and norgestrienone. In the main article they stated that “[t]he need for a highly effective, reversible, estrogen free contraceptive method in which a single administration may suffice for several years has been apparent”^{17,18}. Concluding that the implants showed high levels of effectiveness, safety and acceptability, they claimed that the results warranted “further exploration of the method under less controlled circumstances than these clinical trials represent”¹⁷. Owing to its lengthy durability (5 years), levonorgestrel was chosen for the tests “under less controlled circumstances” and the brand name Norplant[®] was registered¹¹.

The evidence indicates that the method with 6 capsules containing levonorgestrel is ready to be introduced at a limited scale. In expanded clinical trials attention should be given to ensuring the women are adequately prepared for the menstrual irregularities that they may experience¹¹.

Between 1978 and 1983, “expanded clinical trials” were run in various countries, involving thousands of participants. The Population Council was preparing the way for the worldwide introduction of Norplant¹¹.

As sociotechnical objects, the prototypes of the contraceptive implants mediate new associations and networks, putting into social circulation concepts, ways of making, human actors and things (silicon, hormones, institutions, organisations, scientific journals). They “built a word,” as Latour suggests when proposing that we observe

the political and social influences of scientists and biomedical objects and the scientific truths that they fabricate¹⁹. The “evident necessity” of the effective, reversible and long-lasting method involving a single administration is constructed alongside the fabrication of the medical object itself, the subdermal hormonal implant for contraceptive use.

In the 1980s, the commercial sale of Norplant was authorized in countries of Europe, Asia and Latin America and, in 1990, in the United States^{11,12,20,21}. In Brazil, the “expanded clinical trials” of Norplant began in 1984. However, the implant would never actually be sold in the country. Its circulation was brief, lasting only as long as the clinical trials.

The brief life of Norplant in Brazil

Under the command of the researcher Aníbal Faúndes, the Campinas Research Centre, CEMICAMP, assumed the task of coordinating the Brazilian and Latin American research into Norplant, which as well as clinical trials also aimed to develop a regional database on implants^{20,21}.

Faúndes had trained in medicine in Chile, graduating in 1955. He had been part of Salvador Allende’s socialist government, working in the Ministry of Health, coordinating the Women’s Health Program. Included on the list of ‘dangerous medics’ after the military coup, he went into exile in the Dominican Republic in 1973. He moved to Brazil in 1976, bringing his experience in research, teaching and management²². Differently to Coutinho, whose career was marked by his advocacy of demographic control policies, a vision of public health informed Faúndes’s own professional trajectory. In an interview, he points out that the Women’s Health Program developed by himself in Chile took comprehensive care and the right to choose as its guiding principles: “[if you read the text] you will see PAISM”²².

In June 1984, Faúndes sent a letter to the director of the National Medications Division (DIMED), Luís Gonçalves Paulo, informing him that:

The Campinas Reproductive Health Research Centre and the Department of Obstetrics and Gynaecology of the UNICAMP Faculty of Medical Sciences is organising trials for a new hormonal contraceptive method that, according to the medical literature, would present clear pharmacological advantages compared to those in use currently²³.

In the letter, technical and scientific aspects of Norplant are described in minute detail. Faúndes

observes that tests with the implant had been authorised in the United States in 1974, it was already being sold commercially in Finland and would soon be marketed in European countries. Faúndes adds that the Brazilian Federation of Gynaecology and Obstetrics Societies were aware of the research proposal.

The proposal of the research coordination team was “to keep the Ministry of Health informed about the conduction of this research” and to invite the authorities to participate in a meeting of the researchers “with the aim of obtaining the advice of this body.” In one section of the letter, the researcher adds that:

“We know that it is unusual for university researchers to inform DIMED of their research, however [...] we comprehend the convenience of this institution taking part in these experiments”²³.

What would the convenience be? Why had it not been convenient until then to inform the authorities about the studies that had already been undertaken in Brazil? At this juncture, the political setting was different to the 1970s: the transition to democracy was already under way, social movements were up and running, the State was more receptive to public demands and participation, controversies surrounding family planning in Brazil were at a peak, and, as remarked earlier, the profile of the researcher heading the research was very different.

Guided by a conservative idea of scientific autonomy, the scientists considered it exceptional for “[the State] to participate in these experiments.” However, attached to the letter, a lengthy document detailed the research protocol. Emphasis was given to the fact that Norplant was the “most effective reversible contraceptive method developed thus far” and had shown “safety and acceptability in wide variety of cultures and diverse social groups.” The “considerable utility” of the clinical trial was explained by:

1 – The importance of expanding the range of choices for contraceptive methods among the Brazilian population. 2 – The need for Brazilian scientific experiments, which will allow an informed decision on whether the NORPLANT® implants should be used or not in the country. 3 – The possibility of this method comprising a good alternative for many women covered by the Women’s Comprehensive Care Program, which includes Family Planning activities²³.

The emphasis on the relevance of the study for public health and for “expanding the range of choices for Brazilian women” are novelties compared to the research with implants conducted in previous years.

Two months later, in an official letter, DIMED replied to Faúndes’s letter with the verdict: “in the face of the presented documentation, I hereby *authorize* the conduction of the clinical trial”²³. The correspondence sent by Faúndes ‘informing’ the agency about the research received back in reply the ministerial letter ‘authorizing’ the research. During this period, the controversies surrounding contraceptives and family planning forced approximations between two worlds: scientists and the State. The researchers began to frequent the corridors of the State.

As the research unfolded, three reports were sent to DIMED with a growing number of clinics (from an initial 10 to 18) and women (from an initial 2000 to 3103) participating. For the coordinators, “the increase in the number of clinics is a good indication of the growing interest in the method in the country.” As for safety, the reports explain that “no serious side effects attributable to the method were found” (1984)²³.

The creation of favourable dispositions towards the contraceptive implant, the production of a technical capacity for the method and the preparatory steps for its uptake in Brazil’s health services are clear goals.

With the aim of disseminating the method more widely, students and residents of UNICAMP and PUCC are also receiving training from CEMICAMP in use of the method. By taking this step we hope to facilitate the future expansion of the method to various health services [...]²³.

The initial project presented to DIMED was called “Norplant Subdermal Contraceptive Implants. A collaborative clinical trial project in Brazil.” In the final report, the study is now called “A Pre-introductory Evaluation of the Norplant® Subdermal Contraceptive Implants in Brazil.” The headings of the tables in the latter document identify the research as “a pre-introductory study in Brazil” (1985)²³.

At the start of 1980, the Population Council prepared the way for approval and introduction of Norplant on the market. Its strategy involved the development of ‘pre-introductory studies’ in various countries, seeking to accumulate local experience with the method and assess the acceptability and feasibility⁴. For Reis²⁴, the research on Norplant in Brazil was directed more towards divulgation, training, the creation of routines and practice, and the creation of dispositions and conditions favourable to the introduction of the method, rather than towards investigating the effectiveness, doses, side effects and ways of administering the drug.

Following the change in DIMED's management in 1985, Faúndes contacted the new director, Suely Rozenfeld, "to inform her about the development of our work." He sent her a report detailing the rates of insertion and extraction of the implant, its side effects and reasons for removal, and stresses that the results are favourable and "match the international experience with the method"²³.

The scientists are confident. The tests confirm the opinion already formed that Norplant is "an excellent choice for those women who are starting to use contraceptive methods and also for those who are using an unsuitable or contraindicated method"²³. It was effective, easy to use, reversible, with minimal and avoidable side effects – in sum, a consummate technology.

So it was with some perplexity, therefore, that the scientists received news in January 1986 that research into Norplant had been suspended.

The controversies

On January 22, 1986, an edict published in the Official Gazette cancelled authorization for the Norplant research. "Numerous irregularities" were identified: the research had not used the liability agreement proposed by DIMED, the admission and monitoring cards failed to provide sufficiently clear information to test the side effects and health conditions of the volunteers, non-homogenous procedures were being used in diverse clinics, contradictory reports, the use of another product, Norplant 2, and an expansion in the number of participating centres and women without prior authorization from DIMED²³.

The person responsible for the ordinance, the new director of DIMED, Suely Rozenfeld, had connections to feminist and left-wing groups, frontline opponents of the demographic control programs²⁵. Her occupation of an important post at the Ministry of Health was part of the context of the Brazilian political transition to democracy, where sectors of society found gaps enabling them to influence government agendas and decisions. Other bodies created in 1985 – the National Women's Rights Council and the Human Reproductive Rights Studies Commission (CEDRH) of the Ministry of Health – also involved the participation of activists and were important places for feminist advocacy. At international level, the debate on reproductive rights began to shift the axis of the population debate. Through these 'routes,' feminist groups interpellated the Ministry of Health and demanded clarifications concerning the Norplant research²⁶.

CEDRH assumed responsibility for auditing the research and its report formed the basis for DIMED to suspend the clinical trials.

The cancelling of research authorization was greeted by the researchers with surprise and outrage: they voice their opposition in newspapers and sought avenues of dialogue with government authorities. The legality of the edict was questioned since it limited "the free exercise of research in medical and biological areas." The Ministries of Health and Education were mobilized "in expectation of their interest concerning the scientific autonomy of the Universities and in order for the edict to be re-examined and the unconsulted medical bodies heard"²⁷. In the courts, they sued for the decision to be "revoked or annulled through a norm based on better science and impartial in inspiration"²⁷. Faúndes wrote in one newspaper that "for the first time authorization to conduct a trial was requested from health authorities, who banned the research just to show that they were acting as regulators"²⁸. Defence of scientific autonomy, complaints of excluding scientists from official decisions, and distrust concerning the impartiality of the regulatory bodies were all central elements in the protestations made by the researchers.

The two sides of the disputes mobilized to gather support and legitimize their positions. An ally of the researchers, the rector of UNICAMP, José Pinotti, solicited an expert report from the Brazilian Society of Legal Medicine concerning the research. In April 1986, its experts concluded that "suspension of the therapeutic research with Norplant was inappropriate," since "according to the Commission, no evidence was found of ethical lapses in the procedure utilized by the researchers, who respected the rules and spirit of the Brazilian Code of Medical Deontology, as well as international conventions relating to the matter"²³. At the end of the report, the authors discuss the limits of the State in the regulation of scientific practice: "research conducted by scientists with university qualifications cannot be judged, in terms of its merit, by an executive body of the Federal Government without posing a restriction on scientific development incompatible with the liberal spirit that should be flourishing in today's Brazil"²³. The researchers turned to the deontologists to attest to the integrity of the research; medical deontology and the ethics of research on human beings were still not yet clearly distinguished, though the Norplant controversy would contribute precisely to changing this situation.

On the side of DIMED, the Federal Council of Medicine was asked to issue its own expert re-

port on the Norplant research. This report listed a series of irregularities present, assessed on the basis of the regulatory criteria in force at the time. Among the main points, it emphasized that the “liability agreement” signed by the patients to take part in the study failed to comply with Edict 16 of 27/11/1981, issued by DIMED, “which established the Risk Acceptance Agreement to be used mandatorily in any trials with new drugs.” Another issue raised by the report was the existence of “sufficient evidence that the research was already under way in flagrant disregard of Article 30 (Physicians are prohibited from: conducting research on live subjects without due authorization and without the necessary monitoring of the Ethics Commission) and Article 31 (Physicians are prohibited from: Experimentally employing or using any kind of therapy still not released for use in the country without due authorization from the competent bodies, the consent of the patient or someone responsible, properly informed of the situation and the possible consequences) of the Brazilian Code of Medical Deontology.” Given these irregularities and others identified by the report, after reviewing clinical and ethical procedures, the report author concluded that the research “is filled with errors, contradictions and omissions and violates all the national and international mechanisms regulating biomedical research on human beings [...] and should therefore be strongly condemned”²³.

The authorized knowledge mobilized by the opposing sides to legitimize their viewpoints clashed and seemed irreconcilable at that moment²⁹. In November, UNICAMP announced that it would renew the request to study Norplant, but then took no further action²⁸. The end of the tests did not mean a cessation to the circulation of the implants, nor an end to the controversies. Around 2,500 women continued to use the method; follow-up of the users, side effects and the medical refusal to extract implants were all debated. The two sides went into the field, conducted research and presented proof of their arguments. In 1987, Koifman and colleagues published a case-control study with 175 users of Norplant® in Rio de Janeiro, showing “a statistically significant increase in the risks among Norplant users of menstrual disorders, hypertension, serious weight disturbances and hypertrichosis,” and suggested “the removal of Norplant from all Brazilian women, under the supervision of public institutions from the health sector”³⁰.

In 1991, Hardy and other researchers from CEMICAMP published a study involving 280 users of Norplant® in three Brazilian cities. They

concluded that most of the side effects were slight and well tolerated, that “the percentage of women who said that menstrual cramps, discharge, headaches and irritability had diminished with use of the method was higher than the percentage reporting an increase” and that “the large majority of users (77.2%) rated their experience as ‘good’ or ‘very good’”³¹.

In 1993, the feminists Dacach and Israel issued the book *As rotas do Norplant* and reignited the debate. The book contained the findings of research with 52 women from Rio de Janeiro who had participated in the Norplant study, where the interviewees confirmed the theses of the authors concerning medical abuses and the harmful effects of the implant²⁶.

Safety and *effectiveness* are both terms widely used in the context of clinical research. In the trials with hormonal implants in the 1970s, the idea of a *lack of safety* referred less to the side effects than to contraceptive failure – in other words, to their efficaciousness or effectiveness. The idea that unplanned pregnancies among people living in poverty led to higher risks for women than those posed by hormonal products can be traced to previous decades³². Indeed the tendency to minimize side effects was commonplace in early studies of subdermal implants. One researcher said that among a group of 3,000 women, ‘just’ 252 (8.4%) presented side-effects from the implants. For him, this proportion seemed small³³. The logic of the 1960s and 1970s collided with the notions then being developed in the 1980s by feminist and health movements concerning reproductive rights, where personal autonomy and bodily integrity formed the central ethical principles³⁴.

Reconstituting the national and international ‘routes,’ feminists saw the implant as a method that combined an “arsenal of hormonal products” with the objective of making available more ‘effective’ products for demographic control²⁶. This viewpoint was also widespread in the press: “new contraceptive methods are being studied by international bodies to reduce the population of Third World countries and devised for use by poor women from these countries”³⁵.

The researchers from CEMICAMP felt uncomfortable with all the criticism. They reiterated that Norplant® “is nothing more than a new form of administering levonorgestrel, a contraceptive hormone used by millions of women the world over” (O Globo, 04/02/1986)²⁷. In an article entitled “Ideological veto,” Luís Bahamondes claimed that “Norplant is highly effective and safe”³⁶. Juan Diaz stated that the objective of the

Brazilian project was to “broaden the range of contraceptives available with a method capable of responding to the clinical particularities of some women.” In interview, Aníbal Faúndes stressed that the CEMICAMP research had always been guided by the ideals of comprehensive healthcare and an increase in the range of options available to women²².

The episode of controversies over the trials with Norplant in Brazil took place during a phase when the population debate was shifting direction. At international level, the pressure of the rich countries on the other nations was less to control their populations than to downsize the State and open up their markets. In addition, questions that interwove social rights, health and reproduction began to be emerge in the New Public Health movement and in national and international feminist networks. At political-institutional level, Brazil began the process of drafting a new constitution, which would culminate in the 1988 Federal Constitution.

The question of the ethical problems of research is another important facet of the controversies. Newspapers were important vehicles for the denunciations made by users. One testified that she had “signed a liability agreement, which she hadn’t actually read”²⁷. Others reported that they had “gone repeatedly to the doctor to remove the capsules and always received the same negative response”³⁷, “they have had strong headaches for months, but even so they were unable to get the medics responsible for inserting the capsules to remove them”³⁸. A feminist organization revealed that “the majority of women are from low-income families and when the contraceptive was implanted were not told about the risk that it posed”³⁹. The scientists were accused of using the women as ‘guinea pigs.’ In a review of international experiences, Correa identified the research protocols as one of the most problematic aspects of Norplant⁴⁰.

In 1986, the ethical integrity of the research was defended almost solely by the group from Campinas, Aníbal Faúndes in particular. At the Ministry of Health, the São Paulo Regional Council of Medicine (where he was also interpellated) and media outlets argued that the trials had been authorized and that they had regularly sent reports to the ministry, the women had consented to take part in the research, and they had been closely monitored. However there were few direct responses to the women’s press denunciations testifying against the method. What was done at CEMICAMP was not necessarily what was being

done elsewhere: the expansion in the number of participating research centres in the country, increasing the number of physicians, nurses and residents involved and women taking part, meant that the coordinators were seemingly unable to maintain full control over the procedures.

The row practically disappeared from the newspaper reports from 1987 on. The topic returned sporadically, such as in 1990, following approval of Norplant in the United States and, in 1993, with the launch of the book by Dacach and Israel. However, as a legacy of the controversies, the discussion and construction of legal frameworks on ethics in research with human beings proliferated, along with new voices in the debate on ‘family planning.’ In mid-1986, the federal government discussed the “definitive implantation of the program [...] assuming a function that is properly its own, since it will seek to provide global healthcare to women, enhancing those programs that already exist”⁴¹. In 1988, Article 226 of the Federal Constitution declared family planning to be a right, prohibiting coercion and obliging the State to provide reproductive healthcare.

Since the 1960s, Brazil had been an important field of research for international organisations promoting birth control programs and for the multinational pharmaceutical industry. The increase in clinical trials in the country – and the controversies that emerged in the 1980s – contributed to the Federal Council of Medicine including various articles on research ethics in its professional Code of Ethics, published in 1988⁴². Still in the same year, the National Health Council published its Health Research Guidelines, the first national regulatory framework on the topic.

After the episode of controversies over the trial use of Norplant®, Faúndes and other researchers from CEMICAMP incorporated another theme into their studies: ethics in research. In 1989 he presented the paper “Ethics in women’s healthcare” at a national scientific seminar and, a year later, published the text in a scientific journal, co-authored with José Cecatti. In the article “Medical ethics and family planning in Brazil,” co-authored with Hellen Hardy, IUDs and implants are discussed with the observation that these “methods are more open to abuse [...] with consequent ethical problems”⁴³.

From 1987 onward, Faúndes would become a steadfast interlocutor with feminist groups and would enable the approximation between women and FEBRASGO (the Brazilian Federation of Gynaecology and Obstetrics Associations)²⁵.

Final considerations

The trajectory taken by hormonal contraceptive methods is varied in terms of their production, uptake and circulation. No other hormonal contraceptive had such a difficult life in Brazil as Norplant®. Following the suspension of research in 1986, the levonorgestrel implant was definitively banned from the national market. The company Elmeco, founded in 1993 by the researcher Elsimar Coutinho, continued to investigate and produce subdermal hormonal implants. In 2001, following authorization from Agência Nacional de Vigilância Sanitária (ANVISA), a hormonal implant based on etonogestrel – Implanon® – began to be sold. Other methods using the substance levonorgestrel were already sold in the country and continue to be marketed (pills, emergency contraceptives and IUD systems). Unlike Norplant®, these other hormonal technologies were not the target of any big controversies, though their circulation is regulated by the State.

Set in its historical time frame, the brief social life of Norplant® shows the contingency of biomedical objects, the unexpected effects that can occur when they leave the laboratories. Norplant® provoked displacements and reassociations between civil society groups, State authorities, scientists and physicians, industry, pharmaceutical products, research procedures,

bureaucratic procedures and women using contraceptives. Scientific styles of medical thought were shaken up, and new forms of thinking about scientific autonomy began to be discussed in the country.

The study of controversies, the tracking of the object and the scrutiny of its effects unplanned by the scientists – its ‘own life’ – enable a more complex appraisal of the circulation of medical objects. While Norplant® denaturalized the distances between the practices of physicians and scientists, on one hand, and the control of the State and society, on the other, in the world of sexual and reproductive health these relations are still problematic from the viewpoint of sexual and reproductive rights in Brazil. Over the last five decades, innumerable technologies have been introduced and allowed to circulate in the country with negligible regulation and public oversight, but with huge effects on the lives of men and women: assisted reproduction, hormone replacement therapy, erectile dysfunction medications, and various kinds of hormonal chips, to cite just a few examples. Studying their biographies, following them, investigating how they act and interact (beyond the behaviour programmed in the laboratory) and analysing the controversies that they provoke, or wondering why these are absent, can be relevant not only to the world of knowledge, but also to public health and the sphere of human rights.

Collaborations

The authors contributed equally to the elaboration of the work presented to the journal *Ciência e Saúde Coletiva*. ACL Pimentel, the main author, searched the databases, organized the results and helped write up the manuscript. C Bonan is one of the coordinators of the research from which this article draws some of its findings, and elaborated the objectives of the part of the research project focused on the study of the Norplant® contraceptive, as well as selecting the databases and helping write the manuscript. LAS Teixeira is also a coordinator of the research and was involved in organising and analysing the results and revising the final version. P Gaudenzi helped organise and analyse the results and revise the final version of the manuscript.

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